



Connecticut Orthopaedic Specialists, P.C.

THE EXPERIENCE MATTERS



August 19, 2016

Ms. Kimberly Martone
Director of Operations
State of Connecticut Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Connecticut Orthopaedic Specialists, P.C.
Acquisition of a 1.5 Tesla MRI Mobile Unit

Dear Ms. Martone,

Attached please find one (1) hard copy in a 3-ring binder and a USB flash drive of Connecticut Orthopaedic Specialists' Main Certificate of Need Application and the Supplemental Application for the acquisition of a 1.5 Tesla Mobile MRI unit. Also attached is a disc containing both application forms in Adobe format.

Please feel free to contact me if you have any questions with regard to this application.

Very truly yours,



Glenn F. Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

2408 Whitney Avenue, Hamden, Connecticut 06518

Billing 203.407.3560 • Main 203.407.3500 • Fax 203.281.1164 • ct-ortho.com

**State of Connecticut
Department of Public Health
Office of Health Care Access**

**Certificate of Need Application
Main Form**
Required for all CON applications

Contents:

- Checklist
- List of Supplemental Forms
- General Information
- Affidavit
- Abbreviated Executive Summary
- Project Description
- Public Need and Access to Health Care
- Financial Information
- Utilization

Checklist

Instructions:

1. Please check each box below, as appropriate; and
 2. The completed checklist *must* be submitted as the first page of the CON application.
- Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.
 - (*New*). A completed supplemental application specific to the proposal type, available on [OHCA's website under "OHCA Forms."](#) A list of supplemental forms can be found on page 2.
 - Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of \$500.
 - Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication*)
 - Attached is a completed Financial Attachment
 - Submission includes one (1) original hardcopy in a 3-ring binder and a USB flash drive containing:
 1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.
 2. An electronic copy of the applicant's responses in MS Word (the applications) and MS Excel (the financial attachment).

For OHCA Use Only:

Docket No.: 16-32117-CON Check No.: 28893
OHCA Verified by:  Date: ~~8/18~~ 8/21/16

000001

General Information

Name of Applicant:

Name of Co-Applicant:

Connecticut Orthopaedic Specialists, P.C.	N/A
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Connecticut Statute Reference:

C.G.S. Sec. 19a-638

Main Site	MAIN SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	MAIN SITE NAME
	Hamden	#004001020 is the MD group #. Physician # is added also.	Private Physician Practice	Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	2408 Whitney Avenue			
	TOWN		ZIP CODE	
	Hamden		06518	

Project Site	PROJECT SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	PROJECT SITE NAME
	Orange			Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	330 Boston Post Road			
	TOWN		ZIP CODE	
	Orange		06477	

Project Site	PROJECT SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	PROJECT SITE NAME
	Essex			Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	12 Bokum Road			
	TOWN		ZIP CODE	
	Essex		06426	

Operator	OPERATING CERTIFICATE NUMBER	TYPE OF FACILITY	LEGAL ENTITY THAT WILL OPERATE OF THE FACILITY (or proposed operator)
	N/A	Private Physician Practice	Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER		
	2408 Whitney Avenue		
	TOWN		ZIP CODE

Hamden	06518
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Chief Executive	NAME		TITLE		
	Glenn F. Elia		CEO		
	STREET & NUMBER				
	2408 Whitney Avenue				
	TOWN		STATE	ZIP CODE	
	Hamden		CT	06518	
	TELEPHONE	FAX	E-MAIL ADDRESS		
	203 407-3576	203 415-8774	gelia@ct-ortho.com		

Title of Attachment:

Is the applicant an existing facility? If yes, attach a copy of the resolution of partners, corporate directors, or LLC managers, as the case may be, authorizing the project.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
Does the Applicant have non-profit status? If yes, attach documentation.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
Identify the Applicant's ownership type.	PC <input checked="" type="checkbox"/>	LLC <input type="checkbox"/>	Other: _____
Corporation <input type="checkbox"/>			
Applicant's Fiscal Year (mm/dd)	Start January 1 End December 31		

Contact:

Identify a single person that will act as the contact between OHCA and the Applicant.

Contact Information	NAME		TITLE		
	Glenn F. Elia		CEO		
	STREET & NUMBER				
	2408 Whitney Avenue, Hamden, CT 06518				
	TOWN		STATE	ZIP CODE	
	Hamden		CT	06518	
	TELEPHONE	FAX	E-MAIL ADDRESS		
	203 407-3576	203 415-8774	gelia@ct-ortho.com		
RELATIONSHIP TO APPLICANT	CEO				

Identify the person primarily responsible for preparation of the application (optional):

Prepared by	NAME Patricia A. Gerner		TITLE Principal
	The Law Office of Patricia A. Gerner, LLC		
	STREET & NUMBER		
	240 Ramstein Road, P.O. Box 209		
	TOWN	STATE	ZIP CODE
	New Hartford	CT	06057
	TELEPHONE	FAX	E-MAIL ADDRESS
	860 794-1907	860 489-9380	
	RELATIONSHIP TO APPLICANT	Consultant	

000004

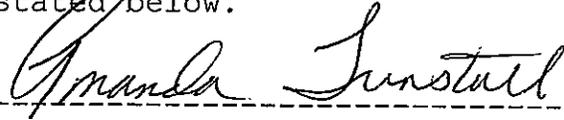
CONNECTICUT POST

410 State Street • Bridgeport, CT 06604

CONNECTICUT ORTHOPAEDIC SPECIALISTS,
PC, KELLY
2408 Whitney Avenue
HAMDEN CT 06518

CONNECTICUT POST CERTIFICATE OF PUBLICATION

This is to certify that the
attached advertisement was published
in the Connecticut Post newspaper as
stated below.



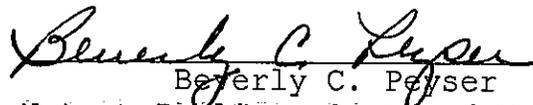
(Advertising Representative)

RECEIVED

JUL 11 2016

COS HAMDEN

Subscribed and sworn to before me,
on this 7.th day of July, A.D. 2016



Beverly C. Peyer
Notary Public - State of New York
No. 01PE6320015

Qualified in Rensselaer County
My Commission Expires
March 2, 2019

PO Number

Amount
\$326.60

Publication
Connecticut Post

Ad Number
0002180047-01

Publication Schedule
7/7/2016, 7/8/2016, 7/9/2016

Ad Caption
Legal Notice Connecticut Orthop

000005

Legal Notice
Connecticut Orthopaedic Special -
ists, P.C. ("COS") is applying to
the CT DPH Office of Health Care
Access for a Certificate of Need
pursuant to Section 19a-638 of
the CT General Statutes in order
to purchase a mobile 1.5 Tesla
MRI to be used two days a week
for orthopedic MRI scanning for
its patients at its office in Orange
and 2 days a week at its office in
Essex. The location in Orange is
330 Boston Post Road. The loca -
tion in Essex is 12 Bokum Road.
The total capital expenditure is
\$ 675,000.00

Hartford Courant

●●●●● media group

AFFIDAVIT OF PUBLICATION

State of Connecticut

June 29, 2016

County of Hartford

I, Janet Tarasuk, do solemnly swear that I am a Sales Assistant of the Hartford Courant, printed and published daily, in the state of Connecticut and that from my own personal knowledge and reference to the files of said publication the advertisement of Public Notices was inserted in the regular edition.

On Dates as Follows:

06/27/2016 72.97; 06/27/2016 10.00; 06/28/2016 72.97;
06/29/2016 72.97

In the Amount of:

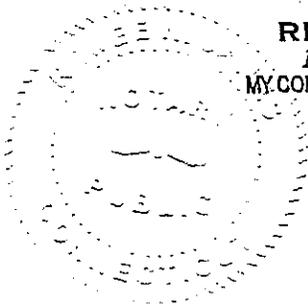
\$228.91
CT Orthopaedic Specialists Inc (HTF) - CU00246101
4281810
Full Run

Janet Tarasuk Sales Assistant,
Janet Tarasuk

Subscribed and sworn before me on June 29, 2016

Renee N. Janes Notary Public

RENEE N. JANES
NOTARY PUBLIC
MY COMMISSION EXPIRES MAR. 31, 2018



RECEIVED

JUL 05 2016

COS HAMDEN

Order # - 4281810

000007

Hartford Courant

media group

Legal Notice

Connecticut Orthopaedic Specialists, PC ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$ 875,000.00.

Order # - 4281810

000008

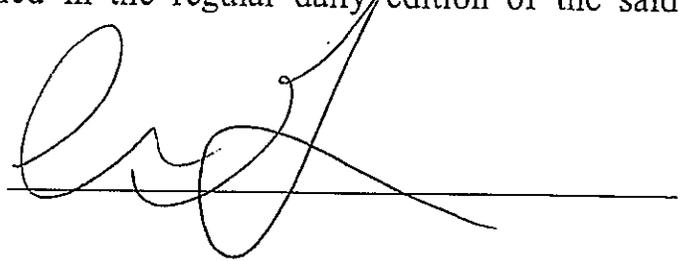
AFFIDAVIT OF PUBLICATION

1050804

NEW HAVEN REGISTER

STATE OF CONNECTICUT, County of New Haven

I Christopher Gilson of New Haven, Connecticut, being duly sworn, do depose and say that I am a Sales Representative of the New Haven Register, and that on the following date 6/27, 28, 29/16..... there was published in the regular daily edition of the said newspaper an advertisement,



Legal Notice
 Connecticut Orthopaedic Specialists, P.C. ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$675,000.00

RECEIVED
JUL 25 2016
COS HAMDEN

And that the newspaper extracts hereto annexed were clipped from each of the above-named issues of said newspaper. Subscribed and sworn to this 15th..... day of July 2016..... Before me.



My commission expires July 31, 2019

000010

Connecticut Orthopaedic Specialists, PC
2408 Whitney Avenue
Hamden, CT 06518

First Niagara
50-7044/2223

28893

DATE: 7/19/2016

PAY **500.00**
ONLY Five Zero Zero CENTS

\$ 500.00

PAY Five Hundred and 00/100 Dollars

TO THE ORDER OF Treasurer, State of Connecticut
Division of Health Systems Regulations
PO Box 1080
Hartford, CT 06143-1080

M. D. Bar
AUTHORIZED SIGNATURE

Security features included. Details on back.

Connecticut Orthopaedic Specialists, PC

NAME: Treasurer, State of Connecticut

CHECK DATE: 7/19/2016

28893

500.00

New-FNB Operating 0

500.00

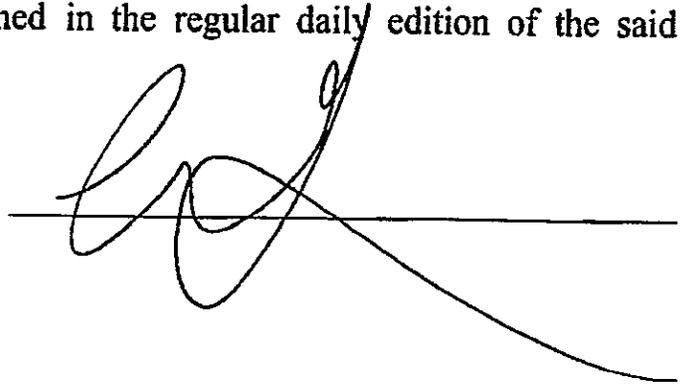
000012

AFFIDAVIT OF PUBLICATION

MIDDLETOWN PRESS

STATE OF CONNECTICUT, County of Middlesex

I Christopher Gilson of New Haven, Connecticut, being duly sworn, do depose and say that I am a Sales Representative of the Middletown Press, and that on the following date .6/27, 28, 29/16..... there was published in the regular daily edition of the said newspaper an advertisement,



Legal Notice

Connecticut Orthopaedic Specialists, P.C. ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$675,000.00

And that the newspaper extracts hereto annexed were clipped from each of the above-named issues of said newspaper. Subscribed and sworn to this 27th... day of July, 2016..... Before me.



My commission expires July 31, 2019

Affidavit

Applicant: Connecticut Orthopaedic Specialists, P.C.

Project Title: Acquisition of a 1.5 tesla Mobile MRI by Private Physician Practice

I, Glenn F. Elia, CEO
(Name) (Position – CEO or CFO)

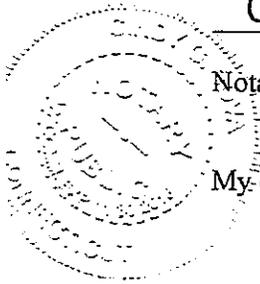
of Connecticut Orthopaedic Specialists, P.C. being duly sworn, depose and state that the (Facility Name) said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Glenn Elia 7-19-16.
Signature Date

Subscribed and sworn to before me on Nov. 30, 2016

Cindy G. Bova
Notary Public/Commissioner of Superior Court

My commission expires: Nov. 30, 2016



**CINDY G. BOVA
NOTARY PUBLIC
MY COMMISSION EXPIRES
NOV. 30, 2016**

Executive Summary

The purpose of the Executive Summary is to give the reviewer a conceptual understanding of the proposal. In the space below, provide a succinct overview of your proposal (this may be done in bullet format). Summarize the key elements of the proposed project. Details should be provided in the appropriate sections of the application that follow.

This Certificate of Need application ("CON") is being filed by Connecticut Orthopaedic Specialists, P.C. ("COS") in order to purchase a 1.5 Tesla mobile MRI. COS is a single specialty orthopedic physician group practice that has operated in Connecticut as a Professional Corporation for over 50 years. COS currently owns two 1.5 T MRIs, one located in its physician office in Hamden and the other on its outpatient surgery campus in Branford. Both have reached maximum capacity. Both MRIs are being utilized over 12 hours each weekday and on the weekends.

COS recently added other orthopedic physician groups to its group practice. Between 2014 and 2015, COS merged with four other orthopedic physician group practices expanding the total number of physicians' offices to from eight (8) to twenty one (21) with a new total of 49 orthopedic doctors. The new COS physicians have patients in need of orthopedic MRI scanning, and as a result, the volume of MRI scanning has increased rapidly. Also, Hamden and Branford have used up any excess capacity they had prior to 2014.

If approved, the MRI will be mobile, and will operate between two existing COS offices – Orange and Essex. At the outset, the mobile will operate 2 days a week in Orange, two days a week in Essex and will travel between the two locations one day.

MRI service is an important component of treatment for orthopedic patients who require this type of scanning. With a COS radiologist to read the images, reports are ordinarily back to the orthopedic physician overnight if not the same day. Keeping all components of the patient's care within COS results in faster treatment, which keeps the patient's condition from worsening, causing more expensive consequences. COS works with numerous health care insurers in CT to bundle payments, and the MRI fee is included in the bundled cost. There is no facility fee involved.

COS provides MRI services exclusively for orthopedic patients who are being treated by COS physicians. COS does not accept referrals for MRI services from any other source outside of the practice.

Pursuant to Section 19a-639 of the Connecticut General Statutes, the Office of Health Care Access is required to consider specific criteria and principles when reviewing a Certificate of Need application. Text marked with a “§” indicates it is actual text from the statute and may be helpful when responding to prompts.

Project Description

1. Provide a detailed narrative describing the proposal. Explain how the Applicant(s) determined the necessity for the proposal and discuss the benefits for each Applicant separately (if multiple Applicants). Include all key elements, including the parties involved, what the proposal will entail, the equipment/service location(s), the geographic area the proposal will serve, the implementation timeline and why the proposal is needed in the community.

Response:

Description of the Proposal

This CON application is a request from Connecticut Orthopaedic Specialists, P.C. (“COS”) to purchase a mobile 1.5 Tesla MRI to be used at two physician offices for COS patients only. The MRI would be used initially two days a week in Orange and two days a week in Essex, with one day of travel mid-week.

COS is a private physician practice treating only orthopedic patients. It has been in existence for over fifty years, treating patients in south-central Connecticut. With highly trained orthopedic surgeons and health care professionals, COS provides extraordinary care for children and adults with musculo-skeletal injuries and diseases. COS physicians are the Team Physicians for 16 Connecticut high schools, the Quinnipiac University Bobcats and Sacred Heart University.

COS currently has two 1.5 Tesla MRI scanners; one in its Hamden office and the other in its outpatient surgery campus in Branford. Prior to 2014, COS had physician offices in Hamden, Branford, Orange, Guilford, New Haven, Milford, Shelton and Wallingford. Patients who were receiving treatment in Hamden and Branford could have any necessary MRI scanning done in those offices. Other COS patients who lived in close proximity to either Hamden or Branford but were being treated in other COS facilities where there is no MRI, could also use the COS Branford or Hamden locations for MRI scanning.

It has always been the practice of COS to do MRI scanning in-house whenever possible because of time and quality, which leads to a better outcome for the patient. COS has an agreement with Dr. Joseph Gagliardi to professionally read and provide appropriate information and reports for MRI images for COS. Dr. Gagliardi is a COS employee who has a fixed salary.

Offering MRI services within COS has a number of benefits for the patient. The COS orthopedic physician can order the MRI, and book the appointment immediately. The COS radiologist will read and return the report to the orthopedic physician within 24 hours, and often during the same day. This allows the orthopedic physician to begin treatment much faster than if the patient has to go elsewhere to book an MRI, wait for the results and wait for the radiologist to contact the orthopedic doctor to transmit those results.

MRI scanning is built in to the cost for orthopedic care at COS if the patient's insurer accepts this payment method. COS has begun using a "bundled payment" system where there is one bill to treat a patient for the particular orthopedic diagnosis, and this one cost includes everything from the first visit to the completion of treatment. It is a value based system, focusing on best practices. Individual costs for each part of the treatment are not billed individually, which makes the overall cost more economical. In addition to the saving of time and the connection between all parts of the patient's care with in-office scanning, COS has negotiated with a couple of its largest payers to lower prices by bundling the fees. These savings are passed on to the patients, and help to lower health care costs in Connecticut.

Need for the Proposal

Until the last two years, COS had enough scanning capacity to treat the COS patients in its Hamden and Branford offices. However, during a two year period between 2014 and 2015, the COS practice grew with the addition of four private practice orthopedic physician groups. This has more than doubled the number of COS offices, and greatly expanded the volume of patients. None of these groups own or lease an MRI, and COS is using its two existing MRIs for a practice that now has 49 physicians and 21 locations (an expansion from 8 to 21 physician offices). See Exhibit A for a map of the current COS offices, a listing of all 21 office locations and a listing of all of the physicians practicing in each of the new COS offices prefaced by a list of the COS physicians prior to the mergers. The two existing COS fixed MRIs located in the Hamden office and on the Branford outpatient surgery campus, have reached maximum capacity, even with expanded hours.

The four orthopedic physician practices that merged with COS are:

- Center for Orthopedics: General and Specialty Care, with physician offices located in Orange, New Haven, Norwalk, Hamden and Branford;
- Shoreline Orthopedics & Sports Medicine with physician offices in Essex, Madison and Guilford;
- The Orthopedic Group with physician offices in Milford, Branford, Hamden and Wallingford; and
- Orthopedic Health with one physician office in Milford.

All of these offices are single-specialty practices where a physician covers the patient care from the beginning of the orthopedic health issue to its conclusion.

As the two COS MRI units experienced greater demand after 2014, both locations began offering expanded office hours. Currently, both COS offices with an MRI unit are open 13 hours on weekdays and 10 hours on Saturdays.¹ In addition, the Hamden office regularly sees patients on Sunday as necessary. The hours have expanded from 64 hours per week to 75 hours per week plus the availability of MRI scanning on Sunday. The current hours for each of the two existing locations are:

Hamden

Monday – Friday: 7:00 A.M. – 8:00 P.M.

Saturday: 7:00 A.M. – 5:00 P.M.

Sunday: By appointment

Branford

Monday – Friday: 7:00 A.M. – 8:00 P.M.

Saturday: 7:00 A.M. – 5:00 P.M.

Need for the Two New Locations

There is a need for additional MRI capacity in order to keep up with the existing demand in Hamden and Branford, and make MRI scanning part of the orthopedic process for the thirteen (13) new offices that have joined COS. The volume of scanning in the Hamden and Branford offices has been growing steadily over the last three years due to the increased number of patients at both locations. See **Exhibit B** for the volume increase from 2013 through June of 2016 (annualized).

The physicians in COS determined that the best way to offer MRI service to as many of the new COS patients as possible is to add a mobile unit which could service two distinct areas. Orange was selected as one location because it has six (6) COS offices within Orange and adjacent towns. Orange is close enough to Hamden that patients living between Orange and Hamden would be able to use Orange instead of driving north to Hamden if the wait in Hamden is too long.

The Essex location was selected because there is no COS MRI service anywhere near the three (3) new offices brought into the COS practice through the merger with Shoreline Orthopedic and Sports Medicine, which has offices in Essex, Guilford and Madison.

¹/ Prior to the 2014 and 2015 mergers with the 4 practices, the two COS MRIs each operated 64 hours per week (12 hours on Monday-Friday for and 4 hours on Saturdays).

In Orange

Depending upon where the patient lives, there will be many COS patients who are currently using the Branford or Hamden MRI who will find the Orange office more accessible for MRI scanning. This new mobile MRI would be able to accommodate COS patients who have been seeing their COS physician in the Orange, Milford, and Shelton physician offices which existed prior to the mergers. It will also be able to accommodate patients who have come in to the COS practice in the last two years as part of the merger with the Center for Orthopaedics, Orthopedic Health and The Orthopedic Group. Of the new orthopedic practices which have joined COS since 2014, one practice is located in Orange and two offices are located in Milford. All three offices are close enough to Orange to have their MRI scanning performed in the Orange office.

- The Center for Orthopedics has a practice in Orange located at 464 Boston Post Road, which is located 0.6 miles and 2 minutes from the existing COS office.
- The Orthopaedic Group has an office located in Milford at 30 Commerce Park which is 3.3 miles and 8 minutes away from the existing COS Orange office.
- Orthopedic Health has an office at 849 Boston Post Road in Milford which is located 6.8 miles and 15 minutes away from the existing Orange office.

There will be no facility fee involved in using the mobile MRI in Orange

In Essex

The Essex location would accommodate patients who had been seeing physicians in the Shoreline Orthopedics & Sports Medicine group which has offices in Essex, Guilford and Madison. This physician practice merged with COS in 2014. The orthopedic physicians in the Shoreline Orthopedics & Sports Medicine practice have three (3) offices. They are located in the following towns:

- Essex located at 12 Bokum Road.
- Madison located at 1353 Boston Post Road, which is 10.6 miles and 16 minutes from the Essex COS office.
- Guilford at which is 18.2 miles and 20 minutes from the COS Essex office.

By using this outpatient MRI service, it would be less costly as there is no facility fee, and all of the other benefits of having an in-practice MRI would also apply. COS patients would be able to have MRI scanning done in an outpatient facility, by a COS radiologist where the scans are read "stat", and transmitted to the treating orthopedic doctor either the same day, but no longer than 24 hours later.

Currently most patients who have been seeing doctors in the three (3) COS orthopedic groups in the Essex area who require an MRI study cannot be accommodated at an existing COS MRI and are referred to other providers for the MRI scan. The provision of a mobile MRI service in Essex would allow the patients of this COS orthopedic group to have the option of having any necessary MRI scan at a COS office. Many COS

patients who live in this service area (*See Table 2B, infra*) and currently have their MRI studies performed at a COS office in Hamden or Branford could have their MRI scans performed at the proposed Essex COS MRI, thereby improving accessibility to care.

The Implementation Timeline

If approved, the mobile MRI would begin installation immediately, and would be available to patients as soon as the installation is complete. It is anticipated that the mobile scanner would be operational within 90 days of approval.

2. Provide the history and timeline of the proposal (i.e., When did discussions begin internally or between Applicant(s)? What have the Applicant(s) accomplished so far?).

Response:

The Applicant was aware that in Hamden, the volume of scans rose from 304 scans in May of 2014 to 397 in October of 2014. It was apparent that the volume was growing, and COS began to add hours to their schedule for MRI scanning to keep up with the demand. In 2015, the volumes were again strong every month, with a maximum of 387 scans in October. (*See Exhibit B*).

In Branford, by 2015, the Applicant first realized that the number of scans being done there was also increasing. Between January and April of 2014, there were less than 200 MRI scans being performed each month. But in October of 2014, the volume rose to 275 per month. In October of 2015, Branford did 390 scans. It was at that point that COS began to feel the full effect of the four new orthopedic practices that had merged with COS and the effect on the MRI capacity it would need to keep pace with their physicians. (*See Exhibit B*).

Discussions began in late 2015 about adding a third MRI for the COS offices. Hours could not be expanded any further without significant added cost, and there simply was not enough space (slots) in the day and evening hours to add a significant number of scans. Sunday scanning was added in Hamden, which costs more due to overtime pay for skilled employees.

Currently in 2016, the volumes are growing even more rapidly. Hamden did 389 scans in March of 2016 and 382 scans in April of 2016. Branford did 409 scans in February of 2016, and 403 scans in March of 2016. And most recently, in June of 2016, 384 scans were performed in Hamden and 436 scans were performed in Branford. (*See Exhibit B*).

Thus far in 2016, Branford's monthly MRI volumes have been:

January: 378
February: 409
March: 403

April: 375
May: 392
June: 436

Hamden's volumes thus far in 2016 have been:

January: 359
February: 345
March: 389
April: 382
May: 355
June: 384

See Exhibit B.

The Applicant started working on a plan at the end of 2015, and has been working with its physicians and the vendors of MRI equipment to try to figure out the best solution. Both mobile and fixed MRIs were considered, and a decision was made in April that a mobile MRI to be shared by Orange and Essex would take the stress out of the existing schedules of Hamden and Branford, and the impossibility in the near future of accommodating even the Hamden and Branford patients for MRI scans within a reasonable period of time due to over-utilization. A mobile MRI will provide two locations, which will provide existing COS patients with better accessibility, while the new COS offices would have additional capacity for MRI scanning for their patients.

If approved, the mobile unit will operate in Orange on Mondays and Tuesday, travel to Essex on Wednesday and operate in Essex on Thursday and Friday. This will add 4 days of MRI scanning to the COS physician practice.

3. Provide the following information:

- a. utilizing OHCA Table 1, list all services to be added, terminated or modified, their physical location (street address, town and zip code), the population to be served and the existing/proposed days/hours of operation;

Response:

Please see OHCA Table 1.

- b. identify in OHCA Table 2 the service area towns and the reason for their inclusion (e.g., provider availability, increased/decreased patient demand for service, market share);

Response: Please see OHCA Table 2.

4. List the health care facility license(s) that will be needed to implement the proposal;

Response:

0 0 0 0 2 0

N/A No health care facility licenses will be required to implement the proposal because COS is a private physician practice.

5. Submit the following information as attachments to the application:

- a. a copy of all State of Connecticut, Department of Public Health license(s) currently held by the Applicant(s);

Response:

COS has a DPH license for its Out-Patient Surgical facility in Branford, which is attached as **Exhibit C**.

- b. a list of all key professional, administrative, clinical and direct service personnel related to the proposal and attach a copy of their Curriculum Vitae;

Response: Please see **Exhibit D**.

- c. copies of any scholarly articles, studies or reports that support the need to establish the proposed service, along with a brief explanation regarding the relevance of the selected articles;

Response: Please see **Exhibit E**.

- d. letters of support for the proposal;

Response: Please see **Exhibit F**.

- e. the protocols or the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet the protocols or guidelines.

Response: COS adheres to the American College of Radiology Standard of Practice Guidelines. In addition, COS has developed its own guidelines in a document entitled, "COS MRI Protocols/Guidelines" which is attached as **Exhibit G**.

- f. copies of agreements (e.g., memorandum of understanding, transfer agreement, operating agreement) related to the proposal. If a final signed version is not available, provide a draft with an estimated date by which the final agreement will be available.

Response:

N/A There is no other party involved in this application and therefore, no memorandum of understanding, transfer agreement or operating agreement.

Public Need and Access to Care

§ "Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;" (Conn.Gen.Stat. § 19a-639(a)(1))

6. Describe how the proposed project is consistent with any applicable policies and standards in regulations adopted by the Connecticut Department of Public Health.

Response:

Both existing MRI scanners have received accreditation from the American College of Radiology (copies of the certificates of accreditation are attached as **Exhibit H**). The MRI services are managed by Dr. Joseph Gagliardi, who is a full-time board certified radiologist and a member in good standing with the American College of Radiology. Dr. Gagliardi is also responsible for the written interpretation of the scans. ACR accreditation will be obtained for the proposed mobile MRI scanner and the proposed MRI service will also be managed by Dr. Gagliardi.

§ "The relationship of the proposed project to the statewide health care facilities and services plan;" (Conn.Gen.Stat. § 19a-639(a)(2))

7. Describe how the proposed project aligns with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan, available on OHCA's website.

Response:

- a. The Applicant's proposal to add a 1.5 Tesla mobile MRI for its patients to be used in-office in Orange and Essex meets the requirements of the CT DPH OHCA Statewide Health Care Facilities and Services Plan both technically, and in the spirit of that document.

Existing Hamden and Branford MRIs

Between 2014 and 2015, COS added 13 new orthopedic physicians private offices to its practice, creating a large number of COS patients who will not be able to have an MRI scan at either Hamden or Branford due to the lack of extra capacity at either location. The need methodology set out in the CT DPH OHCA Statewide Health Care Facilities and Services Plan (p. 61), provides a benchmark of 4,000 scans for an MRI scanner and allows for the addition of a scanner if the existing scanner is operating over 85% capacity (3,400 scans annually). The two existing COS MRI scanners are currently operating at levels that exceed 85%, based on the OHCA benchmark of 4,000 scans per year. (See Table 5, infra).

In 2015, the MRI scanner in Hamden performed 3,773 scans which is 94% utilization of current capacity and is projected to have a 110% utilization of current capacity in 2016 (4,428 scans). Similarly, in 2015 the MRI scanner in Branford performed 3,851 scans which is 96% utilization of current capacity and is projected to have a 120% utilization of current capacity in 2016 (4,786 scans). *See Table 5, infra.* Therefore, the Applicant is in compliance with the standards as set forth in the CT DPH OHCA Statewide Health Care Facilities and Services Plan because these volumes exceed the 4,000 MRI scans per year benchmark contained in the plan.

In order to accommodate the current demand of COS patients for MRI scans, COS extended the hours of operation in 2016. Both scanners are now operating 75 hours per week. Although this is not ideal, it was necessary to enable COS to meet its patients' need for MRI scanning.

The Proposed Mobile MRI

The proposed mobile MRI scanner will initially operate four days per week with one weekday to travel (2 days in Essex and 2 days in Orange). The scanner will operate 12 hours per day at 45 minutes per scan, for a maximum of 32 scans per week or 1,664 scans per year at each location (total capacity of 3,328 MRI scans). If the scanner were to operate 5 days per week, it would have a total capacity of 4,160 MRI scans per year, which exceeds the 4,000 MRI scans per year benchmark contained in the CT DPH OHCA Statewide Health Care Facilities and Services Plan. In 2017, the projected utilization at the Orange location is 90% of the maximum capacity and at Essex it is 92% of the maximum capacity. In Orange the utilization increases to 93% in 2018 and 96% in 2019, while in Essex the utilization increases to 95% in 2018 and 98% in 2019. Based on the projected utilization, it is anticipated that the mobile MRI will need to be operated 5 days per week by 2018. *See Table 6 infra.*

- b. The application complies with the directive to maintain and improve the quality of health care services offered to the state's residents.

Dr. Gagliardi is a board certified radiologist who is a member in good standing with the American College of Radiology. He is able to read the MRI scans and report the findings back to the treating physician usually within the same day and no later than 24 hours after the MRI scan is done. Because this is a single-specialty orthopedic practice, the scanning process is more homogeneous, and Dr. Gagliardi has had years of experience with orthopedic scans. Patients appreciate the fact that they can have the MRI scan done in the doctor's office without having to travel to another location, and without waiting longer for the results. The time between MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of the health care that is provided.

- c. The existing COS service and the proposed service will both be provided in the most cost effective way possible.

There is no facility fee involved. And COS has already begun the process of “bundling costs” so that the cost of an MRI scan is bundled with the other services that are necessary for the patient’s particular orthopedic diagnosis. This reduces the overall cost of the patient’s care. COS has already arranged with a couple of its major payers to offer this consolidated plan, and will reach out to all other payers who are interested in taking this step to reduce health care costs.

- d. The application promotes equitable access to health care services.

COS accepts both Medicare and Medicaid patients, and has recently adopted a Charity Care Policy that will facilitate the process of accepting patients who are unable to pay for access to necessary health care. See **Exhibit I**.

§ “Whether there is a clear public need for the health care facility or services proposed by the applicant;” (Conn.Gen.Stat. § 19a-639(a)(3))

- 8. With respect to the proposal, provide evidence and documentation to support clear public need:
 - a. identify the target patient population to be served;

Response:

Because this application is a proposal to add a mobile MRI for in-house use at private physician offices, the ordinary utilization calculation cannot be used. This MRI will not be dependent upon the ordinary service area calculation which is developed by setting up the service area, and then determining the number of people who would use the service, and whether there is already sufficient capacity in the service area or not. In this case, since the MRI unit that is requested will be used only for COS patients, the number of persons needing the service had to be calculated from the statistics of the COS facilities in the service areas for Orange and Essex (the two areas which will each have use of the mobile scanner 2 days a week).

The target population (as set forth in Tables 2A and 2B) is COS patients who live in either Essex or Orange, COS patients who live in all towns which are contiguous to either Essex or Orange, or towns that are adjacent to the contiguous towns in both locations which provide a significant COS patient volume. Since the mobile MRI will augment the existing COS MRI scanning capability in Hamden and Branford, the Applicant first utilized existing 2015 COS patient MRI data to determine the volume of CT COS patients in each of the service areas. This data is provided by patient zip code in **Exhibit J(1) – J(3)**

Exhibit J(1) is a compilation of zip code data identifying all COS patients living in Connecticut in 2015 who had an MRI scan at a COS scanner in Branford or Hamden. (There are many COS patients who live out-of-state, but they are not included in Exhibit J(1). See p.3 of Exhibit J(1) for the total volume in each service area. From this table, COS could determine how many of their patients live in the towns and contiguous towns where the new mobile MRI would be located. Exhibit J(2) is the compilation of zip code data identifying all COS patients who had an MRI scan at the existing MRI in Branford in 2015. This information was utilized to determine how many COS patients (already using one of the existing COS scanners) would find the mobile scanner either in Essex or Orange more accessible. And Exhibit J(3) is the compilation of zip code data identifying all COS patients who had an MRI scan at the existing MRI in Hamden in 2015 in order to estimate how many of these COS patients, (already being scanned on a COS scanner) would find either Orange or Essex more accessible.

The Applicant also used 2015 data regarding referrals of COS patients from the Essex area to non-COS MRI scanners as Shoreline Orthopedics had a list of all those patients who had been referred to non-COS facilities. The COS office in Orange did not have such a list, so a ratio was created to estimate the number of referrals of COS patients from the Orange area to non-COS MRI scanners (Exhibit L). From this combined information, COS could determine the number of COS patients that could not be accommodated at a COS facility in 2015, but were also likely to use the mobile scanner in either Essex or Orange.

- b. discuss how the target patient population is currently being served;

Response:

To the extent possible, the target population (which involves only COS patients) is currently served by the two COS MRI scanners that are located in Branford and Hamden. Prior to the addition of the 4 physician practices with 13 offices in 2014 and 2015, the COS patients could be accommodated by the 2 existing COS MRI scanners. However, since the size of the target population (COS patients) has increased as a result of the new practices, the COS MRI capacity has been exceeded. Due to the lack of COS MRI availability, most of the patients from the Shoreline Orthopedic offices are currently scanned at non-COS facilities. Please see the response to Question #2 for more detail.

- c. document the need for the equipment and/or service in the community;

Response:

The need for the proposed mobile MRI scanner is based on the current overutilization of the two existing MRI scanners. Both scanners are currently

operating over capacity. As described in the response to Question #1, both COS MRI scanners were operating 64 hours per week prior to 2015. In 2015 the Branford MRI scanner had a percent utilization of current capacity of 96% and the percent utilization of current capacity is projected to be 120% in 2016. The Hamden MRI had a 2015 percent utilization of current capacity of 94% and the percent utilization of current capacity is projected to be 110% in 2016. As a result of the increase in volume, COS was forced to extend the hours of operation of the MRI scanners to approximately 75 hours per week in order to accommodate the increase in MRI studies. Even operating at this level of over-utilization, COS cannot handle the existing or expected increase in patient volume.

The increase in utilization is due to the acquisition of 4 physician practices with thirteen offices. Impact of the acquisitions on MRI utilization at the existing COS scanners began in 2014 when COS experienced a 20% increase in the number of MRI scans performed. In 2015 COS experienced a 21% increase in the number of MRI scans, and the increase in the number of MRI scans is projected to be 21% in 2016.

Orange

As a result of the acquisition of Orthopedic Health, The Orthopedic Group and the Center for Orthopedics, COS now has six (6) physician offices in the Orange area. In 2015, the number of patients seen at the 6 offices had a combined total volume of 9,555 patients. See Exhibit L. Analysis of internal records based on patient records from all 21 COS offices in 2015 indicate that for every new COS patient, 1 out of every 6.38 patients required an MRI scan (15.6%) (See "Ratio Analysis" below the chart in Exhibit L.) This results in an estimated 1,488 scans generated by patients seen at the 6 COS offices in the Orange area offices. See Exhibit L.

The influx of patients from these practices has saturated the capacity of the existing MRI scanners. In 2015, while 1041 patients were able to be scanned on one of the two existing MRIs, an estimated 447 patients of the COS offices in the Orange area could not be accommodated at a COS MRI and were referred to another provider for MRI scan. See Exhibit L.

Essex

The Shoreline Orthopedics and Sports Medicine practice has offices in Essex, Madison and Guilford. Currently most patients who see doctors in this COS orthopedic group who require an MRI study cannot be accommodated at an existing COS MRI and are referred to other providers for the MRI study. In 2015, the Shoreline Orthopedic practice referred 963 patients, including 569 patients from the Essex service area, to non-COS MRI facilities. See Exhibit K.

Additionally, 950 patients who lived in the Essex service area in 2015 and were treated at COS offices other than Shoreline Orthopedics offices received an MRI scan at either the Branford or Hamden MRI scanners in 2015. See Exhibit J(1), p.3. A total of 1,519 COS patients from the service area received an MRI scan in 2015 (950 at a COS MRI and 569 referred to a non-COS MRI scanner). The 950 COS patients who live in the Essex service area and were scanned at either the COS Branford MRI or the COS Hamden MRI in 2015 will likely utilize the Essex mobile MRI if it is approved.

- d. explain why the location of the facility or service was chosen;

Response:

COS might have sought approval from OHCA to add one (1) additional fixed MRI at either its Branford or Hamden location. However, the decision was made to locate the additional MRI in the locations where the service is most needed. Essex was selected as one of the two locations to offer MRI service two days a week because of the influx of new patients in the shoreline area with the addition of Shoreline Orthopedics & Sports Medicine (“Shoreline”) to COS. Shoreline has offices in Essex, Madison and Guilford. Orange was selected as the other site for the additional MRI service because of the volume of scanning at the Hamden and Branford offices and the accessibility it would offer to COS patients well within travel time to use the Orange location depending upon where they live in relation to the service in Orange. These are COS patients currently using a COS MRI who will now transfer to the mobile MRI in Orange.

- e. provide incidence, prevalence or other demographic data that demonstrates community need;

Response:

As discussed in the responses to Questions #1 and #8c, COS is an established orthopedic practice that provides MRI scanning to its patients as part of the continuum of orthopedic treatment. COS scanning services are not available to non-COS patients. The need for mobile MRI services is due to the overutilization of the 2 existing scanners in Hamden and Branford and to the addition of the 4 physician practices which has 13 offices in Connecticut which are now COS physician practices. COS now has 21 physician offices. The two existing scanners can no longer handle the volume that is required. See Exhibit A for a map of the total number of COS locations. COS has extended the normal hours of operation in Hamden and Branford to meet patient need, and is still unable to accommodate all its patients who require an MRI scan at its 2 existing MRI locations.

- f. discuss how low income persons, racial and ethnic minorities, disabled persons and other underserved groups will benefit from this proposal;

Response:

Racial and ethnic minorities are not discriminated against by COS. Physically disabled persons are accommodated with every means available because these patients are coming to COS with an orthopedic problem, which can be very disabling. Mentally disabled persons are encouraged to bring a person with them to the appointments so that they have the support they need in understanding directions to follow. COS has recently adopted a Charity Care Plan to assist low income and underserved groups. *See Exhibit I.*

- g. list any changes to the clinical services offered by the Applicant(s) and explain why the change was necessary;

Response:

There will be no changes to the clinical services offered by COS as a result of this application.

- h. explain how access to care will be affected;

Response:

Access to MRI services will be greatly improved for COS patients who live in the Essex and Orange area. These patients will be able to be accommodated at a COS office location on a more timely basis; the patient will not have to seek MRI services at a different location unless they choose to do so.

- i. discuss any alternative proposals that were considered.

Response:

The only alternative that was considered by COS was a fixed MRI. Ultimately a mobile MRI unit was selected so that the service will match up with the two geographical areas where there is the greatest need for COS patients to have MRI scanning. The service is being tailored to the specific patient need.

§ "Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons; (Conn.Gen.Stat. § 19a-639(a)(5))

9. Describe how the proposal will:

- a. improve the quality of health care in the region;

Response:

For COS patients living along the shoreline between Guilford and Essex, having MRI scanning available at a COS office in Essex will provide better access to MRI scanning than having to drive to Branford (which is the closest COS office with an MRI unit). For patients in the Orange area, the MRI service two days a week will facilitate having the scans performed closer to home than Hamden or Branford, where the closest COS scanning is performed. Drive time can be an important factor for orthopedic patients depending upon what part of the body has been injured or is otherwise in need of medical attention.

The coordination between the COS radiologist and the COS physician is seamless. And the MRI scanning results can be delivered much faster than from another facility. And for many of the orthopedic patients who are being treated by a COS physician, the cost of MRI scanning is built into the cost of their treatment. It is not a separate bill.

- b. improve accessibility of health care in the region; and

Response:

Since the Applicant is a private physician practice, its patients have been using the 2 MRI units in Branford and Hamden without any issues of accessibility until the last year. With the addition of the 4 new physician practices between 2014 and 2015, the 2 COS MRIs are now over capacity. Adding 4 days of MRI scanning in two new locations will make MRI service much more accessible for COS patients in the Essex and Orange areas.

- c. improve the cost effectiveness of health care delivery in the region.

Response:

COS has arranged with a couple of its major commercial insurers to pay one fixed price for a patient's entire treatment for the orthopedic diagnosis the patient presents. For example, if a patient comes to COS with an anterior cruciate ligament ("ACL") injury, there is a fixed price that COS will receive no matter how much care the patient receives. This fixed fee is a bundling of the individual fees.

The ACL patient's one bill will include the physician's care, the use of the facility, (physician's office and surgical center, if required) surgery, and the costs associated with the surgery (anesthesiologist, etc.) and radiology costs, including the fee for the radiologist. Whether the patient needs an X-ray, or an MRI or both, or multiple x-rays or scans or surgery and the use of the outpatient surgical center, the price remains the same. The fixed fee also includes physical therapy if the patient requires it. This is an incentive for the physician to carefully select the tools needed to resolve the patient's problem, and not over utilize the technology

that is available. COS measures the costs involved in treatment, and compares the costs with patient outcomes. This system is known as “Time-Driven Activity Based Costing” or “TDABC”. Please see Exhibit E, “The Big Idea, How to Solve the Cost Crisis in Health Care”, Harvard Business Review, Sept. 2011. This system creates efficiency and lowers the cost of treatment, while maintaining the highest quality.

10. How will this proposal help improve the coordination of patient care (explain in detail regardless of whether your answer is in the negative or affirmative)?

Response:

This proposal will help to improve the coordination of patient care because the patient is being treated under the direction of one physician. If MRI scanning is required, the appointment is set up by the treating orthopedic physician. The radiologist who reads the MRI scan is an employee of COS, and is focused on reading COS scans within hours of receiving them. The radiologist communicates directly with the patient’s treating doctor. If the patient needs outpatient surgery this can be done in the COS outpatient surgery center in Branford. If the patient needs surgical care in a hospital, that is also arranged by, and performed by the COS orthopedic surgeon. This coordination is extremely helpful to the patients who are suffering with orthopedic problems, and who often need medical care as quickly as possible.

11. Describe how this proposal will impact access to care for Medicaid recipients and indigent persons.

Response: Medicaid recipients are accepted at all COS facilities. Indigent persons will be treated under the COS charity care policy.

12. Provide a copy of the Applicant’s charity care policy and sliding fee scale applicable to the proposal.

Response: See Exhibit I.

§ "Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;" (Conn.Gen.Stat. § 19a-639(a)(10))

13. If the proposal fails to provide or reduces access to services by Medicaid recipients or indigent persons, provide explanation of good cause for doing so.

Response: N/A

§ "Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care." (Conn.Gen.Stat. § 19a-639(a)(12))

14. Will the proposal adversely affect patient health care costs in any way? Quantify and provide the rationale for any changes in price structure that will result from this proposal, including, but not limited to, the addition of any imposed facility fees.

Response:

This proposal should benefit patient health care costs in a positive way as COS encourages all of its payers to participate in a "bundled payment" program. MRI scanning fees will remain the same, and there will be no facility fees at any COS location.

Financial Information

§ "Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;" (Conn.Gen.Stat. § 19a-639(a)(4))

15. Describe the impact of this proposal on the financial strength of the state's health care system or demonstrate that the proposal is financially feasible for the applicant.

Response:

This proposal will positively impact the financial strength of the state's health care system because COS will be offering its patients more cost effective collaborative MRI scans. Additionally, this proposal is financially feasible for COS because COS has a proven track record by fully utilizing its existing scanners and it has the utilization numbers to support the proposed mobile MRI scanner.

16. Provide a final version of all capital expenditure/costs for the proposal using **OHCA Table 3**.

Response: See OHCA Table 3 and **Exhibit M**

17. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Response: See **Exhibit N**.

18. Include as an attachment:

- a. audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, provide other financial documentation (e.g., unaudited balance sheet, statement of operations, tax return, or other set of books). Connecticut hospitals required to submit annual audited financial statements may reference that filing, if current;

Response: See **Exhibit O**.

- b. completed **Financial Worksheet A (non-profit entity), B (for-profit entity) or C (\$19a-486a sale)**, available on OHCA's website under OHCA Forms, providing a summary of revenue, expense, and volume statistics, "without the CON project," "incremental to the CON project," and "with the CON project." **Note: the actual results reported in the Financial Worksheet must match the audited financial statement that was submitted or referenced.**

Response: See **Exhibit P**.

19. Complete **OHCA Table 4** utilizing the information reported in the attached Financial Worksheet.

Response: See Table 4 in Section on Tables *infra*.

20. Explain all assumptions used in developing the financial projections reported in the Financial Worksheet.

Response: See **Exhibit Q**.

21. Explain any projected incremental losses from operations resulting from the implementation of the CON proposal.

Response: No projected incremental losses from operations are expected from the implementation of this CON proposal.

22. Indicate the minimum number of units required to show an incremental gain from operations for each projected fiscal year.

Response:

For FY2017, the minimum number of units to show an incremental gain would be 440 scans, for 2018, it would be 707 scans and for 2019 it would be 977 scans.

Utilization

§ "The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;"
(Conn.Gen.Stat. § 19a-639(a)(6))

23. Complete **OHCA Table 5** and **OHCA Table 6** for the past three fiscal years ("FY"), current fiscal year ("CFY") and first three projected FYs of the proposal, for each of the Applicant's existing and/or proposed services. Report the units by service, service type or service level.

Response: Please see **OHCA Table 5** and **OHCA Table 6**, *infra*.

24. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected service volume; explain any increases and/or decreases in volume reported in OHCA Table 5 and 6.

Response:

Assumptions Used in Table 5: Increases in Volume

COS has experienced significant increases in utilization from 2013 to 2015. The increase is projected to continue into 2016. The increases in utilization are as follows:

2013 - 2014	20.4% increase
2014 - 2015	21% increase
2015 - 2016	21% increase (projected)

The increases that occurred between 2013 and 2016 (through June) are due to two factors, the merger of four existing physician practices into COS and an increase in the hours of operation. (Please see response to Question 1 for more detail on the mergers, the impact on volume, and extended hours of operation). The rate of increase is anticipated to slow in 2017 due to the "maturation" of the merger (with the exception of the patients from the Shoreline Orthopedics & Sports Medicine who are still being referred to other providers).

Assumptions used in OHCA Table 6

Overall Assumptions

- An MRI scan takes 45 minutes.
- The optimum use rate for each scanner is 85% of the maximum number of scans possible within the scheduled hours of operation. This allows the scheduling for maintenance, downtime, cancellations and holidays, etc.
- The MRI scanners located in Hamden and Branford will operate 64 hours per week (Monday – Friday for 12 hours per day and 4 hours on Saturday) for a maximum of 85 scans per week or 4,420 scans per year. At an 85% use rate, the number of scans for each scanner on an annual basis is 3,757 scans. (This represents a reduction in hours of operation and number of scans currently performed at these locations).
- The reduction in the volume at Hamden and Branford will bring these scanners back to a normal, maximum use rate, and the overflow of patients is expected to utilize the mobile units in Orange and Essex.
- Initially, the mobile MRI scanner will operate 2 days per week in Orange and 2 days per week in Essex. The scanner will operate 12 hours per day at each location (a maximum of 32 scans per week or 1664 scans per year at each location). At an 85% use rate, the number of scans at each location in 2017 is 1414 (1664 scans x 85%).
- The annual rate of increase in MRI volume at each of the four locations for 2018 to 2019 is 3%. This is based on the historic rate of increase experienced by the Applicant prior to the mergers of physician practices. Between 2012 and 2013, the rate of increase was 2.7%. *See OHCA Table 5.*
- In 2019 a third day of scanning can be added, if necessary, to either the Essex office or the Orange office depending upon which location has the largest volume of MRI scanning.

Essex Mobile MRI Assumptions

- The 2015 volume of COS patients from the Essex service area who received an MRI scan serves as the base for the projected utilization. Of the total 1,519 COS patients who received an MRI scan, 950 COS patients received an MRI scan at a COS MRI scanner and 569 were referred to a non-COS MRI. (Please see Table 8b, “Utilization by Town” and Exhibits J(1) & K.

- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the patients residing in the Essex service area will utilize either the Branford or Hamden MRI as they have in the past.

Orange Mobile MRI Assumptions

- An analysis of COS internal records for 2015 for 6 COS offices in Orange, Shelton and Milford was undertaken. Three of these are original COS offices (Orange, Shelton and Milford) and three are from the merger (one in Orange and two in Milford). It is assumed that the persons most likely to use the Orange MRI are residents of these towns or patients who use the COS offices in these towns.
 - Based on the review of COS internal records for 2015, it is estimated that 9,555 new patients were seen at these offices and 15.6% required an MRI study (1,488 patients). 1,041 of these patients were accommodated at the COS Branford or Hamden MRI scanner and 447 were referred to a non-COS MRI. These 1,488 COS patients serve as the base for the projected utilization. *See Table #8a and Exhibit L.*
 - An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
 - It is assumed that approximately 5% of the 1,488 COS patients will utilize either the Branford or Hamden MRI as they have in the past.
25. Provide the current and projected patient population mix (number and percentage of patients by payer) for the proposal using **OHCA Table 7** and provide all assumptions. **Note: payer mix should be calculated from patient volumes, not patient revenues.**

Response: Please see OHCA Table 7, infra.

The patient population mix is based on COS actual experience in 2015 and 2016, year to date. The patient population mix is not expected to change as a result of this proposal.

§ "Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;"
(Conn.Gen.Stat. § 19a-639(a)(7))

26. Describe the population (as identified in question 8(a)) by gender, age groups or persons with a specific condition or disorder and provide evidence (i.e., incidence, prevalence or other demographic data) that demonstrates a need for the proposed service or proposal. **Please note: if population estimates or other demographic data are submitted, provide only publicly available and verifiable information (e.g., U.S. Census Bureau, Department of Public Health, CT State Data Center) and document the source.**

Response:

As stated above in the response to Question 8(a), the target population to be served is COS's existing orthopedic patient base. Based on the overutilization of the two existing MRI scanners, and the expansion of COS orthopedic offices from eight (8) to twenty-one (21), the COS current patient base is sufficiently large to support the addition of a mobile CON without demonstrating additional need.

27. Using **OHCA Table 8**, provide a breakdown of utilization by town for the most recently completed fiscal year. Utilization may be reported as number of persons, visits, scans or other unit appropriate for the information being reported.

Response: Please see **OHCA Table 8**, *infra.*

§ "The utilization of existing health care facilities and health care services in the service area of the applicant;" (Conn.Gen.Stat. § 19a-639(a)(8))

28. Using **OHCA Table 9**, identify all existing providers in the service area and, as available, list the services provided, population served, facility ID (see table footnote), address, hours/days of operation and current utilization of the facility. Include providers in the towns served or proposed to be served by the Applicant, as well as providers in towns contiguous to the service area.

Response: Please see **OHCA Table 9**, *infra.*

29. Describe the effect of the proposal on these existing providers.

Response:

The effect on existing providers should be minimal. There will only be two days a week of scanning in each location, and the two locations are far apart geographically. Most of the patients who will be using the new mobile scanner are patients who have gone to the Hamden or Branford COS locations for MRI scanning in the past because they are either patients who see a COS physician in one of those two offices, or they are COS patients from other offices who live close enough to Hamden or Branford to use either of those two locations. With more capacity to ease the over-capacity issue at both of these locations, no other provider should be greatly affected by the change

in location of these patients. These patients will have their MRI scanning done in Orange or Essex if Hamden or Branford are over capacity.

For the COS patients who have had to use other providers in the past, COS will be recapturing its own patients so that their treatment can be delivered under the direction of one orthopedic specialist. However, all COS patients have the option of using any other radiology service that provides MRI scanning if they want to, or if the COS MRI is not accessible to them. For COS patients in the Essex area who have used another radiology provider prior to becoming COS patients (the Shoreline patients), the geographic area where these patients live is so large that no one existing provider should be more than minimally impacted. It is assumed that claustrophobic or obese patients will continue to be scanned by providers with open MRI scanners.

If a COS patient decides to use another provider for the MRI scan, and the patient's insurer participates in the COS "bundling of costs", COS will contact the other provider to let that office know that the MRI scan is already paid for since it is one of the payments bundled together for a single payment to COS. Arrangements will be made for COS to pay the other provider on behalf of the patient.

30. Describe the existing referral patterns in the area served by the proposal.

Response:

COS physicians are the sole referral for the two existing MRI scanners. There is no publically available data on existing referral patterns for other physicians in the service area.

31. Explain how current referral patterns will be affected by the proposal.

Response:

Current referral patterns will not change as COS physicians continue to be the sole referral source for the two existing MRI scanners and the proposed MRI scanner. It is anticipated that the proposal will have no effect on non-COS referring physicians as COS will be able to accommodate future patient base growth.

§ "Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;" (Conn.Gen.Stat. § 19a-639(a)(9))

32. If applicable, explain why approval of the proposal will not result in an unnecessary duplication of services.

Response:

This is a request for in-office MRI scanning for patients who have already chosen a COS orthopedic specialist. It is anticipated that the mobile MRI will take stress off the two existing COS scanners who which have no hours left in the week that are reasonable to offer more capacity. COS has the patient population that could fill up the slots available on the new mobile MRI within two years. Immediately, COS patients who live in Orange, Milford or Shelton, or use the COS offices in Orange, Milford or Shelton and have been using the Branford MRI or the Hamden MRI will be able to switch over to the closer location. Those patients along the shoreline and in Essex who are COS patients will undoubtedly switch from the COS Branford MRI to the Essex location. Since the mobile MRI is for the use of COS patients only, it should not have the same effect as opening a new imaging center or a new radiology center with MRI capacity. The COS patients are already established. And for them, it is makes more sense to use the MRI services that are already connected to the rest of their treatment, and possibly included in their fee for treatment.

§ *“Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region;” (Conn.Gen.Stat. § 19a-639(a)(11))*

33. Explain in detail how the proposal will impact (i.e., positive, negative or no impact) the diversity of health care providers and patient choice in the geographic region.

Response:

For some patients, having MRI scanning for an orthopedic medical condition is more suited, or necessary, in a hospital location. For others patients, who have not yet selected an orthopedic physician, they may get a referral from a primary care doctor and have the MRI scan done at an outpatient clinic or imaging center operated by a radiologist.

For those patients already seeing an orthopedic physician, MRI scanning done by the same physician practice makes sense. At COS practices, in-office scanning is scheduled immediately and the results are back to the treating physician within 24 hours of the MRI scan. Also at COS, the fee for the MRI scan can be bundled in with the other costs of treatment so that it saves costs for the patient, depending upon the insurer.

This diversity is healthy for Connecticut patients because there is a choice of how to have MRI scanning done. Finding the right practitioner or facility for the patient’s specific medical condition as early as possible leads to better treatment for the patient and potentially less expensive treatment later.

Tables

TABLE 1
APPLICANT'S PROPOSED SERVICES AND SERVICE LOCATIONS
ORANGE AND ESSEX

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
Adding 2 days of MRI Scanning at Existing COS Office	330 Boston Post Road Orange, CT 06477	COS patients	7:00 am – 7:00 pm Monday & Tuesday	COS Mobile MRI
Adding 2 days of MRI Scanning at Existing COS Physician Office f/k/a Shoreline Orthopedics & Sports Medicine	12 Bokum Road Essex, CT 06426	COS Patients	7:00am – 7:00pm Thursday & Friday	COS Mobile MRI

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**TABLE 2A
ORANGE
SERVICE AREA TOWNS**

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
<p style="text-align: center;">Orange New Haven Woodbridge Shelton Derby West Haven Milford Stratford East Haven North Haven</p>	<p>The service area consists of Orange, the site of the proposed mobile MRI scanner for 2 days a week, the towns that are contiguous to Orange (Milford, West Haven, New Haven, Woodbridge, Derby, and Shelton), and North Haven, East Haven and Stratford which are contiguous with other service area towns. North Haven, East Haven and Stratford are included in the service area because residents of these towns are a significant part of the volume at the existing Orange COS facility. In 2015 3,049 residents of these towns received a MRI scan at a COS facility. It is anticipated that the mobile scanner will provide access for the COS patients who use the existing Orange, Milford, Shelton and New Haven offices as well as the new COS offices which are located in Orange and Milford.</p>

* Village or place names are not acceptable

In 2015, 3049 residents of the service area received an MRI scan at a COS facility. See **Exhibit J (1)**, p.3. Additionally, the Applicant is able to estimate that approximately 447 patients from the COS offices located in Orange, Milford and Shelton were referred to non-COS providers for MRI scans. See **Exhibit L**.

Hamden has not been included in the service area because a COS MRI scanner is located in Hamden and that scanner has its own COS service area.

**TABLE 2B
ESSEX
SERVICE AREA TOWNS**

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
<p style="text-align: center;">Essex</p> <p>Madison Guilford Clinton Old Saybrook Westbrook Old Lyme Deep River Chester</p>	<p>The service area consists of Essex, the site of the proposed mobile MRI scanner for 2 days a week, Madison and Guilford which are the site of other COS physician offices, f/k/a Shoreline Orthopedics & Sports Medicine, and the towns that are contiguous to Essex. Chester was also included in the service area because of the number of external referrals for MRI scans. It is anticipated that the mobile scanner will provide access to the new COS offices which are located in Essex, Madison and Guilford.</p>

* Village or place names are not acceptable.

In 2015, 950 residents of the COS Essex service area received an MRI scan at a COS facility. See Exhibit J (1), p.3.. Additionally, the new COS office in Essex (f/k/a Shoreline Orthopedics & Sports Medicine) referred 569 residents of the COS service area patients to a non-COS facility. The referrals out of that office to other providers for MRI scanning are listed in Exhibit K, p.2..

**TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$ 575,000.00
Land/Building Purchase*	
Construction/Renovation**	\$ 730,000
Other (specify)	
Total Capital Expenditure (TCE)	\$ 730,000
Lease (Medical, Non-medical, Imaging)***	
Total Lease Cost (TLC)	
Total Project Cost (TCE+TLC)	\$ 730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

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*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term

A copy of the Purchase Agreement for the MRI and an estimate for the trailer installations are attached in Exhibit N.

**TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2017*	FY 2018*	FY 2019*
Revenue from Operations	\$ 801,262	\$ 992,096	\$ 1,187,746
Total Operating Expenses	\$ 497,687	\$ 525,314	\$ 554,975
Gain/Loss from Operations	\$ 303,575	\$ 466,782	\$ 632,771

*Fill in years using those reported in the Financial Worksheet attached.
Note: COS Fiscal Year is Jan.1–Dec.31 (calendar year)

**TABLE 5
HISTORICAL UTILIZATION BY SERVICE**

MRI Service	Actual Volume MRI Scans (Last 4 Completed FYs)				CFY Volume*
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	2,886	2,095	2,577	3,851	4,786
Connecticut Orthopaedic Specialists 2416 Whitney Ave Hamden, CT (MRI)	2,214	3,141	3,725	3,773	4,428
Total	5,100	5,236	6,302	7,624	9,214

• Annualized based on first 6 months of FY 2016

Note: This data does not include the COS patients who could not be scanned at the COS scanners in Branford or Hamden due to the lack of capacity at those locations. The estimated number of COS patient who could not be scanned at a COS facility in 2015 was 1,016 and in 2016 is projected to be 1,046.

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**TABLE 6
PROJECTED UTILIZATION BY SERVICE**

Existing MRI Service	Projected Volume MRI Scans		
	FY 2017	FY 2018	FY 2019
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	3,757	3,870	3,986
Connecticut Orthopaedic Specialists 2416 Whitney Avenue Hamden, CT (MRI)	3,757	3,870	3,986
Proposed MRI Service			
Connecticut Orthopaedic Specialists 330 Boston Post Road, Orange (MRI)	1,500	1,545	1,591
Connecticut Orthopaedic Specialists 12 Bokum Road, Essex, CT (MRI)	1,531	1,577	1,624
Total	10,545	10,862	11,187

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.

** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

Note: The volumes for COS MRIs performed in Branford and Hamden have been scaled back from their volumes in 2015 and 2016. This is due to the expected number of COS patients who live closer to Orange than to Hamden or Branford and will likely use the new

mobile scanner in Orange. It also reflects the likely use of the mobile scanner in Essex by COS patients who live in the Essex service area and not had access to a COS scanner closer than Branford.

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**TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX**

Payer	Current FY 2016		Projected					
	Discharge s	%	FY 2017		FY 2018		FY 2019	
			Discharge s	%	Discharge s	%	Discharge s	%
Medicare*	1,659	18%	1,898	18%	1,955	18%	2,014	18%
Medicaid*	64	0.7%	74	0.7%	76	0.7%	78	0.7%
CHAMPUS & TriCare								
Total Government	1,723	18.7%	1,972	18.7%	2,031	18.7%	2,092	18.7%
Commercial Insurers	6,358	69%	7,276	69%	7,495	69%	7,719	69%
Uninsured	37	0.4%	42	0.4%	43	0.4%	45	0.4%
Workers Compensation	1096	11.9%	1255	11.9%	1,293	11.9%	1,331	11.9%
Total Non- Government	7,491	81.3%	8,573	81.3%	8,831	81.3%	9,095	81.3%
Total Payer Mix	9,214	100%	10,545	100%	10,862	100%	11,187	100%

* Includes managed care activity.

**TABLE 8A
COS ORANGE
UTILIZATION BY TOWN**

Town	COS MRI FY 2015*
Orange	232
New Haven	626
West Haven	517
Milford	503
Woodbridge	158
Shelton	56
Derby	35
North Haven	416
East Haven	450
Stratford	56
Total	3,049

*Number of patients from the Orange service area receiving MRI scans performed on Hamden or Branford COS MRI scanner in 2015. See Exhibit J (1), P 3.

**TABLE 8B
ESSEX
UTILIZATION BY TOWN**

Town	COS MRI FY 2015*	COS MRI External Referrals FY 2015**	Total MRI FY 2015
Essex	12	120	132
Madison	299	64	363
Clinton	121	6	127
Old Saybrook	39	141	180
Westbrook	33	77	110
Old Lyme	28	107	135
Deep River	12	1	13
Chester	8	40	48
Guilford	398	13	411
Total	950	569	1,519

*Number of patients from primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner. See **Exhibit J(1), p.3.**

Number of patients from primary service area that Shoreline Orthopedics & Sports Medicine referred to other locations for MRI. These patients will be able to utilize the COS Essex Mobile MRI. The data on the referrals is from the electronic medical record system used by Shoreline Orthopedics & Sports Medicine. It is not known where these patients received their MRI, only that their COS physician gave the patients an order to have an MRI scan performed. See **Exhibit K., pp. 1-2.

**TABLE 9
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS**

ORANGE, CT

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
1.5 T Fixed, Closed	Not publically available	Not publically available	Milford Hospital, Inc. 300 Seaside Avenue Milford, CT 06460	24 hours/day, 7 days/week	2005 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Griffin Hospital 130 Division Street Derby, CT	Monday, Wednesday & Friday 7:00am - 7:00pm Saturday 7:00am- 2:00pm	1888 scans in 2013
1.2 T Mobile, Closed	Not publically available	Not publically available	Griffin Imaging and Diagnostic Center at Ivy Brook 2 Ivy Brook Road Shelton, CT 06484	Monday - Friday 7:30am - 6:00pm	2341 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday- Saturday 24 hours	4010 scans in 2013
1.5T	Not publically	Not	Yale-New Haven Hospital, Inc. d/b/a	Sunday-	4454 scans

Fixed, Closed	available	publicly available	New Haven-Main Campus 20 York Street, New Haven 06510	Saturday 24 hours	in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	4020 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	2556 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6231 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6130 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6003 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. at Chapel Street Campus 1450 Chapel Street, New Haven 06511	Sunday-Saturday 24 hours	812 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. at Chapel Street Campus 1450 Chapel Street, New Haven 06511	Sunday-Saturday 24 hours	713 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. (Temple Radiology New Haven) 60 Temple Street, New Haven 06510	Monday-Friday 8:30-4:30	2582 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Saint Raphael Magnetic Resonance Center 330 Orchard Street, New Haven 06511	Monday – Friday 6:30am – 10:30pm	1827 scans in 2013
1.5 T Fixed, Closed	Not publically available	Not publically available	Bridgeport Hospital 2595 Main Street Stratford, CT 06615	Monday – Friday 8:00am – 5:00pm	1492 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Bridgeport Hospital 267 Grant Street Bridgeport, CT 06610	24 hours per day, 7 days per week	3,500 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	St. Vincent's Medical Center 2800 Main Street Bridgeport, CT 06606	24 hours per day, 7 days per week	4,277 scans in 2013
3 T Fixed, Open	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 297 Boston Post Road Orange, CT 06477	Monday-Friday 8:30am – 5:00 pm, Saturday 8:30am-12:00pm	3114 scans in 2013
1.5 T Fixed, Closed	Not publically available	Not publically available	Advanced Radiology Consultants, LLC	Monday – Friday	5,700 scans in 2013

		available	2876 Main Street Stratford, CT 06614	7:00am- 11:00pm Saturday – Sunday 7:00am – 7:00pm	
1.5 T Fixed, Closed	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 4 Corporate Drive Shelton, CT 06484	Monday – Friday 8:30am – 5:00pm	3,975 scans in 2013
1.5T Fixed, Open	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 15 Corporate Drive Trumbull, CT 06611	Monday – Friday 8:30am – 5:00pm	1480 scans in 2013
1.5 T Fixed, Closed	COS patients		Connecticut Orthopaedic Specialists 2416 Whitney Avenue, Hamden, CT 06518	Monday – Friday 7:30am – 8:15 pm Saturday 7:30am – 4:30 m Sunday by appointment	3773 scans in 2015
1.5T Fixed, Closed	COS patients		Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT 06405	Monday – Friday 6:45 am – 8:00pm Saturday 7:00am – 5:00 pm	3851 scans in 2015
1.5T Mobile, Closed	Not publically available	Not publically available	Southern Connecticut Imaging Center LLC d/b/a Whitney Imaging Center 2200Whitney Avenue Hamden, CT 06518	Friday 7:30am – 4:30 pm	88 scans in 2013
1.5T Fixed, Open	Not publically available	Not publically available	Meriden Imaging Center, Inc. d/b/s Wallingford Diagnostic Imaging Center 863 North Main Street Wallingford, CT 06492	Monday – Friday 8:00am – 5:00pm	3276 scans in 2013
0.3T Fixed, Open	Not publically available	Not publically available	Diagnostic Imaging Services of CT, LLC d/b/a Branford Open MRI 1208 Main Street Branford, CT 06405	Monday, Tuesday, Thursday, Friday 8:00am - 5:00pm Wednesday 8:00am – 8:00pm	924 scans in 2013

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ESSEX, CT

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
1.5T Mobile, Closed	Not publically available	Not publically available	Middlesex Hospital d/b/a Shoreline Medical Center, ED 250 Flat Rock Place Westbrook, CT 06498	Tuesday, Thursday – Saturday 7:00am – 5:30pm	2,546 in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. Shoreline Medical Center 111 Goose Lane Guilford, CT 06437	Sunday – Saturday 24 hours	4,260 in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Guilford Radiology 1591 Boston Post Road Guilford, CT 06437	Monday – Friday 8:30am – 5:00pm	833 in 2013

* Provide the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

Source: *Statewide Health Care Facilities and Services Inventory – 2014. Table 8 (data from calendar year 2013).*

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Supplemental CON Application Form
Acquisition of Equipment
Conn. Gen. Stat. § 19a-638(a)(10),(11)

Applicant: **Connecticut Orthopaedic Specialists, P.C.**

Project Name: **Acquisition of a 1.5T Mobile MRI by a
Private Physician Practice**

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Affidavit

Applicant: Connecticut Orthopaedic Specialists, P.C.

Project Title: Acquisition of a 1.5 T Mobile MRI by a Private Physician Practice

I, Glenn F. Elia, CEO

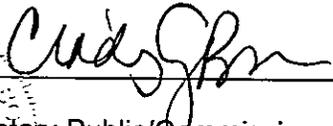
of Connecticut Orthopaedic Specialists, P.C., being duly sworn, depose and state that the said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.


Signature

7-19-16.

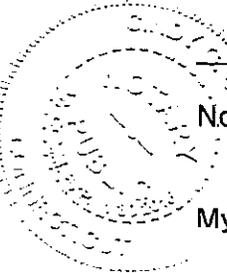
Date

Subscribed and sworn to before me on July 19, 2016


Notary Public/Commissioner of Superior Court

Notary Public/Commissioner of Superior Court

My commission expires: Nov. 30, 2016


CINDY G. BOVA
NOTARY PUBLIC
MY COMMISSION EXPIRES
NOV. 30, 2016

1. Project Description: Acquisition of Equipment

- a. Provide the manufacturer, model and number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

Response: The proposed mobile MRI scanner is a 2000 Mobile GE 1.5T scanner. The model is Excite (11X) 8 Channel MRI System.

- b. List each of the Applicant's sites and the imaging modalities currently offered by location.

Response: The two locations where COS currently offers MRI scanning are in Hamden and Branford. Each location has a fixed 1.5 Tesla MRI. X-Ray and fluoroscopy are also located in these two existing locations, but there are no other imaging modalities. The proposed mobile MRI scanner will be located at the COS office at 330 Boston Post Road, Orange, Connecticut on Monday and Tuesday. On Thursday and Friday it will be located at the COS office at 12 Bokum Road, Essex, Connecticut. MRI will be the only imaging modality offered at these locations.

2. Clear Public Need

- a. Complete Table A for each piece of equipment of the type proposed currently operated by the Applicant at each of the Applicant's sites.

TABLE A
EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization***
Connecticut Orthopaedic Specialists, P.C. 84 North Main Street Branford, CT 06405	1.5 fixed, closed MRI	Monday – Friday, 7:00 am-8:00 pm Saturday - 7:00 am – 5:00 pm	3851 in 2015
Connecticut Orthopaedic Specialists, P.C. 2416 Whitney Avenue Hamden, CT 06518	1.5 fixed closed MRI	Monday – Friday, 7:00am-8:00pm Saturday, 7:00am – 5:00pm Sunday: By appointment	3773 in 2015

*Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)

**Days of the week unit is operational, and start and end time for each day

***Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

- b. Provide the rationale for locating the proposed equipment at the proposed site;

Response:

Essex was selected as one of the two locations to offer MRI service two days a week because of the influx of new patients in the shoreline area with the addition of Shoreline Orthopedics & Sports Medicine (“Shoreline”) to COS. Shoreline has offices in Essex, Madison and Guilford. Orange was selected as the other site for the additional MRI service because of the volume of scanning at the Hamden and Branford offices and the accessibility it would offer to COS patients well within travel time to use the proposed Orange MRI depending upon where they live in relation to the service in Orange. These are COS patients currently using a COS MRI who will now transfer to the mobile MRI in Orange.

3. Actual and Projected Volume

- a. Complete the following tables for the past three fiscal years (“FY”), current fiscal year (“CFY”), and first three projected FYs of the proposal, for each of the Applicant’s existing and proposed pieces of equipment (of the type proposed, at the proposed location only). In **Table B**, report the units of service by piece of equipment, and in **Table C**, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

TABLE B
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)		
	FY 2013	FY 2014	FY 2015		FY 2016	FY 2017	FY 2018
Branford MRI	2,095	2,577	3,851	4,786 (annualized)	3,757	3,870	3,986
Hamden MRI	3,141	3,725	3,773	4,428 (annualized)	3,757	3,870	3,986
Orange MRI					1,500	1,545	1,591
Essex MRI					1,531	1,577	1,624
Total	5,236	6,302	7,624	9,214	10,545	10,862	11,187

*Annualized based on the first 6 months of FY 2016 (January to June). For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

Note: Applicant’s FY is a calendar year

TABLE C
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY TYPE OF SCAN/EXAM

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)		
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Orthopedic MRI scans	5,234	6,302	7,624	9,214	10,545	10,862	11,187
Total	5,264	6,302	7,624	9,214	10,545	10,862	11,187

*Annualized based on the first 6 months of FY 2016 (January to June). For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

Note: Applicant's FY is a calendar year

- b. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected volume by scanner and scan type.

Overall Assumptions

- A MRI scan takes 45 minutes.
- The optimum use rate for each scanner is 85% of the maximum number of scans possible within the scheduled hours of operation. This allows the scheduling for maintenance, downtime, cancellations and holidays, etc.
- The MRI scanners located in Hamden and Branford will operate 64 hours per week (Monday – Friday for 12 hours per day and 4 hours on Saturday) for a maximum of 85 scans per week or 4,420 scans per year. At an 85% use rate, the number of scans for each scanner on an annual basis is 3,757 scans. (This represents a reduction in hours of operation and number of scans currently performed at these locations).
- The reduction in the volume at Hamden and Branford will bring these scanners back to a normal, maximum use rate, and the overflow of patients is expected to utilize the mobile units in Orange and Essex.
- Initially, the mobile MRI scanner will operate 2 days per week in Orange and 2 days per week in Essex. The scanner will operate 12 hours per day at each location (a maximum of 32 scans per week or 1664 scans per year at each location). At an 85% use rate, the number of scans at each location in 2017 is 1414 (1664 scans x 85%).
- The annual rate of increase in MRI volume at each of the four locations for 2018 to 2019 is 3%. This is based on the historic rate of increase experienced

by the Applicant prior to the mergers of physician practices. Between 2012 and 2013, the rate of increase was 2.7%. *See* OHCA Table 5.

- In 2019 a third day of scanning can be added, if necessary, to either the Essex office or the Orange office depending upon which location has the largest volume of MRI scanning.

Essex Mobile MRI Assumptions

- The 2015 volume of COS patients from the Essex service area who received a MRI scan serves as the base for the projected utilization. Of the total 1,519 COS patients who received a MRI scan, 950 COS patients received a MRI at a COS MRI scanner and 569 were referred to a non-COS MRI. (Please see Table 8b, "Utilization by Town" and Exhibit J(1), p. 3 & Exhibit K).
- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the patients will utilize either the Branford or Hamden MRI as they have in the past.

Orange Mobile MRI Assumptions

- An analysis of COS internal records for 2015 for 6 COS offices in Orange, Shelton and Milford was undertaken. Three of these are original COS offices (Orange, Shelton and Milford) and three are from the merger (one in Orange and two in Milford). It is assumed that the persons most likely to use the Orange MRI are residents of these towns or patients who use the COS offices in these towns.
- Based on the review of COS internal records for 2015, it is estimated that 9,555 new patients were seen at these offices and 15.6% required a MRI study (1,488 patients). Of these patients, 1,047 were accommodated at the COS Branford or Hamden MRI scanner and 447 were referred to a non-COS MRI. These 1,488 COS patients serve as the base for the projected utilization. *See* Table #8a and Exhibit L in the Main Application.
- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the 1,488 COS patients will utilize either the Branford or Hamden MRI as they have in the past

- c. Explain any increases and/or decreases in the volume reported in the tables above.

Response:

COS has experienced significant increases in utilization from 2013 to 2016. This increase exists on both the Hamden and Branford existing 1.5 T fixed MRIs that are now over-capacity. The increase is projected to continue through 2016. The increases in utilization are as follows:

2013 - 2014	20.4% increase
2014 - 2015	21% increase
2015 - 2016	21% increase (projected)

The increases that occurred between 2013 and 2016 (through June) are due to two factors, the merger of four existing orthopedic physician practices into COS, and an increase in the hours of operation. (Please see response to Question #1 in the Main Application for more detail on the mergers, the impact on volume, and extended hours of hours of operation). The rate of increase is anticipated to slow in 2017 due to the “maturation” of the merger (with the exception of the patients from the Shoreline Orthopedics & Sports Medicine who are still being referred to other providers).

- d. Provide a breakdown, by town, of the volumes provided in **Table C** for the most recently completed FY.

**TABLE D1
COS ORANGE
UTILIZATION BY COS SCANNER BY SERVICE AREA TOWN**

Town	Hamden COS MRI FY 2015	Branford COS MRI FY 2015	Total COS MRI FY 2015*
Orange	150	82	232
New Haven	357	269	626
West Haven	238	279	517
Milford	240	263	503
Woodbridge	112	46	158
Shelton	39	17	56
Derby	29	6	35
North Haven	291	125	416
East Haven	60	390	450
Stratford	42	14	56
Total Service Area Towns	1,558	1,491	3,049

*Number of patients from the primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner in FY2015

See **Exhibit J(2) & J(3) in the Main Application for a total MRIs by patient town for 2015 for each of the Hamden and Branford COS MRI scanners.

**TABLE D2
ESSEX
UTILIZATION BY COS SCANNER BY SERVICE AREA TOWN**

Town	Hamden COS MRI FY 2015*	Branford COS MRI FY 2015**	Total COS MRI FY 2015
Essex	2	10	12
Madison	23	276	299
Clinton	7	114	121
Old Saybrook	3	36	39
Westbrook	5	28	33
Old Lyme	3	25	28
Deep River	0	12	12
Chester	1	7	8
Guilford	29	369	398
Total Service Area Towns	73	877	950

*Number of patients from primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner

See **Exhibit J(2) & J(3) in the Main Application for the total MRIs by patient town for 2015 for each of the Hamden and Branford COS MRI scanners.

The Applicant proposes to add one 1.5 Tesla mobile scanner which will be utilized in an orthopedic physicians' office (outpatient). It will move between Orange for 2 days per week and Essex for two days per week. Both existing MRI scanners are fixed, 1.5 T, closed units.

Exhibit List

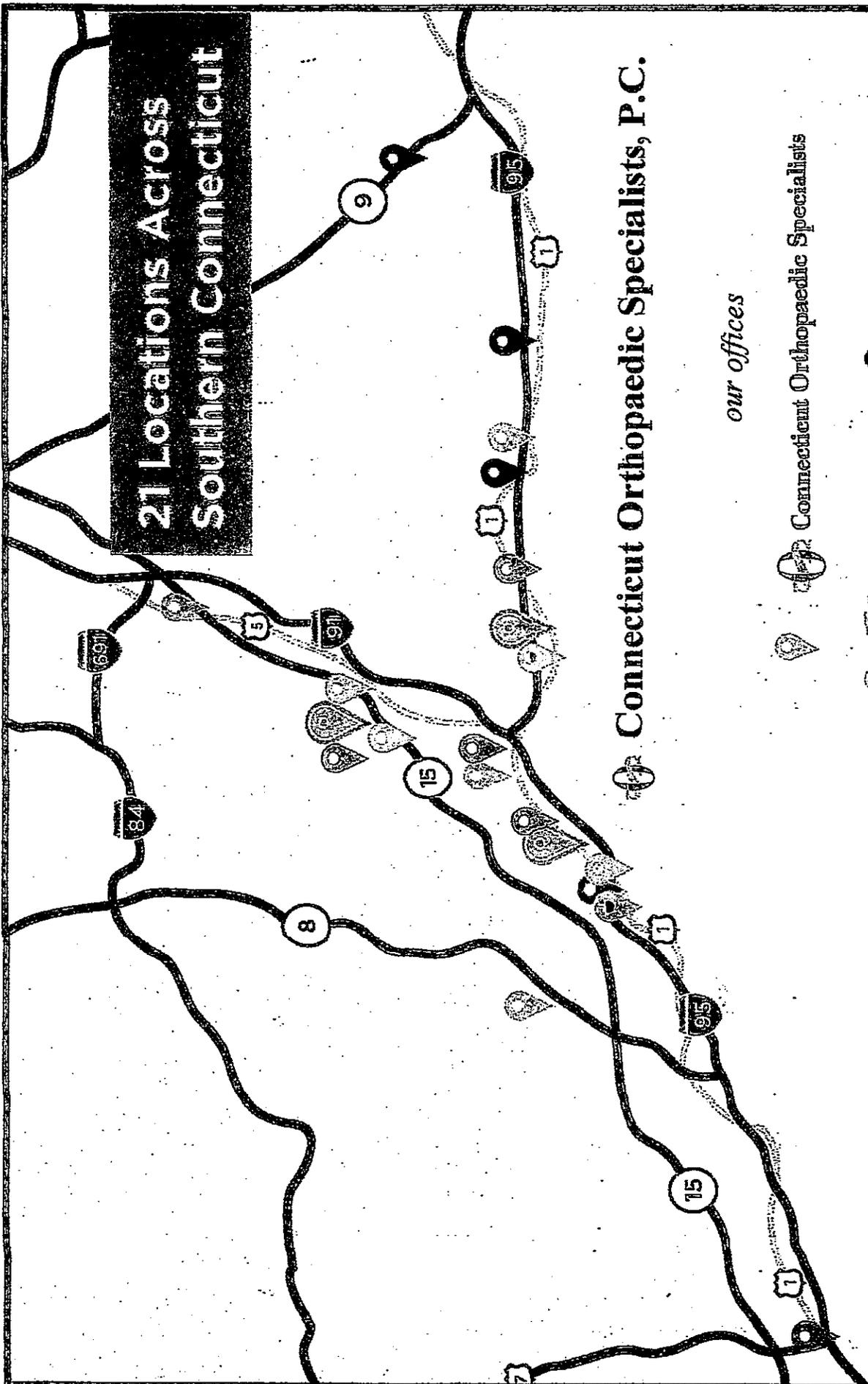
Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 - 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae	75 - 91
E	Scholarly Articles	92 - 122
F	Letters of Support	123 - 130
G	COS Standard of Practice Guidelines	131 - 171
H	American College of Radiology Accreditation for Existing MRI Scanners	172 - 174
I	COS Charity Care Policy	175 - 176
J	Target Populations: Patient Zip Codes	177 - 193
K	FY2015MRI Scans in the Essex Area for COS Patients	194 - 196
L	FY2015MRI Scans in the Orange Area for COS Patients	197 - 198
M	Capital Expenditures for Mobile MRI and Quotation for Trailer Installations	199 - 203
N	Funding or Financial Resources for the Project	204 - 208

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O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015	209 - 213
P	Financial Worksheet	214 - 215
Q	Assumptions Used in Financial Worksheet	216 - 218

EXHIBIT A

**21 Locations Across
Southern Connecticut**



Connecticut Orthopaedic Specialists, P.C.

our offices

- Connecticut Orthopaedic Specialists
- The Orthopaedic Group
- Orthopaedic Health
- SHORELINE ORTHOPEDICS & SPORTS MEDICINE
- Center for Orthopaedics



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

Orthopedic Health



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

Office address	address 2	city	state	zip	phone
1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
469 West Main Street		Branford	CT	06405	203.865.6784
84 North Main Street		Branford	CT	06405	203.407.3516
12 Bokum Road		Essex	CT	06426	860.767.9053
450 Boston Post Road		Guilford	CT	06437	203.407.3505
47 Clapboard Hill Road	Suite 4	Guilford	CT	06437	203.433.0906
2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
2408 Whitney		Hamden	CT	06518	203.407.3505
9 Washington Avenue		Hamden	CT	06518	203.865.6784
1353 Boston Post Road		Madison	CT	06443	203.245.7447
6 Woodland Road	Suite 3B	Madison	CT	06443	203.433.0906
258 South Broad Street		Milford	CT	06460	203.867.6448
30 Commerce Park		Milford	CT	06460	203.865.6784
849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
230 George Street	5th Floor	New Haven	CT	06510	203.752.3100
330 Orchard Street		New Haven	CT	06511	203.407.3516
148 East Avenue	Suite 2E	Norwalk	CT	06851	203.853.2967
330 Boston Post Road		Orange	CT	06477	203.407.3505
464 Boston Post Road		Orange	CT	06477	203.752.3100
889 Bridgeport Avenue		Shelton	CT	06484	203.407.3516
1000 Yale Avenue		Wallingford	CT	06492	203.407.3505

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The Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

SHORELINE ORTHOPEDICS & SPORTS MEDICINE


The Orthopaedic Group Orthopedic Health Center For Orthopaedics

Listed by Office of Origin:

Physicians	Office address	address 2	city	state	zip	phone
Connecticut Orthopaedic Specialists P.C.						
John M. Aversa, MD	450 Boston Post Road		Guilford	CT	06437	203.407.3505
	2408 Whitney		Hamden	CT	06518	203.407.3505
	330 Boston Post Road		Orange	CT	06477	203.407.3505
John M. Beiner, MD	1000 Yale Avenue		Wallingford	CT	06492	203.407.3505
	2408 Whitney		Hamden	CT	06518	203.407.3516
	84 North Main Street		Branford	CT	06405	203.407.3516
	450 Boston Post Road		Guilford	CT	06437	203.407.3516
	330 Orchard Street		New Haven	CT	06511	203.407.3516
	889 Bridgeport Avenue		Shelton	CT	06484	203.407.3516
Hubert B. Bradburn, MD	1000 Yale Avenue		Wallingford	CT	06492	203.407.3516
	450 Boston Post Road		Guilford	CT	06437	203.407.3510
	2408 Whitney		Hamden	CT	06518	203.407.3518
David B. Cohen, MD	330 Boston Post Road		Orange	CT	06477	203.407.3518
	84 North Main Street		Branford	CT	06405	203.407.3518
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3518
Peter A. Deluca, MD	84 North Main Street		Branford	CT	06405	203.867.6448
	1000 Yale Avenue		Wallingford	CT	06492	203.867.6448
	889 Bridgeport Avenue		Shelton	CT	06484	203.867.6448
	258 South Broad Street		Milford	CT	06460	203.867.6448
Richard Diana, MD	2408 Whitney		Hamden	CT	06518	203.407.3540
	84 North Main Street		Branford	CT	06405	203.407.3540
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3540
	330 Boston Post Road		Orange	CT	06477	203.407.3540

Physicians	Office address	address 2	city	state	zip	phone
Allen M. Ferrucci, MD	2408 Whitney		Hamden	CT	06518	203.407.3525
	450 Boston Post Road		Guilford	CT	06437	203.407.3525
	84 North Main Street		Branford	CT	06405	203.407.3525
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3525
Norman R. Kaplan, MD	330 Boston Post Road		Orange	CT	06477	203.407.3525
	258 South Broad Street		Milford	CT	06460	203.407.3520
	330 Boston Post Road		Orange	CT	06477	203.407.3520
	2408 Whitney		Hamden	CT	06518	203.407.3520
John D. Kelley, MD	1000 Yale Avenue		Wallingford	CT	06492	203.407.3520
	450 Boston Post Road		Guilford	CT	06437	203.407.3520
	450 Boston Post Road		Guilford	CT	06437	203.407.3535
	330 Boston Post Road		Orange	CT	06477	203.407.3535
Jeffrey M. Klauser, MD Kenneth M. Kramer, MD	84 North Main Street		Branford	CT	06405	203.407.3535
	2408 Whitney		Hamden	CT	06518	203.407.3535
	889 Bridgeport Avenue		Shelton	CT	06484	203.538.0022
	2408 Whitney		Hamden	CT	06518	203.407.3530
John D. McCallum, MD	330 Boston Post Road		Orange	CT	06477	203.407.3530
	450 Boston Post Road		Guilford	CT	06437	203.407.3530
	84 North Main Street		Branford	CT	06405	203.407.3530
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3530
Philip A. Minotti, MD	84 North Main Street		Branford	CT	06405	203.407.3545
	258 South Broad Street		Milford	CT	06460	203.407.3545
	2408 Whitney		Hamden	CT	06518	203.407.3545
	450 Boston Post Road		Guilford	CT	06437	203.407.3545
Thomas P. Moran, MD	889 Bridgeport Avenue		Shelton	CT	06484	203.407.3544
	330 Orchard Street		New Haven	CT	06511	203.407.3544
	2408 Whitney		Hamden	CT	06518	203.407.3544
	84 North Main Street		Branford	CT	06405	203.407.3544
Thomas P. Moran, MD	330 Boston Post Road		Orange	CT	06477	203.407.3544
	450 Boston Post Road		Guilford	CT	06437	203.407.3510
	84 North Main Street		Branford	CT	06405	203.407.3510
	2408 Whitney		Hamden	CT	06518	203.407.3510
	258 South Broad Street		Milford	CT	06460	203.407.3510

John D. McCallum, MD	450 Boston Post Road	Guilford	06437	203.407.3530
	84 North Main Street	Branford	06405	203.407.3530
	1000 Yale Avenue	Wallingford	06492	203.407.3530
	84 North Main Street	Branford	06405	203.407.3545
	258 South Broad Street	Milford	06460	203.407.3545
	2408 Whitney	Hamden	06518	203.407.3545
	450 Boston Post Road	Guilford	06437	203.407.3545
Philip A. Minotti, MD	889 Bridgeport Avenue	Shelton	06484	203.407.3544
	330 Orchard Street	New Haven	06511	203.407.3544
	2408 Whitney	Hamden	06518	203.407.3544
	84 North Main Street	Branford	06405	203.407.3544
	330 Boston Post Road	Orange	06477	203.407.3544
	450 Boston Post Road	Guilford	06437	203.407.3510
Thomas P. Moran, MD	84 North Main Street	Branford	06405	203.407.3510
	2408 Whitney	Hamden	06518	203.407.3510
	258 South Broad Street	Milford	06460	203.407.3510
	84 North Main Street	Branford	06405	203.407.3534
	258 South Broad Street	Milford	06460	203.407.3534
	450 Boston Post Road	Guilford	06437	203.407.3534
	330 Boston Post Road	Orange	06477	203.407.3534
	2408 Whitney	Hamden	06518	203.407.3534
	2408 Whitney	Hamden	06518	203.407.3539
Mark W. Scanian, MD	1000 Yale Avenue	Wallingford	06492	203.407.3539
	258 South Broad Street	Milford	06460	203.407.3539
	330 Boston Post Road	Orange	06477	203.407.3539
	84 North Main Street	Branford	06405	203.407.3539
	2408 Whitney	Hamden	06518	203.407.3568
	450 Boston Post Road	Guilford	06437	203.407.3568
	330 Boston Post Road	Orange	06477	203.407.3568
	2408 Whitney	Hamden	06518	203.407.3585
Enzo J. Sella, MD	330 Orchard Street	New Haven	06511	203.407.3585
	330 Boston Post Road	Orange	06477	203.407.3585
	450 Boston Post Road	Guilford	06437	203.407.3585
	84 North Main Street	Branford	06405	203.407.3585
	2408 Whitney	Hamden	06518	203.407.3528
Sanda L. Tomak, MD	450 Boston Post Road	Guilford	06437	203.407.3528
David S. Caminear, DPM				

Jeffrey M. DeLott, DPM	1000 Yale Avenue	Wallingford	CT	06492	203.407.3528
	330 Boston Post Road	Orange	CT	06477	203.407.3528
	258 South Broad Street	Milford	CT	06460	203.407.3586
	84 North Main Street	Branford	CT	06405	203.407.3586
	2408 Whitney	Hamden	CT	06518	203.407.3586
	889 Bridgeport Avenue	Shelton	CT	06484	203.407.3586
	330 Orchard Street	New Haven	CT	06511	203.407.3586
John Marino, MD	330 Boston Post Road	Orange	CT	06477	203.407.3589
	84 North Main Street	Branford	CT	06405	203.407.3589
	258 South Broad Street	Milford	CT	06460	203.407.3589
	1000 Yale Avenue	Wallingford	CT	06492	203.407.3589
Rakesh Patel, MD	1000 Yale Avenue	Wallingford	CT	06492	203.407.3574
	258 South Broad Street	Milford	CT	06460	203.407.3574
	2408 Whitney	Hamden	CT	06518	203.407.3574
	889 Bridgeport Avenue	Shelton	CT	06484	203.407.3574
Jonas Lieponis, MD	258 Broad Street	Milford	CT	06460	203.433.0906
	6 Woodland Road	Madison	CT	06443	203.433.0906
	47 Clapboard Hill Road	Guilford	CT	06437	203.433.0906
(administrative only)	6 Woodland Road	Madison	CT	06443	203.453.2780
Michael J. Murphy, MD	258 Broad Street	Milford	CT	06460	203.453.2780
(administrative only)	47 Clapboard Hill Road	Guilford	CT	06437	203.453.2780

Physicians	Office address	address 2	city	state	zip	phone
Orthopedic Health Center for Orthopaedics						
Tedd L. Weisman, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Amit Lahav, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Aaron Schachter, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Oluwaseun Akinbo, MD	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Mark P. Altman, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
	148 East Avenue	Suite 2E	Norwalk	CT	06851	203.853.2967
Stephanie Arlis-Mayor, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
John Daigneault, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
David H. Gibson, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Rowland B. Mayor, MD	230 George Street	5th Floor	New Haven	CT	06510	203.752.3100
	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Durgadas P. Sakalkale, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Jeffrey M. Sumner, MD	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Joseph C. Wu, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100

The Orthopaedic Group

Richard A. Bernstein, MD

9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
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9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784

John F. Irving, MD

Christopher B. Lynch, MD

Alan M. Reznik, MD

Derek S. Shia, MD

Shirvinda A. Wijesekera, MD

Richard A. Zell, MD

Adriana Blanco, MD

Shoreline Orthopedics and Sports Medicine

Mark D. Lorenze, MD

Steven M. Luster, MD

Martin J. White, MD

Connecticut Orthopaedic Specialists

John M. Aversa, MD

12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
330 Boston Post Road	Orange	CT	06477	203.407.3505
1000 Yale Avenue	Wallingford	CT	06492	203.407.3505
2408 Whitney	Hamden	CT	06518	203.407.3505
450 Boston Post Road	Guilford	CT	06437	203.407.3505

The Orthopaedic Group

Richard A. Bernstein, MD

9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
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469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784

John F. Irving, MD

Christopher B. Lynch, MD

Alan M. Reznik, MD

Derek S. Shia, MD

Shirvinda A. Wijesekera, MD

Richard A. Zell, MD

Adriana Blanco, MD

Shoreline Orthopedics and Sports Medicine

Mark D. Lorenze, MD

Steven M. Luster, MD

Martin J. White, MD

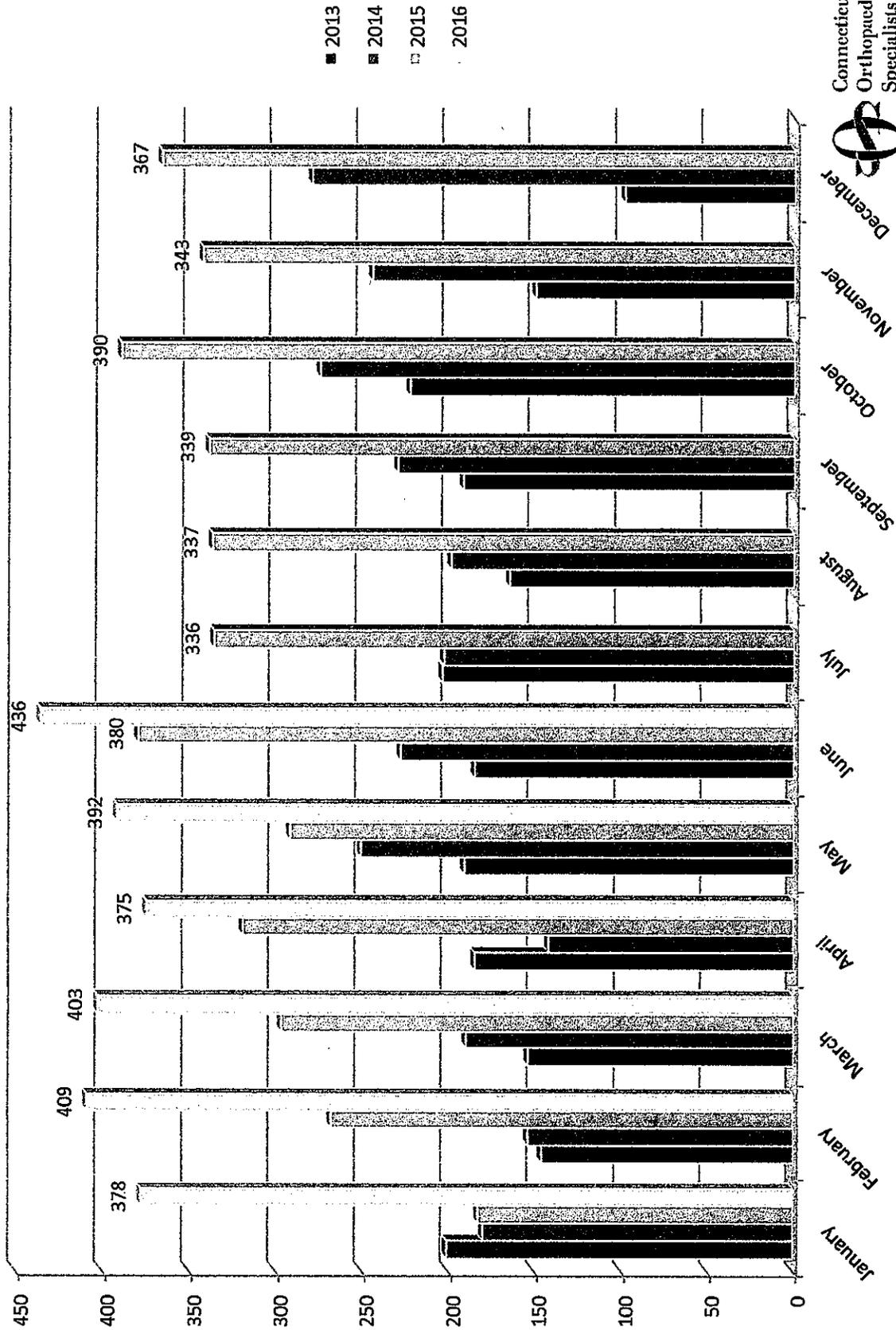
Connecticut Orthopaedic Specialists

John M. Aversa, MD

12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
330 Boston Post Road	Orange	CT	06477	203.407.3505
1000 Yale Avenue	Wallingford	CT	06492	203.407.3505
2408 Whitney	Hamden	CT	06518	203.407.3505
450 Boston Post Road	Guilford	CT	06437	203.407.3505

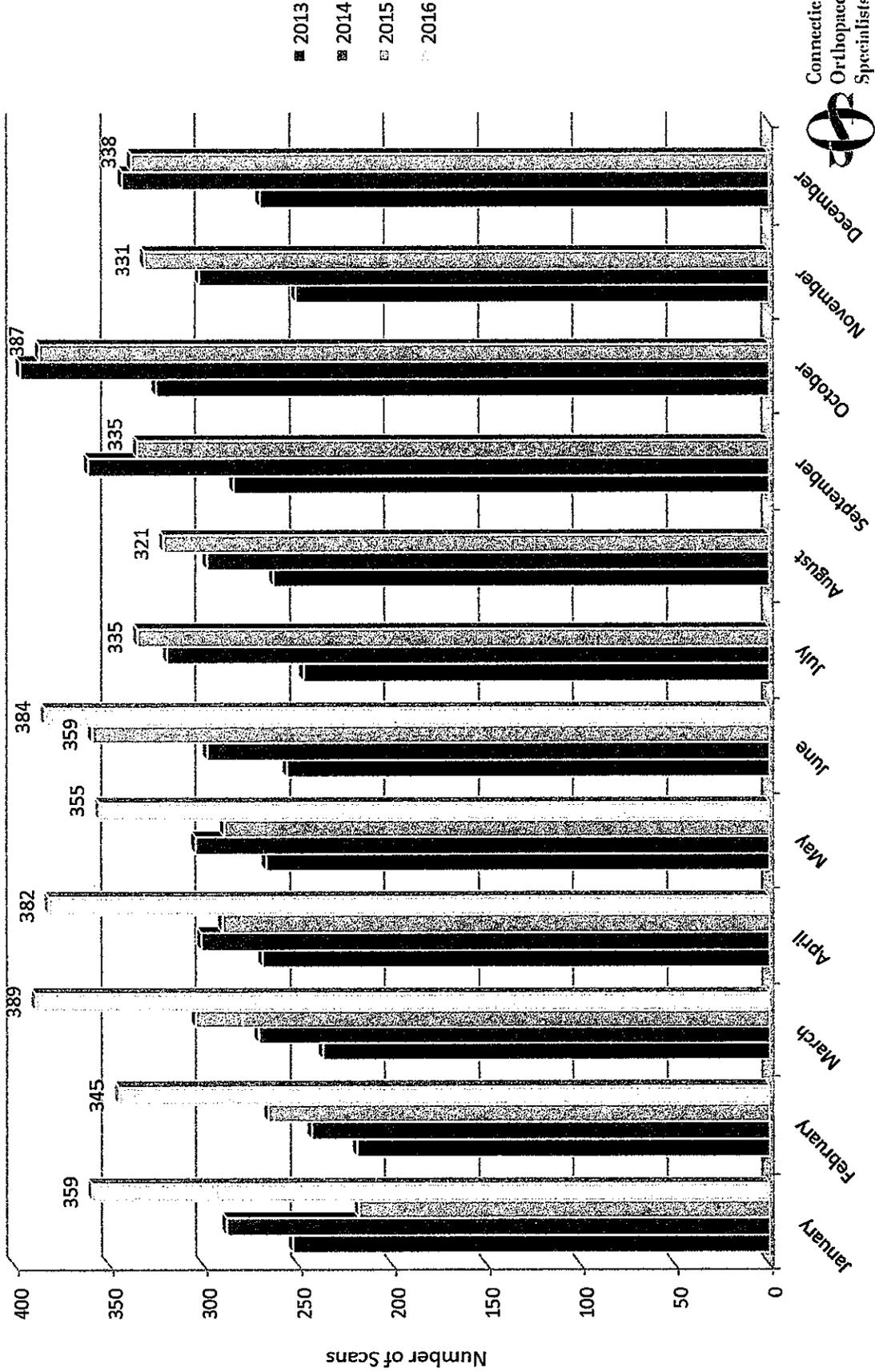
EXHIBIT B

Connecticut Orthopaedic Specialists Branford MRI Facility Number of Scans 2013 through June of 2016



010070

Connecticut Orthopaedic Specialists Hamden MRI Facility Number of Scans 2013 through June of 2016



120071

Connecticut Orthopaedic Specialists

The Orthopaedic Group Orthopaedic Health  Center For Orthopaedics  SHORELINE ORTHOPEDICS & SF

2013 -2016 Connecticut Orthopaedic Specialists Monthly MRI Data by Scanner

Branford

	January	February	March	April	May	June	July	August	September	October	November	December	Total
2013	201	146	154	185	191	185	204	165	192	223	150	99	2,095
2014	180	154	190	142	251	228	203	199	230	275	245	280	2,577
2015	183	268	297	319	292	380	336	337	339	390	343	367	3,851
2016	378	409	403	375	392	436							

Hamden

	January	February	March	April	May	June	July	August	September	October	November	December	Total
2013	253	219	237	269	267	256	247	263	284	325	251	270	3,141
2014	288	243	271	301	304	298	319	298	361	397	302	343	3,725
2015	218	266	304	290	289	359	335	321	335	387	331	338	3,773
2016	359	345	389	382	355	384							

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EXHIBIT C

000073

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0339

Out-Patient Surgical Facility

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

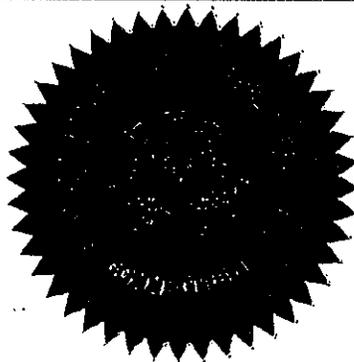
Connecticut Orthopaedic Specialists Outpatient Surgical Center, LLC of Branford, CT, d/b/a is hereby licensed to maintain and operate an Out-Patient Surgical Facility.

Connecticut Orthopaedic Specialist Outpatient Surgical Center, LLC is located at 84 North Main Street, Building 2, 1st. Floor, Branford, CT 06405.

This license expires **December 31, 2017** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, January 1, 2016. **RENEWAL**

Waiver Section 19-13-D56(e)(8)(B) exp: n/a eff: 1-13-16



A handwritten signature in cursive script, appearing to read "Raul Pino".

Raul Pino, MD, MPH
Acting Commissioner

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EXHIBIT D

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List of all Key Professional, Administrative, Clinical and Direct Service Personnel
Related to the Proposal:

1. Anthony Gagliardi, M.D.; Radiologist
2. Joanne E. Elderidge; MRI Senior Tech/Supervisor for COS, and MRI Tech
(Branford)
3. Billie Jo Foraker; Clinical Office Manager and Radiology Manager – COS
Division
4. Carlene Fox; RT, (R) (MR); MRI Technologist
5. Glenn F. Elia, M.B.A., R.P.T.; CEO of CT Orthopaedic Specialists, P.C.

CURRICULUM VITAE

PERSONAL DATA:

Joseph Anthony Gagliardi
DOB: May 20, 1959
Place: New Haven, CT
Citizenship: USA

EDUCATION:

Yale University, BS, Psychobiology, 1978-82
New York Medical College, Valhalla, NY, M.D., Medicine, 1982-86

TRAINEESHIP:

Internship: St. Vincent's Medical Center, Bridgeport, CT, Transitional, 1986-87
Residency: St. Vincent's Medical Center, Bridgeport, CT, Diagnostic Radiology, 1987-91
Chief Resident, 1990-1991

LICENSURE:

Connecticut #029458, 1988
Hawaii #7589, 1991-1995
DEA #BG2862374, 1989

MILITARY SERVICE:

Active Duty US Army M.C., Tripler A.M.C., Honolulu, HI, 1991-1995

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

Radiological Society of North America
Hawaii Radiologic Society 1991-1995
American Roentgen Ray Society
Connecticut Radiologic Society 1995-2010
Association of Program Directors in Radiology 2004-2010

ACADEMIC APPOINTMENTS:

Associate Clinical Professor, Department of Radiology, University of Hawaii, Manoa, 1992-1997
Assistant Clinical Professor, Department of Radiology, New York Presbyterian Healthcare, 1999-present
Clinical Adjunct Associate Professor, Quinnipiac University School of Health Sciences, 2004-present
Assistant Clinical Professor, Department of Diagnostic Radiology, Yale School of Medicine, 2010-present

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HOSPITAL APPOINTMENTS:

Chief, Musculoskeletal Radiology, Tripler Army Medical Center, Honolulu, HI, 1991-1992

Chief, Genitourinary Radiology, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Academic Council/Surgical Case Review, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Chief, Musculoskeletal Radiology, St. Vincent's Medical Center, Bridgeport, CT, 1995-2009

Residency Program Co-Director, St. Vincent's Medical Center, Bridgeport, CT, 1999-2003

Vice Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2001-2005

Residency Program Director, St. Vincent's Medical Center, Bridgeport, CT, 2003-2009

Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2006-2009

Veterans Administration Medical System, West Haven, CT, 2010-present

REGULAR TEACHING ACTIVITIES:

St. Vincent's Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

Yale University Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

PROFESSIONAL ACTIVITIES:

Manuscript Reviewer, Consultant Magazine, Cligott Publishing Co., 55 Holly Hill Lane, Greenwich, CT 06831, 1998-present.

FDA Investigational New Drug Number 48,354 issued for Magnetic Resonance Imaging research of musculoskeletal disorders following intra-articular administration of Gadolinium.

American Board of Radiology, Board Examiner, Musculoskeletal Section, 1999-present.

Board Member, Musculoskeletal Section, Mediaworks, Inc. Electronic journal: *Radiology web.Com*. 1999-present.

Professional Liability Committee member, St. Vincent's Medical Center. 2001-2009.

Medical Executive Committee Member, St. Vincent's Medical Center, 2004-2009.

American Board of Radiology Item Writing Task Force for Written Board Exam, 2005-present.

American College of Radiology, 2006-2010.

Manuscript Reviewer, Journal of Neuroimaging, Blackwell Publishing, 2008 – present.

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PUBLICATIONS:

A. Original Articles

1. Gagliardi JA, Interventional Radiology Complication Rates. *Administrative Radiology* 1992; 11:90-99
2. Chandnani VP, Yeager TD, DeBerardino TM, Christensen K, Gagliardi, JA, Heitz DR, Baird DE, Hansen MF. Glenoid Labral Tears: Prospective Evaluation with MR Imaging, MR Arthrography and CT Arthrography. *AJR* 1993; 161:1229-1235
3. Chandnani VP, Harper MT, Ficke J, Gagliardi JA, Rolling L, Christensen K, Hansen MF. Chronic Ankle Instability. Evaluation with MR Arthrography, MR Imaging, and Stress Radiography. *Radiology* 1994; 192:189-94
4. Gagliardi, JA, Chung EM, Chandnani VP, Kesling KL, Christensen KP, Null RN, Radvany MG, Hansen MF. Detection and Staging of Chondromalacia Patella: Relative Efficacies of Conventional MR Imaging, MR Arthrography and Computed Arthrotomography. *AJR* 1994; 163: 629-636
5. Chandnani VP, Gagliardi JA, Murnane TG, Bradley YC, DeBerardino TM, Spaeth J, Hansen MF. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. *Radiology* 1995; 196:27-32
6. Bradley YC, Chandnani VP, Gagliardi JA, Reeves TQ. Partial Thickness Supraspinatus Tears; Diagnosis by Magnetic Resonance Arthrography. *Australas Radiol* 1995; 39(2): 124-127
7. Riccio GJ, Gagliardi JA. Pitfalls in Hysterosalpingographic Interpretation. *Postgraduate Radiology* 1997; 17:190-208
8. Gagliardi JA, Nunberg SM, Fisher T. Fracture Detection: A Possible Method to Aid in Diagnosis and Improve Reporting Accuracy. *Radiologyweb.com*. April Issue 2001

B. Case Reports

1. Gagliardi, JA, Chaddha, SKB. CNS Toxoplasmosis. *Consultant* 1991; 31: 45-48
2. Gagliardi JA, Torstenson G. Fibrous Dysplasia in the Skull Base. *Applied Radiology* 1991; 20: 42-43
3. Gagliardi JA, Chaddha SKB. Mid Gut Volvulus with Computed Tomography. *Applied Radiology* 1992; 21: 58-59
4. Gagliardi JA, Posch R. Flare Response in Nuclear Medicine Secondary to Chemotherapy Toxicity to the Kidneys. *Applied Radiology* 1992; 21:24-25
5. Gagliardi JA, Eline MJ. Minimal Plain Film Findings of a Femoral Neck Osteoid Osteoma Diagnosed by Radionuclide Bone Scintigraphy and MRI. *Clinical Nuclear Medicine* 1993; 18:446-447
6. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Cancer Investigation* 1993; 11:306-309

7. Shanley DJ, Gagliardi JA, Daum-Kowalski R. Choledochal Cyst Complicating Pregnancy: Antepartum Diagnosis with MRI. *Abdom Imaging* 1994; 19: 61-62
8. Radvany MG, Shanley DJ, Gagliardi JA. Magnetic Resonance Imaging with Computed Tomography of a Renal Leiomyoma. *Abdom Imaging* 1994; 19:67-69
9. Quan SS, Gagliardi JA*, Russo RD. Neurofibromatosis. *Applied Radiology* 1994; 23: 35-26
10. Samlaska CP, Gagliardi JA. Diffuse Venous Malformation with Intraosseous Involvement. *Hawaii Medical Journal* 1994; 53: 218-221
11. Gagliardi JA, Evans EM, Chandnani VP, Myers JB, Pacheco CM. Osteogenesis Imperfecta Complicated by Osteosarcoma. *Skeletal Rad* 1995; 24(4): 308-310
12. Munter FM, Gagliardi JA, Russo RD. Familial Hyperphosphatasemia. *Applied Radiology* 1995; 25(7): 44-45
13. Eclavea A, Gagliardi JA, Jezior J, Burton B, Donahue J. Pheochromocytoma with Central Nervous System Manifestations. *Australasian Radiology* 1997 41(4): 373-376
14. Lustberg H, Gagliardi JA, Lawson JP. Digital Enlargement in Tuberous Sclerosis. *Skeletal Radiology* 1999; 28:116-118
15. Gagliardi JA. Musculoskeletal Involvement of Sarcoidosis in the Hands. Electronic Journal: *Radiologyweb .Com*. December Issue, 1999
16. Gagliardi JA. Silicone Implant Arthropathy of the Wrist. Electronic Journal: *Radiologyweb.Com*. September Issue, 2000
17. Gagliardi JA, Duff MK, Callahan T, Pannese JR. Abnormal Dilatation to the Internal Carotid Artery on Angiography without Abnormal Finding at Craniotomy: Connecticut Medicine 2004; 68:3-5
18. Hyo-Jeong Lee, Gagliardi JA. Diffuse pigmented villonodular synovitis. *Applied Radiology* 2004; 33(12):41-43
19. Udeshi M, Gagliardi JA. Foreign body giant cell reaction to polytetrafluoroethylene used as interposition material in scaphoid-trapezium arthroplasty. *Australasian Radiology* 2006; 50:233-236
20. Martinez F, Gagliardi JA, Olsavsky TD. Gastrointestinal stromal tumor originating in the stomach. *Applied Radiology* 2006; 35(7): 43-46.
21. Gripp M, Gagliardi JA. Calciphylaxis On Technetium Bone Scan: Two Case Reports. *Radiology Case Reports* 2007; 2(2):30-32.
22. Rastogi P, Gagliardi JA, Bharucha R. Manifestations of Von Hippel-Lindau disease. *Applied Radiology* 2007; 36(11):62-65.
23. Swain FR, Udeshi M, Gagliardi JA, Armm M. Fracture of the Penis: MR Imaging with Surgical Correlation. *Radiology Case Reports Epub* 2007; 2 (3).
24. Werder GM, Razdan RS, Gagliardi JA, Chaddha SKB. Conservatively managed pineal apoplexy in an anticoagulated patient. *Radiography* 2008; 14:69-72.
25. Tagg W, Woods S, Razdan R, Gagliardi J, Steenbergen P. Hemoperitoneum after Colonoscopy. Endoscopy. *Accepted for publication ID ENDOS -2008-1226.R1*

26. Martinez F., Cho Y., Gagliardi JA, Razdan R. Spontaneous Pneumomediastinum. *Applied Radiology* 2008;37(4):40-44.
27. Werder GM, Tangri RK, Gagliardi JA. Bleeding diathesis with hemophilic arthropathy. *Applied Radiology* 2008;37(9):35-36.
28. Chirindel A, Martinez F, Gagliardi JA, Armm MF. Testicular Tuberculosis without epididymitis simulating neoplasm. *Radiology Case Reports* 2008;3(3):1-6.
29. Cho Y, Gagliardi JA, Chaddha SK. Cystic Meningioma. *Applied Radiology* 2009; 38(5):29-30.
30. Khan AA, Agarwal A, Chaddha SK, Gagliardi JA. Histiocytic sarcoma of the Terminal Ileum Presenting as a Large Ulcerating Lesion: CT Diagnosis. *Radiology Case Reports*, 2009; 4(2):262
31. Singhal A, Torstenson GE, Gagliardi JA. Celiac Artery Dissection on Computed Tomography. *Clinical Challenges and Images in GI. Gastroenterology* 2010; 139(3):733.
32. Gagliardi JA and Agarwal A. Gamekeeper's Thumb (Skier's thumb). [http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-\(Skier's-thumb\).aspx](http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-(Skier's-thumb).aspx)
33. Gagliardi, JA and Carino, M. Glenoid Bare Spot. *Applied Radiology* 2013; 42(10):29-30.

C. Reviews and Book Chapters

1. Gagliardi JA, Freestone KA, Shanley DJ. Testicular Microlithiasis: Ultrasound Appearance and Associated Complications. *Hawaii Medical Journal* 1993; 452:192-193
2. Gagliardi JA, Lengyel RJ. A Review of the Radiographic Manifestations of Gout. *Hawaii Medical Journal* 1994; 53: 40-43
3. Gagliardi JA, Radvany MG, Kilkenny TE, Russo RD. Colonic Sphincters Revisited: Simulator's of Organic Disease. *Hawaii Medical Journal* 1994; 53:278-282
4. Wilbur MJ, Gagliardi JA, Riccio GJ, Vincent NR, Haber S, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. *Applied Radiology* 1997; 26(12): 30-37
5. Meyer NR, Gagliardi JA, Lawson JP. Musculoskeletal Radiology. Practical Guide of Diagnostic Imaging, CV Mosby Co., 1998, page 220-279
6. Wilbur MJ, Gagliardi JA, Lawson JP, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. *Postgraduate Radiology* 1999; 19:3-12
7. Lustberg H, Gagliardi JA, Lawson JP, Fugate M, Micalizzi GJ, Specht NT. Intramedullary Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiologyweb.Com*. December Issue, 1999
8. Lustberg H, Gagliardi JA, Lawson JP, Lawson AJ, Fugate M, Specht NS, Micalizzi GJ. Surface Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiology web.com*. January Issue, 2000
9. Lustberg H, Gagliardi JA, Lawson JP, Specht NS, Fugate M, Micalizzi GJ. Secondary Osteosarcoma. *Radiologyweb.com*. February Issue, 2000
10. Lustberg H, Gagliardi JA, Lawson JP, Kilkenny TE, Donkor D, Fugate M, Micalizzi GJ, Specht NS. Extraskelatal and Gnathic Osteosarcoma. *Radiologyweb.com*. March-April Issue, 2000

11. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part One: Benign Lesions. *Radiologyweb.com*. January Issue, 2001
12. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part Two: Malignant Lesions. *Radiologyweb.com*. February Issue, 2001
13. Gagliardi JA, Ibrahim S, Kumar M. Paget's Disease: Radiologic Findings. *Rheumatologyweb.com*. July Issue, 2002
14. Swain FR, Martinez F, Gripp M, Razdan R, Gagliardi JA. Traumatic complications from placement of thoracic catheters and tubes. *Emergency Radiology* 2005; 12: 11-18
15. Tagg WG, Razdan RS, Swain FR, Gagliardi JA, Chaddha SKB. Posterior Reversible Encephalopathy Syndrome Following a Cesarean Delivery: Case Report and Literature Review. *Connecticut Medicine* 2008 (72) 5: 267-269.

D. Abstract:

1. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Connecticut Medicine* 1992; 56:623

E. Presentations:

1. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrotomography. Society of Skeletal Radiology, Marco Island, FL. 1993
2. Chandnani VP, Harper MT, Gagliardi JA, Ficke J, Rolling L, Christensen K. Chronic Ankle Instability: Evaluation by Stress Radiography, Magnetic Resonance Imaging and Magnetic Resonance Arthrography. Society of Skeletal Radiology, Marco Island, FL. 1993
3. Chandnani VP, Yeager TD, DeBaradino TM, Christensen K, Heitz DR, Gagliardi JA, Hansen MF. Glenoid Labral Tears: A Comparison of the Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrotomography. American Roentgen Ray Society, San Francisco, CA. 1993
4. Gagliardi JA. Reading Chest Radiographs: The Secrets. Fifth Annual Aloha Medical Conference, Honolulu, HI. 1993
5. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. Radiological Society of North America, Chicago, IL. 1993
6. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrotomography. Radiological Society of North America, Chicago, IL. 1993
7. Chandnani VP, Harper MT, Gagliardi JA, Ficke J, Rolling L, Christensen K. Chronic Ankle Instability: Evaluation by Stress Radiography, Magnetic Resonance Imaging and Magnetic Resonance Arthrography. Radiological Society of North America, Chicago, IL. 1993
8. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. 18th International Congress of Radiology, Singapore. 1994
9. Bradley YC, Chandnani VP, Gagliardi JA, Yeager TD, Harper MT, Hansen MF. Magnetic Resonance Arthrography of the Musculoskeletal System. 18th International Congress of Radiology, Singapore. 1994

10. Harper MT, Chandnani VP, Evans EM, Gagliardi JA, Hansen MF. Chronic Ankle Injuries: Evaluation with MR Arthrography, MR Imaging and Conventional Imaging Techniques. Annual 42nd meeting of the Association of University Radiologists, Boston, MA. 1994
11. Chandnani VP, Spaeth J, Bradley YC, Radvany MG, DeBerardino TM, Gagliardi JA. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. Radiological Society of North America, Chicago, IL. 1994
12. Gagliardi JA, Chung EM, Chandnani VP, Hansen MF. Chondromalacia Patellae: Prospective Evaluation of Relative Efficacies of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrography. USARPAC Asia-Pacific Military Medical Conference, New Delhi, India. 1995
13. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. European Congress of Radiology, Vienna, Austria. 1995
14. Harper MT, Murnane TG, Chandnani VP, Gagliardi JA, Spaeth JH, Boutin R. MR Imaging of Musculoskeletal Ganglia: A Pictorial Essay. European Congress of Radiology, Vienna, Austria. 1995
15. Chandnani VP, Murnane TG, Harper MT, Gagliardi JA, Bradley YC. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. European Congress of Radiology, Vienna, Austria. 1995
16. Chandnani VP, Gagliardi JA, Harper MT. Glenohumeral Ligaments and Capsular Mechanism: Evaluation with MR Arthrography. The First Kuwait International Conference of Radiology and Nuclear Medicine, Kuwait. 1995
17. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. American Roentgen Ray Society, Washington, DC. 1995
18. Chandnani VP, Bradley YC, Gagliardi JA, Murnane TG, DeBerardino TM. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. Roentgen Centenary Congress, Birmingham, England. 1995
19. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. 43rd Annual J. C. Kimbrough Urological Seminar, Washington, DC. 1995
20. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. 19th International Congress of Radiology, Beijing, China. 1996
21. Gagliardi JA, Riccio GJ, Eclavea A. Pitfalls in Hysterosalpingographic Interpretation. 19th International Congress of Radiology, Beijing, China. 1996
22. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. 19th International Congress of Radiology, Beijing, China. 1996
23. Gagliardi JA, Riccio GJ. Pitfalls in Hysterosalpingographic Interpretation. . Radiological Society of North America, Chicago, IL. 1996
24. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1996

25. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. Western Section of American Urological Association, San Diego, CA. 1996
26. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. American Roentgen Ray Society, Boston, MA. 1997
27. Gagliardi JA, Lawson JP, Bonnet AL, Fugate MJ, Micalizzi GJ. Parosteal Lipoma: A Review of the Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1997
28. Gagliardi JA. Genitourinary System Trauma: Classification and Management Strategies. St. Vincent's College, Bridgeport, CT. 1998
29. Gagliardi JA, Lustberg H, Lawson JP, Specht N, Fugate MJ, Micalizzi GJ. Osteosarcoma: The Radiologic Appearances and Imaging Strategies. American Roentgen Ray Society, New Orleans, LA. 1999
30. Gagliardi JA. One Week Genitourinary and Musculoskeletal Review. Visiting Consultant: Tripler Army Medical Center, Honolulu, HI. March 20-24, 2000
31. Gagliardi JA. Magnetic Resonance Imaging of the Knee. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. September 25, 2002
32. Gagliardi JA. X-Ray Callbacks in the Emergency Department. Emergency Medicine Grand Rounds, St. Vincent's Medical Center, Bridgeport, CT. March 19, 2003
33. Gagliardi JA. Breast Calcifications on Mammography: Characterization and Management. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
34. Gagliardi JA. Understanding the BI-RADS Lexicon in Mammography. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
35. Gripp MJ, Coleman B, Tangri R, Udeshi M, Gagliardi JA. Review of Iatrogenic Trauma to the Thorax. American Roentgen Ray Society, Miami FL. 2004
36. Gripp MJ, Gagliardi JA, Russo G, Callahan T. A Patterned Approach for Evaluating Patients with Arthritis. International Congress of Radiology, Montreal, Canada. 2004
37. Gripp MJ, Tangri R, Coleman B, Gagliardi JA. A Review of Iatrogenic Trauma to the Thorax. International Congress of Radiology, Montreal, Canada. 2004
38. Gripp MJ, Bangash H, Russo G, Callahan T, Gagliardi JA. A Patterned Approach for Evaluating Patients with Arthritis of the Extremities. RANZCR Annual Scientific Meeting, Perth, Australia. 2004
39. Gagliardi JA. Shoulder MRI: Imaging Protocols, Normal and Abnormal Findings. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. April 25, 2005
40. Coleman B, Kleysler-Sugrue K, Passeri D, Gagliardi J. The Safe and Effective use of Lidocaine with Epinephrine for Stereotactic Breast Biopsy. European Congress of Radiology, Vienna, Austria. 2007
41. Coleman B, Kleysler-Sugrue K, Passeri D, Gagliardi J. The Safe and Effective use of Lidocaine with Epinephrine for Stereotactic Breast Biopsy. Association of University Radiologists Conference. Denver, Colorado. 2007

42. Conklin PS, Gagliardi JA, Swain FR. MR Findings in Acute Brachial Neuritis (Parsonage-Turner Syndrome). Association of University Radiologists Conference. Seattle, Washington. 2008
43. El-Haddad G, Olsavsky TD, Gagliardi JA. Altered Biodistribution of FDG can lead to incorrect diagnoses on FDT-PET: Important of Patient Preparation and Pre Scan Interventions. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
44. Tagg W, Amankona R, Razdan R, Mejia V, Gagliardi JA. Diffuse Alveolar Hemorrhage after Abciximab Use. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
45. Martinez F, Razdan R, Armm MF, Chirindel A, Gagliardi JA. Testicular Tuberculosis without Epidydimitis Simulating Neoplasm. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
46. Agarwal A, Chhatwal A, Gagliardi J. Pulmonary Hemorrhage following Tracheal Extubation. American College of Physicians Meeting. Southington, Connecticut. 2009
47. Perez JC, Razdan RN, Gagliardi JA. Radiation Induced Myonecrosis Mimicking a Lower Extremity Abscess. American College of Physicians Meeting. Southington, Connecticut. 2009
48. Visiting Physician Consultant, Tripler Army Medical Center. ABR Musculoskeletal Board Review. Honolulu Hawaii. 2011.
49. Visiting Physician Consultant, Tripler Army Medical Center. ABR Musculoskeletal Board Review. Honolulu Hawaii. 2012.
50. Visiting Physician Consultant, SUNY Downstate Medical Center. ABR Musculoskeletal Board Review. Brooklyn, New York. 2012
51. Specht ES, Gagliardi JA. Common Shoulder Injuries: provider examination, imaging and physical therapy intervention. Webinar for Concentra Inc. March 2013.
52. Visiting Physician Consultant, SUNY Downstate Medical Center. What you need to know to practice MSK radiology. Brooklyn, New York. 2013.

JOANNE E. ELDRIDGE B.S. R.T. (R) (MR)
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Objective: To obtain a challenging position in the MRI field that best utilizes my experience and education and has excellent opportunities for advancement.

Employment History

2012-Present MRI Senior Tech/Supervisor

In addition to being a working tech, also responsible for scheduling staff in two offices for tech and desk coverage. Collaborate with the radiologists in the design of the MRI protocols, order supplies, schedule PMs and cryogen fills, manage equipment failures, Mentor, train and coach all new technologists and Quinnipiac students, evaluate student competencies update training manuals, manage all technical aspects of ACR accreditation, monitor expiration dates of contrast injectables
Trained all MRI staff on Greenway system and extended training to anyone needing assistance in ordering MRI exams.

2006- Present Connecticut Orthopaedic Specialists Branford, CT

MRI Tech

Perform examinations , of the spine, pelvis, hip, femur, knee, tib-fib, ankle, foot, shoulder, humerus, elbow, forearm, wrist and hand for orthopaedic
Evaluation using GE 1 Tesla and 1.5 Tesla

Consistent production of high quality diagnostic images while working independently
Maintained high standard for patient MRI safety including pre-screening for contra-
indications

X RAY TECH

Fill in as the Ortho Now tech as needed. Cover surgery center on last minutes notice for surgeries and epidural injections.

2004-2006 Connecticut Orthopaedic Specialists Hamden, CT

MRI Tech

Perform examinations of the knee down and elbow down on ONI extremity unit.

2000-2004 Connecticut Orthopaedic Specialists Guilford, CT

X-Ray Tech

Perform routine orthopedic examinations.

1997-2000 Stay at home Mom

1994-1997 Osteoporosis and Diagnostic Treatment Center, Hamden, CT

Bone Density Tech

Perform bone density exams for private and research study protocols using Hologic machine.

1991-1993 Home X-ray, New Haven, CT

CT Tech

Perform CT examinations with and without contrast.

1989-1991 Radiology Group, Hamden, Ct

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X-ray/CT Tech

Perform routine x-rays, fluoro, mammography, and CT exams.

1988-1989 Yale New Haven Hospital, New Haven, Ct

X-Ray Tech

Perform routine x-ray examinations while rotating through fluoro, portables, pediatrics, bone densitometry, orthopedics, OR.

Education:

B.S., Radiologic Sciences, 1988

Quinnipiac University, Hamden, CT

References:

Dr Joseph Gagliardi, St Vincent's Medical Center Residency Director 203-576-5061

Teresa Ostrander, St Mary's MRI Chief Tech/Director 203-709-3674

Lori Baldwin, Connecticut Orthopaedic Specialists Dr's Assistant 203-407-3518

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Curriculum Vitae

Billie Jo Foraker
101 Bailey Road
North Haven, CT
(203) 619-2607

EDUCATION:

Gateway Community College, New Haven, CT

- Certified Nurse Assistant 1989
- Associate Degree in Science 1995
- Radiological internship YNH 1993-1995
- Radiological certification & CT State license granted 1995

EMPLOYMENT:

2015- present: Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Clinical Office Manager – Hamden location
 - Management of front desk, X-ray and medical assistant personal
 - Responsible for clinical and front desk operations for COS Hamden office
- Radiology Manager – COS Division
 - Supervisor of x-ray for 7 clinical locations
 - Responsible for clinical staff allocations, maintenance of licensure for staff and radiological equipment

2008 - 2015 : Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Medical Administrative Assistant for Dr. Philip Minotti
 - Instrumental in development Dr. Minotti patient practice
 - Responsible for management of all patient communication, including lab, imaging results and surgical equipment
 - Pre cert and booked surgical cases for joint reconstruction cases performed at YNH
 - Managed referral relationship(s) into Dr. Minotti from outside primary care referral physicians

1989 to 2008: New Haven Orthopaedic Group P.C.
Connecticut Orthopaedic Specialists, P.C.,

- Receptionist & clinical floater 1989-1995
- Billing & Collections 1989-1993
- Physical Therapy aide 1993-1995
- X Ray Technician 1995- 2008
 - Lead X Ray Tech Hamden, responsible for managing all supplies for clinical rooms and x-ray suite

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LICENSES / CERTIFICATIONS / COURSE WORK :

Certified Nursing Assistant 1989
Connecticut X Ray License 1995
Certified Medical Assistant June 2013
Greenway Practice Management training program 2015
PC and Apple Software formats

OUTSIDE INTERESTS :

- Freelance photographer
- Equestrian
 - Horse owner & trainer
 - Member of Cheshire Horse Counsel

Carlene Fox RT (R)(MR)

169 Westfield Road
Meriden, CT 06450
Cell: 203-671-0786
cmg611@yahoo.com

Education/Job Experience

Quinnipiac University, Hamden, CT
Bachelor of Science in Diagnostic Imaging
Advanced Specialization in MRI
Board Certified X-Ray and MRI Technologist
A.A.M.A certified
Currently employed at Connecticut Orthopedic Specialist as a MRI Technologist

Qualifications

Clinical Skills

- 10 years of working experience in MRI
- Setting up and performing routine MRI scans
- Proper MRI coil selection
- Knowledge of GE and ONI MRI systems
- Archiving images and creating MRI CD's
- Completing patient and procedure information using PACS systems (Fusion, Efilm, and Viztek)
- Weekly QA Testing
- Knowledge of Greenway/Primesuite chart systems

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Curriculum Vitae

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EDUCATION:

Springfield College, Springfield, Massachusetts ; BS, Biology, June 1978

University of Pennsylvania, Philadelphia, PA. ; Certificate, Physical Therapy May 1979

Sacred Heart University, Fairfield, CT ; Masters of Business Administration, May 1992

EMPLOYMENT:

1993 to present : Connecticut Orthopaedic Specialists, P.C. ,
Sports Therapy & Rehabilitation
Temple Physical Therapy & Cardiac Rehabilitation,
Hamden, CT

- Chief Executive Officer

1991 to 1993 : Neurosurgery Associates of Northwest CT, P.C., Waterbury, CT

- Practice Administrator

1985 to 1993 : Immediate Medical Care & Connecticut Physical Therapy & Sports Medicine

- Director of Operations
- Director of Physical Therapy

1979 to 1985 : Private Practice Physical Therapist

1990 to present ; Owner / Operator , Quality Assurance Reviews

- Physical Therapy peer review company
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LICENSES ;

Connecticut Physical Therapy License # 002530

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EXHIBIT E

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COS submits "The Big Idea: How to Solve the Cost Crisis in Health Care" written by Robert S. Kaplan and Michael E. Porter from the September 2011 issue of the Harvard Business Review. The article is pertinent because COS is in the process of moving its billing practice from a fee-for-service arrangement, where each component of the orthopedic treatment is billed individually, to a "bundled payment" system where the cost involved in the most common orthopedic procedures can be bundled into one payment. This article sets forth the benefits of cutting costs without losing value – and the focus on a patient's health care result.

COSTS

The Big Idea: How to Solve the Cost Crisis in Health Care

by Robert S. Kaplan and Michael E. Porter

FROM THE SEPTEMBER 2011 ISSUE

Watch the video interview with Robert S. Kaplan and Michael E. Porter, "Solving the Health Care Cost Crisis."

Listen to an interview with Robert S. Kaplan.

14:42

US. health care costs currently exceed 17% of GDP and continue to rise. Other countries spend less of their GDP on health care but have the same increasing trend. Explanations are not hard to find. The aging of populations and the development of new treatments are behind some of the increase. Perverse incentives also contribute: Third-party payors (insurance companies and governments) reimburse for procedures performed rather than outcomes achieved, and patients bear little responsibility for the cost of the health care services they demand.

But few acknowledge a more fundamental source of escalating costs: the system by which those costs are measured. To put it bluntly, there is an almost complete lack of understanding of how much it costs to deliver patient care, much less how those costs compare with the outcomes achieved. Instead of focusing on the costs of treating individual patients with specific medical conditions over their full cycle of care, providers aggregate and analyze costs at the specialty or service department level.

Making matters worse, participants in the health care system do not even agree on what they mean by costs. When politicians and policy makers talk about cost reduction and "bending the cost curve," they are typically referring to how much the government or insurers pay to providers—not to the costs incurred by providers to deliver health care services. Cutting payor reimbursement does reduce the bill paid by insurers and lowers providers' revenues, but it does nothing to reduce the actual costs of delivering care. Providers share in this confusion. They often allocate their costs to procedures, departments, and services based not on the actual resources used to deliver care but on how much they are reimbursed. But reimbursement itself is based on arbitrary and inaccurate assumptions about the intensity of care.

Poor costing systems have disastrous consequences. It is a well-known management axiom that what is not measured cannot be managed or improved. Since providers misunderstand their costs, they are unable to link cost to process improvements or outcomes, preventing them from making systemic and sustainable cost reductions. Instead, providers (and payors) turn to simplistic actions such as across-the-board cuts in expensive services, staff compensation, and head count. But imposing arbitrary spending limits on discrete components of care, or on specific line-item expense categories, achieves only marginal savings that often lead to higher total systems costs and poorer outcomes. For example, as payors introduce high copayments to limit the use of expensive drugs, costs may balloon elsewhere in the system should patients' overall health deteriorate and they subsequently require more services.

Poor cost measurement has also led to huge cross-subsidies across services. Providers are generously reimbursed for some services and incur losses on others. These cross-subsidies introduce major distortions in the supply and efficiency of care. The inability to properly measure

cost and compare cost with outcomes is at the root of the incentive problem in health care and has severely retarded the shift to more effective reimbursement approaches.

Finally, poor measurement of cost and outcomes also means that effective and efficient providers go unrewarded, while inefficient ones have little incentive to improve. Indeed, institutions may be penalized when the improvements they make in treatments and processes reduce the need for highly reimbursed services. Without proper measurement, the healthy dynamic of competition—in which the highest-value providers expand and prosper—breaks down. Instead we have zero-sum competition in which health care providers destroy value by focusing on highly reimbursed services, shifting costs to other entities, or pursuing piecemeal and ineffective line-item cost reductions. Current health care reform initiatives will exacerbate the situation by increasing access to an inefficient system without addressing the fundamental value problem: how to deliver improved outcomes at a lower total cost.

The remedy to the cost crisis does not require medical science breakthroughs or new governmental regulation. It simply requires a new way to accurately measure costs and compare them with outcomes.

Fortunately, we can change this state of affairs. And the remedy does not require medical science breakthroughs or top-down governmental regulation. It simply requires a new way to accurately measure costs and compare them with outcomes. Our approach makes patients and their conditions—not departmental units, procedures, or services—the fundamental unit of analysis for measuring costs and outcomes. The experiences of several major institutions currently implementing the new approach—the Head and Neck Center at MD Anderson Cancer Center in Houston, the Cleft Lip and Palate Program at Children’s Hospital in Boston, and units performing knee replacements at Schön Klinik in Germany and Brigham & Women’s Hospital in Boston—confirm our belief that bringing accurate cost and value measurement practices into health care delivery can have a transformative impact.

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Understanding the Value of Health Care

The proper goal for any health care delivery system is to improve the value delivered to patients. Value in health care is measured in terms of the patient outcomes achieved per dollar expended. It is not the number of different services provided or the volume of services delivered that matters but the value. More care and more expensive care is not necessarily better care.

To properly manage value, both outcomes and cost must be measured at the patient level. Measured outcomes and cost must encompass the entire cycle of care for the patient's particular medical condition, which often involves a team with multiple specialties performing multiple interventions from diagnosis to treatment to ongoing management. A medical condition is an interrelated set of patient circumstances that are best addressed in a coordinated way and should be broadly defined to include common complications and comorbidities. The cost of treating a patient with diabetes, for example, must include not only the costs associated with endocrinological care but also the costs of managing and treating associated conditions such as vascular disease, retinal disease, and renal disease. For primary and preventive care, the unit of value measurement is a particular patient population—that is, a group with similar primary care needs, such as healthy children or the frail and elderly with multiple chronic conditions.

Let's explore the first component of the health care value equation: health outcomes. Outcomes for any medical condition or patient population should be measured along multiple dimensions, including survival, ability to function, duration of care, discomfort and complications, and the sustainability of recovery. Better measurement of outcomes will, by itself, lead to significant improvements in the value of health care delivered, as providers' incentives shift away from performing highly reimbursed services and toward improving the health status of patients. Approaches for measuring health care outcomes have been described previously, notably in Michael Porter's 2010 *New England Journal of Medicine* article, "What Is Value in Health Care?"

While measuring medical outcomes has received growing attention, measuring the costs required to deliver those outcomes, the second component of the value equation, has received far less attention. In the value framework, the relevant cost is the total cost of all resources—clinical and administrative personnel, drugs and other supplies, devices, space, and equipment—used during

a patient's full cycle of care for a specific medical condition, including the treatment of associated complications and common comorbidities. We increase the value of health care delivered to patients by improving outcomes at similar costs or by reducing the total costs involved in patients' care while maintaining the quality of outcomes.

A powerful driver of value in health care is that better outcomes often go hand in hand with lower total care cycle costs. Spending more on early detection and better diagnosis of disease, for example, spares patients suffering and often leads to less complex and less expensive care later. Reducing diagnostic and treatment delays limits deterioration of health and also lowers costs by reducing the resources required for care. Indeed, the potential to improve outcomes while driving down costs is greater in health care than in any other field we have encountered. The key to unlocking this potential is combining an accurate cost measurement system with the systematic measurement of outcomes. With these powerful tools in place, health care providers can utilize medical staff, equipment, facilities, and administrative resources far more efficiently, streamline the path of patients through the system, and select treatment approaches that improve outcomes while eliminating services that do not.

The Challenges of Health Care Costing

Accurate cost measurement in health care is challenging, first because of the complexity of health care delivery itself. A patient's treatment involves many different types of resources—personnel, equipment, space, and supplies—each with different capabilities and costs. These resources are used in processes that start with a patient's first contact with the organization and continue through a set of clinical consultations, treatments, and administrative processes until the patient's care is completed. The path that the patient takes through the system depends on his or her medical condition.

The already complex path of care is further complicated by the highly fragmented way in which health care is delivered today. Numerous distinct and largely independent organizational units are involved in treating a patient's condition. Care is also idiosyncratic; patients with the same condition often take different paths through the system. The lack of standardization stems to some extent from the artisanal nature of medical practice—physicians in the same organizational

unit performing the same medical process (for instance, total knee replacement) often use different procedures, drugs, devices, tests, and equipment. In operational terms, you might describe health care today as a highly customized job shop.

Existing costing systems, which measure the costs of individual departments, services, or support activities, often encourage the shifting of costs from one type of service or provider to another, or to the payor or consumer. The micromanagement of costs at the individual organizational unit level does little to reduce total cost or improve value—and may in fact destroy value by reducing the effectiveness of care and driving up administrative costs. (For more on the problems with current costing systems, see the three Myth sidebars.)

Myth #1: Charges are a good surrogate for provider costs.

The widespread confusion between what a provider charges, what it is actually reimbursed, and its costs is a major barrier to reducing the cost of health care. Providers have aggravated this problem by structuring important aspects of their costing systems around the way they are reimbursed. In the U.S., this is partly a historical artifact of the Medicare cost-plus reimbursement system, which requires hospital departments to prepare an annual Medicare Cost Report (MCR), detailing costs and charges by department. Rather than developing and maintaining accurate costing systems that are based on actual resource usage, separate from the regulatory standard required for reimbursement, hospitals defaulted to reimbursement-driven systems.

Unfortunately, that approach was flawed from the start because it was based on the use of highly aggregate data for

Myth #2: Hospital overhead costs are too complex to allocate accurately.

Most health care leaders will eventually accept the idea that the direct costs of patient care, such as nurses, physicians, and consumable supplies (drugs, bandages, and syringes), ought to be assigned more accurately to individual patients. But many leaders believe that allocating the costs of indirect and support units cannot be done except with crude, arbitrary methods, often dressed up to look sophisticated. Typically, they use a “peanut butter” method, which spreads overhead and support costs across each department’s billable activities (see Myth #1) using metrics such as the size of direct costs, head count, length of stay, assigned physical space, number of patients, number of procedures, RVUs supplied, or costs-to-charge ratios (Myth #1 again).

estimating costs and the deeply flawed assumption that every billable event in a department has the same profit margin. Reimbursement-based costing also buries the costs of valuable but nonbillable events, such as patient consultations, in large overhead pools that are allocated arbitrarily and inaccurately to billable events.

Although costing systems for physician services differ from those used by hospitals, they suffer from the same problems. As is the case for hospitals, U.S. physicians are reimbursed not on the basis of an individual patient's resource use but on average estimates of relative demands—relative value units, or RVUs—on physician labor, practice expenses, and malpractice expenses in performing billable activities. These resource estimates are derived from specialty panels and national surveys of physicians, who stand to gain from overestimating the time and complexity of their work. Despite the required sign-off by government payors, the RVU estimates are not systematically measured or confirmed in practice settings. Reimbursing physicians on the basis of highly aggregate and likely inaccurate estimates of their costs introduces major incentive problems into the health care system. But the problems are compounded when the reimbursement rates are also used to allocate physician costs to patients, a purpose for which they were never intended.

We need to abandon the idea that charges billed or reimbursements paid in any way reflect costs. In reality, the cost

The effect of such arbitrary support-department allocations on the measured cost of services can be profound. In the past, Schön Klinik, like other hospitals in Germany, had reduced the capacity of its total knee replacement rehabilitation units in part because the existing cost system portrayed them as less profitable than acute-care units. During Schön Klinik's cost pilot, the project team discovered that the existing cost system allocated support-department costs largely on the basis of length of patient stay, not on the patient's use of support resources. Since Schön total knee replacement patients spent 75% of their stay in the rehab facility, rehab had been allocated about 75% of support department costs.

The TDABC analysis showed, however, that the demand for many support-unit services, such as medical billing, is far higher during the days a patient spends in the acute-care facility than during rehab days. With support costs properly assigned, the rehab facility showed improved profitability. Schön Klinik began to contemplate the expansion of its rehabilitation capacity—a complete reversal of its previous decision—and shifted its focus more intensively on reducing support costs incurred during the acute-care stay.

Once indirect costs have been accurately

Myth #3: Most health care costs are fixed.

of using a resource—a physician, nurse, case manager, piece of equipment, or square meter of space—is the same whether the resource is performing a poorly or a highly reimbursed service. Cost depends on how much of a resource's available capacity (time) is used in the care for a particular patient, not on the charge or reimbursement for the service, or whether it is reimbursed at all.

Many health care system participants, including economists and accountants, believe that most costs in health care are fixed because so much care is delivered using shared staff, space, and equipment. The result of this misguided thinking is that cost reduction efforts tend to focus on only the small fraction of costs seen as variable, such as drugs and supplies, which are sometimes referred to as marginal or incremental costs. This myth also motivates some health care organizations to expand through mergers, acquisitions, and organic growth in order to reap economies of scale by spreading their fixed costs over an increased volume of business.

But if most health care costs were truly fixed, we would not have the health care cost problem we do today. If most costs were fixed, growth in demand for health care would increase only that small fraction of costs that are variable, leading to lower average costs in the system, not the dramatically higher share of GDP now being devoted to health care.

To understand why most health care costs are not fixed, start with personnel costs, which are generally at least 50% of the total costs of health care providers, according to American Hospital Association statistics. Hint: Personnel costs are not fixed. Hospital executives can set the quantity, mix, and compensation of their personnel each year, or even more frequently. Personnel costs are fixed only when executives allow them to be. The claim that

personnel costs are fixed is a reflection of management inattention, not of the nature of those costs.

Space costs are also not fixed. Space is perhaps an organization's most fungible resource. If demand for space is reduced, units can be consolidated into smaller space, and excess space can be repurposed, sold, or subleased. Similarly, equipment costs can be avoided if changes in processes, treatment protocols, or patient mix eliminate the demand for the resources. Equipment no longer needed can be retired or sold to other health care institutions that are expanding their capacity.

All told, we estimate that upwards of 95% of what health care managers think of as fixed costs are actually under their control and therefore not really fixed.

Any accurate costing system must, at a fundamental level, account for the total costs of all the resources used by a patient as she or he traverses the system. That means tracking the sequence and duration of clinical and administrative processes used by individual patients—something that most hospital information systems today are unable to do. This deficiency can be addressed; technology advances will soon greatly improve providers' ability to track the type and amount of resources used by individual patients. In the meantime, it is possible to determine the predominant paths followed by patients with a particular medical condition, as our pilot sites have done.

With good estimates of the typical path an individual patient takes for a medical condition, providers can use the time-driven activity-based costing (TDABC) system to assign costs accurately and relatively easily to each process step along the path. This improved version of

activity-based costing requires that providers estimate only two parameters at each process step: the cost of each of the resources used in the process and the quantity of time the patient spends with each resource. (See Robert S. Kaplan and Steven R. Anderson's "Time-Driven Activity-Based Costing," HBR 2004.)

In its initial implementation, such a costing system may appear complex. But the complexity arises not from the methodology but from today's idiosyncratic delivery system, with its poorly documented processes for treating patients with particular conditions and its inability to map asset and expense categories to patient processes. As health care providers begin to reorganize into units focused on conditions, standardize their protocols and treatment processes, and improve their information systems, using the TDABC system will become much simpler.

To see how TDABC works in the health care context, we first explore a simplified example.

Costing the Patient: A Simple Example

Consider Patient Jones, who makes an outpatient visit to a clinic. To estimate the total cost of Jones's care, we first identify the processes he undergoes and the resources used in each process. Let's assume that Jones uses an administrative process for check-in, registration, and obtaining documentation for third-party reimbursement; and a clinical process for treatment. Just three clinical resources are required: an administrator (Allen), a nurse (White), and a physician (Green).

We begin by estimating the first of the two parameters: the quantity of time (capacity) the patient uses of each resource at each process. From information supplied by the three staffers, we learn that Jones spent 18 minutes (0.3 hours) with Administrator Allen, 24 minutes (0.4 hours) with Nurse White for a preliminary examination, and nine minutes (0.15 hours) with Physician Green for the direct examination and consultation.

Next, we calculate the capacity cost rate for each resource—that is, how much it costs, per hour or per minute, for a resource to be available for patient-related work—using the following equation:

$$\text{Capacity Cost Rate for Resource} = \frac{\text{Expenses Attributable to Resource}}{\text{Available Capacity of Resource}}$$

The numerator aggregates all the costs associated with supplying a health care resource, such as Allen, White, or Green. It starts with the full compensation of each person, including salary, payroll taxes, and fringe benefits such as health insurance and pensions. To that we add the costs of all other associated resources that enable Allen, White, and Green to be available for patient care. These typically include a pro rata share of costs related to employee supervision, space (the offices each staffer uses), and the equipment, information technology, and telecommunications each uses in the normal course of work. In this way, the cost of many of the organization's shared or support resources can be assigned to the resources that directly interact with the patient.

Supervision cost, for example, can be calculated on the basis of how many people a manager supervises. Space costs are a function of occupancy area and rental rates; IT costs are based on an individual's use of computers and communications products and services. Assume that we find Nurse White's total cost to be as follows:

Annual compensation (including fringe benefits)	\$65,000
Supervision cost (10% of nursing supervisor's full cost)	\$9,000
Occupancy (9 sq. meters of space @ \$1,200/sq. meter/year)	\$10,800
Technology and support	\$2,560
Annual total cost of Nurse White	\$87,360
Monthly total cost of Nurse White	\$7,280

We next calculate Nurse White's availability for patient care—the denominator of our capacity cost rate equation. This calculation starts with 365 days per year and subtracts all the time that the employee is not available for work. The calculation for Nurse White is as follows:

Start with	365 days per year
less weekend days	104
less vacation days	20
less holidays	12
less sick days	5
	224 available days per year
	18.7 days per month

Start with	7.5 hours per available day
less scheduled breaks (hours)	0.5
less meetings, training, education	1.0
Available clinical hours	6 hours per day

Nurse White is therefore available for patient work 112 hours per month (6 hours a day for 18.7 days). Dividing the monthly cost of the resource (\$7,280) by monthly capacity (112 hours) gives us Nurse White's capacity cost rate: \$65 per hour.

Let's assume that similar calculations yield capacity cost rates for Administrator Allen and Physician Green of \$45 per hour and \$300 per hour, respectively.

We calculate the total cost of Jones's visit to the facility by simply multiplying the capacity cost rate of each resource by the time (in hours) Jones spent using the resource, and then adding up the components:

(0.3 hours × \$45)
(0.4 hours × \$65)
+ (0.15 hours × \$300)
Total cost of visit: \$84.50

As this example demonstrates, accurately calculating the cost of delivering health care is quite straightforward under the TDABC system. Although the example is admittedly simplified, it captures almost all the fundamental concepts any health care provider needs to apply to estimate the cost of treating patients over their full cycles of care.

By capturing all the costs over the complete cycle of care for an individual patient's medical condition, we allow providers and payors to address virtually any costing question. Providers can aggregate and analyze patients' cost of care by age, gender, and comorbidity, or by treatment

facility, physician, employer, and payor. They can calculate total and average costs for any category or subcategory of patients while still capturing the detailed data on individual patients needed to understand the sources of cost variation within each category.

The Cost Measurement Process

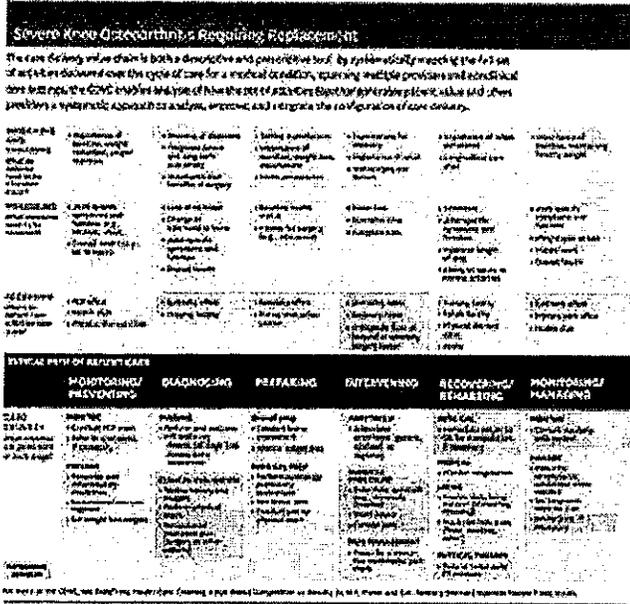
Moving beyond the simplified example, let's now look at the seven steps our pilot sites are using to estimate the total costs of treating their patient populations.

1. Select the medical condition.

We begin by specifying the medical condition (or patient population) to be costed, including the associated complications and comorbidities that affect processes and resources used during the patient's care. For each condition, we define the beginning and end of the patient care cycle. For chronic conditions, we choose a care cycle for a period of time, such as a year.

2. Define the care delivery value chain.

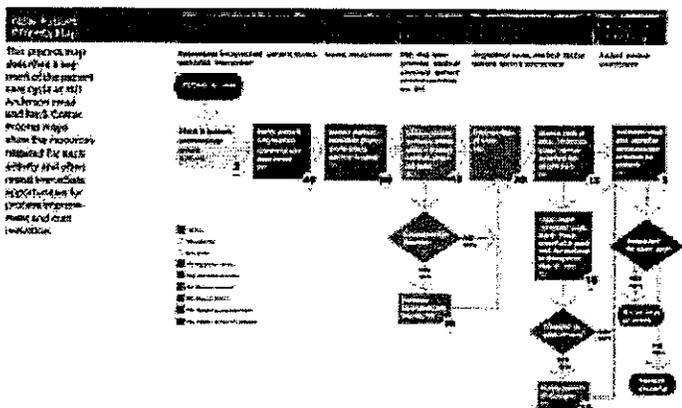
Next, we specify the care delivery value chain (CDVC), which charts the principal activities involved in a patient's care for a medical condition along with their locations. The CDVC focuses providers on the full care cycle rather than on individual processes, the typical unit of analysis for most process improvements and lean initiatives in health care. (The exhibit "The Care Delivery Value Chain" shows the CDVC developed with the Brigham & Women's pilot site for patients with severe knee osteoarthritis.) This overall view of the patient care cycle helps to identify the relevant dimensions along which to measure outcomes and is also the starting point for mapping the processes that make up each activity.



Click here for a larger image of the graphic.

3. Develop process maps of each activity in patient care delivery.

Next we prepare detailed process maps for each activity in the care delivery value chain. Process maps encompass the paths patients may follow as they move through their care cycle. They include all the capacity-supplying resources (personnel, facilities, and equipment) involved at each process along the path, both those directly used by the patient and those required to make the primary resources available. (The exhibit “New-Patient Process Map” shows a process map for one segment of the patient care cycle at the MD Anderson Head and Neck Center.) In addition to identifying the capacity-supplying resources used in each process, we identify the consumable supplies (such as medications, syringes, catheters, and bandages) used directly in the process. These do not have to be shown on the process maps.



Click here for a larger image of the graphic.

Our pilot sites used several approaches for creating process maps. Some project teams interviewed clinicians individually to learn about patient flow, while others organized “power meetings” in which people from multiple disciplines and levels of management discussed the process together. Even at this early stage in the project, the sessions occasionally identified immediate opportunities for process and cost improvement.

4. Obtain time estimates for each process.

We also estimate how much time each provider or other resource spends with a patient at each step in the process. When a process requires multiple resources, we estimate the time required by each one.

For short-duration, inexpensive processes that vary little across patients, we recommend using standard times (rather than investing resources to record actual ones). Actual duration should be calculated for time-consuming, less predictable processes, especially those that involve multiple physicians and nurses performing complex care activities such as major surgery or examination of patients with complicated medical circumstances.

TDABC is also well suited to capture the effect of process variation on cost. For example, a patient who needs a laryngoscopy as part of her clinical visit requires an additional process step. The time estimate and associated incremental resources required can be easily added to the overall time equation for that patient. (See again the process map exhibit.)

To estimate standard times and time equations, our pilot sites have found it useful to bring together all the people involved in a set of processes for focused discussion. In the future, we expect providers will use electronic handheld, bar-code, and RFID devices to capture actual times, especially if TDABC becomes the generally accepted standard for measuring the cost of patient care.

5. Estimate the cost of supplying patient care resources.

In this step, we estimate the direct costs of each resource involved in caring for patients. The direct costs include compensation for employees, depreciation or leasing of equipment, supplies, or other operating expenses. These data, gathered from the general ledger, the budgeting system,

and other IT systems, become the numerator for calculating each resource's capacity cost rate.

We must also account for the time that many physicians, particularly in academic medical centers, spend teaching and doing research in addition to their clinical responsibilities. We recommend estimating the percentage of time that a physician spends on clinical activities and then multiplying the physician's compensation by this percentage to obtain the amount of pay accounted for by the physician's clinical work. The remaining compensation should be assigned to teaching and research activities.

Next, we identify the support resources necessary to supply the primary resources providing patient care. For personnel resources, as illustrated in the Patient Jones example, these include supervising employees, space and furnishings (office and patient treatment areas), and corporate functions that support patient-facing employees. When calculating the cost of supplies, we include the cost of the resources used to acquire them and make them available for patient use during the treatment process (for instance, purchasing, receiving, storage, sterilization, and delivery).

Finally, we need to allocate the costs of departments and activities that support the patient-facing work. We map those processes as we did in step 3 and then calculate and assign costs to patient-facing resources on the basis of their demands for the services of these departments, using the process that will be described in step 6.

This approach to allocating support costs represents a major shift from current practice. To illustrate, let's compare the allocation of the resources required in a centralized department to sterilize two kinds of surgical tool kits, those used for total knee replacement and those used for cardiac bypass. Existing cost systems tend to allocate higher sterilization costs to cardiac bypass cases than to knee replacement cases because the charges (or direct costs) are higher for a cardiac bypass than for a knee replacement. Under TDABC, however, we have learned that more time and expense are required to sterilize the typically more complex knee surgery tools, so relatively higher sterilization costs should be assigned to knee replacements.

When costing support departments, a good guideline is the “rule of 1.” Support functions that have only one employee can be treated as a fixed cost; they can be either not allocated at all or allocated using a simplistic method, as is currently done. But departments that have more than one person or more than one unit of any resource represent variable costs. The workload of these departments has expanded because of increased demand for the services and outputs they provide. Their costs should and can be assigned on the basis of the patient processes that create demand for their services.

Project teams tasked with estimating the cost to supply resources—the numerator of the capacity cost rate—should have expertise in finance, human resources, and information systems. They can do this work in parallel with the process mapping and time estimation (steps 3 and 4) performed by clinicians and team members with expertise in quality management and process improvement.

6. Estimate the capacity of each resource, and calculate the capacity cost rate.

Determining the practical capacity for employees—the denominator in the capacity cost rate equation—requires three time estimates, which are gathered from HR records and other sources:

- a. The total number of days that each employee actually works each year.
- b. The total number of hours per day that the employee is available for work.
- c. The average number of hours per workday used for nonpatient-related work, such as breaks, training, education, and administrative meetings.

$$\text{Monthly Practical Capacity of Resource} = \frac{a}{12} \times (b-c)$$

For physicians who divide their time among clinical, research, and education activities, we subtract time spent on research and education activities to obtain the number of hours per month that they are available for clinical work.

For equipment resources, we measure capacity by estimating the number of days per month and the number of hours per day that each piece of equipment can be used. This represents the upper limit on the capacity of the equipment. The actual capacity utilization of much health care equipment is sometimes lower because equipment capacity is supplied in large lumps. For instance, suppose a piece of equipment can do 10,000 blood tests a month. A hospital decides to buy the equipment knowing that it needs to process only 6,000 tests per month. In this case, we make an adjustment: The costing system should use the time required to perform 6,000 tests as the capacity of the resource. Otherwise, the tests actually performed on the equipment will, at best, cover only 60% of its cost. If the provider subsequently ends up using the equipment for a higher number of tests, it can adjust the capacity rate accordingly.

This treatment of capacity follows the rule of 1 and should be applied when the organization has only one unit of the equipment. Now suppose a provider has 12 facilities that each use equipment capable of performing 10,000 blood tests per month—but each facility performs only 6,000 tests per month. In that case, the capacity of each resource unit should be set at the full 10,000 tests per month, not its expected number. We want the system to signal the cost of unused capacity when a provider chooses to supply capacity at multiple locations or facilities rather than consolidating its use of expensive equipment.

In addition to the lumpiness with which capacity gets acquired, factors such as peak load demands, surge capacity, and capacity acquired for future growth should be accounted for. This applies to both equipment and personnel. (Those factors can be incorporated, but the treatment is beyond the scope of this article.)

In practice, we have found that underutilization of expensive equipment capacity is often not a conscious decision but a failure of the costing system to provide visibility into resource utilization. That problem is corrected by the TDABC approach. We describe opportunities to improve resource capacity utilization later in the article.

To calculate the resource capacity cost rate, we simply divide the resource's total cost (step 5) by its practical capacity (step 6) to obtain a rate, measured in dollars or euros per unit of time, typically an hour or a minute.

7. Calculate the total cost of patient care.

Steps 3 through 6 establish the structure and data components of the TDABC system. In the final step, the project team estimates the total cost of treating a patient by simply multiplying the capacity cost rates (including associated support costs) for each resource used in each patient process by the amounts of time the patient spent with the resource (step 4). Sum up all the costs across all the processes used during the patient's complete cycle of care to produce the total cost of care for the patient.

Opportunities to Improve Value

Our new approach actively engages physicians, clinical teams, administrative staff, and finance professionals in creating the process maps and estimating the resource costs involved in treating patients over their care cycle. This bridges the historical divide between managers and clinical teams that has often led to tensions and stalemates over cost-cutting steps. TDABC builds a common information platform that will unleash innovation based on a shared understanding of the actual processes of care. Even at our pilot site Schön Klinik, which already had an excellent departmental cost-control system, introducing TDABC revealed powerful new ways to improve its processes and restructure care delivery. Capitalizing on these value-creating opportunities—previously hidden by inadequate and siloed costing systems—is the key to solving the health care cost problem. Let's examine some of the most promising opportunities that proper costing reveals.

Eliminate unnecessary process variations and processes that don't add value.

In our pilots, we have documented significant variation in the processes, tools, equipment, and materials used by physicians performing the same service within the same unit in the same facility. For example, in total knee replacement, surgeons use different implants, surgical kits, surgeons' hoods, and supplies, thereby introducing substantial cost variation in treating patients with the same condition at the same site. The surgical unit now measures the costs and outcomes that each surgeon produces. As a result, clinical practice leaders are able to have more constructive and better informed discussions about how best to standardize care and treatment processes to reduce the costs of variability and limit the use of expensive approaches and materials that do not demonstrably lead to improved outcomes.

In addition to reducing process variations, our pilot sites have eliminated steps or entire processes that did not improve outcomes. Schön Klinik, for example, lowered costs by reducing the breadth of tests included in its common laboratory panel after learning that many of the tests did not provide new information that would lead to improvement in outcomes.

Comparing practices across different countries for the same condition also reveals major opportunities for improvement. The reimbursement for a total joint replacement care cycle in Germany and Sweden is approximately \$8,500, including all physician and technical services and excluding only outpatient rehabilitation. The comparable figure in U.S. medical centers is \$30,000 or more. Since providers in all three countries report, in aggregate, similar margins on joint replacement care, U.S. providers' costs are likely two to three times as high as those of their European counterparts. By comparing process maps and resource costs for the same medical condition across multiple sites, we can determine how much of the cost difference is attributable to variations in processes, protocols, and productivity and how much is attributable to differences in resource or supply costs such as wages and implant prices. Our initial research suggests that although inputs are more expensive in the United States, the higher cost in U.S. facilities is mainly due to lower resource productivity.

Improve resource capacity utilization.

The TDABC approach identifies how much of each resource's capacity is actually used to perform processes and treat patients versus how much is unused and idle. Managers can clearly see the quantity and cost of unused resource capacity at the level of individual physicians, nurses, technicians, pieces of equipment, administrators, or organizational units. Resource utilization data also reveal where increasing the supply of certain resources to ease bottlenecked processes would enable more timely care and serve more patients with only modestly higher expenditures.

When managers have greater visibility into areas where substantial and expensive unused capacity exists, they can identify the root causes. For example, some underutilization of expensive space, equipment, and personnel is caused by poor coordination and delays when a patient is handed off from one specialty or service to the next. Another cause of low resource utilization is having specialized equipment available just in case the need arises. Some facilities that serve patients with unpredictable and rare medical needs make a deliberate decision to carry

extra capacity. In such cases, an understanding of the actual cost of excess capacity should trigger a discussion on how best to consolidate the treatment of such patients. Much excess resource capacity, however, is due not to rare conditions or poor handoffs but to the prevailing tendency of many hospitals and clinics to provide care for almost every type of medical problem. Such fragmentation of service lines introduces costly redundancy throughout the health care system. It can also lead to inferior outcomes when providers handle a low volume of cases of each type. Accurate costing gives managers a valuable tool for consolidating patient care for low-volume procedures in fewer institutions, which would both reduce the high costs of unused capacity and improve outcomes.

Deliver the right processes at the right locations.

Many services today are delivered in over-resourced facilities or facilities designed for the most complex patient rather than the typical patient. By accurately measuring the cost of delivering the same services at different facilities, rather than using figures based on averaged direct costs and inaccurate overhead allocations, providers are able to see opportunities to perform particular services at properly resourced and lower-cost locations. Such realignment of care delivery, already under way at Children's Hospital Boston, improves the value and convenience of more routine services for both patients and caregivers while allowing tertiary facilities to concentrate their specialized resources on truly complex care.

Match clinical skills to the process.

Resource utilization can also be improved by examining whether all the processes currently performed by physicians and other skilled staff members require their level of expertise and training. The process maps developed for TDABC often reveal opportunities for appropriately skilled but lower-cost health care professionals to perform some of the processes currently performed by physicians without adversely affecting outcomes. Such substitutions would free up physicians and nurses to focus on their highest-value-added roles. (For an example from one of our pilot sites, see the sidebar "A Cancer Center Puts the New Approach to Work.")

**PILOT: A Cancer Center Puts
the New Approach to Work,**

Speed up cycle time.

000114

**by Heidi W. Albright, MHA,
and Thomas W. Feeley, MD**

The University of Texas MD Anderson Cancer Center is a National Cancer Institute–designated Comprehensive Cancer Center, located in Houston, Texas. Seeing more than 30,000 new patients every year, MD Anderson accounts for approximately 20% of cancer care within the Houston region and 1% of cancer care nationally. MD Anderson is a medical condition–focused center that provides integrated, interdisciplinary care across the care cycle.

In collaboration with Michael Porter, we embarked on a major effort to expand clinical outcome measurement, beginning with a study of 2,468 patients in the Head and Neck Center, in 2008. We created the Institute for Cancer Care Excellence in December 2008 to support this effort. In 2010, with Robert Kaplan, we launched a pilot project, also within the Head and Neck Center, to assess the feasibility of applying modern cost accounting to health care delivery.

Traditionally, at MD Anderson, we used a charge-based cost accounting system. However, we realized that its cost allocations were problematic at several levels. For a start, the drivers of cost in health care had changed but the allocation methodology had not, with the result that our costing no longer reflected reality. What’s more, MD Anderson routinely allocated more costs to services that were highly reimbursed. With impending health care reform set to shift the industry away from fee-for-

Health care providers have multiple opportunities to reduce cycle times for treating patients, which in turn will reduce demand for resource capacity. For example, reducing the time that patients have to wait will reduce demand for patient supervision and space. Speeding up cycle time also improves outcomes, both by minimizing the duration of patient uncertainty and discomfort and by reducing the risk of complications and minimizing disease progression. As providers improve their process flows and reduce redundancy, their patients will no longer have to be so “patient” as they receive a complete cycle of care.

Optimize over the full cycle of care.

Health care providers today are typically organized around specialties and services, which complicates coordination, interrupts the seamless, integrated flow of patients from one process to the next, and leads to the duplication of many processes. In the typical care delivery process, for example, patients see multiple providers in multiple locations and undergo a separate scheduling interaction, check-in, medical consultation, and diagnostic workup for each one. This wastes resources and creates delays. The TDABC model makes visible the high costs of these redundant administrative and clinical processes, motivating professionals from different departments to work together to integrate care across departments and

service reimbursement to bundled or global payments, we needed a costing system that could provide more accurate patient-level costs by medical condition.

To determine whether time-driven activity-based costing (TDABC) would provide this level of accuracy, we worked with a team of clinicians and internal financial staff members in a pilot study. The team began by developing a care delivery value chain that mapped out the full treatment of a patient. Within each segment of care—the outpatient clinic, diagnostic imaging, the operating room, inpatient care, radiation therapy, and chemotherapy administration—we created process maps that also included all the resources involved. Each segment of the process map took approximately 40 hours to complete, with a team consisting of a project manager, a project coordinator, a process mapping expert, financial staff, clinical and business managers, and staff members from each function being mapped. (See the exhibit “New-Patient Process Map” for an example.)

The new process resulted in a 16% reduction in process time, a 12% decrease in costs for technical staff, and a 67% reduction in costs for professional staff.

The project team then estimated how much time it takes to perform each task and the capacity cost of each health care provider. We validated all the process steps, time estimates, and branching points with the help of frontline health

specialties. Eliminating unnecessary administrative and clinical processes represents one of the biggest opportunities for lowering costs.

With a complete picture of the time and resources involved, providers can optimize across the entire care cycle, not just the parts. Physicians and staff may shift more of their time and resources to the front end of the care cycle—to activities such as patient education and clinical team consultations—to reduce the likelihood of patients experiencing far more costly complications and readmissions later in the cycle.

Additionally, this resource- and process-based approach gives providers visibility into valuable nonbilled events in the cycle of care. These activities—such as nurse counseling time, physician phone calls to patients, and multidisciplinary care team meetings—can often make major contributions to efficiency and favorable outcomes. Because existing systems hide these costs in overhead (see Myth #1), such important elements of care are prone to be minimized or left unmanaged.

Capturing the Payoffs

personnel who were actually performing the tasks—not just departmental managers and senior leaders.

We then estimated the per-patient cost for each process step. Initially, we examined only personnel costs because they accounted for approximately 75% of total costs at the Head and Neck Center. Because of personnel and time constraints, we used an approximate procedure on the first pass to allocate the overhead costs of support departments.

Our pilot study also sought to evaluate whether the new costing approach would allow us to measure the cost consequences of changes in care processes. We examined the process for a patient visit to our Anesthesia Assessment Center (AAC), which occurs prior to surgery. The medical director of the AAC had developed two initiatives to improve performance: (1) implementing new clinical guidelines for preoperative diagnostic testing and (2) reorganizing personnel tasks—that is, having medical assistants perform some tasks previously performed by nurses and using nurses to perform some tasks previously performed by physicians.

The project team developed process maps for the AAC before and after the performance improvements, and then applied costs from the TDABC model to each map. The modified process resulted in a 16% (11-minute) reduction in process time, a 12% decrease in costs for technical staff, and a 67% reduction in costs for professional staff (physicians and other providers). Total costs fell

“Calculating the return on investment of performance improvement has been missing from most of the quality improvement discussions in health care,” Dr. Thomas Feeley at MD Anderson told us. “When measurement does occur, the assumptions are usually gross, inaccurate, and sometimes overstated,” he added. “TDABC gave us a powerful tool to actually model the effect an improvement will have on costs.” Accurate costing allows the impact of process improvements to be readily calculated, validated, and compared.

The big payoff occurs when providers use accurate costing to translate the various value-creating opportunities into actual spending reductions. A cruel fact of life is that total costs will not actually fall unless providers issue fewer and smaller paychecks, consume less (and less expensive) space, buy fewer supplies, and retire or dispose of excess equipment. Facing revenue pressure due to lower reimbursements—particularly from government programs such as Medicare and Medicaid—providers today use a hatchet approach to cost reduction by mandating arbitrary cuts across departments. That approach jeopardizes both the quality and the supply of care. With accurate costing, providers can target their cost reductions in areas where real improvements in resource

36%, from approximately \$250 per patient (including direct and indirect costs) to \$160. Our existing costing system could not provide visibility into the cost savings from these process improvements.

To see whether the cost reductions affected outcomes, we examined day-of-surgery cancellations due to inadequate preoperative workup and found that this critical outcome of the anesthesia assessment process did not change. Thus, the more efficient and less costly process improved value.

TDABC, which we have found straightforward to implement, requires a significant time investment to develop process maps for all care areas. But this investment has yielded additional benefits by supporting process improvement opportunities and facilitating the standardization of care. Perhaps most important, the new costing approach helps us set priorities for process improvements and measure their cost impact.

We are now completing the analysis of our pilot project data and will be extending the methodology to all our other integrated cancer care units. As we merge ongoing measurement of clinical outcomes in each of our care centers with patient-level costs for a full care cycle, we will be better positioned to drive value improvement and develop bundled prices for clinical care. Through this work, we hope to provide convincing evidence of the health care value that MD Anderson's integrative cancer treatment strategy actually delivers.

utilization and process efficiencies enable providers to spend less without having to ration care or compromise its quality.

Health care organizations today, like all other firms, conduct arduous and time-consuming budgeting and capacity planning processes, often accompanied by heated arguments, power negotiations, and frustration. Such difficulties are symptomatic of inadequate costing systems and can be avoided.

When providers understand the total costs of treating patients over their complete cycle of care, they can contemplate innovative reimbursement approaches without fear of sacrificing their financial sustainability.

A TDABC budgeting process starts by predicting the volume and types of patients the provider expects. Using these forecasts combined with

Heidi W. Albright is the director of the Institute for Cancer Care Excellence at MD Anderson Cancer Center.

Thomas W. Feeley is the Helen Shafer Fly Distinguished Professor of Anesthesiology and the vice president of medical operations at MD Anderson Cancer Center.

the process maps for treating each patient condition, providers can predict the quantity of resource hours required. This can then be divided by the practical capacity of each resource type to obtain accurate estimates of the quantity of each resource needed to meet the forecasted demand. Estimated monthly expense budgets for future periods can be easily obtained by multiplying the quantity of each resource category required by the monthly cost of each

resource.

In this way, managers can make virtually all their costs "variable." They can readily see how efficiency improvements and process innovations lead to reduced spending on resources that are no longer needed. Managers also have the information they need to redeploy resources freed up as a result of process improvements. Leaders gain a tool they never had before: a way to link decisions about patient needs and treatment processes directly to resource spending.

Reinventing Reimbursement

If we are to stop the escalation of total health care costs, the level of reimbursement must be reduced. But how this is done will have profound implications for the quality and supply of health care. Across-the-board cuts in reimbursement will jeopardize the quality of care and likely lead to severe rationing. Reductions that enable the quality of care to be maintained or improved need to be informed by accurate knowledge of the total costs required to achieve the desired outcomes when treating individual patients with a given medical condition.

The current system of reimbursement is disconnected from actual costs and outcomes and discourages providers and payors from introducing more cost-effective processes for treating patients. With today's inadequate costing systems, reimbursement rates have often been based

on historical charges. That approach has introduced massive cross subsidies that reimburse some services generously and pay far below costs for others, leading to excess supply for well-reimbursed services and inadequate delivery and innovation for poorly reimbursed ones.

Accurate costing allows the impact of process improvements to be readily calculated, validated, and compared.

Adjusting only the level of reimbursement, however, will not be enough. Any true health care reform will require abandoning the current complex fee-for-service payment schedule altogether. Instead, payors should introduce value-based reimbursement, such as bundled payments, that covers the full care cycle and includes care for complications and common comorbidities. Value-based reimbursement rewards providers who deliver the best overall care at the lowest cost and who minimize complications rather than create them. The lack of accurate cost data covering the full cycle of care for a patient has been the major barrier to adopting alternative reimbursement approaches, such as bundled reimbursement, that are more aligned with value.

We believe that our proposed improvements in cost measurement, coupled with better outcome measurement, will give third-party payors the confidence to introduce reimbursement methods that better reward value, reduce perverse incentives, and encourage provider innovation. As providers start to understand the total costs of treating patients over their complete cycle of care, they will also be able to contemplate innovative reimbursement approaches without fear of sacrificing their financial sustainability. Those that deliver desired health outcomes faster and more efficiently, without unnecessary services, and with proven, simpler treatment models will not be penalized by lower revenues.***

Accurately measuring costs and outcomes is the single most powerful lever we have today for transforming the economics of health care. As health care leaders obtain more accurate and appropriate costing numbers, they can make bold and politically difficult decisions to lower costs while sustaining or improving outcomes. Dr. Jens Deerberg-Wittram, a senior executive at Schön Klinik, told us, "A good costing system tells you which areas are worth addressing and gives you

confidence to have the difficult discussions with medical professionals.” As providers and payors better understand costs, they will see numerous opportunities to achieve a true “bending of the cost curve” from within the system, not in response to top-down mandates. Accurate costing also unlocks a whole cascade of opportunities, such as process improvement, better organization of care, and new reimbursement approaches that will accelerate the pace of innovation and value creation. We are struck by the sheer size of the opportunity to reduce the cost of health care delivery with no sacrifice in outcomes. Accurate measurement of costs and outcomes is the previously hidden secret for solving the health care cost crisis.

The authors would like to acknowledge the extensive and invaluable assistance of Mary Witkowski, Dr. Caleb Stowell, and Craig Szela in the preparation of this article.

A version of this article appeared in the September 2011 issue of *Harvard Business Review*.

For Further Reading

Measuring Value and Outcomes

“What Is Value in Health Care?” by M.E. Porter, *New England Journal of Medicine*, 2010

Redefining Health Care: Creating Value-Based Competition on Results by M.E. Porter and E.O. Teisberg, Harvard Business Review Press, 2006

“A Strategy for Health Care Reform: Towards a Value-Based System” by M.E. Porter, *New England Journal of Medicine*, 2009

Time-Driven Activity-Based Costing

Time-Driven Activity-Based Costing: A Simpler and More Powerful Path to Higher Profits by R.S. Kaplan and S.R. Anderson, Harvard Business Review Press, 2007

Cost and Effect: Using Integrated Cost Systems To Drive Profitability and Performance by R.S. Kaplan and R. Cooper, Harvard Business Review Press, 1998



Robert S. Kaplan is a senior fellow and the Marvin Bower Professor of Leadership Development, Emeritus, at Harvard Business School. He is co-developer of Time-Driven Activity-Based Costing and the Balanced Scorecard.



Michael E. Porter is a University Professor based at Harvard Business School.

This article is about COSTS

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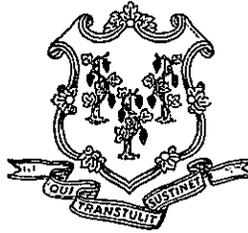
Comments

000122

EXHIBIT F

SENATOR GAYLE SLOSSBERG

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Capitol 860-240-0482
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State of Connecticut
SENATE
Fourteenth District

Chair
Education
Vice Chair
Human Services
Member
Appropriations
General Law
Regulation Review

June 17, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application for One Additional 1.5 Tesla MRI filed by
Connecticut Orthopaedic Specialists, P.C.

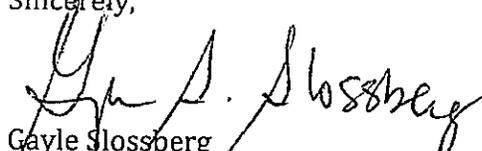
Dear Ms. Martone,

I am writing in support of the application of Connecticut Orthopaedic Specialists, P.C. ("COS") to allow them to purchase a mobile 1.5 Tesla magnetic resonance imaging unit ("MRI"). Currently, COS has two MRI units: one in their surgery center in Branford, and the other in their Hamden office. However, COS has grown over the last few years and has more than doubled the size of its practice. It is heartening to see that talented physicians in the orthopedic specialty have chosen to join COS to provide the people in south/central Connecticut and the shoreline with outstanding orthopedic services. COS is a leader in reimbursement reform and has established a number of bundled payment programs with major payers in the State. Due to the growth of its practice, COS needs an additional MRI unit in order to continue to keep the quality of care at its best.

COS has always attempted to keep all of the affiliated services surrounding their orthopedic care within their offices so that they can manage the patient's medical condition without delays, and also to keep the cost as reasonable as possible. COS does not charge facility fees. With the addition of a mobile MRI that could service the offices COS has had for years in Orange and Essex, they can offer an MRI service where the physicians will have the results overnight, and the radiologist who reads the scan will be part of the COS practice. COS will not accept referrals for MRIs from outside the COS practice.

I strongly urge the Office of Health Care Access to approve this application

Sincerely,


Gayle Slossberg
State Senator, 14th District



Selectmen's Office

www.essexct.gov

Norman M. Needleman, First Selectman

Email: nneedleman@essexct.gov

Board of Selectmen:

Stacia R. Libby

Bruce M. Glowac

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29 West Avenue

Essex, Connecticut 06426

Telephone: 860-767-4340

Fax: 860-767-8509

June 15, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

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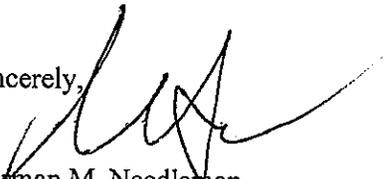
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I am told that COS is a leader in reimbursement reform and has established a number of bundled payment programs with major payers in the State. Due to the growth of its practice, especially in the Essex region, COS needs an additional MRI unit in order to continue to keep the quality of care at its best and to allow the members of our community to receive diagnostic services close to home. There are no other MRI units in our town and the MRI service in Madison, CT is no longer available to our residents.

I strongly urge the Office of Health Care Access to approve this application, which I believe will be a great enhancement to the healthcare available to residents of Essex.

Sincerely,


Norman M. Needleman
First Selectman

000125





State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE PHILIP MILLER
THIRTY-SIXTH ASSEMBLY DISTRICT

LEGISLATIVE OFFICE BUILDING, ROOM 2103
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CO CHAIR
PLANNING & DEVELOPMENT

MEMBER
ENVIRONMENT COMMITTEE
LEGISLATIVE PROGRAM REVIEW & INVESTIGATIONS
COMMITTEE

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
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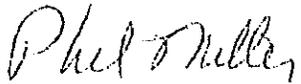
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Finding ways to lower the cost of healthcare has been a strongly debated topic not only in Hartford but on a national level. Connecticut Orthopaedic Specialists has established itself as a leader in CT not only in the quality of care it provides but also through innovative payment reform strategies including a number of bundled payment programs with major payers in the State. In order for COS to be able to take on reimbursement reform, manage risk, and provide high quality accessible care, they need an additional MRI unit to service the greater Essex community.

I strongly support the application for a mobile MRI that could service the offices COS has had for years in Orange and Essex.

Sincerely,

A handwritten signature in cursive script that reads "Philip Miller".

State Representative Philip Miller

000127



State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE PHILIP MILLER
THIRTY-SIXTH ASSEMBLY DISTRICT

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CO CHAIR
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Kimberly R. Martone
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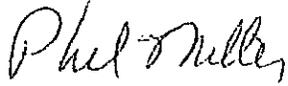
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I strongly support the application for a mobile MRI that could service the offices COS has had for years in Orange and Essex.

Sincerely,

A handwritten signature in cursive script that reads "Philip Miller".

State Representative Philip Miller

000129



July 11, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application for One Additional 1.5 Tesla MRI filed by
Connecticut Orthopaedic Specialists, P.C.

Dear Ms. Martone,

I am writing in support of the application of Connecticut Orthopaedic Specialists, P.C. ("COS") to purchase a mobile 1.5 Tesla magnetic resonance imaging unit ("MRI"). COS providers' are part of the Workers' Compensation Trust's managed care plan and deliver exceptional care to our injured workers in the south/central and shoreline communities. With the utilization of COS' MRI units in Branford and Hamden, we are able to schedule an MRI scan shortly after the provider has requested it, thus resulting in a faster diagnosis and treatment plan. By having on-site MRI, it allows for the results to be delivered to us much sooner due to their in-house radiologist who interprets the scan and reports back to the provider through their EMR. With the expedited service that COS offers, our injured workers are able to begin their recovery process without delays.

It is my understanding from COS that due to the growth of its practice and the demand on their current MRI units, COS is in need of an additional MRI unit in order to continue to keep the quality of care that they provide our injured workers at its best. Therefore, I am in support of COS obtaining a mobile MRI unit to service our clients in the Essex and Orange geographic regions to continue with the continuum care model that COS executes so well.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Downs", is written over a light blue horizontal line.

Brian S. Downs
Vice President, Quality & Provider Relations

EXHIBIT G

000131



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

COS MRI Protocols / Guidelines

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Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

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Connecticut Orthopaedic Specialists

AND OUR DIVISIONS



The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

PURPOSE:

- Establish the policies and procedures to maintain safe clinical practice involving magnetic resonance imaging (MRI) devices at COS facilities.
- Implement an MRI program that models the safety recommendations structured by the American College of Radiology (ACR) for safe practices.
- Perform high quality imaging under the discretion of the medical director

RESPONSIBILITIES OF MRI MANAGER:

- Manage the maintenance of the MRI equipment by working with qualified vendors to perform frequent assessments including alignment, calibration and repairs
- Review credentialing of MRI technicians upon hire and annually for purposes of verifying licences and training requirements
- Educate all individuals who assist with patient care in the vicinity of MRI unit on the use of equipment, their work space and the potential health hazards associated with specific zones while MRI testing is in progress
- Perform frequent checks of the coils for wear and tear

TRAINING/QUALIFICATIONS

- MRI safety training is required for MRI technicians and non-technical staff (dependent of their job description) to be informed of the potential work hazards in our MRI suites
- Technicians and non-technical staff are required to complete an MRI safety training refresher course annually through the practice's intranet site. The results are documented and kept on file for the duration of their employment plus three years thereafter.
- Training documentation must be approved by the Radiology Safety Officer

MEDICAL DIRECTOR

- Joseph Gagliardi, MD



MRI SUITE SAFETY INFORMATION

STATIC MAGNETIC FIELD:

The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. Any individual may be struck, injured or trapped against the magnet by a magnetically attracted object. If such an instance were to occur the equipment may be damaged due to the collision of the magnetically charged object and the magnet; as the object with attract to the magnet at a high velocity.

- Field Strength
 - The strength of the static field is regulated by the federal government with 3.0 Tesla magnets being maximum strength for clinical use. Connecticut Orthopaedic Specialists' MRI units meet the federal requirement with the use 1.5 Tesla magnets
- Projectile Effect
 - Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field.
 - Projectiles have the potential of causing serious injury, including death to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet, if the magnetically charged object is attached to the individual. Equipment may be irreparably damaged by a projectile in such an event.



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RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS

Safety risks from RF include potential tissue heating and burns to the patients. RF may damage electronic or implanted devices. Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Therefore, all conducting material not in use should be removed from the magnet bore.

Cables, wires and other accessories should be inspected regularly by the MRI Technicians to ensure insulation, connectors and other components are intact and functioning safely. Any malfunctioning or broken equipment should be reported to the MRI Supervisor.

LIQUID HELIUM AND LIQUID NITROGEN

In their liquid state, helium and nitrogen are extremely cold and will freeze human tissue. Only authorized persons should fill liquid nitrogen and liquid helium containers. Injuries caused by freezing must be washed with water and treated as burns. The ventilation should be running in the examination room and only non-ferrous containers should be brought into the magnetic area.

When they evaporate, helium and nitrogen form a cold mist. Helium rises and nitrogen descends to the ground level. While these gases are odorless, non flammable, and non-poisonous, they pose a risk of suffocation because they dilute the oxygen in the air. Always keep the ventilation running in the examination room. The quench pipe will prevent evaporation of nitrogen and helium into the magnet room and release it into the air outside the building.



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ZONES OF THE MRI DEPARTMENT

- **ZONE I**
 - Open to general public access.
 - This is generally the reception and waiting area for the MRI suites.
 - Purpose of this zone is to channel patients to the prescreening area (Zone II)
- **ZONE II**
 - This is the first interaction site for the patients, visitors, and others with the technical staff in the MRI suite,
 - The purpose of this zone is to restrict further public access to the site, provide direct supervision of patients and visitors by the technical staff, and provide an opportunity to prescreen all patients and visitors.
 - All ferromagnetic objects must be collected and secured within Zone II.
- **ZONE III**
 - Zone III is the entry zone to the MRI scanning room.
 - Without exception, only the certified technical staff, MRI desk staff, students, and COS doctors should be allowed free access between Zones III and IV.
 - All technical staff must be prescreened upon employment prior to entering Zone III to make sure no unscreened individuals are allowed access to Zone IV.
 - Doors are labeled and locked to prevent access by unscreened individuals.
- **ZONE IV**
 - Only those personnel required so that the patient can complete the exam will be allowed in the MRI scanning room during the procedure. Family members should remain in the waiting area unless the patient requires their presence for exam completion.
 - Code red situations (FIRE) will require the use of MRI-safe fire extinguishers and restrictions of first responders from Zone IV, until MRI safe conditions can be established or first responders verified as MRI safe.
 - In Code Red (Fire) situations, first responders **do not** have free access to either Zone III or IV
 - The entrance to this room is visually marked by signage on the normally closed room door indicating Authorized Personnel Only and entrance is restricted.

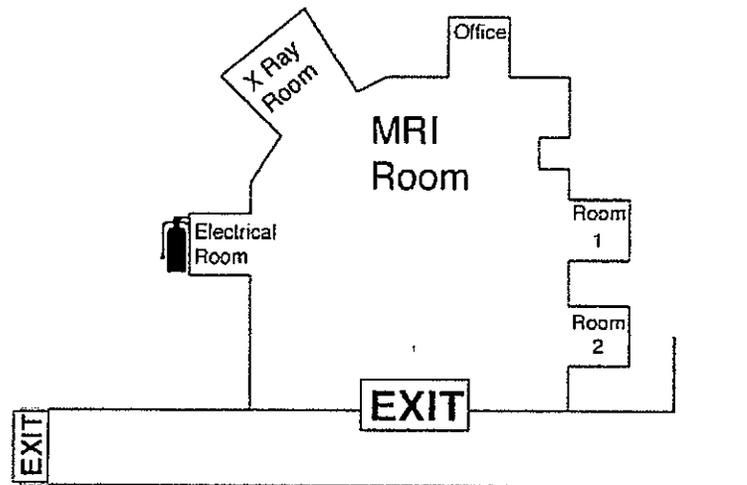
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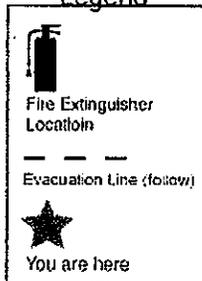
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Legend



EQUIPMENT SCREENING

All equipment used for MRI scans, must be tested for MRI safety BEFORE entering the fringe field. Individuals are cautioned to NEVER take equipment into the fringe field or into the magnet room without prior testing for magnetic attraction.



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MRI UNIT EMERGENCY PROCEDURES

- **Emergency Stop**
 - If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the scanner operator should immediately perform an emergency stop and report faulty equipment to the MRI Supervisor.

- **Magnet Emergency- quench**
 - If it is necessary to quench the magnetic field immediately (e.g. in case of fire, or a person pinned to a magnet), push the emergency magnet shut-off switch located on the magnet safety panel. Pushing the emergency switch quenches the magnet and causes the field to collapse within 10 seconds; this should only be done in a severe emergency.
 - If the door into the MRI magnet room is unable to be opened, use the specialized hammer on the window ledge to break the window.
 - Report the quench immediately to the MRI Supervisor.

- **Response to leaks of liquid helium and liquid**
 - If the door into the MRI magnet room is unable to be opened, use the specialized hammer on the window ledge to break the window.
 - Remove all jewelry from hands and wrists.
 - If skin comes in contact with cryogenics, run the affected area under lukewarm water for 15 minutes DO NOT rub the affected area.
 - If injured, notify the MRI supervisor as soon as possible.
 - In the case of someone severely burned from spill, call **911**



RESPONSE TO A FIRE IN MRI

Due to the high magnetic field, fighting fires in a suite with an MRI unit pose an additional hazard. The following procedures should be followed in the event of a fire in order to prevent additional hazards to the individual, suite or facility.

- **PART A**

- **If you discover a fire, follow this order of response:**
 - Rescue
 - Alert
 - Contain
 - Extinguish

- **PART B**

- **In trying to extinguish or contain the fire, do not jeopardize your own safety.**
Do the following:
 - Disconnect electrical power to the MRI system by pressing the emergency "off" buttons.
 - Use only a non-magnetic extinguisher found in the mechanical room
 - If the fire is not extinguished after emptying the available extinguisher, or if your safety is endangered remove the magnetic field by pressing the "quench" button.
 - Screen all personnel, including firefighters, for entry to the magnetic field area.

- **PART C**

- **If a fire breaks out in the computer room:**
 - Disconnect electrical power by pressing the emergency "off" buttons.
 - If the fire is not extinguished after you have emptied the fire extinguisher, or if personnel are endangered, evacuate the room and call 911.



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DISASTER AND FIRE EVACUATION FROM BUILDING

In the event of a disaster all employees of the **Branford MRI location** are to follow these procedures:

- 1) Call 911 if required
- 2) Alert all employees and patients in the facility and escort them to the nearest appropriate exit
- 3) Check examination rooms, restrooms and offices to ensure all persons are accounted for
- 4) All employees and patients should evacuate through the same exit if possible via use of stairs if not on the ground level as use of elevators are prohibited during an emergency evacuation
- 5) Once evacuated from the building all employees and patients are to gather in the front of the building parking lot closest to North Main Street (between the Surgical Center and OrthoNOW)
(unless otherwise indicated)
- 6) Supervisor will have a copy of the current day's clinical schedule to confirm attendance once evacuated.
- 7) Once everyone is deemed safe from danger call the Operations Officer for an appropriate plan of action.

In the event of a disaster all employees of the **Hamden MRI location** are to follow these procedures:

- Follow steps 1-4 as described above
- 5) Once evacuated from the building all employees and patients are to gather in parking lot behind MRI, halfway to back of lot. (unless otherwise indicated)
- Complete steps 6-7 as described above

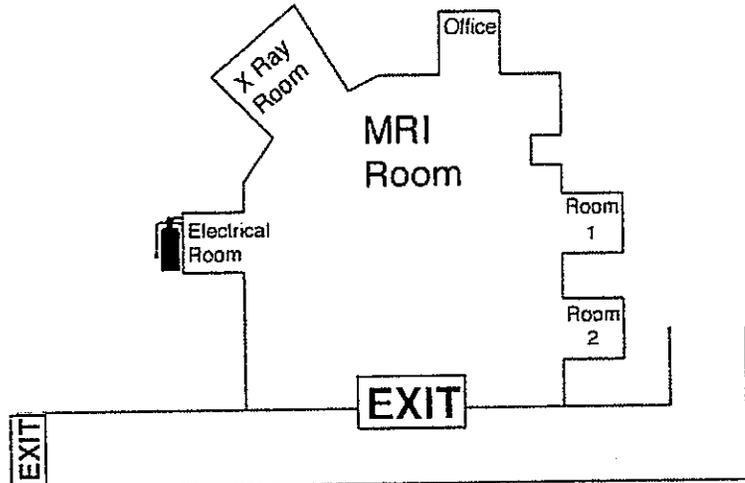
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 Fire Extinguisher Location

 Evacuation Line (follow)

 You are here



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MRI SAFETY SCREENING

Each person must be checked for safety or pre screened prior to entering the magnetic environment of the scanner room. An important aspect of protecting people from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the person.

- **Employees**

- All individuals, including clinical, employees, and students, who work within the magnetic environment, must be trained according to COS policy and screened for personal safety prior to entering the magnetic field.
- In addition, individuals who have the responsibility to screen patients must complete the MRI Safety Training program.
- Any individual who has a need to enter the magnet room (I.E. facility maintenance, engineers, site visitors) must be screened on a case by case basis.

- **Patients**

- Preliminary screening of patients for MRI procedures should take place during the ordering doctor's visit as an order is placed.
- A second screening takes place during the scheduling process. Such screening helps to prevent scheduling of patients who may be at risk for safe MR imaging.
- Upon arrival, it is **mandatory** for every MRI patient (even patient who have had a previous MRI) to undergo comprehensive screening in preparation for the MRI study prior to entering Zone IV.
- Family members of patients whose presence is required for exam completions are held to the same screening requirements as patients.
- Pregnancy
 - Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any possible minimal risk to the fetus by referring physician and radiologist and are required to sign a waiver.

- **Claustrophobia Screening**

- Statistics indicate that about 10% -20% of the general population is claustrophobic to some degree. By using prism glasses, lavender scented tablets and gentle breathing instructions, most patients can continue with the exam.
- If the patient does not complete the exam, the ordering doctor is contacted to decide if medication will be ordered or the patient will have an Open MRI.



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- **Thermal Heating and Burns**

- Dental hardware

- Most dental hardware is generally safe in the MRI environment although some orthodontic components may be ferromagnetic.

- Tattoos

- RF heating of tattooed tissue has been reported especially with the use of iron oxide containing inks. The patient should be informed of the potential for heating and burns and instructed to alert the technologist immediately if warming occurs.

- Transdermal Medicated Patches

- These patches contain a metallic layer which has been reported to cause heating of tissue during scanning and producing a burn on the patient. It is essential that any patient wearing a transdermal patch that has a metallic component be identified during the pre-screening process, prior to undergoing MRI.

- Coils

- Coils are the devices that transmit and receive the RF signals and can be produced in a variety of configurations. The MRI Technician must have some basic knowledge of coil technology to properly conduct MRI scans.

Safety issues can occur as follows:

- Transmitting RF energy through a receive-only coil may damage or ruin the device
- Transmitting more RF power than the coil was designed to accommodate, may damage or ruin the device.
- Twisting, looping or crossing cables may cause current to be induced, resulting in damaging the coil, abnormal heating or potential arcing
- Keep the cables off the patient and run them over blankets whenever possible
- To avoid burns or peripheral nerve stimulation, a minimum distance of 5mm should be maintained between the patient's body and the wall of the scanner tunnel. MR pads or cotton sheets available in the MR scan can be used to assure the distance is maintained,



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- **Implants and devices**

- Implants and devices are rapidly evolving and must be thoroughly investigated if potential patients or individuals who will enter the magnetic environment indicate their presence. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:
 - Look up the item by manufacturer in the current Reference Manual for Magnetic Resonance Safety, Implants, and Devices by Frank G. Shellock, PhD. Or on the web site : <http://www.mrisafety.com>
 - If the device or object is listed, but has not been tested at the field strength patient is subjected to, then contact the manufacturer for the following information and written documentation:
 - Have the manufacturer fax certified document that states the device is MRI safe and at which field strength and conditions it is safe.
 - The document should also include the FDA date stamp that verifies the device is MRI safe.

- **Orbit Wavier**

- If a patient admits to having had metal in their eye or past history of working with metal, an orbits test will be ordered. An orbits test will be able to rule out if the patient has any metal fragments in their eyes as a preventative measure to protect the patient against harm during MR testing; due to the strong magnetic fields used for imaging.

HEARING PROTECTION POLICY

Acoustic levels in the MRI scan room may exceed 99dBA. Hearing protection is required for all people in the magnet room during a scan to prevent hearing impairment. Staff must adhere to the following rules:

- All patients will be provided hearing protection.
- All patients will either receive ear plugs or head phones to protect their hearing.
- All patients' family members that go into the MRI scan room will be required to wear ear plugs.



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LASER LIGHT LOCALIZER HAZARDS

A laser is available for land marking the patient's position in the 1.5 GE scanners. Patients should be instructed to keep their eyes closed while the laser light is turned on to avoid eye injury. If the laser light appears as a spot, rather than as crosshairs, it should be reported to the MRI supervisor.

COS POLICY FOR PREGNANT MRI EMPLOYEES

There are no nationally uniform or accepted guidelines for the pregnant technologist working with MRI units. An abstract was presented by Dr. Kanal in 1993, "Survey of reproductive health among female MRI workers" evaluating potential risks. ACR published, "ACR Guidance Document for Safe MR Practice 2007." Based on the findings presented by Dr. Kanal the following is the recommendation from ACR's document for Safe MR Practice.

Pregnancy-Related Issues

Health care practitioner pregnancies

Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast material, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning.



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PATIENT PREGNANCY POLICY

- Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any possible minimal risk to the fetus by referring physician and radiologist and are required to sign a waiver.

PATIENT PREGNANCY WAIVER

- Patients that identify that they are pregnant are presented with a document, of which they are to consent to the terms prior to receiving the MR scan.
- Pregnant patients are required to consent to the following terms:
 - There is no national accepted guideline for M.R.I. scanning of a pregnant woman. The safety of the General Electric 1.5 Tesla (MRI) system when used during pregnancy has not been established and it is strongly recommended by the manufacturer that scanning should not be performed during the first trimester of pregnancy due to possible health effects to the fetus. Considering that there are no official guidelines for pregnant women the decision to have a M.R.I. examination is at the discretion of the patient. If you wish to proceed with the MRI examination please be aware that you are willing to accept full responsibility for any complications which may affect your unborn child. I have read the above criteria pertaining to my pregnancy and the health of my unborn child and I wish to proceed with the MRI.

PATIENT MONITORING

Monitoring during an MRI examination is indicated whenever a patient requires observation of vital physiologic parameters due to an underlying health problem or is unable to respond or alert the MRI technologist regarding pain, respiratory problem, cardiac distress, or difficulty that may arise during the examination. The technologist will provide verbal communication throughout the examination.

The scanners are also equipped with a squeeze ball that allows the patient to set off an audible alarm to attract the operator's attention. The squeeze ball is made available to the patients at the conclusion of positioning.

In 1992, the Safety Committee of the Society of Magnetic Resonance Imaging published guidelines and recommendations concerning the monitoring of patients during MRI procedures. This information indicates that all patients undergoing MRI procedures should, at the very least, be visually and/or verbally monitored; for which Connecticut Orthopaedic Specialists meets the requirement.



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Severe injuries and fatalities have occurred in association with MRI procedures. These may have been prevented with the proper use of monitoring equipment and devices. Importantly, guidelines issued by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) indicate that patients receiving sedatives or anesthetics require monitoring during administration and recovery from these medications. Connecticut Orthopaedic Specialists currently do not use sedation/anesthesia.

- **Patients that require extra monitoring and support during MRI procedures are:**
 - Physically or mentally unstable patients
 - Patients with compromised physiologic functions
 - Patients who are unable to communicate
 - Pediatric patients
 - Patients who may have a reaction to an MRI contrast agent
 - Critically ill or high risk patients

*Connecticut Orthopaedic Specialists does not scan patients that require additional monitoring devices (i.e. EKG, ECG, blood pressure, oxygen, neonatal, sedated, anesthetized etc.)

CONTRAST ADMINISTRATION AND REACTIONS

Gadolinium chelates have been approved for parenteral use since the late 1980's. Although these agents can be differentiated on the basis of stability, viscosity, and osmolality, they can not be differentiated on the basis of efficacy. Gadolinium chelates are extremely well tolerated in the vast majority of patients that are injected. Acute adverse reactions are encountered with a lower frequency than is observed after administration of iodinated contrast media.

The frequency of all acute reactions of all acute events after an injection of 0.1 or 0.2 mmol/kg of gadolinium chelate ranges from 0.07% to 2.4%. The vast majority of reactions are mild, including coldness at the injection site, nausea with or without vomiting, headache, warmth, or pain at the injection site, paresthesias, dizziness, itching. Reactions resembling an "allergic" response are very unusual and vary in frequency. A rash, hives, or urticaria are the most frequent of this group, and very rarely there may be bronchospasm. Severe, life threatening anaphylactoid or nonallergic reactions are exceedingly rare (0.001% to 0.01%). Fatal reactions to gadolinium chelate agents occur but are extremely rare.

- **Patients with a higher possibility of a reaction**
 - Persons with asthma



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- Various allergies to medications or foods
- Persons with reports of adverse reactions to gadolinium in the past
- Persons with reports of allergic-like reactions to iodinated contrast media

TREATMENT OF ACUTE ADVERSE REACTIONS

It is imperative that personnel are trained in recognizing and handling reactions with medications and equipment needed for treatment on site if applicable.

Patients should be taken out of the imaging room immediately and away from the magnet so that none of the resuscitative equipment becomes a magnetic hazard.

STORAGE AND DISPENSING MEDICATION POLICY

The COS MRI department does not prescribe or dispense medication to patients scheduled for diagnostic testing.

The organization evaluates its contrast management system by maintaining adequate contrast supply. The Lot number and expiration dates are documented for all patients receiving contrast injections. The staff technologist is responsible to check and log expiration dates monthly and notify the manager of any supplies that are expired.

Supply is rotated when a new supply is received.

All contrast reactions are reported to the manufacturer and an incident report is filed for the patient's who experience a contrast reaction.

Multi-dose medications or contrast used for more than one patients are dated when they are first opened and discarded within 28 days after opening or the manufacturer's recommendations whichever comes first. Medications will be labeled with the date of expiration.

All medication and contrast material is maintained in a secured location.

In the event of a contrast reaction, the Radiologist is the sole administrator of emergency drugs used to treat the reaction.

These drugs are stored locked and the key returned to the lock box at the end of the shift and when the exam room is not staffed. These drugs are monitored for expiration by the assigned technologist. During hours of operation these drugs are readily available.



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MEDICATION DISPOSAL

Medication's expiration dates are checked and logged monthly by the staff technologist. Expired drugs are disposed according to state and federal guidelines.

Recalled medications will be removed from the locked storage area and disposed of according to state and federal guidelines.

MEDICAL EMERGENCY PROCEDURES

- **Written emergency procedures**
 - Written emergency procedures should be made available in the areas where MRI devices are used.
 - All MRI users shall familiarize themselves with these emergency procedures.
- **Medical Attention**
 - MRI Technical Staff shall immediately seek appropriate medical attention for any individual injured within the MRI environment.
 - The emergency team must report outside the appropriate MRI scanner room to begin treatment for the patient.
 - Crash carts and other emergency equipment containing ferromagnetic material **must not** be brought into the scanning room.

OSHA TRAINING

- Training is provided at the time of initial assignment to tasks where occupational exposure to blood and OPIM may occur. Training is also conducted annually thereafter. Training is provided during work hours and at no cost to employees.
- Training includes but is not limited to:
 - An accessible copy of the Bloodborne Pathogen Standard
 - An explanation of the epidemiology and symptoms of bloodborne diseases
 - Modes of transmission of bloodborne pathogens
 - Explanation of COS' bloodborne pathogen exposure plan, where it is located, and how a copy can be obtained.
 - How to recognize tasks which may result in exposure to blood and OPIM
 - An explanation of COS' engineering controls, work practice controls and PPE
 - The type of PPE available
 - How to select appropriate PPE and the minimum requirements for various tasks



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- How to properly dispose of PPE which is soiled and/or contaminated
- Information on the hepatitis B vaccination including benefits, efficacy, etc. and that it is offered free of charge
- Who to contact in case of an emergency involving exposure to blood or OPIM
- What to do in the case of an exposure
- Information on post exposure evaluation and follow-up treatment, which is available at no charge to employees
- Explanation of biohazard symbols
- How to handle biomedical waste generated in the office

REPORTING REQUIREMENTS - SAFETY

Mandatory MRI safety training is required for individuals who work in the magnetic environment. Any event or occurrences that may compromise the safety of the individual or patients in or near the magnetic environment need to be reported and addressed by the MRI supervisor and Safety Officer.

- **Accidents, Injuries and Incidents**
 - Any accidents causing injury to an individual or patient must be reported to the MRI Supervisor and Safety Officer.
- **Equipment Damage or Failure**
 - Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and patients. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made, Equipment problems should be reported to the MRI Supervisor as soon as reasonably possible.
- **Notification of injury or death**
 - Any COS employee or student who becomes aware of an incident resulting in the injury or death of an individual caused by an MRI device shall immediately notify the MRI Supervisor and Safety Officer.
- **Notification of near misses**
 - Any COS employee or student who becomes aware of an event that could have resulted in the injury or death of an individual caused by an MRI device shall immediately notify the MRI Supervisor and Safety Officer within 24 hours of becoming aware of the event.



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Consent for Intra-Articular Joint Injection

Your doctor has ordered an MRI arthrogram for you. The arthrogram requires an injection of gadolinium and nonionic iodine containing contrast agent into your joint space. The contrast agent or contrast materials stand out on the MRI images and help the radiologist interpret the examination.

The contrast media is given to you through a small needle placed in the joint space. Normally, a contrast material is safe. Any injection, however, carries a slight risk of harm, including an infection. Reactions are possible with any contrast agent. Approximately 95% of adverse reactions are mild to moderate in degree and nausea, warmth, and rash.

Certain patients are at higher risk for experiencing a reaction to the contrast material. Please check each medical condition that applies to you:

- _____ History of adverse reaction to previous injection of contrast media
- _____ History of asthma
- _____ History of allergies to:
- _____ History of diabetes
- _____ History of heart disease
- _____ History of renal disease or failure

If NONE of the above conditions apply to you, initial here: _____

If you have any questions, please ask the x-ray technologist or the attending radiologist.

I have read the above information, have had my questions answered, and consent to the arthrogram examination of my _____. I am satisfied that the general purpose, potential benefits, and reasonably foreseeable problems and complications of this procedure have been discussed with me. I agree that in the event of any unforeseen condition arising during the course of the procedure, my physician will do whatever he/she deems medically appropriate.

I have read and understand the contents of this questionnaire and verify that my answers are accurate to the best of my knowledge.

Patient Name: _____ Signature: _____
 Relationship to Patient: _____ Date: _____
 Radiologist Signature: _____ Witness: _____

Radiographer Use Only:

Injectable: _____ Lot#: _____ Exp Date: _____

Addendum A

000151



BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

The purpose of this standard is to reduce, eliminate or minimize employee bloodborne pathogen exposure. Connecticut Orthopaedic Specialists (COS) is committed to providing a safe and healthful work environment. Therefore, Connecticut Orthopaedic Specialists has created this Bloodborne Pathogens Exposure Policy to inform our employees of prevention methods and how to respond to an event in accordance to OSHA standards.

1. Those who are at risk of exposure are employees who work in the following departments:

- Clinic
- Physical/Occupational Therapy
- Radiology
- Ambulatory Surgical Center

2. Per OSHA all employees that work in the above departments have the opportunity to receive hepatitis B vaccinations, and, if necessary, post-exposure evaluation and follow-up. All of these are provided at no cost to the employee.

3. All employees will be notified that this Bloodborne Pathogens Exposure Control Plan is made available to all employees at the time of hire, readily available on the intranet and available via paper at the time of request.

4. Connecticut Orthopaedic Specialists bloodborne pathogens control plan is required to be adhered to while within the confines of COS' operating facilities including but not limited to the divisions within.

This standard was developed primarily to prevent occupational exposure to HBV and HIV. It applies to all work procedures in our practice where employees may be exposed to blood or other potentially infectious materials (OPIM) during the day-to-day execution of their duties.

Connecticut Orthopaedic Specialist's OSHA Compliance Officer and Health and Safety Committee must review and update COS' Bloodborne Pathogens Exposure Control Plan at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure. The review and update of the plan will address:

1. Changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
2. Annual consideration and implementation of appropriate and commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.
3. Input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation and selection of engineering and work practice controls

OCCUPATIONAL EXPOSURE DETERMINATION

Occupational Exposure is defined by OSHA as any reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that could result from the performance of an employee's duties. Incidental exposures, which are neither reasonable nor routinely expected, are excluded. Departmental classifications at COS which are at risk of exposure to blood and/or OPIM are listed on page 1 of this bloodborne pathogen control plan. The classification of departments will determine whether or not an employee is at risk of exposure to bloodborne pathogens and therefore will need special protections while performing their duties.

PROTECTION AGAINST BLOODBORNE DISEASES IN THE HEALTHCARE ENVIRONMENT

Hepatitis B, hepatitis C and HIV are serious diseases. It is important for all employees to understand and follow COS' Bloodborne Pathogens Exposure Control Plan. Following the guidelines in this plan will reduce the likelihood of occupational exposure incidents. All employees at risk of exposure are offered to receive the hepatitis B vaccination, which is available to them at no charge within 10 working days of their hire. COS sees this as an effective means of preventing the disease.

All employees are encouraged to report all concerns regarding safety and health to your Health and Safety Site Representative or your OSHA Compliance Officer. It is important that you periodically re-evaluate your Bloodborne Exposure Control Plan to take into consideration new procedures; new technology and new products that will help prevent bloodborne exposure incidents.

All employees who work in a department at risk of exposure to blood and other potentially infectious materials must be trained on COS' Bloodborne Exposure Control Plan to educate themselves on the steps they must take to prevent transmission of bloodborne diseases. This training includes information on the following bloodborne diseases:

HEPATITIS B VIRUS (HBV) INFECTION

Epidemiology

Many healthcare workers exposed to blood have a high level of serum HBV (hepatitis B virus) markers indicating a previous infection. The level is several times higher than the general public and higher than that of healthcare workers who are not exposed to blood or who do not handle needles.

Symptoms

Hepatitis B symptoms can be divided into three basic groups. One third of the infected individuals have no symptoms. Another third may have mild cases exhibiting flu-like symptoms and are not usually diagnosed as having hepatitis. The remaining third may have severe symptoms such as jaundice, dark urine, nausea, abdominal pains, extreme fatigue and anorexia. There will sometimes be joint pains, fever and a rash. The virus destroys liver cells and individuals infected with hepatitis are at risk of liver cancer, cirrhosis and chronic liver disease.

Modes of Transmission

Hepatitis B is spread by contact with blood and other potentially infectious materials (OPIM). Exposure can result from any contact with blood or OPIM by non-intact skin. For example, chapped hands, cuts and any type of lesion can provide a route of entry for the virus. Direct contact with a contaminated source patient is not the only mode of transmission. Healthcare workers should be aware that transmission could occur through contact with work surfaces and other objects in the workplace that may have become contaminated with blood or OPIM.

Injuries from contaminated needles or other sharp instruments or devices are the primary modes of occupational transmission in the healthcare environment.

Hepatitis B Vaccination

Connecticut Orthopaedic Specialists follows current recommendations for the hepatitis B vaccination based on information available from the Centers for Disease Control and Prevention (the CDC). The vaccinations are given in the deltoid muscle in 3 intramuscular doses over a 6-month period. The vaccine produces protective antibodies in approximately 85-97% of healthy adults. Protection is considered to be lifelong. The antibody level may fall below detectable levels over several years but when these individuals are exposed to the hepatitis B virus (HBV), they develop a rapid antibody response and do not become ill or develop the HBV carrier state. Therefore, the CDC does not recommend booster doses at this time. If booster doses are required by future CDC recommendations, you should make them available to your at-risk employees.

Per current CDC recommendations, the initial 3-dose series must be followed by a test for the antibody to the hepatitis B surface antigen. This test (titer check) is best performed 1 to 2 months after the third dose of the vaccine. This is the *only way* that an individual can be sure that he or she seroconverted. Non-responders must be vaccinated with a second 3-dose series and retested.

Policy for Hepatitis B vaccinations

Connecticut Orthopaedic Specialists employees who are at risk of occupational exposure should be identified by their departmental classification. Hepatitis B vaccinations are offered at the time of initial employment at COS and all "at-risk" employees are actively encouraged to take advantage of the opportunity. The hepatitis B vaccine is offered at no charge to our employees within 10 days of the date of hire. Employees are allowed to conduct patient care procedures during the time it takes to complete the series. COS follows the current CDC guidelines and offers employees antibody tests after the third dose followed by revaccination for all non-responders. These procedures are available at no charge to COS employees.

COS employees who elect not to receive the hepatitis B vaccination series must sign a copy of COS' Declination Form (Informed Refusal of the Hepatitis B Vaccination). If a COS employee changes their mind during their term of employment with COS, the vaccine is available to you at no charge.

HEPATITIS C VIRUS (HCV) INFECTION

Epidemiology

At this time, it is estimated that approximately 4 million American adults are infected with hepatitis C. (This is approximately 1 out of 50.) A majority of the infections resulted from blood transfusions or dialysis treatments prior to 1992 since the blood supply was not routinely screened for this virus. The disease can also be contracted through bloodborne exposure incidents in healthcare environments although it is less likely than hepatitis B to be transmitted this way. In the United States, hepatitis C is the single leading cause for liver transplants.

Symptoms

Hepatitis C is called the "silent killer" because a person can be infected with the disease and either have no symptoms or mild flu-like symptoms, which often go undiagnosed. It is often the case that hepatitis C is not diagnosed until years after transmission occurred.

Modes of Transmission

Hepatitis C is spread by contact with blood and OPIM and occurs when these fluids enter the body of someone who is not infected. It is primarily sexually transmitted but sharing needles when "shooting" drugs can also spread it. Infection can pass from an infected mother to her child during birth. The risk of HCV infection in healthcare settings is low but infection can occur in healthcare workers who have repeated contact with blood and/or multiple needlestick injuries.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Epidemiology

Currently, there are approximately one million reported cases of HIV infections in the United States with about 40,000 new HIV infections every year. Recent medical advances have reduced the number of deaths attributed to AIDS however there is still no cure nor a successful vaccine to prevent HIV infection. While infections were originally limited to male homosexuals, they now occur in heterosexuals as well. Recent statistics show increasing numbers of women who are infected with the virus.

Symptoms

The first symptoms of HIV may show up within a month of exposure and include a flu-like sickness with possible fever, diarrhea, fatigue, rash, lymphadenopathy, and joint pains. After this self-limiting illness, the HIV-infected person may be asymptomatic and in apparently good health for an indeterminate length of time. Then he or she may develop symptoms associated with generalized lymphadenopathy, fever for more than a month, significant weight loss, persistent diarrhea or a combination of any of these symptoms. AIDS is diagnosed by certain indicator diseases. These are pneumonia, esophageal cancers, neurological disorders or dementia and cancers such as Kaposi's sarcoma and non-Hodgkin's lymphoma.

Modes of Transmission

Human Immunodeficiency Virus (HIV) has been found in human blood, semen, vaginal secretion, saliva, tears, breast milk, urine, cerebrospinal fluid, and amniotic fluid. Transmission of the virus is implicated only in blood, semen, vaginal secretions, and possibly breast milk. While HIV has been found in very low concentration in some body fluids like saliva and tears, it is important to understand that finding a small amount in a body fluid does not necessarily mean that HIV can be transmitted by that body fluid. Contact with saliva, tears or sweat has never been shown to result in the transmission of the disease.

Modes of transmission include: sexual intercourse with an infected person, using contaminated needles, having parenteral, mucous membrane or non-intact skin contact with HIV infected blood or blood products, receiving transfusion of infected blood or transplants of infected organs, and transmission of the virus from mother to child around the time of birth. Occupational exposure can also occur in healthcare settings. Workers can be infected after being stuck with needles containing infected blood or, less frequently, after infected blood enters an open cut or mucous membrane. Scientists and medical authorities agree that HIV does not survive well in the environment making the possibility of environmental transmission remote.

UNIVERSAL PRECAUTIONS

Connecticut Orthopaedic Specialists observes and complies with the concept of "Universal Precautions". COS employees are required to treat all patients, all blood, and other potentially infectious materials as if infected with HIV, hepatitis B or C and/or any other diseases caused by bloodborne pathogens. Because it is not possible to identify patients with bloodborne diseases by standard medical procedures (such as medical history, laboratory tests, appearance or physical examination), blood and OPIM of all patients treated in our facilities office must be handled as if infectious. There are no exceptions to this policy. All employees must practice Universal Precautions.

WORK PRACTICE CONTROLS

It is important to perform tasks in a manner that minimizes the risk of exposure to blood or OPIM. When tasks are performed in the safest manner possible, exposure or risks are greatly reduced. COS employees are therefore trained on the use of appropriate work practice controls and are encouraged to ask their Health and Safety Site Representative or OSHA Compliance Officer if there are any questions or concerns. COS' work practices include the following:

- Hands must be washed immediately or as soon as feasible when gloves are removed
- Hands must be washed immediately or as soon as feasible following contact with blood or OPIM
- Contaminated needles and other contaminated sharps will not be bent, recapped or removed unless there is no feasible alternative or unless the action is required by a specific medical procedure
- If needles must be recapped or removed, the action will be accomplished by using a mechanical device or by a one-handed technique

- All contaminated sharps and other regulated waste will be disposed of into appropriate containers located as close as feasible to the area of use
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in areas where there is a reasonable likelihood of contamination
- Sharps containers will not be overfilled
- The practice of Universal Precautions is mandatory
- All tasks involving blood or OPIM must be performed in a manner that minimizes splashing, spraying, spattering and/or generation of droplets of these substances
- Mouth pipetting/suctioning of blood or OPIM is prohibited
- Food and drink will not be kept in refrigerators, shelves, cabinets or countertops where blood or OPIM are likely to be present
- Contaminated instruments, syringes and other sharp devices are not passed hand-to-hand.

SAFER SHARPS EVALUATION

Connecticut Orthopaedic Specialists OSHA Compliance Officer will solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation and selection of engineering and work practice controls. The solicitation and responses will then be documented and added to your OSHA Compliance Plan as needed or on an annual basis.

COS will conduct an initial review of the use of safer sharps in our practice. COS will give each participating employee the Evaluation of Safety Syringes and/or Other Safety Devices form (form # OS-018) to complete. Once all forms have been submitted the responses will then be summarized and results will be transposed to the Safer Sharps Review and Evaluation form (form # OS-017). The results will also be added to COS' Bloodborne Pathogens Exposure Control Plan. This Safer Sharps Evaluation will be conducted at least annually.

ENGINEERING CONTROLS

Engineering controls reduce the risk of exposure to blood or OPIM by eliminating, isolating or removing the hazard from the workplace. It is COS' policy to evaluate engineering controls on a regular basis and at least annually. If items and/or devices are found to be appropriate for your needs and, at the same time, reduce risks to your employees, their use should be implemented. Engineering controls include, but are not limited to:

- Hand washing facilities near or in all work areas (or antiseptic hand cleaner available)
- Eye wash station (within 100 feet or 10 seconds from exposure area) – *included in first aid kit*
- Needleless devices
- Self-sheathing needles, retractable needles or other needles or syringes with "built-in" engineering controls
- Scalpels and/or other blades which are retractable or have a shield that can be activated with the hand behind the blade

- Puncture-resistant sharps disposal containers
- Reusable sharps containers with sides that prevent items from falling out when containers are moved
- Resuscitation bags or other ventilation devices – *included in first aid kit*
- Plastic capillary tubes
- Plastic blood collections tubes
- Blunt suture needles

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) is another way of minimizing exposure to blood and OPIM. It provides a barrier to protect the skin and mucous membranes from exposure. The selection of PPE depends upon the procedure and is performance-based. Routine procedures seldom require more than gloves. Invasive procedures, tasks where spattering and /or splashing are likely, may require gloves, masks, eye-protection and gowns. PPE that is provided in our facilities includes:

- Gloves, latex or latex-free exam gloves
- Gloves, sterile
- Masks
- Eye protection, safety glasses
- Eye protection, face shield
- Eye protection, other (protecting the sides of the eyes)
- Barrier garments, disposable
- Barrier garments (washable lab coats, scrubs, gowns, etc.)

Guidelines for Selecting PPE

- **Gloves** - Wear gloves anytime there is a risk of your hands having direct contact with blood or OPIM. Gloves must be worn when handling -items or touching surfaces that might be contaminated. Replace disposable gloves after each patient or as soon as possible if visibly soiled, torn or punctured. Never re -use disposable gloves.
- **Masks** - Wear a mask when there is a risk of splashing or spattering of blood or OPIM. The mask should fit snugly against the face. Change it when it gets wet and never let it "dangle" around the neck. Handle the mask by the strings and avoid touching the mask itself.
- **Eye Protection** - Safety glasses, a chin-length face shield or glasses equipped with non-perforated side shields are appropriate protection since the sides of the eyes are protected. Use eye - protection any time there is a risk of splashes, sprays or spattering of blood or OPIM.
- **Barrier Garments** - Selection of barrier garments is performance-based. Barrier garments can be either disposable or washable as long as they protect the skin, street clothes or uniform from exposure to blood and OPIM. Barrier garments must be removed and replaced as soon as possible when visibly soiled. Garments used as PPE must not be taken home to be laundered.

LAUNDRY

All soiled laundry or linen must be handled as if potentially contaminated with body fluids. All clean linen must be stored in an area where no soiled linen will come in contact with it. All soiled laundry or linen must be bagged at the site where it is used. It must be placed in bags that can be easily identified. PPE must be used by the person handling and laundering linens and soiled laundry. COS is contracted with a linen/laundrying service for laundering our soiled linen and laundry. The name of the company is Pathacura.

HOUSEKEEPING

The term "housekeeping" is used to include all procedures involving cleaning and decontamination of environmental surfaces and equipment which may be contaminated with blood or OPIM. It is the overall responsibility of the Health and Safety Site Representative and the OSHA Compliance Officer to ensure that COS' facilities are maintained in a clean, sanitary and orderly manner. COS' employees are assigned certain responsibilities and must adhere to the following guidelines:

- Use a disinfectant that is EPA registered (SaniZide) or (A diluted bleach solution of 1 part bleach to 10 parts water is appropriate if it is mixed daily)
- All equipment and working surfaces must be cleaned after each procedure if there has been a reasonable likelihood of contamination while wearing PPE
- All equipment and working surfaces must be cleaned at the end of the day (or work shift) if they have been contaminated since the last cleansing
- Remove and replace all protective coverings, such as plastic, paper, etc. after each patient visit
- Inspect and decontaminate, on a regular basis, all reusable receptacles such as bins, cans, etc. that have a likelihood of becoming contaminated. Clean them immediately, or as soon as feasible when visibly contaminated while wearing PPE
- Ensure that sharps containers are easily accessible and located as close as feasible to the area where they are used
- Check disposable sharps containers regularly to ensure that they are not overfilled
- Check sharps containers to ensure that they are assembled correctly and are upright
- Discard non-sharp medical waste into appropriate containers immediately, or as soon as feasible
- Never manually open, empty or clean disposable sharps containers
- Equipment that may be contaminated with blood or OPIM must be cleaned and decontaminated prior to servicing and/or shipping
- Notify your Health and Safety Site Representative or OSHA Compliance Officer if there is a spill of blood or OPIM
- All work surfaces must be immediately cleaned after any spill of blood or OPIM while wearing PPE
- Obtain a spill kit or appropriate supplies (absorbent materials, utility gloves, cleaning material, including a detergent and a disinfection product and appropriate disposal containers)
- Employees are made aware of the location of these supplies

- Always use mechanical means (tongs, forceps, or brush and dust pan) to pick up any contaminated broken glass. NEVER pick up these items with your hands even if wearing gloves. Discard broken contaminated glass into a sharps container.

COS' internal housekeeping procedures are always be performed prior to the general cleaning done by our contracted housekeeping service, "Cleaning Services Group."

DISINFECTION AND STERILIZATION

Disinfection and sterilization procedures currently recommended by the Centers for Disease Control, the ADA, and the AMA are used for all reusable instruments, devices and other items that are contaminated with blood and/or OPIM. COS uses the following definitions as guidelines for appropriate sterilization and/or disinfection procedures:

- High level disinfection are used on all semi-critical care items that could be damaged by heat sterilization. Use a product labeled "disinfectant/sterilant" and leave the items immersed for the shorter time recommended by the manufacturer. (The longer time is used for "cold sterilization".)
- Intermediate level disinfection is not to be used on semi-critical care items. However is used for disinfection of non-critical care items that are contaminated with blood or OPIM. A bleach solution (1 part bleach to 10 parts water) is strong enough but must be mixed fresh daily. Wipe the item to be cleaned with the bleach solution (or a commercial disinfectant - SaniZide) and allow it to air dry.
- Low level disinfection is not necessary for non-critical care items that have not been contaminated with blood or OPIM. Proper cleaning is usually sufficient. If you choose to use a low-level disinfection, wipe or spray an EPA registered disinfectant on the surfaces of the cleaned items and let them air dry.
- Sterilization is the process that destroys all microorganisms (including viruses) and their spores. Sterilization can be accomplished by the use of steam (steam autoclave), dry heat, chemicals under pressure (chemical autoclave) or an EPA registered product that is labeled "disinfectant/sterilant" (sometimes referred to as "cold sterilization").
- Critical care items are all instruments and/or devices that are introduced directly into the bloodstream. They touch bone or penetrate tissue. All of these items are sterilized.
- Semi-critical care items are instruments that touch mucous membranes but do not touch bone or penetrate tissue. If the items are not damaged by heat, sterilize them or use a high-level disinfection process following the manufacturer's guidelines.
- Non-critical care items are equipment and environmental surfaces that will come into contact with intact skin only. Floors, exam tables, crutches, and countertops are examples of noncritical care items. Use intermediate-level disinfection for non-critical care items. (Cleaning alone is sufficient unless the items are visibly contaminated with blood.)
- Biological monitoring is a "spore test" and is the only way to ensure that heat sterilization is effectively killing all types of microorganisms. Check with the manufacturer of your sterilizer for

the proper spore test. You can mail the exposed test spores to an appropriate microbiology lab for testing or check them yourself in a special incubator designed for that purpose.

COMMUNICATION OF HAZARDS TO EMPLOYEES

Biohazard labels and signs are used to identify biohazardous materials such as biomedical waste, blood, specimens and other potentially infectious materials. These labels are used on all containers with biohazardous items. The labels are fluorescent orange or orange-red with lettering or symbols in a contrasting color. Red bags or red containers are allowed to be substituted for labels.

The Health and Safety Site Representative and OSHA Compliance Officer ensure that all of the following items, equipment, and/or containers are properly labeled as "biohazardous". COS employees should notify their Health and Safety Site Representative or OSHA Compliance Officer if they discover any items, equipment or containers that are not correctly labeled.

- All biohazardous waste containers, including bags and/or disposable sharps containers
- Biohazardous waste storage areas
- Contaminated laundry containers
- Reusable contaminated sharps containers
- Contaminated equipment
- Refrigerators and/or freezers containing blood, specimens or OPIM
- Containers used to store, transport, or ship blood or OPIM (Individual containers of blood or OPIM that are placed into a labeled container are exempt from this requirement. For example, a test tube rack can be labeled rather than each blood collection tube.)
- Signs will be posted at the entrance of designated "work areas" if it contains contaminated materials

EXPOSURE INCIDENTS: POST-EXPOSURE EVALUATIONS AND FOLLOW-UP

An exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or OPIM that result from the performance of an employee's duties. Always consider bloodborne exposure incidents to be matters of urgent medical concern. COS offers immediate medical evaluation and follow-up to all employees who have an exposure incident through our contracted medical providers Physician One Urgent Care and Stony Creek Urgent Care. The medical services rendered will be provided at no charge to the individual and is based on current recommendations from the Centers of Disease Control and Prevention (CDC).

Should an exposure incident occur, COS employees are instructed to immediately report the incident to their Health and Safety Site Representative and/or OSHA Compliance Officer. Details of the incident are important and must be recorded on the Bloodborne Exposure Incident Report form and, if applicable, the Sharps Injury Report and Sharps Injury Log.

Post-exposure evaluation includes:

- A blood sample must be drawn and tested as soon as feasible for HIV, hepatitis B and C if the exposed individual consents. If consent to test is not given, the sample must be kept for 90 days in case the individual elects to have the sample tested during that time frame.
- The individual will be advised that he or she is entitled to medical evaluation in addition to testing
- Counseling will be offered
- He or she will be advised to report any acute illness, which is accompanied by fever, within the next 12 weeks and to seek medical attention for any such occurrence
- If the initial test is seronegative for HIV, re-testing must be offered at 6 weeks, 12 weeks and 6 months after the incident based on recommendations of the consulting physician and current CDC guidelines.

STEPS TO TAKE IN CASE OF AN EXPOSURE INCIDENT

(If another designated healthcare provider is used)

If the COS employee involved in an exposure incident requests medical evaluation, they will be sent designated contracted healthcare provider (Physician One Urgent Care and Stony Creek Urgent Care) for testing, evaluation and other appropriate action immediately. COS will cover the medical expenses to provide post-exposure medical evaluation and follow-up based on current CDC recommendations. COS will provide the healthcare professional with the following per OSHA regulations:

1. A copy of the bloodborne pathogen standard
2. A description of the employees's duties as they relate to this exposure incident. (This information is on the Bloodborne Exposure Incident Report (form #OS-005) and the Sharps Injury Report (form # OS-014).
3. The route of entry and circumstances surrounding the incident (This information is also on the Exposure/Sharps Incident Report or Employee Incident Report)
4. Information COS may have in the COS employee's medical record as it relates to HBV vaccination, other exposure incidents, etc. (This disclosure is allowed by HIPAA Privacy as it applies to Public Health and is required by law.)
5. Results of the patient's blood testing, if known.

If a source patient is involved in the reported incident, a member of COS' health and safety committee, OSHA compliance officer or administrative personnel will explain the situation to him or her and, if possible, obtain consent to test his or her blood. Complete a copy of the Consent to Draw and Test Blood form (form # OS-006).

COS will have the employee complete a Bloodborne Exposure Incident Report and a Sharps Injury Report. The healthcare provider to whom the employee will see will be furnished with this information. OSHA requires COS that the employee complete all of the information on the Bloodborne Exposure Incident Report. The completed information will be used by management to evaluate how the exposure occurred and what can be done to prevent a recurrence of the type of occupational injury.

If the employee declines medical evaluation and follow-up, the employee will need to sign a copy of the Informed Refusal of Medical Evaluation form (form # OS-012). Once the form is signed it will be placed with the employee's confidential medical records and no further action is required. COS encourages employees that have been exposed under-go the testing perimeters and they will be explain the risks to assist the employee in making the right decision.

The healthcare provider must send a written opinion to you stating that the employee was notified of the results and the need, if any, for follow-up. This opinion will inform COS if the hepatitis B vaccine was required and if it was given. Other information resulting from the evaluation is confidential and is released only to the employee.

The exposed employee will be given a copy of this written opinion within 15 days and COS will keep another copy with the employee's confidential medical records that the Human Resources Department maintains.

If it is a Sharps Injury, the injury will be recorded on the Sharps Injury Log (form # OS-015). Please note this is not confidential information since no names are recorded on the log. It will help identify patterns to sharps injuries so problems can be corrected. For example, change to a different device or provide additional training if COS identifies injuries caused by the same syringe or medical device.

RECORDKEEPING

OSHA has specific recordkeeping requirements. Since records are used to document compliance with the bloodborne pathogen standard, it is important that COS keeps and maintains accurate records. The following records that COS is required to maintain are as follows:

Training Records

An important part of COS Exposure Control Plan is employee training. It is required at the time of hire and prior to assignment to any "at risk" tasks. OSHA also requires annual "re-training". OSHA requires that COS keeps all training records for 3 years. The training records consist of the following:

1. The dates of the training sessions.
2. The contents or a summary of the training sessions.
3. The names and qualifications of the persons conducting the training.
4. The names and job titles of all persons attending the training sessions.

All training records are made available to employees for examination and copying and to OSHA.

Medical Records (form # OS-009)

Employee exposure and medical records will be established for each employee and will include the following:

1. Name, address and Social Security number
2. Copies and information on his/her hepatitis B vaccination records
3. Any records which may pertain to his/her inability to receive the HBV vaccination
4. Documentation of all exposure incidents including date, location, name of source patient, type of incident (needlestick, etc.)
5. Copies of all physical examinations, testing and follow-up results as they relate to his/her ability to receive vaccination or to any post-exposure evaluation
6. Information provided to another healthcare professional regarding the employee's exposure and possible need for hepatitis B vaccination
7. Healthcare professional's written opinion as to whether hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination (form #OS-025)

These records will be kept confidential and in a secure location. They will not to be disclosed to anyone within COS or to anyone outside of the confines of COS except as required by law. The records are available to the employee about whom the records pertain, or the employee's designated representative, and to OSHA. Medical records will be kept for 30 years plus the term of employment.

Informed Refusal for Hepatitis B Vaccination (form # OS-Oh)

If an employee refuses vaccination for hepatitis B for any reason, he or she must sign the Informed Refusal, or Declination (form # OS-Oil) form. The wording OSHA requires is very specific. This form, when signed, becomes part of an employee's medical record and, as such, must be kept confidential. 'As part of an employee's medical record it must be kept for 30 years plus the term of employment. If records of an employee's vaccination history are not available, he or she should sign the Declination form and check the appropriate statement at the bottom of the form. This acknowledges that the individual has been previously vaccinated but does not have written proof.

Informed Refusal of Post-Exposure Evaluation (form # OS-012)

If an employee has a bloodborne exposure incident and refuses post-exposure evaluation and follow-up for any reason, he or she must sign the Informed Refusal of Post-Exposure Medical Evaluation form. This form becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Bloodborne Pathogen Exposure Incident Report (form # OS-005)

All bloodborne pathogen exposure incidents will be reported and documented. The report becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Sharps Injury Report (form # OS-014)

This form will be used to report all sharps-related bloodborne pathogen exposure incidents. As with the Bloodborne Pathogen Exposure Incident Report above, this report becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Sharps Injury Log (form # OS-015)

OSHA's recordkeeping regulations require COS to keep a log of sharps injuries. The purpose of the log is to identify certain patterns, or re-occurrences, of sharps injuries. The name of the exposed individual is not included on the form so a Sharps Injury Log does not fall under confidentiality requirements. The Sharps Injury Log must contain:

1. The type and brand of device involved in the incident.
2. The department or work area where the exposure incident occurred.
3. An explanation of how the injury occurred.

EMERGENCY PROCEDURES/CONTINGENCY PLANS

Blood Spills

If there is a spill of blood or OPIM, immediately notify your Health and Safety Site Representative and/or OSHA Compliance Officer. Use a spill kit and/or appropriate materials to contain, clean and disinfect spills. It is mandatory that appropriate PPE be worn for clean-up procedures. If employees are not sure of the appropriate action, they should consult their Health and Safety Site Representative and/or OSHA Compliance Officer prior to cleaning the spill.

Life-Threatening Emergencies

Sometimes an emergency situation occurs and there may not be time to don appropriate PPE. If possible, use practices consistent with Universal Precautions. When the situation is stabilized, immediately use necessary equipment. In such an emergency, the decision not to use PPE rests solely with the employee. He or she should be informed that they are expected to exercise professional judgment in this action and should be aware that he or she will be asked to explain the reasoning.

WORK AREAS AND NON-WORK AREAS

The purpose for designating Work Areas and Non-Work Areas is to avoid cross contamination. All work and non-work areas are adequately lighted and all floor surfaces are dry and/or skid resistant.

Use the following guidelines and remove contaminated PPE before entering any area classified as a Non-Work Area:

Work Areas Guidelines

Appropriate PPE must be worn in these areas if exposure to blood or OPIM can be reasonably anticipated. The **guidelines** for Work Areas are as follows:

It is reasonable to expect exposure to blood and/or other potentially infectious materials in certain areas. Therefore, eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses are prohibited in areas where contamination is likely. Food and drink are never permitted in work areas and must not be left on countertops in any area where there is a reasonable likelihood of contamination. Work areas usually include all patient treatment areas, labs, sterilization areas and hallways connecting these areas. Work areas will be maintained in a clean and orderly manner.

Non-Work Areas Guidelines

There are no procedures performed in these areas that could result in contamination with blood or OPIM. PPE must be removed prior to entering these areas. The **guidelines** for Non-Work Areas are as follows:

These areas usually include staff lounges, kitchens, administrative and/or clerical areas, front office, reception or waiting room, and other business-related offices or areas.

TRAINING REQUIREMENTS (See forms #OS-010 and #OS-013)

Training will be provided at the time of initial assignment to tasks where occupational exposure to blood and OPIM may occur. Training will also be conducted at least annually thereafter. Training will be provided during work hours and at no cost to our employees. In the event employees are given new tasks, or existing tasks are modified, additional and appropriate training will be conducted. The training will be documented and the records will be kept for 3 years.

Training will include the following elements:

- An accessible copy of the Bloodborne Pathogen Standard
- An explanation of the epidemiology and symptoms of bloodborne diseases
- Modes of transmission of bloodborne pathogens
- An explanation of your bloodborne exposure control plan, where it is located, and how a copy can be obtained
- How to recognize tasks which may result in exposure to blood and OPIM
- An explanation of COS' engineering controls, work practice controls and PPE
- The type of PPE available and where it is located
- How to select appropriate PPE and your minimum requirements for various tasks and procedures
- How to properly dispose of PPE which is soiled and/or contaminated

- Information on the hepatitis B vaccination including benefits, efficacy, etc. and that it is offered free of charge
- Who to contact in case of an emergency involving exposure to blood or OPIM
- What to do in case of an exposure incident
- Information on post exposure evaluation and follow-up treatment, which is available at no charge to COS employees
- An explanation of the color code and biohazard symbol
- How to handle biomedical waste generated in a COS office



REGULATED WASTE MANAGEMENT

This standard refers to Regulated Waste, Medical Waste, Biomedical Waste and Biohazardous Waste. These terms are meant to be interchangeable for the purposes of this Standard.

BIOMEDICAL WASTE PLAN

Policy

Connecticut Orthopaedic Specialists (COS) has created and implemented a Biomedical Waste Plan that addresses the handling, storage and disposal of Biohazardous Waste.

Procedure

COS trains our employees on the handling, storage and disposal of Biohazardous Waste.

Our **Biomedical Waste Plan** consists of the following elements:

Handling Medical Waste

Policy

All of our employees are required to follow our basic rules for handling medical waste.

Procedure

COS trains all of our employees to adhere to the **following basic rules** when handling medical waste:

- We identify and segregate Biomedical (or Biohazardous) Waste from other waste at its **point of origin** (or as close as feasible to the area where it is generated).
- All non-sharp Biohazardous Waste is disposed of directly into red bags identified with biohazard symbols.
- All items classified as sharps are placed immediately into puncture-resistant, leak-proof sharps containers.
- Sharps containers are set up in such a way that the biohazard symbols are clearly visible and the lids are securely fastened in place. They are never to exceed the fill line (approximately 1" from the top). It is clearly understood that under no circumstances are disposable sharps containers to be emptied and reused.
- All employees who handle Biohazardous Waste wear appropriate PPE. All PPE that comes in contact with Biohazardous materials is disposed of into red Biohazardous Waste bags.



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- When filled, all sharps containers and red bags are sealed promptly and properly in the area of use. Containers and/or bags of biomedical waste are securely closed prior to moving.
- All biomedical waste prepared for off-site transport is enclosed in a rigid type container and is then labeled for transport.
- Our employees report any concerns about biomedical waste to our Health and Safety Site Representative who then informs the OSHA Compliance Officer.
- All of our employees observe the Biohazard Symbol at all times

Labeling Biomedical Waste for Transport

Policy

Biomedical Waste is labeled prior to transport off-site.

Procedure

We ensure the labeling of all Biomedical Waste to be transported off-site. The label is securely attached to the outer layer of packaging and it is clearly legible. The following information is included on the label:

- Our name and address
- The date the first biomedical waste was placed into the container and the date the container was closed and sealed
- The International Biohazardous Symbol
- The phrase “Biohazardous Waste”, “Infectious Waste”, “Biomedical Waste”, or equivalent wording

Storage of Biohazardous Waste

Policy

All on-site storage of Biohazardous Waste is carefully handled.

Procedure

All on—site storage of Biohazardous Waste is in an area away from general traffic flow patterns and accessible only to authorized personnel. Storage of Biohazardous Waste is not greater than 2 days. This time period commences when the first item of non-sharp, biohazardous waste is placed in the container or bag. Sharps containers that contain only sharps can be kept until full.

All areas primarily used for the storage of Biohazardous Waste are constructed of smooth, easily cleanable materials that are leak-proof and capable of being maintained in a sanitary condition. All storage areas are kept clean and orderly. Outdoor areas and containers are secured from vandalism. All outdoor storage areas are conspicuously marked with the International Biohazard Symbol.

All Biohazardous Waste is treated either by heat, incineration or other equivalent methods suitable for hazard inactivation. Our contracted off-site waste hauler, when used, is registered

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with the Department of Environmental Regulations.

Co-Mixing Waste

Policy

It is never permissible to dispose of any material identified as biohazardous into regular trash receptacles.

Procedure

We always comply with the following rules for co—mixing waste:

- All Biohazardous Waste, which is mixed with Hazardous Waste, is managed as Hazardous Waste.
- All Biohazardous Waste, which is mixed with Radioactive Waste, is managed as Radioactive Waste.
- All solid waste, other than Hazardous or Radioactive Waste, which is mixed with Biohazardous Waste, is managed as Biohazardous Waste.

Handling Spills

Policy

Surfaces contaminated with spilled and/or leaked Biohazardous Waste are promptly cleaned under the supervision of our Health and Safety Site Representative.

Procedure

Appropriate PPE is worn by all employees handling spills of Biohazardous Waste or what is suspected to be Biohazardous Waste. Surfaces contaminated with spilled and/or leaked Biohazardous Waste are cleaned of all liquids using absorbent materials (paper towels, kitty litter or a commercial product for spills). After the liquids have been absorbed, the surface is cleaned with a solution of industrial strength detergent to remove any remaining liquids and/or soil. After cleaning, the surface and/or area is thoroughly disinfected. All materials used to clean the spill are disposed of into red Biohazardous Waste bags. When the task is complete, all PPE worn while cleaning and disinfecting the spill area is disposed of into red Biohazardous Waste bags. To disinfect the surface and/or area, we use one of the following products:

- A bleach solution containing 1 part bleach to 10 parts water mixed fresh daily
- A chemical germicide that is registered by the EPA as hospital grade disinfectant.

If broken glass, hard plastic, syringes, blades, needles and other contaminated items capable of lacerating the skin are present, we do NOT pick up the items with our hands. We use a whiskbroom and dustpan, forceps or other devices. We place all contaminated sharps into an appropriate sharps container which is brought to the area.



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The

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OrthopedicHealth



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SHORELINE

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Training

Policy

All of our employees receive training on Biohazardous Waste as it applies to their tasks.

Procedure

All of our medical employees receive this training on Biohazardous Waste within 10 days of hire and to any employee prior to assignment to any task that requires the handling of biomedical waste and OPIM.

Our training includes:

- The definition of Biohazardous Waste that is generated by our practice
- Point-of-origin disposal and segregation of Biohazardous Waste
- How to properly assemble and use sharps containers
- How to properly move biomedical waste from disposal area to storage area
- The use and disposal of PPE while handling any biomedical waste
- On-site biomedical waste storage requirements including where and how the waste is stored
- Our plan for cleaning spills and the location of appropriate PPE and cleaning supplies
- Training is conducted at least annually and is required of all employees who handle biomedical waste

EXHIBIT H



American College of Radiology

Magnetic Resonance Imaging Services of

Connecticut Orthopaedic Specialists, PC

2416 Whitney Ave
Hamden, Connecticut 06518

were surveyed by the
Committee on MRI Accreditation of the
Commission on Quality and Safety

The following magnet was approved

General Electric SIGNA 1.5T 2001

For

Spine, MSK

Accredited from:

May 01, 2014 through September 27, 2017

CHAIRMAN, COMMITTEE ON MRI ACCREDITATION

PRESIDENT, AMERICAN COLLEGE OF RADIOLOGY



American College of Radiology

Magnetic Resonance Imaging Services of

Connecticut Orthopaedic Specialists, PC

84 North Main Street
Branford, Connecticut 06405

were surveyed by the
Committee on MRI Accreditation of the
Commission on Quality and Safety

The following magnet was approved

General Electric 1.5 GE SIGNA LX 2006

For

Spine, MSK

Accredited from:

May 08, 2014 through February 02, 2018

Anthony J. Scuderi, M.D.

Paul H. Ellertogen, M.D.

CHAIRMAN, COMMITTEE ON MRI ACCREDITATION

PRESIDENT, AMERICAN COLLEGE OF RADIOLOGY

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MRAP#0

EXHIBIT I

000175



Charity Care Policy

COS Imaging Services

PURPOSE:

To provide a policy and procedure for the determination and handling of Connecticut Orthopaedic Specialists, P.C. (COS) Charity Care for patients who require imaging services. This policy and procedure is offered by COS as a means by which patients who require imaging services but can otherwise not afford this service. Any COS patient that either has no health insurance or whose household income is less than 250% of the Federal Income Poverty Guideline will be considered for reduced rate consideration.

PROCEDURE:

Patients may be required to complete a financial assistance application and / or provide the following requested documents. COS may also at its own discretion chose to offer the discounted rate without verification of documentation.

- Copies of items to support income
 - Pay stubs, bank statements, tax returns or other proof of income
- Copies of monthly expenses
 - Mortgage statement, rent check, utilities
- Number of dependants in household

COS will endeavor to work out a payment plan that will allow all patients regardless of their financial situation to be able to afford necessary imaging services. If necessary, and at it's discretion, COS may elect to provide the service at no cost to the patient.

EXHIBIT J

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Exhibit J (1)

2015 Total COS MRI Scans by Patient Towns



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

2015 MRI Scans by Town*

Zip Code	City	# of Scans
06401	Ansonia, CT	58
06001	Avon, CT	2
06403	Beacon Falls, C	15
06037	Berlin, CT	9
06524	Bethany, CT	76
06801	Bethel, CT	2
06751	Bethlehem, CT	1
06405	Branford, CT	625
06604	Bridgeport, CT	32
06010	Bristol, CT	9
06013	Burlington, CT	2
06409	Centerbrook, C	2
06410	Cheshire, CT	295
06412	Chester, CT	8
06413	Clinton, CT	121
06414	Cobalt, CT	1
06415	Colchester, CT	2
06238	Coventry, CT	1
06416	Cromwell, CT	5
06810	Danbury, CT	6
06417	Deep River, CT	12
06418	Derby, CT	35
06422	Durham, CT	39
06023	East Berlin, CT	2
06423	East Haddam,	2
06424	East Hampton,	1

Zip Code	City	# of Scans
06762	Middlebury, CT	2
06455	Middlefield, CT	8
06457	Middletown, C	36
06460	Milford, CT	503
06467	Milldale, CT	1
06468	Monroe, CT	22
06469	Moodus, CT	3
06354	Moosup, CT	1
06355	Mystic, CT	3
06770	Naugatuck, CT	23
06053	New Britain, C	6
06840	New Canaan, C	1
06812	New Fairfield, I	1
06503	New Haven, C	626
06320	New London, C	2
06776	New Milford, C	1
06111	Newington, CT	7
06470	Newtown, CT	2
06357	Niantic, CT	11
06471	North Branfor	152
06473	North Haven, C	416
06778	Northfield, CT	1
06472	Northford, CT	130
06850	Norwalk, CT	6
06360	Norwich, CT	1
06370	Oakdale, CT	1

Zip Code	City	# of Scans
06288	Storrs, CT	1
06614	Straford, CT	56
06786	Terryville, CT	4
06084	Tolland, CT	1
06790	Torrington, CT	2
06611	Trumbull, CT	44
06382	Uncasville, CT	1
06066	Vernon, CT	1
06492	Wallingford, C	436
06704	Waterbury, CT	24
06385	Waterford, CT	8
06795	Watertown, CT	3
06107	West Hartford,	6
06516	West Haven, C	517
06093	West Suffield,	2
06498	Westbrook, CT	33
06883	Weston, CT	2
06880	Westport, CT	5
06109	Wethersfield, C	4
06279	Willington, CT	1
06095	Windsor, CT	1
06096	Windsor Locks	1
06716	Wolcott, CT	18
06525	Woodbridge, C	158
06798	Woodbury, CT	1
06492	Yalesville, CT	6

06118	East Hartford,	2	06870	Old Greenwich	1
06512	East Haven, C	450	06371	Old Lyme, CT	28
06333	East Lyme, CT	5	06475	Old Saybrook,	39
06612	Easton, CT	3	06477	Orange, CT	232
06029	Ellington, CT	1	06478	Oxford, CT	44
06426	Essex, CT	12	06379	Pawcatuck, CT	1
06824	Fairfield, CT	15	06062	Plainville, CT	7
06033	Glastonbury, C	5	06479	Plantsville, CT	11
06351	Griswold, CT	1	06480	Portland, CT	4
06340	Groton, CT	2	06712	Prospect, CT	27
06437	Guilford, CT	398	06375	Quaker Hill, CT	3
06438	Haddam, CT	3	06896	Redding, CT	2
06511	Hamden, CT	798	06877	Ridgefield, CT	1
06247	Hampton, CT	1	06420	Salem, CT	3
06105	Hartford, CT	2	06482	Sandy Hook, C	3
06791	Harwinton, CT	1	06483	Seymour, CT	69
06441	Higganum, CT	6	06484	Shelton, CT	56
06442	Ivoryton, CT	8	06073	South Glaston	1
06419	Killingworth, C	57	06074	South Windsor,	2
06339	Ledyard, CT	1	06488	Southbury, CT	10
06443	Madison, CT	299	06489	Southington, C	35
06040	Manchester, CT	4	06890	Southport, CT	2
06444	Marion, CT	2	06076	Stafford Spring	1
06447	Marlborough, (2	06902	Stamford, CT	2
06450	Meriden, CT	148	06378	Stonington, CT	2

*Does not include scans of non-Connecticut residents

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Orange MRI Town	Scan
North Have	416
East Haven	450
New Haven	626
Derby	35
Milford	503
Orange	232
Shelton	56
Stratford	56
Woodbridgr	158
W. Haven	517
	3049

Essex MRI Town	Scan
Essex	12
Madison	299
Guilford	398
Clinton	121
Old Saybro	39
Westbrook	33
Old Lyme	28
Deep River	12
Chester	8
	950

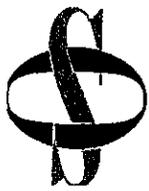
000181

Exhibit J (2)

COS Branford

2015 COS Branford MRI Scans by Patient Towns

000182



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

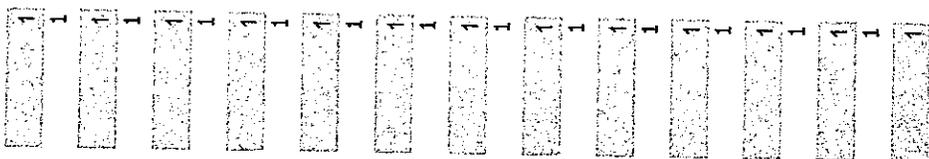
2015 Branford MRI Zip Code Analysis by Volume

Zip code	City	State	Units
06405	Branford	CT	565
06437	Gulford	CT	369
06512	East Haven	CT	335
06516	West Haven	CT	279
06443	Madison	CT	276
06460	Millford	CT	263
06471	North Branford	CT	134
06473	North Haven	CT	125
06413	Clinton	CT	114
06492	Wallingford	CT	108
06513	New Haven	CT	100
06472	Northford	CT	87
06477	Orange	CT	82
06410	Cheshire	CT	56
06512	New Haven	CT	56
06513	East Haven	CT	55
06514	Hamden	CT	55
06511	New Haven	CT	51
06419	Killingworth	CT	50
06525	Woodbridge	CT	46
06518	Hamden	CT	45
06475	Old Saybrook	CT	36
06515	New Haven	CT	31
06517	Hamden	CT	29
06498	Westbrook	CT	28
06422	Durham	CT	25
06450	Meriden	CT	25

Zip Code	City	State	Units
06053	New Britain	CT	4
06111	Newington	CT	4
06037	Berlin	CT	3
29909	Bluffton	SC	3
06606	Bridgeport	CT	3
06825	Fairfield	CT	3
06040	Manchester	CT	3
06469	Moodus	CT	3
06355	Mystic	CT	3
06712	Prospect	CT	3
06375	Quaker Hill	CT	3
06420	Salem	CT	3
06880	Westport	CT	3
06403	Beacon Falls	CT	2
06801	Bethel	CT	2
02813	Charlestown	RI	2
06415	Colchester	CT	2
06811	Danbury	CT	2
06423	East Haddam	CT	2
06612	Easton	CT	2
06438	Haddam	CT	2
06455	Middlefield	CT	2
06320	New London	CT	2
06850	Norwalk	CT	2
06855	Norwalk	CT	2
06074	South Windsor	CT	2
06488	Southbury	CT	2

Zip Code	City	State
28277	Charlotte	NC
28211	Charlotte	NC
01507	Charlton	MA
7928	Chatham	NJ
05038	Chelsea	VT
46304	Chesterton	IN
06414	Cobalt	CT
33071	Coral Springs	FL
92118	Coronado	CA
6416	Cromwell	CT
75204	Dallas	TX
30032	Decatur	GA
01062	Florence	MA
53732	Franklin	WI
11530	Garden City	NY
6033	Glastonbury	CT
53220	Greenfield	WI
6351	Griswold	CT
06340	Groton	CT
6511	Hamden	CT
06247	Hampton	CT
27944	Hertford	NC
12533	Hopewell Junction	NY
77063	Houston	TX
04449	Hudson	ME
32225	Jacksonville	FL
02835	Jamestown	RI

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000184

06371	Old Lyme	CT	25
06401	Ansonia	CT	19
06519	New Haven	CT	19
06484	Shelton	CT	17
06611	Trumbull	CT	16
06614	Stratford	CT	14
06483	Seymour	CT	15
06417	Deep River	CT	12
06457	Middletown	CT	12
06510	New Haven	CT	11
06426	Essex	CT	10
06357	Niantic	CT	10
06524	Bethany	CT	8
06385	Waterford	CT	8
06412	Chester	CT	7
06442	Ivoryton	CT	7
06468	Monroe	CT	7
06418	Derby	CT	6
06441	Higganum	CT	6
06478	Oxford	CT	6
06489	Southington	CT	6
06770	Naugatuck	CT	5
06010	Bristol	CT	4
06333	East Lyme	CT	4
06824	Fairfield	CT	4

06890	Southport	CT	2
06902	Stamford	CT	2
06378	Stonington	CT	2
34997	Stuart	FL	2
78332	Alice	TX	1
27502	Apex	NC	1
02474	Arlington	MA	1
06001	Avon	CT	1
06751	Bethlehem	CT	1
04614	Blue Hill	ME	1
33486	Boca Raton	FL	1
02116	Boston	MA	1
06604	Bridgeport	CT	1
06605	Bridgeport	CT	1
06608	Bridgeport	CT	1
02135	Brighton	MA	1
62634	Broadwell	IL	1
11205	Brooklyn	NY	1
11222	Brooklyn	NY	1
34604	Brooksville	FL	1
06013	Burlington	CT	1
20866	Burtonsville	MD	1
28428	Carolina Beach	NC	1
06409	Centerbrook	CT	1
20151	Chantilly	VA	1

30022	Johns Creek	GA	
33477	Jupiter	FL	
90046	Los Angeles	CA	
06354	MOOSUP	CT	
3254	Moultonboro	NH	
10552	Mount Vernon	NY	
29576	Murrells Inlet	SC	
34112	Naples	FL	
2746	New Bedford	MA	
53151	New Berlin	WI	
13413	New Hartford	NY	
06532	New Haven	CT	
10014	New York	NY	
10021	New York	NY	
10028	New York	NY	
10028	New York	NY	
6470	Newtown	CT	
02852	North Kingstov	RI	
34287	North Port	FL	
06360	Norwich	CT	
6370	Oakdale	CT	
06870	Old Greenwich	CT	
32174	Ormond Beach	FL	
06379	Pawcatuck	CT	
96782	Pearl City	HI	

Zip Code City State Units
08861 Perth Amboy NJ 1

06062	Plainville	CT	1
08742	Point Pleasant	NJ	1
34952	Port St Lucie	FL	1
85142	Queen Creek	AZ	1
06482	Sandy Hook	CT	1
33777	Seminole	FL	1
25181	Seth	WV	1
11787	Smithtown	NY	1
12580	Staatsburg	NY	1
10980	Stony Point	NY	1
12582	Stormville	NY	1
85374	Surprise	AZ	1
33603	Tampa	FL	1
06786	Terryville	CT	1
32163	The Villages	FL	1
06382	Uncasville	CT	1
34285	Venice	FL	1
06066	Vernon	CT	1
22180	Vienna	VA	1
02081	Walpole	MA	2
06705	Waterbury	CT	1
06706	Waterbury	CT	1
06708	Waterbury	CT	1
33414	Wellington	FL	1
06095	Windsor	CT	1
06492	Yalesville	CT	1

Exhibit J (3)

COS Hamden

2015 COS Hamden MRI Scans by Patient Towns

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Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

2015 Hamden MRI Zip Code Analysis by Volume

Zip Code	City	State	Units
06492	Wallingford	CT	328
06473	North Haven	CT	291
06514	Hamden	CT	271
06518	Hamden	CT	246
06460	Milford	CT	240
06410	Cheshire	CT	239
06516	West Haven	CT	238
06517	Hamden	CT	151
06477	Orange	CT	150
06450	Meriden	CT	123
06511	New Haven	CT	119
06515	New Haven	CT	112
06525	Woodbridge	CT	112
06513	New Haven	CT	79
06524	Bethany	CT	68
06405	Branford	CT	60
06483	Seymour	CT	54
06512	East Haven	CT	47
06472	Northford	CT	43
06614	Stratford	CT	42
06401	Ansonia	CT	39
06484	Shelton	CT	39
06478	Oxford	CT	38
06418	Derby	CT	29
06437	Gulford	CT	29
06489	Southington	CT	29
06611	Trumbull	CT	28
06498	Westbrook	CT	5
06492	Yalesville	CT	5
06605	Bridgeport	CT	4
06416	Cromwell	CT	4
06810	Danbury	CT	4
06824	Fairfield	CT	4
06825	Fairfield	CT	4
06033	Glastonbury	CT	4
06480	Portland	CT	4
06109	Wethersfield	CT	4
06608	Bridgeport	CT	3
06111	Newington	CT	3
06371	Old Lyme	CT	3
06475	Old Saybrook	CT	3
01262	Stockbridge	MA	3
06704	Waterbury	CT	3
06795	Watertown	CT	3
06107	West Hartford	CT	3
75002	Allen	TX	2
06604	Bridgeport	CT	2
06607	Bridgeport	CT	2
06023	East Berlin	CT	2
06118-2370	East Hartford	CT	2
06426	Essex	CT	2
06340	Groton	CT	2
07039	Livingston	NJ	2
06444	Marion	CT	2
11249-3259	Brooklyn	NY	1
80020-9515	Broomfield	CO	1
30518	Buford	GA	1
1803	Burlington	MA	1
06013	Burlington	CT	1
81623	Carbondale	CO	1
12033	Castleton	NY	1
6409	Centerbrook	CT	1
06412	Chester	CT	1
6238	Coventry	CT	1
46307	Crown Point	IN	1
52807	Davenport	IA	1
21035	Davidsonville	MD	1
2026	Dedham	MA	1
03038	Derry	NH	1
48239	Detroit	MI	1
84020	Draper	UT	1
6424	East Hampton	CT	1
01028	East Longmead	MA	1
6333	East Lyme	CT	1
06612	Easton	CT	1
92020	El Cajon	CA	1
06029	Ellington	CT	1
11735	Farmingdale	NY	1
33312	Fort Lauderdale	FL	1
33907	Fort Myers	FL	1
11530	Garden City	NY	1

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06519	New Haven	CT	26
06457	Middletown	CT	24
06712	Prospect	CT	24
06443	Madison	CT	23
06770	Naugatuck	CT	18
06471	North Branford	CT	18
06716	Wolcott	CT	18
06468	Monroe	CT	15
06422	Durham	CT	14
06403	Beacon Falls	CT	13
06512	New Haven	CT	12
06513	East Haven	CT	13
06479	Plainville	CT	11
06606	Bridgeport	CT	10
06488	Southbury	CT	8
06708	Waterbury	CT	8
06413	Clinton	CT	7
06419	Killingworth	CT	7
06706	Waterbury	CT	7
06037	Berlin	CT	6
06455	Middlefield	CT	6
06510	New Haven	CT	6
06062	Plainville	CT	6
06610	Bridgeport	CT	5
06010	Bristol	CT	5

Zip Code	City	State	Units
06812	New Fairfield	CT	1

06447	Marlborough	CT	2
06762	Middlebury	CT	2
06053	New Britain	CT	2
01950-3050	Newburyport	MA	2
06357	Niantic	CT	2
07446	Ramsey	NJ	2
06896	Redding	CT	2
06482	Sandy Hook	CT	2
06786	Terryville	CT	2
06790	Torrington	CT	2
06710	Waterbury	CT	2
06110	West Hartford	CT	2
06093	West Suffield	CT	2
06883	Weston	CT	2
06880	Westport	CT	2
12208-3331	Albany	NY	1
11701	Amityville	NY	1
06001	Avon	CT	1
11933-1616	Baiting Hollow	NY	1
07920	Basking Ridge	NJ	1
08502	Belle Mead	NJ	1
07922	Berley Heights	NJ	1
48301	Bloomfield Hill	MI	1
28777	Bremen	NC	1
10708	Bronxville	NY	1

Zip Code	City	State	Units
06096	Windsor Locks	CT	1

10923	Garnerville	NY	1
91205-2036	Glendale	CA	1
27858-1607	Greenville	NC	1
12834	Greenwich	NY	1
966	Guaynabo	PR	1
06438	Haddam	CT	1
6105	Hartford	CT	1
06112	Hartford	CT	1
6791	Hartwinton	CT	1
06442	Ivoryton	CT	1
2130	Jamaica Plains	MA	1
33458	Jupiter	FL	1
11754	Kings Park	NY	1
12401	Kingston	NY	1
03766-4417	Lebanon	NH	1
06339	Ledyard	CT	1
6040	Manchester	CT	1
01756	Mendon	MA	1
6467	Milldale	CT	1
44654	Millersburg	OH	1
12549	Montgomery	NY	1
08057	Moorestown	NJ	1
60540	Naperville	IL	1
11767	Nesconset	NY	1
6840	NEW CANAAN	CT	1

06798	Woodbury	CT	1
07481	Wyckoff	NJ	1

06503	New Haven	CT	1
06505	New Haven	CT	1
06525	New Haven	CT	1
06776	New Milford	CT	1
77358	New Waverly	TX	1
10018	New York	NY	1
19702-8506	Newark	DE	1
06470	Newtown	CT	1
07006	North Caldwell	NJ	1
34287-2156	North Port	FL	1
06778	Northfield	CT	1
06850	Norwalk	CT	1
06851	Norwalk	CT	1
07436	Oakland	NJ	1
66062	Olathe	KS	1
07050	Orange	NJ	1
32174	Ormond Beach	FL	1
07652	Paramus	NJ	1
85016-4604	Phoenix	AZ	1
11803	Plainview	NY	1
33981	Port Charlotte	FL	1
34952-6620	Port St Lucie	FL	1
03801	Portsmouth	NH	1
12603	Poughkeepsie	NY	1
27606	Raleigh	NC	1
06877	Ridgefield	CT	1
07456	Ringwood	NJ	1
33579-2316	Riverview	FL	1
08880	S Bound Brook	NJ	1
55116	Saint Paul	MN	1
12159	Slingerlands	NY	1
11787	Smithtown	NY	1
06073	South Glastonct	CT	1
06076	Stafford Springs	CT	1
10312	Staten Island	NY	1
10980	Stony Point	NY	1

06268	Storrs	CT	1
53589	Stoughton	WI	1
11791	Syosset	NY	1
07666	Teaneck	NJ	1
10594	Thornwood	NY	1
06084	Tolland	CT	1
34293	Verice	FL	1
02889	Warwick	RI	1
06705	Waterbury	CT	1
02481	Wellesley	MA	1
11704	West Babylon	NY	1
06107-2053	West Hartford	CT	1
07675	Westwood	NJ	1
06279	Willington	CT	1

000192

			New Haven
			119
			112
			26
			12
Orange PSA scanned			6
at Hamden			79
Orange	150		3
New Haven	357	←	Essex PSA
W Haven	238		at Hamden
Milford	240		Essex
Woodbridge	112		Madison
Shelton	39		Clinton
Derby	29		Old Saybro
N Haven	291		Westbrook
E Haven	60		Old Lyme
Stratford	42		Deep River
	<u>1558</u>		Chester
			Guilford
			<u>29</u>
			73

EXHIBIT K

000194



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

2015 Shoreline (Essex) MRI Referrals by Town

ZIP Code	Town	MRI Referrals
06334	Bozarth, CT	1
06405	Branford, CT	3
06234	Brooklyn, CT	1
33904	Cape Coral, FL	1
06410	Cheshire, CT	1
06412	Chester, CT	40
06412	Clinton, CT	6
06415	Colchester, CT	4
06413	Cromwell, CT	100
06416	Deep River, CT	1
06422	Durham, CT	7
06419	East Haddam, CT	33
06423	East Haddam, CT	28
06420	East Hampton, CT	1
06424	East Hampton, CT	7
06333	East Lyme, CT	4
06357	East Lyme, CT	17
06029	Ellington, CT	1
06082	Enfield, CT	1
06409	Essex, CT	11
06426	Essex, CT	63
06442	Essex, CT	46
06032	Farmington, CT	1
06085	Farmington, CT	1
34994	Fort Myers, FL	1
06033	Glastonbury, CT	1
01034	Granville, MA	1
06340	Groton, CT	5
06437	Guilford, CT	13
06438	Haddam, CT	10
06441	Haddam, CT	12
06439	Haylyme, CT	6
06417	Killingworth, CT	69
06443	Madison, CT	64
06447	Marlborough, CT	1
06450	Meriden, CT	2
06455	Middlefield, CT	1
06457	Middletown, CT	11
06461	Milford, CT	1
06370	Montville, CT	2
06382	Montville, CT	1

ZIP Code	Town	MRI Referrals
06469	Moodus, CT	20
06355	Mystic, CT	1
06448	N/A	1
06513	New Haven, CT	1
06320	New London, CT	5
10016	New York, NY	1
10025	New York, NY	2
06471	North Branford, CT	1
06472	Northford, CT	2
06371	Old Lyme, CT	104
06376	Old Lyme, CT	3
06475	Old Saybrook, CT	141
33410	Palm Beach Gardens, FL	1
06480	Portland, CT	2
06375	Quaker Hill, CT	2
11377	Queens, NY	1
06067	Rock Hill, CT	1
06417	Salem, CT	1
06467	Southington, CT	1
06479	Southington, CT	1
06378	Stonington, CT	1
06066	Vernon, CT	1
27587	Wake Forest, NC	1
06492	Wallingford, CT	1
06706	Waterbury, CT	1
06385	Waterford, CT	9
06498	Westbrook, CT	77

000195

2NS

ITS MEDICINE

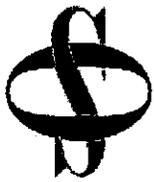
Essex	120	120
Madison	64	64
		6
Guilford	13	141
Clinton	6	77
Old Saybrook	141	107
Westbrook	77	1
Old Lyme	107	40
Deep River	1	556
Chester	40	
	569	

11
63
46
120

000196

EXHIBIT L

000197



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS



The Orthopaedic Group Orthopaedic Health



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

Ratio of the Number of MRI Scans to the Number of New Orthopaedic Patients Seen at COS

Location	# of New Patients	Estimated # of New Patients who Received MRI (15.6%)	# of Internal COS Scans	Estimated # of MRI External Referrals
Shelton 889 Bridgeport Ave	947	147	118	29
Orange 330 Boston Post Road	3675	573	567	6
Orange 464 Boston Post Road	376	58	20	38
Milford 30 Commerce Park	859	134	66	68
Milford 258 South Broad Street	1413	220	165	55
Milford 849 Boston Post Road	2285	356	105	251
Totals	9555	1488	1041	447

Ratio Exercise

Total number of new patients in 2015 across all locations/divisions = 29,303

Total number of new patients who received an MRI scan via a COS machine in 2015 = 4,589

Ratio 1:6.38 – 1 out of every 6.38 (15.6%) new patients seen in 2015 received an MRI scan via a COS machine

000198

EXHIBIT M

000199



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Purchase Agreement

Contract # 061516-01

June 15, 2016

Page 1 of 3

Buyer:

Connecticut Orthopedic Specialist
 2408 Whitney Avenue
 Hamden, CT 06518

Attention: Glen Elia

Seller:

Med Exchange International, Inc.
 127 Ramah Circle
 Agawam, MA 01001

Attention: Steve Neffinger

Terms: A 50% deposit (\$287,500) is due upon acceptance of this agreement. An additional 30% payment (\$172,500) is due prior to installation. The final 20% payment (\$115,000) is due once the system is completely operational at the buyer's site.

Quantity	Products and Services	Price
	2000 Mobile GE 1.5T Excite (11x) 8 Channel MRI System AK Trailer 2007 ACGD Gradients Software Level: 11X Software Options: Echo planar, fast gradient echo, cine, fast gradient echo & flair, time of flight, phase contrast vascular imaging, SGD Echo Speed, DW EPI, Flair EPI, Special, Smart Prep, SSFSE, Three Plan Localizer, Modality Work list, e3dtof, FSX_XL, Blood supp, Fast Cine, iDrive pro, iDrive, Smart prep 2000 upgrade, probe 2000 upgrade, Func tool 2, Vox tool, interactive vascular imaging, Clairview, iDrive pro plus, ultra-short tr, ssfse mrcp, t1 breathhold, ACGD plus, Fluoro-triggered MRA, mrcp3, dynamic r1, fiesta 2d, fiesta 3d, asset, 3dfrfse, asset plus, tricks, fiesta-c, breast2, propeller dwi, 3d fat sat fiesta, propeller t2 Coil package: 3" round (2) GP Flex (2) 8 Channel Body 8 Channel CTL 8 Channel Neuro-Vascular 8 Channel Head Quad Head Quad Extremity	\$575,000.00



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Full 30 day all parts and labor warranty on system. Includes shipping of system to your location.

Buyer's Initials: _____ **Date:** _____

Seller's Initials: _____ **Date:** _____



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Page 3 of 3
Contract #061516-01
June 15, 2016

Sale will be on the following terms and conditions:

1. **Inspection.** The Equipment will have been inspected prior to the sale by the buyer to verify that the Equipment meets all OEM specifications for image quality and condition. The Equipment shall be deemed to be satisfactory upon certification by the inspector. Buyer shall be deemed to have accepted any nonconforming Equipment unless Buyer notifies Seller in writing within 24 hours of site inspection and discovery of any such nonconformity.
2. **Warranty.** Included in the price is the cost of a 30-day full coverage maintenance agreement with GE or a third party. The customer can choose the service provider that they wish to use. Med Exchange reserves the right to negotiate the cost of the contract.
3. **Taxes.** Prices do not include applicable sales, excise, use, value added or other taxes, duties or fees now in effect or hereafter levied which Seller may be required to pay or collect in connection with the sale of goods to the Buyer, whether or not expressly set forth herein or in any quotation furnished with respect to the Equipment. Buyer shall promptly pay all such taxes, duties and fees to Seller upon demand. Duties and fees include, but are not limited to, applicable customs duties and custom broker charges.
4. **Offer.** This offer is expressly limited to the terms hereof. The terms of this offer may not be modified or altered unless such modification is in writing, signed by Seller. Any additional or different terms purposed by Buyer are hereby rejected and will be of no effect upon Seller unless expressly agreed to in writing by authorized representative of Seller.
5. **Acceptance of Terms.** Buyer shall be deemed to have accepted the terms of this offer by signing below or by ordering the Equipment from Seller.
6. **Security Interest.** Buyer grants Seller a security in interest in the Equipment to secure payment in full of the purchase price. Seller may perfect its security interest by filing a financing statement signed only by Seller as attorney in fact for Buyer.
7. **Title and Risk of Loss.** Unless otherwise specified, the Equipment shall be delivered to Buyer F.O.B. shipping point. Title to goods shall pass to the Buyer upon delivery at the F.O.B. shipping point. Unless otherwise stated on the invoice, all shipping costs shall be the Buyer's responsibility.
8. **Governing Law.** The laws of the State of Massachusetts shall govern the enforcement and interpretation of this Agreement and all other issues concerning the sale contemplated herein. Buyer consents to the jurisdiction of Massachusetts courts and further agrees that the exclusive venue for any matter relating to payment for the Equipment shall be in the courts of Hampden County, Massachusetts.
9. **Default.** If Buyer fails to make timely payment of all amounts due Seller, Seller may recover, in addition to the balance due of the purchase price, all of its incidental and consequential damages caused by Buyer's breach, including all fees paid to collection agencies, attorney's fees, and costs of collection.
10. **Entire Contract.** This Agreement constitutes the entire contract between Buyer and Seller concerning the Equipment.

Buyer:

Seller:

By: _____

By: _____

Glen Elia
Connecticut Orthopedic Services

Steve Neffinger
Med Exchange International, Inc.

Date: _____

Date: _____



Kingsbrook
DEVELOPMENT CORP.

July 21, 2016

Mr. Glenn Elia, CEO
CONNECTICUT ORTHOPAEDIC SPECIALISTS, PC
2408 Whitney Avenue
Hamden, CT 06518

RE: MRI Trailer Installations - Essex & Orange Offices

Dear Glenn,

Per your request we completed an initial review for the installation of an MRI trailer at both of the above offices relative to building, parking and site layout for Project budget purposes. At this time, we have not met with Town/City officials to establish site specific requirements at each location as they will differ and this in itself is an actual project. Based on the aforementioned and our past experience of installations we established a Project budget which can be utilized for each site and as you can see Project cost will be directly attributed to required scopes at each location. Should these potential Projects move to the next Phase then it is our recommendation that a "Design Development" scope be initiated. Project Budget as follows:

Project Scope Establishment & Mobilization
Survey & Site Plan Approval
Site Work & Associated Pad/Paving Work
Landscaping & Associated Screening
Canopy & Walkway Enclosures
Building Power Upgrade & Associated Distribution Work.
Electrical Work & Interior Construction.

Project Budget \$135,000.00 - \$155,000

Thank you for the opportunity to review these Projects and should you have any questions please do not hesitate to contact me.

Respectfully submitted,
KINGSBROOK DEVELOPMENT CORP.

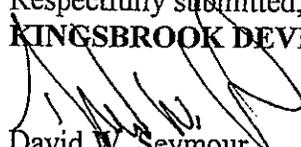

David W. Seymour
President

EXHIBIT N

000204



August 15, 2016

Connecticut Orthopaedic Specialists, PC
2408 Whitney Avenue
Hamden, CT 06518
Attention: Glenn Elia, CEO

Ladies and Gentlemen:

First Niagara Bank, N.A. is pleased to advise you that your application for a loan has been approved, subject to the following principal terms and conditions:

The terms of the credit facilities that Lender offers to commit to make available (individually a "Loan" or "Facility", collectively the "Loans" or the "Facilities") are as follows:

- I. LENDER: First Niagara Bank, N.A., a national banking association having an address of 726 Exchange Street, Buffalo, NY 14210, Attention: Commercial Loan Administration.
- II. BORROWER: Connecticut Orthopaedic Specialists, PC.
- III. GUARANTORS: The same as for the company's existing line of credit.
- IV. FACILITY/TERM LOAN:
 1. Amount: \$730,000.00.
 2. Term/Amortization: Sixty Months.
 3. Interest Rate: A fixed rate equal to the FHLB NY Rate, plus 2.00% per annum.
 4. Collateral: a first lien on all of Borrower's Assets and a purchase money lien on the MRI being financed.
 5. Use of Proceeds: Purchase of an MRI and leasehold improvements to accommodate it.
- V. LOAN TERMS APPLICABLE TO ALL FACILITIES:
 1. COLLATERAL PERFECTION: Liens on non-real estate collateral will be perfected by filing a UCC financing statement or as otherwise appropriate.
 2. CROSS-DEFAULT/CROSS COLLATERALIZE: All facilities will be cross-defaulted with all other debt of Borrower and cross-collateralized with all other existing and future indebtedness from Lender to Borrower
 3. REPORTING REQUIREMENTS: Borrower shall submit or require to be submitted Financial Statements and all other reporting requirements as required under their existing line of credit agreement.

All financial reports furnished to Lender will be prepared in accordance with GAAP, consistently applied, be in form and content satisfactory to Lender, certified to be true and correct by the party offering such statement, and include a representation that Lender may rely on such statements.

000205

Borrower and any Guarantor(s) will be required to comply with the above financial reporting requirements throughout the term or terms of the Facility. The documents evidencing and securing the Facility will provide that failure to comply with such requirements shall constitute an event of default under the Loan Documents.

CONDITION PRECEDENT: On or prior to the closing date, Borrower shall provide to Lender such items as shall be required by Lender.

CONDITIONS/COVENANTS: Usual and customary for loans of this size and duration

INSURANCE: Borrower shall at all times keep all of Borrower's assets that are pledged as collateral for the Facility(ies) insured against such hazards and in such amounts satisfactory to Lender, naming Lender as Lender Loss Payee and/or Mortgagee and as Additional Insured at Lender's address as follows: First Niagara Bank, N.A. ISAOA, P.O. Box 514, Lockport, NY 14095-0514, Attention: Enterprise Insurance Tracking. Borrower shall as a condition to closing and at least annually thereafter submit to Lender, on or prior to the anniversary of the Loans, certificates of such insurance issued to Lender and its successors and/or assigns, together with evidence of payment of premiums for such insurance.

PAYMENT ALLOCATION: Unless otherwise specified in the Loan Documents, Lender reserves the right to apply payments at its discretion.

LOAN DOCUMENTS: This letter includes only a brief description of the principal terms of the Facility. The definitive terms of the Facility will be documented in the Loan Documents. Borrower shall execute and deliver to Lender credit and loan documentation evidencing and securing the Facility(ies) in form and substance satisfactory to Lender and its counsel (collectively, the "Loan Documents") containing such representations, warranties, conditions, covenants, defaults and remedies as are customary in transactions of similar type to the Facility. Other conditions precedent to closing the Loans will include, but are not limited to, lien searches with results acceptable to Lender, and completion of Lender's due diligence which is satisfactory to Lender.

NO SURVIVAL: It is understood that the terms and conditions of this letter shall not survive the execution and delivery of the Loan Documents except that all indemnities and reimbursement obligations shall survive any such termination.

EXPENSES AND INDEMNIFICATION: By its acceptance of this letter, Borrower agrees to pay or cause to be paid at or before the closing all charges and fees in connection with the Facility(ies), including and not by way of limitation, the fees and disbursements of Lender's counsel (including outside and internal counsel). Borrower shall pay any and all costs associated with Lender (1) performing or ordering any searches or updates of Borrower, credit history or the collateral, or (2) Lender preparing, terminating, discharging or assigning any of its Loan Documents. If the closing does not take place for any reason, except for Lender's willful refusal to make the Loan, Borrower will be obligated to pay upon demand all of Lender's out-of-pocket fees and expenses in connection with the transactions contemplated by this letter, including, without limitation, fees and expenses of Lender's counsel. Borrower hereby indemnifies and holds Lender and its employees, agents, directors and affiliates harmless from and against any and all losses, claims, damages, expenses and liabilities incurred that arise out of or relate to this letter or the transaction contemplated hereby, including, without limitation, reasonable fees and expenses of Lender's counsel. Lender shall not be responsible or liable to Borrower or any other person for any damages, consequential or otherwise, which may be incurred or alleged as a result of this letter or the transaction, and Borrower's obligations shall survive any termination of this letter except for the execution of definitive Loan Documents.

WAIVER OR MODIFICATION: The provisions of this letter cannot be waived or modified unless such waiver or modification is in writing and signed by Lender.

RIGHT TO REFUSE TO CLOSE: Lender reserves the right to refuse to make the Facility available (which is not willful refusal) if (1) there is any material adverse change in the financial condition or assets of Borrower or any Guarantor; (2) any of the transactions contemplated by this letter would violate any governmental rule, regulation or statute in force at the time of the closing; (3) any of the information submitted by Borrower or any Guarantor to Lender is false, incomplete or inaccurate in any material respect; or (4) the conditions of this letter are not satisfied prior to its expiration.

000206

CONFIDENTIALITY OF COMMITMENT: This letter and the terms hereof are confidential, and neither the contents of this letter nor the details hereof may be shown or disclosed by Borrower without the prior express written consent of Lender.

ENTIRE AGREEMENT: This letter constitutes the entire agreement and understanding between Lender and Borrower with respect to the Facilities and supersedes all prior negotiations, understandings and agreements between such parties with respect to the terms hereof, including, without limitations, those expressed in any prior proposal, term sheet or commitment letter delivered by Lender to Borrower.

APPLICABLE LAW: This letter, and the transactions contemplated hereby or arising hereunder, shall be construed under and governed by the laws of the State of Connecticut, without regard to principles of conflicts of laws. The Loan documentation will contain (1) consents to jurisdiction, (2) waiver of right to jury trial, and (3) prejudgment remedy waiver. This letter shall be interpreted and the rights and liabilities of the parties shall be governed by the laws of the State of Connecticut, without regard to principles of the conflict of laws. This letter has been delivered to and accepted by Lender and will be deemed to be made in the State of Connecticut.

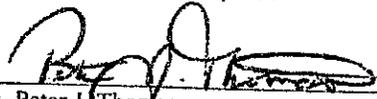
If this offer is acceptable, please indicate your acceptance by signing and returning the enclosed copy of this letter. We look forward to working with you on successfully completing this transaction. We will begin documenting the credit after we have received your signed copy of this letter.

[SIGNATURE PAGE FOLLOWS.]

000207

Very truly yours,

FIRST NIAGARA BANK, N.A.

By: 
Name: Peter J. Thomas
Its: First Vice President

Enclosure

Accepted and agreed to this 16 day of August, 2016
with the intent to be legally bound hereby.

Connecticut Orthopaedic Specialists, PC
(Borrower)

By: 
Name: CLEMELIA
Its: CEO

000208

EXHIBIT O

000209

To the Board of Directors
Connecticut Orthopaedic Specialists, PC
Hamden, CT

Management is responsible for the accompanying financial statements of Connecticut Orthopaedic Specialists, PC, which comprise the balance sheets as of December 31, 2015 and 2014, and the related income statements, for the years ended December 31, 2015 and 2014, and for determining that the income tax basis of accounting is an acceptable financial reporting framework. We have performed a compilation engagement in accordance with Statements on Standards for Accounting and Review Services promulgated by the Accounting and Review Services Committee of the AICPA. We did not audit or review the financial statements nor were we required to perform any procedures to verify the accuracy or completeness of the information provided by management. Accordingly, we do not express an opinion, a conclusion, nor provide any form of assurance on these financial statements.

The financial statements are prepared in accordance with the income tax basis of accounting, which is a basis of accounting other than accounting principles generally accepted in the United States of America.

Management has elected to omit substantially all of the disclosures and the statement of cash flows ordinarily included in financial statements prepared in accordance with the income tax basis of accounting. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Company's assets, liabilities, stockholders' equity, revenues, and expenses. Accordingly, the financial statements are not designed for those who are not informed about such matters.

Woodbridge, Connecticut

Teplitzky & Co. PC

August 1, 2016

Connecticut Orthopaedic Specialists, PC
Balance Sheets
December 31, 2015 and 2014

	2015	2014
<u>ASSETS</u>		
Current Assets		
Cash	\$ 1,490,210	\$ 1,499,747
Due from COS Outpatient Surgical Center, LLC	552,003	298,945
Due from TPT, LLC	59,775	59,775
Due from Center for Orthopedics	965,941	-
Fixed Asset Construction in Progress	-	345,291
Total Current Assets	3,067,929	2,203,758
Accounts Receivable		
Patient Accounts Receivable	31,208,585	18,110,020
Allowance for uncollectible accounts	(4,802,859)	(1,247,537)
Net Accounts Receivable	26,405,726	16,862,483
Fixed Assets		
Furniture, Fixtures & Equipment	3,728,272	3,449,344
Leasehold Improvements	2,744,370	2,720,931
Software & Licenses	1,116,634	242,758
Other Intangibles	13,977	13,977
Total Fixed Assets	7,603,253	6,427,010
Accumulated Depreciation	(3,926,041)	(3,548,041)
Net Fixed Assets	3,677,212	2,878,969
Other Assets		
Investment in COS Outpatient Surgical Center, LLC	546,723	414,557
Note Receivable - S. Tomak	146,447	146,447
Life Insurance - Cash Surrender Value, net	-	298,421
Security Deposit	10,619	10,619
Total Other Assets	703,789	870,044
Total Assets	\$ 33,854,656	\$ 22,815,254

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Income Statements
For the Years Ended December 31, 2015 and 2014

	<u>2015</u>	<u>%</u>	<u>2014</u>	<u>%</u>	<u>Change</u>
Revenue					
Gross Charges	\$ 218,511,430	100.00	\$ 144,566,534	100.00	\$ 73,944,896
Billing Adjustments	(143,911,628)	(65.86)	(93,546,858)	(64.71)	(50,364,770)
Net Revenue	<u>74,599,802</u>	<u>34.14</u>	<u>51,019,676</u>	<u>35.29</u>	<u>23,580,126</u>
Cost of Revenues					
Medical Supplies	3,322,935	1.52	2,626,385	1.82	696,550
X-Ray Supplies	46,335	0.02	20,817	0.01	25,518
Physical Therapy Supplies	134,505	0.06	129,740	0.09	4,765
Anesthesia Services	1,469,600	0.67	1,481,455	1.02	(11,855)
Total Cost of Revenues	<u>4,973,375</u>	<u>2.28</u>	<u>4,258,397</u>	<u>2.95</u>	<u>714,978</u>
Gross Profit	<u>69,626,427</u>	<u>31.86</u>	<u>46,761,279</u>	<u>32.35</u>	<u>22,865,148</u>
Operating Expenses					
Salaries - Officers	19,704,054	9.02	17,592,498	12.17	2,111,556
Salaries	23,921,787	10.95	17,933,550	12.41	5,988,237
Administrative Management Fees	324,169	0.15	778,889	0.54	(454,720)
Repairs & Maintenance	156,704	0.07	128,823	0.09	27,881
Rents	2,822,250	1.29	1,804,023	1.25	1,018,227
Payroll Taxes	2,441,955	1.12	1,727,023	1.19	714,932
Property Tax	119,786	0.05	83,827	0.06	35,959
Miscellaneous Taxes	1,268	0.00	5,708	0.00	(4,440)
Interest	130,506	0.06	137,156	0.09	(6,650)
Depreciation	378,000	0.17	680,594	0.47	(302,594)
Advertising	551,558	0.25	500,879	0.35	50,679
Pension	2,566,823	1.17	1,735,175	1.20	831,648
Meals & Entertainment	129,212	0.06	87,167	0.06	42,045
Answering Service	53,283	0.02	38,143	0.03	15,140
Auto Reimbursement	587,792	0.27	553,801	0.38	33,991
Less: Auto Add-Back	-	-	(96,600)	(0.07)	96,600
Bank Charges	228,973	0.10	119,361	0.08	109,612
Cleaning	290,341	0.13	154,488	0.11	135,853
Computer Expenses	1,251,750	0.57	593,791	0.41	657,959
Dues	151,435	0.07	118,755	0.08	32,680
Equipment Lease	534,911	0.24	271,536	0.19	263,375
Health Insurance	1,782,934	0.82	1,656,384	1.15	126,550
Insurance	667,093	0.31	219,493	0.15	447,600
Licenses	48,954	0.02	47,709	0.03	1,245
Malpractice Insurance	703,731	0.32	796,113	0.55	(92,382)
Meetings	42,571	0.02	83,849	0.06	(41,278)
Office Supplies	221,460	0.10	142,878	0.10	78,582
Outside Services	1,973,065	0.90	821,414	0.57	1,151,651
Parking	19,211	0.01	10,810	0.01	8,401
Patient Gifts	80,081	0.04	54,621	0.04	25,460
Payroll Processing	61,723	0.03	41,252	0.03	20,471
Postage	89,916	0.04	76,895	0.05	13,021
Professional Development	259,673	0.12	223,246	0.15	36,427

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Balance Sheets
December 31, 2015 and 2014

	2015	2014
<u>LIABILITIES & STOCKHOLDERS' EQUITY</u>		
Current Liabilities		
Accounts Payable	\$ 1,946,798	\$ 1,776,810
Accrued Profit Sharing	2,566,823	1,735,176
Accrued Payroll and Tax Related Expenses	5,954	832
Due to the Orthopaedic Group	-	778,889
Due to Lieponis	-	19,000
Total Current Liabilities	4,519,575	4,310,707
Notes Payable		
Line of Credit - Center for Orthopaedics	798,403	-
Notes Payable - First Niagara	3,000,295	2,691,832
MRI Loan	27,495	106,763
Notes Payable - Physicians	735,353	214,063
Total Notes Payable	4,561,546	3,012,658
Total Liabilities	9,081,121	7,323,365
Stockholders' Equity		
Common Stock	3,080	3,080
Paid in Capital	415,777	400,777
Retained Earnings	24,354,678	15,088,032
Total Stockholders' Equity	24,773,535	15,491,889
Total Liabilities & Stockholders' Equity	\$ 33,854,656	\$ 22,815,254

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Income Statements
For the Years Ended December 31, 2015 and 2014

	<u>2015</u>	<u>%</u>	<u>2014</u>	<u>%</u>	<u>Change</u>
Operating Expenses (continued)					
Professional Fees	\$ 319,957	0.15	\$ 327,956	0.23	\$ (7,999)
Refuse	6,423	0.00	5,935	0.00	488
Service Agreement	203,231	0.09	163,231	0.11	40,000
Stationary & Printing	56,485	0.03	36,642	0.03	19,843
Subscriptions	49,058	0.02	16,639	0.01	32,419
Telephone	178,374	0.08	136,626	0.09	41,748
Transcription	433,732	0.20	389,802	0.27	43,930
Uniforms	14,951	0.01	16,142	0.01	(1,191)
Utilities	404,808	0.19	267,488	0.19	137,320
Total Operating Expenses	<u>63,963,988</u>	<u>29.27</u>	<u>50,483,712</u>	<u>34.92</u>	<u>13,480,276</u>
Other Income					
Interest Income	378	0.00	6,114	0.00	(5,736)
Income from COS Surgical Center, LLC	3,595,191	1.65	418,056	0.29	3,177,135
Gain on sale of assets	8,638	0.00	3,939,647	2.73	(3,931,009)
Total Other Income	<u>3,604,207</u>	<u>1.65</u>	<u>4,363,817</u>	<u>3.02</u>	<u>(759,610)</u>
Net Income	<u>\$ 9,266,646</u>	<u>4.24</u>	<u>\$ 641,384</u>	<u>0.44</u>	<u>\$ 8,625,262</u>

See independent accountant's compilation report.

EXHIBIT P

000214

EXHIBIT Q

000216

Assumptions for Financial Worksheet

Revenue assumptions

Without the new mobile scanner, assume number of scans would remain constant from 2016 levels since both existing scanners are at nearly full capacity.

Utilized payer mix assumptions for number of scans and 2015 per scan reimbursements by payer.

Salaries & Wages

Includes MRI technicians, support staff and authorizations staff as well as supervisor for business unit. Assume addition of 1 staff member during 2016 to support extended hours and authorizations for additional scans. Assume 3% annual cost of living increases for existing staff. With addition of new unit to be utilized in Essex and Orange, 2.0 FTE's would be added to support additional locations.

Fringe benefits

Includes payroll taxes, health and dental coverage for staff members, disability and life insurance and retirement plan contributions.

Physician fees

Includes radiologist expense based on annual number of scans.

Depreciation and amortization

Includes depreciation expense for existing units. Assumes addition of 5 year depreciation on capital expenditure of \$730,000 for purchase of new unit and installation costs.

Interest expense

Includes interest on existing two units. Projected incremental assumes 4% interest rate on \$730,000 loan for purchase of additional unit and installation.

Malpractice Expense

Includes malpractice expense for two radiologists supporting MRI units.

Other Operating Expenses

000217

Includes rent, utilities, property taxes and other real estate operating costs for existing equipment and locations.

Includes equipment maintenance expenses as well as repairs and maintenance for locations.

Includes IT support expenses, and office supplies expense as well as billing and collections staff and corporate administrative support including accounting, human resources and management team supervision.

Without the proposal, and not taking into account any increase for inflation, it is assumed that 2017 levels of the items listed above will remain constant with the exception of billing and collections expense, which will increase based on volume of scans. Projected incremental increases also includes moving expense for mobile unit, two moves per week.

Greer, Leslie

From: Fernandes, David
Sent: Wednesday, September 21, 2016 3:28 PM
To: gelia@ct-ortho.com
Cc: Greer, Leslie; Riggott, Kaila
Subject: 16-32117-CON Completeness Letter
Attachments: 16-32117-Completeness Letter 2.docx

Good afternoon Mr. Elia,

Please see the attached completeness letter in the matter of the proposed acquisition of a mobile 1.5 Tesla MRI by Connecticut Orthopedic Specialists. In responding to the completeness letter questions, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by November 20, 2016.

Email to OHCA@ct.gov and cc: David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letter, please contact David Fernandes (860) 418-7032 or Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

September 21, 2016

VIA EMAIL ONLY

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialists, P.C.
2408 Whitney Avenue
Hamden, CT 06518

RE: Certificate of Need Application; Docket Number: 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Completeness Letter

Dear Mr. Elia:

On August 22, 2016, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application filing on behalf of Connecticut Orthopedic Specialist, P.C. ("COS"). This proposal requests authorization to acquire a mobile 1.5 Tesla MRI unit with an associated capital expenditure of \$760,000.

OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). *Please electronically confirm receipt of this email as soon as you receive it.* Provide responses to the questions below in both a Word document and PDF format at the earliest convenience as an attachment to a responding email. **Please email your responses to all of the following email addresses: OHCA@ct.gov, David.Fernandes@ct.gov, and Kaila.Riggott@ct.gov.**

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **November 20, 2016**, otherwise your application will be automatically considered withdrawn.



Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer

Paginate and date your response (i.e., each page in its entirety). Repeat each OHCA question before providing your response. Information filed after the initial CON application submission (e.g., completeness response letter, prefiled testimony, late file submissions, etc.) must be numbered sequentially from the Applicant’s preceding document. Begin your submission using **Page 218** and reference “**Docket Number: 16-32117-CON.**”

1. Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Fiscal Year:	Essex Service Area	
Provider Name and Address	Number of Patients Referred	Distance from Essex
Total		

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?
3. Who will staff the mobile MRI? Will the staff be the same for both locations?
4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.
5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.
6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?
7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).
8. Why was there a drop in MRI volume at the Branford facility in FY2013?
9. Why was FY2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?
10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI.
11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark).

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7032, or Kaila Riggott at (860) 418-7037.

Greer, Leslie

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, November 08, 2016 2:17 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila; 'klg1@aol.com'
Subject: OCHA Docket No. 16-32117- CON Completeness Responses
Attachments: COS Completeness Answers 11.3.16.docx; Exhibit R.pdf; Combined Docs 11.3.16.pdf

Dear Ms. Riggott and Mr. Fernandez:

Attached please find the word version of the COS Responses to OHCA's Completeness Questions which were dated September 21, 2016 and a copy of Exhibit R. A copy of the completeness responses in pdf format is also attached, which consists of the responses, a revised Index, a cover sheet for Exhibit R, and the pdf version of the Exhibit R.

Please note that I have copied, Attorney Pat Gerner in on this email. I would appreciate it if Attorney Gerner could be included in all future communication between COS & OCHA regarding this application.

Please let me know if you need anything further. Thank you.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Docket Number 16-32117-CON
Completeness Questions Responses

- Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Essex Service Area

Fiscal Year: 2015

Provider Name and Address	Number of Patients Referred	Distance from Essex
Middlesex Hospital dba Shoreline Medical Center ED 250 Flat Rock Place Westbrook, CT 06498	639	4.5 miles
Middlesex Hospital Outpatient Center 534 Saybrook Road Middletown, CT 06457	78	19 miles
Middlesex Hospital 28 Crescent Street Middletown, CT 06457	49	22 miles
Open MRI of Middletown 140 Main Street #7 Middletown, CT 06457	48	22 miles
Guilford Radiology 1591 Boston Post Road 106 Guilford, CT 06437	29	18 miles
Groton MRI 565 Long Hill Road Groton, CT 06340	11	23 miles
Middlesex Hospital dba Marlborough Medical Center 12 Jones Hollow Road Marlborough, CT 06447	5	26 miles
Yale MRI 801 Howard Avenue New Haven, CT 06510	6	30.7 miles
Lawrence and Memorial 196 Waterford Parkway S # 102 Waterford, CT 06385	3	17 miles
Radiology Associates of Wallingford 67 Masonic Avenue #7 Wallingford, CT 06492	3	41 miles

Provider Name and Address	Number of Patients Referred	Distance from Essex
Jefferson Radiology 1260 Silas Dean Highway Wethersfield, CT 06109	5	31 miles
Radiology Associates of Middletown 57 S Main Middletown, CT 06457	4	23 miles
Open MRI of Branford 1208 Main Street Branford, CT 06405	3	24 miles
Open MRI of Glastonbury 123 Hebron Avenue Glastonbury, CT 06033	3	36 miles
Radiology Associates of Hartford 31 Sycamore Street #102 Glastonbury, CT 06033	2	27.5 miles
Whitney Imaging 2200 Whitney Avenue #120 Hamden, CT 06518	1	38 miles
Backus Hospital 326 Washington Street Norwich, CT 06360	1	30 miles
Day Kimball Hospital 320 Pomfret Street Putnam, CT 06260	1	63 miles
Naugatuck Valley Radiology 1389 West Main Street Waterbury, CT 06708	1	46 miles
Hartford Hospital 85 Seymour Street #200 Hartford, CT 06106	1	38 miles
Madison Radiology 2 Samson Park Drive Madison, CT 06443	1	13 miles
MRI of New Britain 100 Grand Street New Britain, CT 06052	1	34 miles
St. Francis MRI 114 Woodland Street Hartford, CT 06106	1	39 miles
Manhattan Diagnostic Radiology 400 E 66 Street New York, NY 10066	1	104 miles

The above table provides information for all patients (951) who were referred by Shoreline Orthopedic and Sports Medicine to a non-COS MRI scanner in 2015. Please note that this information could not be extracted electronically from the medical records, and was compiled manually from each patient record. As a result, there is a 12 person difference between the total number of patients reported here and what was reported in Exhibit L of the CON application (963).

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?

Accessibility is more than just having an open time slot in another MRI provider schedule. COS improves our patient accessibility by working directly with each patient to accommodate to their personal schedule. COS has early morning hours at 7 am so patients can be seen before work and they are open until 9 pm for after work hours. Likewise, if a patient cannot be seen during the week, COS will open on a weekend to accommodate the patient. If a patient presents with an acute injury and there is an emergent need for MRI, COS holds daily stat slots to accommodate these patients, again providing improved accessibility over traditional radiology centers. If the patient is in pain or in a position where the injury is made worse by moving around, traveling to another office creates a situation where having the MRI scan at a different location is not as accessible as walking (or being wheeled) down a hallway within the COS office to have the MRI performed. The time delay is also a factor, as orthopedic treatment should be administered as early as possible after the injury.

Currently almost all of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS, and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to non-COS providers for MRI scans. This is due to lack of capacity of the existing scanners in Hamden and Branford, and the geographic distance of these COS scanners from the Shoreline Orthopedic offices. Accessibility will be improved because the COS patients who use the proposed 1.5T mobile MRI will be able to have the MRI scan performed in the doctor's office without having to schedule and travel to another location and without waiting longer for the results.

3. Who will staff the mobile MRI? Will the staff be the same at both locations?

One FTE receptionist and 1 FTE MRI tech will be required for services provided in the mobile MRI unit. It is anticipated that both the receptionist and MRI tech will travel to both locations. Both the receptionist and the MRI tech will be COS employees. COS will continue to utilize Dr. Joseph Gagliardi as our radiologist to read the MRI studies in the two additional locations.

4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.

In numerous locations in the above-referenced CON application, the method of "bundled payments" is discussed. COS has a bundled payment program with 3 major payors for outpatient reconstructive of both total knees and hips, and is working to include all of its payors in this program.

There is a correction that needs to be brought to the attention of OHCA which was only recently discovered as the applicant prepared for OHCA's Completeness Answers. The bundled payment program does not yet include the cost of the MRI. The MRI is often utilized as part of the diagnosis, and currently the bundled payment program does not begin until the injury is diagnosed and treatment begins. As both COS and the payor community become more familiar with the intricacies of bundled payment reimbursement, which includes the collection of data for post-operative complications

and patient outcomes, it is anticipated that more services (including MRI), can be included into the bundle. As both COS and the payor community become more familiar with the intricacies of bundled payments as well as further transformation from fee for service to value based reimbursement, it is anticipated that more services, including MRI will be included in risk based payment models. As the bundle becomes more complete, with both pre-operative and post-operative services, the risk sharing between provider and payor will allow for even greater savings to the delivery system.

The existing bundled payment plan already reduces the cost for the patient and payor. The efficiency of the outpatient total joint procedures (i.e., total hip and knee replacements) has allowed the payor to lower patient deductibles associated with inpatient procedures while lowering the total cost of the surgical event by several thousands dollars as compared to the same procedure done on an inpatient basis. The savings to the patient and the payor that are incurred for these procedures are as follows:

Pre- op visit	\$50
Home visit assessment	\$250
Physical therapy 16 visits @ \$35 / visit	\$560
ASC deductible or co insurance	\$3,000
Professional fee deductible or co insurance	\$1,995
Anesthesia fee deductible or co insurance	\$1,020
Pain block fee deductible or co insurance	\$420
DME deductible or co insurance	<u>\$100</u>
TOTAL	\$7,395

5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.

Presently, the patients in COS who are under the bundled payment program make up approximately 3%. This is due to the fact that bundled payment programs are new and COS is the only practice in CT that is providing outpatient total joint procedures under a bundled payment arrangement. As healthcare reimbursement transitions from fee for service to pay for performance, capitations and bundled payment programs, it is anticipated that the percentage will increase in a dramatic fashion.

6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?

COS accepts Medicaid recipients at all of its offices and facilities; COS does not discriminate patients based on insurance type or ability to pay. The availability of MRI service in Orange and Essex at the physicians' offices will enhance the ability of all patients to access this necessary diagnostic modality. The MRI service is managed by Dr. Gagliardi, a board certified radiologist, who is able to read the MRI scan and report the findings back to the treating physician within the same day, but no later than 24 hours after the scan. The short time between the MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of health care provided. While this service will only be available two days a week in both locations, it will allow more COS patients (Medicaid and all others) to take advantage of a seamless health care service.

7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).

The estimated costs for the installation of the MRI trailer at the Orange and Essex locations were revised subsequent to the publication of the newspaper notice which listed a capital expenditure of \$675,000. At the time of the publication the installation costs were projected to be \$100,000 and the revised estimate increased the costs by \$35,000 to \$55,000. Therefore, the costs now range from \$135,000 to \$155,000. We have used the higher installation estimate in projecting the project costs. Additionally, a clerical error occurred in the completion of Table 3 as submitted in the CON application. The corrected Table 3 follows. Copies of the purchase agreement for the MRI unit and trailer with MedExchange International, Inc., and an estimate for the trailer installation by Kingsbrook Development Corp. are found in Exhibit M of the CON application, starting on page 199.

**REVISED TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$575,000
Land/Building Purchase*	
Construction/Renovation**	\$155,000
Other (specify)	
Total Capital Expenditure (TCE)	\$730,000
Lease (Medical, Non-medical, Imaging)***	0
Total Lease Cost (TLC)	0
Total Project Cost (TCE+TLC)	\$730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

8. Why was there a drop in MRI volume at the Branford facility in FY2013?

The drop in MRI Branford volume at the Branford facility was multi-faceted. Problems existed with the 1T MRI unit that was located in Branford and it was replaced at the end of 2013. There were several significant down time periods throughout 2013 when the unit was out of commission, and patients were either referred to COS MRI unit located in Hamden or other facilities. In December of 2013, the 1T unit was replaced with a refurbished 1.5T GE magnet. This installation took 2 weeks and resulted in additional loss of patient volumes.

9. Why was FY 2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?

Between 2014 and 2015, COS merged with four (4) other orthopedic physician group practices. (See CON App., Q. #1, p.16). This merger expanded the total number of physician offices from 8 to 21 for a practice that now has 49 physicians. Patient volume increased from 6,302 scans in FY 2014 to 7,624 scans in FY 2015. The significant expansion of COS in 2014 - 2015 is the primary reason that a second MRI is needed. This volume is not expected to go down in the future because of the large increase of physicians in the COS practice. Therefore, FY2015 is a true reflection of COS patient volume because it reflects the expanded size of COS. It was selected as the base year because it was the most recently completed FY, and the number of scans is actual, not projected.

The four practices that merged with COS are Center for Orthopedics, Shoreline Orthopedics and Sports Medicine, The Orthopedic Group and Orthopedic Health. The merger and resultant increase in the number of COS physicians resulted in a significant increase in the number of MRI scans in 2014, 2015 and projected for 2016. Both of the existing COS scanners (located in Branford and Hamden) experienced increases in the number of scans, all related to the expansion of COS.

10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI?

There are no articles that speak specifically to mobile MRI units. The reality is that there is no difference between a "fixed" MRI vs. a mobile MRI. Both units are 1.5 T in magnet strength. The only difference is that a mobile unit is located within a tractor trailer and is therefore capable of being moved from one location to another. There is no difference in the resolution of the MRI study. The patient experience is essentially the same because the units are identical in capability.

Both existing COS "fixed" MRI scanners have received accreditation from the American College of Radiology (ACR). ACR accreditation will be obtained for the proposed mobile MRI scanner if approved. (CON App., p. 22 and Exhibit H).

11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark)

The proposal meets the in-office ancillary services ("IOAS") exception that is provided to group practices under the Stark law.

The Stark Law, 42 USC §1395nn(a)(1)(b), prohibits a physician from making a referral to a Designated Health Services entity ("DHS entity") for the furnishing of designated health services that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies 42 USC § 1395nn(a)(1)(b).

The exceptions include the In-Office Ancillary Services (“IOAS”) exception, which allows radiology services such as MRI to be performed within a physician group as long as certain requirements are met. The Applicant, COS, complies with all of the Stark requirements in order to meet the demands of the exception to the general rule.

This is the current law in effect, and there does not appear to be any intent on the part of Congress to eliminate the In-Office Ancillary Services exception. To the contrary, there has been discussion that many of the Stark restrictions are impeding the ability to lower the cost of health care – and as a result, some of the restrictions should be eliminated. In December of 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral rule, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. “Support for Stark law reform has grown in recent years, and following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger.” See Senate Finance Committee Majority Staff Report, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models” Exhibit R, p. 1.

This “white paper”, published after round table discussions on issues related to the physician self-referral law, stated, “The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models.” Exhibit R, p. 2. The case is being made to eliminate the Stark Law completely, not to eliminate the In-Office Ancillary Exception.

While there is still debate about whether to eliminate or restructure the Stark Law in the future, at this time the In-Office Ancillary Service exception is still the law, and the Applicant, COS, conforms to this federal law.

Revised Exhibit List

Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 – 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae	75 - 91
E	Scholarly Articles	92 – 122
F	Letters of Support	123 - 130
G	COS Standard of Practice Guidelines	131 – 171
H	American College of Radiology Accreditation for Existing MRI Scanners	172 – 174
I	COS Charity Care Policy	175 – 176
J	Target Populations: Patient Zip Codes	177 – 193
K	FY2015MRI Scans in the Essex Area for COS Patients	194 – 196
L	FY2015MRI Scans in the Orange Area for COS Patients	197 – 198
M	Capital Expenditures for Mobile MRI	199 – 203
N	Funding or Financial Resources for the Project	204 - 207

O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015	209 – 213
P	Financial Worksheet	214 – 215
Q	Assumptions Used in Financial Worksheet	216 – 218
R	Senate Finance Committee Majority Staff Report, “Why Stark, Why Now?”	228 - 248

EXHIBIT R

Why Stark, Why Now?

Suggestions to Improve the Stark Law to Encourage
Innovative Payment Models



A Senate Finance Committee Majority Staff Report

Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

Senate Committee on Finance, Majority Staff
Chairman Orrin Hatch (R-Utah)

I. INTRODUCTION

On December 10, 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral law, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the Stark law.

The Stark law prohibits a physician from referring Medicare patients for “designated health services” (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.¹ Financial relationships include both ownership and investment interests, as well as compensation arrangements. In addition, the law prohibits an entity from billing the Medicare program for services provided pursuant to an impermissible, or tainted, referral.

Support for Stark law reform has grown in recent years, and, following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger. The strict liability regime, huge penalties, and the breadth, complexity, and ambiguities of the Stark law and its regulations have created what is often referred to as a minefield for the health care industry. With this backdrop, attempts by Congress, the Centers for Medicare & Medicaid Services (CMS), and the private sector to encourage value-based payment models have not effected change as quickly as some had hoped. While many providers would like to move toward alternative payment models, most are reluctant to do so because they must contend with the tension between the Stark law and alternative payment models and the possibility of devastating penalties if they guess wrong.

The round table participants discussed whether changes to the law were necessary to implement MACRA and, if so, what options would work best in a system that includes both the fee-for-service (FFS) payment model and alternative payment models. After the meeting, the Committees invited the round table participants and others to share their views on the Stark law.²

The round table participants and the groups that submitted comments for the Committees’ review included Stark law experts, academics, attorneys in private practice who work with

¹ Section 1903 of the Social Security Act, 42 U.S.C. § 1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.

² In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a “Convener on Stark law” (Convener Session) held on April 24 and June 30, 2009, in Washington, D.C. A white paper was published entitled, [A Public Policy Discussion: Taking the Measure of the Stark Law](#), which summarizes the discussion and proposals for changing the

hospitals and/or physicians, attorneys in the private sector who previously served in government regulatory and enforcement agencies, hospital systems, electronic health record providers, as well as associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.

II. EXECUTIVE SUMMARY

Congress enacted the Stark law to limit the influence of financial relationships on physician referrals. If a physician (or an immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of DHS under Medicare and, to some extent, Medicaid, unless an exception applies. 42 U.S.C. § 1395nn; 42 U.S.C. § 1396b. A “financial relationship” is defined as any direct or indirect (1) ownership or investment interest or (2) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS. An entity may not bill for DHS provided as the result of a tainted referral.

Congress intended the Stark law to provide a bright line test to curb physician self-referral. But despite CMS’s efforts to provide clear rules and interpretations to address the strict liability regime, the Stark law’s breadth, complexity, and impenetrability have created a minefield for the health care industry. As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted last year, “even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.” [United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.](#), No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Before Congress passed health care reform, the health care industry recognized that the Stark law would be an obstacle to hospitals’ and other providers’ efforts to align incentives with physicians for certain alternative payment models, including pay-for-performance, gainsharing, bundled payment or outcomes measures. During the American Health Lawyers Association’s (AHLA) 2009 Stark discussion, many participants noted that alternative payment programs inevitably link physician payments to

law itself or its administration or enforcement. Although the topics covered do not overlap precisely, our December 2015 round table was an effort to look at what changes had taken place since 2009, given the passage of the Affordable Care Act in 2010 and MACRA in 2015. The views shared by the round table participants and subsequent commenters reflect the changing legal landscape between 2009 and the present, but they also echo many of the underlying issues discussed in the 2009 AHLA session.

the volume or value of physician referrals³ – a payment formula that generally will not pass muster under the compensation arrangement exceptions to the Stark law.⁴

Congress also recognized that alternative payment models would be difficult or impossible to establish in the current FFS enforcement environment. As a result, the Affordable Care Act (ACA) included an authorization for the Health and Human Services (HHS) Secretary to issue regulatory waivers from the Stark law and other fraud and abuse laws for innovative payment and service delivery models.⁵ Under that authority, the Secretary has issued waivers from fraud and abuse laws for participants in the Medicare Shared Savings Programs (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI), the Comprehensive Care for Joint Replacement (CJR), and other Accountable Care Organization (ACO) programs.

MACRA's modification of the Civil Monetary Penalties (CMP) law, 42 U.S.C. § 1320a-7a, (specifying that the gainsharing prohibition applies only to inducements made to reduce or limit medically necessary services to beneficiaries) has removed some barriers to gainsharing and pay-for-performance programs. Nevertheless, as the waivers for CMS demonstrations illustrate, the Stark law continues to pose significant risks for implementation of such programs. Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

The Committees invited the round table participants to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

Although the comments that we received were wide-ranging, there were many recurring themes. To implement health care reform, many comments focused on potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS's regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety. Comments also concentrated on other important non-MACRA issues, including changes to standard Stark law definitions, like fair market value, the volume and value of referrals, and commercial reasonableness. In distinguishing technical and substantive violations, comments centered on documentation requirements and harm to beneficiaries or federal health care programs.

³ Reducing unnecessary FFS procedures or services reduces costs but increases profit (*i.e.*, value).

⁴ AHLA, [A Public Policy Discussion: Taking the Measure of the Stark law](#), at 9 (2009) (hereinafter, [AHLA 2009 White Paper](#)).

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, (2010).

Some commenters submitted other suggestions for improving the law, including changes or clarifications to in-office ancillary services exception, the physician-owned hospital exception, documentation requirements, and others. This white paper focuses on potential changes to the Stark law to remove hurdles to implementing health care reform and on how to distinguish technical and substantive violations. The other issues that are not addressed in detail in this white paper may be considered by the Committee at a future point in time.

III. STARK LAW BACKGROUND

Under an FFS payment model, physicians have a financial incentive to provide more services. When a physician has a financial interest in an entity to which he or she refers patients, the incentive extends to ordering tests, procedures, or referring patients to that entity. The issue received attention in the 1980s, and, by 1989, the HHS Office of Inspector General found that physician self-referral related to laboratory tests was associated with a marked increase in utilization.⁶

That year, Congress passed the Ethics in Patient Referrals Act of 1989 (Stark I) prohibiting a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. Stark I also prohibited the lab from billing for any services furnished pursuant to a tainted referral. To prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership, Congress also prohibited circumventions schemes and compensation arrangements. Stark I became effective January 1, 1992. Congress soon expanded the clinical laboratory prohibition to ten “designated health services” in the Omnibus Budget Reconciliation Act of 1993 (Stark II), which became effective January 1, 1995. Stark I and Stark II each included exceptions to the general prohibition.

CMS has published a series of regulations implementing the Stark law, beginning in 1992.⁷ The final rules, listed below, are codified at 42 C.F.R. § 411.350–411.389.⁸

- Stark I regulations, August 14, 1995.
- Stark II Phase I regulations, January 4, 2001 (interim final rule).
- Stark II Phase II regulations, March 26, 2004 (interim final rule).
- Stark II Phase III regulations, September 5, 2007.
- Stark II Phase IV, Inpatient Prospective Payment System (IPPS) regulations, August 19, 2008.
- Stark II Phase V, IPPS regulations, October 30, 2015.

⁶ OIG-Office of Analysis and Inspections, Report to Congress, [Financial Arrangements Between Physicians and Health Care Businesses](#), 3 (May 1989).

⁷ AHLA’s [2009 White Paper](#) includes a chart with a helpful description of the regulatory changes from 1992 through 2009, at pages 4-5.

⁸ The CMS website has a list detailing the Stark law’s [significant regulatory history](#).

Several commenters stated that the Stark law is not a “fraud” statute, but a regulation of payment. There is no requirement of an intent to violate the statute and compliance is a straightforward condition of payment. These commenters noted that Congress intended to provide a bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.

Even with regulatory exceptions and guidance, the result has been an extremely broad prohibition on physician referrals. If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions.⁹ But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, “takes into account” volume or value of referrals, and commercially reasonable—are factual, which means parties must prove that their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes. The unpredictability is especially frustrating given the enormous penalties under the Stark law, which can be much higher than penalties for fraudulent activity.¹⁰

Commenters also noted the high cost and difficulty of complying with the Stark law. Even tracking non-monetary compensation issues can cause headaches for hospitals and physicians. For instance, if a physician agrees to join an ACO, it makes sense to provide access to the same electronic health record system used by the rest of the network. While the current MSSP waivers address this concern, if the physician leaves the ACO, or when the waivers expire, the physician may face Stark liability, which is just one additional hurdle to physicians joining ACOs and other integrated health care entities.

Some participants noted the law’s inflexibility, as it prohibits any financial arrangement with a physician that does not fit within an exception. This inflexibility is underscored as providers attempt to implement alternative payment models like ACOs, pay-for-performance, shared savings, and bundled payments, which do not always fit into existing exceptions. Participants and commenters generally agreed that the Stark law does not have a place in the pay-for-value world because it was created to address overutilization in an FFS environment. Many participants and commenters believe that the law is disruptive to the development and implementation of value-based models.

⁹ The requirement that the financial relationship fit within an exception is different than the option to fit a relationship within a safe harbor to the Anti-Kickback Statute (AKS). Under the AKS, financial relationships that do not fit squarely within a safe harbor do not necessarily violate the AKS.

¹⁰ If a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services from that physician are “overpayments” and must be returned, regardless of the amount of the “tainted” transaction or nature of the payment. In contrast, even the new authority in the ACA expanding the false claims liability for violations of the AKS is limited to claims “resulting from” the kickback.

Although many areas for improvement were discussed, especially those to usher in health care reform, round table participants and commenters also recognized that the Stark law has been effective in restricting physician ownership and investment in entities such as free-standing imaging centers and other providers of ancillary services. The law has also encouraged the industry to focus on compliance because of the need to closely scrutinize physician relationships, but several commenters noted that in practice the burden of compliance falls upon hospitals. Round table participants praised the establishment of the Self-Referral Disclosure Protocol, which enables providers to disclose Stark violations and permits CMS to compromise repayment amounts. Some participants noted that the settlements under the Protocol have been fair and reasonable. But several participants believe that the process is too time consuming and does not provide certainty to disclosing parties. Some commenters point to exceptionally high settlements for disclosures of technical violations based on documentation issues alone.

IV. STARK LAW IN CONTEXT

Round table participants and commenters discussed the Stark law in the context of other enforcement authorities and reimbursement rules that may also address physician self-referral practices.

Anti-Kickback Statute. Many commenters noted the imperfect and often confusing overlap between the Anti-kickback statute (AKS), 42 U.S.C. § 1320a-7b, and the Stark law.¹¹ Relationships that are permissible under the Stark law may violate the AKS, which some commenters said means the Stark law occasionally undermines the enforcement of the AKS. When Congress passed the Stark law, there was no civil liability for anti-kickback violations under the CMP law, and it was unclear whether the government could use an anti-kickback violation as a predicate for a False Claims Act (FCA) case.

With the expansion of the scope and application of the AKS over the years, however, many participants and commenters argue that the Stark law is no longer needed. The AKS can now be enforced in the civil context through the FCA and the CMP law. Not all participants agreed that the Stark law was no longer needed, in part because the FFS payment model would still be used to some extent for years to come.

Compounding the complicated overlap between these two statutes, is the disproportion in penalty levels. Penalties are smaller for AKS violations, which require knowing and willful intent, meaning the underlying conduct is arguably much more egregious.

False Claims Act. The FCA has become the primary enforcement mechanism of the Stark law. 31 U.S.C. § 3729–3733. While the Stark law prohibits physician referrals to an entity based on non-compliant financial relationships, from an FCA perspective, the focus is on the prohibition on billing for services furnished pursuant to a tainted referral. FCA exposure is created if the claims were submitted with the requisite intent (reckless disregard or deliberate

¹¹ While this may be an area that would benefit from further examination by Congress, the AKS is outside the Finance Committee's jurisdiction, and while we may refer to comments that mention the AKS, we are unable to address those concerns at this time.

ignorance of their truth or falsity). The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the potential for FCA exposure by revising the definition of a claim to include the knowing and improper retention of an overpayment.¹² 31 U.S.C. § 3729(a)(1)(G). In 2010, the ACA added the “60-day rule” requiring providers to “report and return” a Medicare or Medicaid overpayment within 60 days “after the date on which the overpayment was identified.” 42 U.S.C. § 1320a-7k(d)(1)–(3). Thus, under the FCA’s reverse false claims provision, an entity that submits a claim with no knowledge that it may be prohibited by the Stark law may face FCA exposure if (1) the entity later discovers the Stark violation and (2) fails to report and return any reimbursement associated with the tainted claim within the 60-day period.¹³

Some commenters expressed concerns with recent FCA litigation, noting that certain aspects of the Stark law have led to a number of recent FCA settlements that threaten the development of integrated delivery systems. The commenters pointed to several recent FCA settlements based on a *qui tam* theory that an accounting loss for hospital-owned physician practices is *ipso facto* evidence that the employed physicians are paid more than fair market value and that the arrangement is not commercially reasonable. The commenters acknowledge that the complaints for some of the recent settlements may involve extreme facts but are nonetheless concerning as potential examples of bad facts making bad law.

Reimbursement. Some round table participants noted that reforming reimbursement rules may address the Stark law’s underlying concern of overutilization. Some suggestions included decreasing reimbursement for ancillary services provided through a physician’s group practice, bundling the payment for physician office visits and ancillary services, and adopting bundled payment plans that promote shared risk among providers involved in an episode of care.¹⁴ Although we did not receive comments in direct opposition to these suggestions, we received numerous comments both in favor of and against any changes to the in-office ancillary services exception which could serve as an alternative to payment changes for such services.

V. IMPLEMENTING MACRA AND OTHER ALTERNATIVE PAYMENT MODELS

As noted above, the Committees invited round table participants and others to share their perspectives on what changes to the Stark law might be necessary to implement health care reforms promoting alternative payment models, such as MACRA. Participants were asked to

¹² Prior to FERA, liability for retention of an overpayment required an affirmative step to evade repayment through a false record or statement and only if it could be established that repayment was an “obligation.” This provision became known as a reverse false claim.

¹³ In rejecting two motions to dismiss, the District Court for the Southern District of New York recently addressed what it means to “identify” an overpayment and start the clock for the 60-day rule under the FCA. *U.S. ex rel. Kane v. Healthfirst, Inc., et al.*, No. 11 CIV 2325, 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

¹⁴ For additional reimbursement suggestions shared during AHLA’s Convener Session, see, [AHLA 2009 White Paper](#), at 12.

include in their suggestions options that would work in a payment environment that includes both FFS and alternative payment models.

The comments generally focused on potential new waivers or exceptions, expansions of existing waivers or exceptions, changes to standard Stark law definitions, broadening the Secretary's authority, or repealing the law or the compensation arrangement prohibition. The relevant comments are summarized by category below.

Repeal. Many commenters suggested that the Stark law has outlived its utility. These commenters argue that the AKS in its current form can address the conduct that the Stark law seeks to curtail. However, some commenters noted that the Stark law addresses conduct that may not fall under the AKS. Additionally, while the FFS payment model is being phased out, it will continue in some form for many years. With this in mind, some commenters advocating repeal recommended that the Stark law be sunset once Medicare had transitioned to alternative payments to a meaningful extent.

Repeal Compensation Arrangement Prohibitions. A larger group of commenters believed that repealing the compensation arrangement requirements would address many of the concerns not only with implementing health care reform but with the Stark law's most difficult provisions. They recommend limiting the Stark law to ownership and investment interests, which they believe was Congress's original intent. However, as some commenters noted, prohibitions on compensation arrangements have been in the law from the beginning and were included to avoid schemes to circumvent the law with creative arrangements that would give physicians the benefits, and dangers, of ownership but that did not involve equity.¹⁵ Other commenters argued that the compensation arrangement prohibitions are no longer necessary because the AKS can now be enforced in a civil context through both the FCA and the CMP law.

New Risk Revenue Waiver/Exception. To lessen the burden of health care entities making the transition from FFS to alternative payment models, two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. Health care entities receiving such a waiver would be required to meet certain criteria, for example, having the governing board of the ACO entity approve applicable financial relationships through a process that validated Triple Aim¹⁶ principles and shows no motivation to increase utilization. Noting that some health care entities would never reach this level of risk based revenue, one of the commenters acknowledged that entities that did not reach such a level of risk engagement would still be required to meet a Stark

¹⁵ [AHLA 2009 White Paper](#), at 12.

¹⁶ See Donald M. Berwick, et al., [The Triple Aim: Care, Health, And Cost](#), Health Affairs, May/June; 2008, 27(3) at 759-769. "The Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the "Triple Aim": Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care." IHI website, [Triple Aim Initiative](#).

exception for certain arrangements. The other commenter framed the exception in terms of health care systems that derive no less than 50 percent of their health care revenue from alternative payment methodologies, and recommended that such systems receive a broad waiver from the Stark law similar to those now in effect for ACOs.

The commenters believe that enforcement agencies could use the AKS and the gainsharing CMP to address problematic arrangements. This idea accommodates the incremental transition to value-based payment models. However, some round table participants questioned how health care entities could reach a threshold percentage without being at risk, arguing that this type of fix would simply shorten the period of exposure for a subset of providers.

Create New or Expand Currently Restricted Waivers. Most commenters suggested extending the waivers that are currently highly limited to CMS-run programs to all payers. Many commenters believed that expanding the waivers for the MSSP to qualifying alternative payment model participants would be the best solution.¹⁷ Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current Center for Medicare & Medicaid Innovation (CMMI) waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority.

Commenters agreed not only that Congress should create waivers to address the problem but also that Congress should give HHS broader authority to create regulatory waivers. While commenters generally agreed that some new waivers could be created through existing but limited CMS rulemaking authority, most agreed that Congress should give CMS express authority to create broader waivers than currently authorized by law.¹⁸

Some commenters argued for consistency in fraud and abuse laws' applicability to ACO programs for all government-supported innovative payment models. One suggestion to accomplish such consistency was the creation of a new Stark law exception at 42 U.S.C. § 1395nn(b) that would apply to MIPS, physician-focused payment models, and payments associated with alternative payment models. Another suggestion was to create a waiver that would apply to MIPS, alternative payment models, and ACOs, modeled on current Stark exceptions for Medicare prepaid plan enrollees. These type of waivers could address issues in an environment that includes both FFS (MIPS) and alternative payment models.

¹⁷ CMS and OIG, HHS, [Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66,726](#) (Oct. 29, 2015) (codified at 42 C.F.R. Chs. IV and V).

¹⁸ Recommendations to expand the Secretary's authority to create waivers and exceptions are discussed below.

Create New Exceptions. Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the “APM Exception”) apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a fair market value requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals.

Other commenters stated that a new exception should be available for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care (referring to integrated delivery systems, accountable care, team-based care, or value-based payment arrangements). Some commenters, concerned that an exception may focus on institutional providers, expressed the need for an exception that took into account the breadth and scope of providers and entities necessary for truly integrated health care. Other commenters emphasized that the new exception should be available for truly clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. Commenters also noted the need to protect shared savings and incentive programs, as well as any arrangement start-up or support contribution, when certain conditions are met.

One commenter suggested an approach to accommodate alternative payment models, either under MACRA or more broadly, that would involve adding an additional statutory exception for alternative payment models that promote and advance accountability for quality, cost/risk, care coordination, patient experience, and outcomes. To qualify for the exception, which could be added to the compensation arrangement exceptions at 42 U.S.C. § 1395nn(e), arrangements would need to meet conditions that are already used to qualify ACOs and other risk-sharing arrangements under the Stark law and AKS. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

Special Compensation Rule. The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA alternative payment model financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

Modify Existing Exceptions. Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives.

Most Stark law exceptions protect a “financial relationship” and except the relationship from triggering the prohibition on DHS referrals. Other exceptions, like the prepaid plan exception at 42 U.S.C. § 1395nn(b)(3), only protect the services that would otherwise be

prohibited DHS referrals. The prepaid plan exception, for example, only protects referrals of services to the prepaid plan but still prohibits FFS referrals to the same party. Several commenters recommended Congress broaden the statutory prepaid plan exception so that the prohibition on referrals for DHS would not apply to services rendered by an entity that has a contract with CMS or its agent that contemplates the use of alternative payment models. Alternatively, the exception could be framed so that it protects DHS furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO, or any other ACO model established by CMS or tested under CMMI. Either scenario should protect services that would otherwise be prohibited DHS referrals; FFS referrals to the same party would still be prohibited. These commenters argue that this would provide more certainty for the regulated community than an extension of the regulatory waiver approach for ACO arrangements.

Several commenters recommended Congress expand the risk-sharing exception at 42 C.F.R. § 411.357(n) to apply to Medicare and Medicaid FFS programs. Other commenters would expand the exception to incentive payment arrangements between a DHS entity and a physician participating in a qualified alternative payment model (others framed this as applying to compensation arrangements involving integrated care organizations). Some commenters recommended that a new exception be created based on the risk-sharing exception that would apply to MSSP, Pioneer, Next Generation ACO, or other CMS or CMMI ACO models, as long as the arrangement is reasonably related to one of the purposes of the respective program. The exception would explicitly cover payment arrangements that are downstream of bundled payments, shared savings, and other alternative payment programs implemented by governmental or private payers. Commenters advocated for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, as amended by MACRA, specifically the modifications to the gainsharing prohibition. They also recommended a clarification that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to the hospital.

One commenter recommended Congress codify the existing exception applicable to services furnished by an organization (or its contractors or subcontractors) to enrollees set forth at 42 C.F.R. § 411.355(c), and modify it to incorporate alternative payment models, including those involving integrated care organizations, as being eligible for protection.¹⁹

Another commenter noted that although the current Stark rules do not pose major obstacles for parties to enter into bundled payment or gainsharing arrangements, some legislative changes or clarifications to the Stark law could provide much needed comfort for parties who are uncertain how to proceed or fear inappropriate enforcement efforts.

One area the commenter identified for clarification is the definition of an indirect compensation arrangement, which, along with the exception for indirect compensation

¹⁹ For purposes of consistency, the commenter recommended that the definitions of health plan and enrollees under 42 C.F.R. § 1001.952(1) be modified to contemplate ownership and compensation relationships arising out of alternative payment models.

arrangements, is one of the most complex and frustrating areas of Stark regulation. The definition includes three components. One of those components is based on the referring physician's receipt of aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. *See* 42 C.F.R. § 411.354(c)(2)(ii). The commenter recommends that Congress clarify that where the physician's compensation from an entity with which he or she has a direct compensation arrangement does not necessarily rise as a direct result of more referrals or higher paying referrals, the aggregate compensation test is not met.

Additionally, the commenter notes that although arrangements where physicians are paid a percentage of savings are common, CMS has never expressly recognized that a percentage of savings can be fair market value and commercially reasonable. To resolve uncertainty and to promote non-abusive shared savings arrangements, the commenter recommended that Congress adopt CMS's deeming provision for per-click compensation arrangements, 42 C.F.R. § 411.354(d)(2), and extend it to percentage compensation arrangements. The commenter also recommended that Congress amend the Stark law to state that an arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception. Alternatively, Congress could provide that an arrangement under which a physician would receive a percentage of savings realized by the hospital or other provider or supplier will be presumed (or deemed) to satisfy the fair market value and commercial reasonableness requirements of an applicable exception if the parties relied in good faith on an opinion from a nationally recognized appraisal firm. To prevent opinion shopping, the statute must provide that all opinions (draft or otherwise) of fair market value and commercial reasonableness would be taken into account when determining whether the parties relied in good faith on a favorable opinion. One commenter suggested that such a change should include some standard to govern the amount that can be shared with physicians, such as a cap or threshold.

Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions. Some commenters noted that the Stark law and regulations are payment regulations that providers must comply with to receive payment. An effective regulatory regime requires that the regulated community be able to obtain timely and clear guidance. Commenters offered a number of suggestions in this regard.

Commenters generally agreed that Congress should expand the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

The Stark law permits the Secretary to create regulatory exceptions that the Secretary determines do "not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). CMS has taken a cautious approach in issuing Stark exceptions.²⁰ Commenters believe that many of

²⁰ Although CMS recently provided additional guidance on the Stark law, [Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885](#), 71300-71341 (Nov. 16, 2015), at least one commenter

the existing exceptions are too narrow or complicated to be useful but that more practical exceptions could be issued if the Secretary were given authority to create exceptions where an arrangement does not pose an undue or significant risk of program or patient abuse. Commenters also noted that HHS has greater authority and flexibility to create safe harbors to the AKS, a criminal statute, than it has to create exceptions to the Stark law, a regulation of Medicare payment.

Several commenters also urged Congress to strengthen the Secretary's authority to issue Stark advisory opinions and promote timely agency guidance. One commenter noted that if an exception for innovation arrangements were adopted, it could permit the submission of a request through the CMS advisory opinion process, which would provide added comfort to both CMS and the industry. The commenter noted that Congress could direct CMS to modify its current regulations to accommodate the review process and set forth other requirements CMS considers necessary to organize, facilitate, and fund the analysis and the timely issuance of advisory opinions dealing with innovation arrangements that promote the Triple Aim. This commenter noted that such advisory opinions should not be required, but that they should be available to provide added comfort to the industry in a time of innovation and change.

The participants and commenters agreed that the creation of the Self-Referral Disclosure Protocol (SRDP) and the expansion of the Secretary's authority to compromise Stark repayment obligations were positive developments in Stark law enforcement. Nevertheless, some said the process was too lengthy and left providers in limbo while they waited for a disposition. Many commenters argued Congress should give CMS more discretion to settle Stark law violations, such as providing CMS with the explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount.²¹ One commenter suggested Congress give CMS discretion to determine whether to prohibit billing for violations, which could have far-reaching implications, including taking Stark law violations out of the realm of FCA litigation.

Some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex. These commenters also believed it would not be effective to simply strengthen the Secretary's advisory opinion authority to promote timely agency guidance because, based on 25 years' worth of rule-making, they believe Congress should revise the law entirely. In their view, advisory opinions only help at the margins, and, in almost all cases, very slowly.

VI. DEFINING TECHNICAL VIOLATIONS

Commenters generally agreed that "technical" violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment

believed that the agency could be more hesitant to issue exclusions after the recent decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). This concern underscores the importance of consideration of an explicit grant of authority to the Secretary.

²¹ Recommendations concerning a revised penalty structure are discussed below.

liability.²² Several commenters noted that Congress recognized the disparity between technical and substantive violations when it created the SRDP and authorized the Secretary to reduce amounts owed. In distinguishing technical and substantive violations, comments focused on documentation requirements, adherence to fair market value, the volume or value of referrals, or harm to beneficiaries or federal health care programs. But some commenters questioned whether drawing such a distinction would be helpful because it would be difficult to determine penalty provisions and enforcement priorities in an already hyper-technical environment. Their solution to the complexity would be to eliminate the compensation arrangements prohibition. As for penalties for technical violations, all commenters recommended that CMPs be assessed in lieu of penalties or that no penalty be assessed. Some commenters recommended further reducing the CMP if a party self-disclosed a violation within 60 days of discovery.

Documentation Requirements. Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement. Commenters and round table participants pointed to Representative Charles Boustany’s proposed legislation, the Stark Administrative Simplification Act of 2015, as a move in the right direction, specifically in terms of its definition of technical violations.²³ The proposed legislation defines “technical noncompliance” as arrangements that violate the law’s prohibition of self-referral “only because (i) the arrangement is not set forth in writing; (ii) the arrangement is not signed by 1 or more parties to the arrangement; or (iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.”²⁴

Several commenters added that technical violations are those that pose a low risk of affecting the Medicare fisc and are unlikely to result in increased use of medically unnecessary services.

Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making. In describing technical violations, some commenters included along with documentation requirements violations that are irrelevant to whether an arrangement incentivizes referrals. Outside the context of ownership, they only consider “substantive” violations of the Stark law to be compensation structures that induce or reward referrals (*i.e.*, the physician is paid for referrals). Some of these commenters recommended eliminating any technical violations that do not harm patients or Medicare and authorizing the Secretary to impose a CMP for each arrangement to reduce the impact of technical violations. One commenter suggested that a financial arrangement that a reasonable person would conclude creates a significant incentive to a physician to refer to a particular entity is substantive.

Fair Market Value. Some commenters suggested dividing violations into two categories: (1) those where compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume

²² [AHLA 2009 White Paper](#), at 16.

²³ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

²⁴ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

or value of referrals; and (2) those where compensation is not. However, commenters recognized that the division is not clear cut in practice due to the technical nature of the rules on fair market value and volume or value of referrals. Many commenters and participants agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.²⁵ One suggestion was to define technical violations to include any violation that does not involve fair market value (and perhaps commercial reasonableness) or the volume or value prohibition; and that, depending on the facts and circumstances, technical violations may include violations that involve fair market value, commercial reasonableness, or the volume or value prohibition.

Compensation Arrangements That Do Not Violate the AKS. Several commenters recommended defining technical violations as compensation arrangements that do not otherwise violate the AKS. In other words, as suggested above, prohibited ownership violations would be substantive noncompliance, and problematic compensation arrangements would be enforced through the AKS or the CMP law. One commenter suggested that any arrangements that do not confer a financial benefit to the referring physician should not be considered substantive and that technical violations should not carry Stark penalties.

Create Bright Line Requirements For Substantive Noncompliance. One commenter suggested first creating bright line requirements to improve clarity and then considering all noncompliance with those bright line requirements to be substantive. The commenter recommended that Congress direct CMS to specify, on a regular basis (*e.g.*, through Medicare Physician Fee Schedule rule making), compensation practices that are not permitted based on the agency’s experience. Only noncompliance with such specifically non-permitted compensation practices should be viewed as substantive noncompliance. As discussed below, concerns have been raised about Congress’s or CMS’s ability to create a list that would effectively cover all financial arrangements that may involve self-referral concerns.

Clarify Compensation Arrangement Terms. Several commenters recommended clarification of the three key terms in the compensation arrangement exceptions: fair market value (FMV), “takes into account” the “volume or value” of referrals, and commercially reasonable. The comments we heard echoed those raised during the AHLA discussion, including concerns about the difficulty of establishing and documenting FMV.²⁶

Some commenters recommended allowing physician compensation for providing high-quality and efficient care without violating the Stark law’s FMV standard, even if the compensation is related to the volume or value of the referrals. These commenters argue that the statutory definition of FMV simply reflects the clear rule that arrangements must reflect arm’s length bargaining and that the “volume or value” standard was a regulatory addition created by CMS. Another commenter also rejected CMS’ definition of FMV and recommended that Congress clarify that intent is not material in the strict liability law, and bar CMS from defining

²⁵ We received many comments recommending changes to terms associated with compensation arrangement exceptions. They are discussed in Section VI, below.

²⁶ See [AHLA 2009 White Paper](#), at 11-12.

essential terms (*i.e.*, FMV, commercially reasonable and volume or value of referral standards) in a purportedly circular, interconnected manner.

One commenter suggested amending the statute to provide that the FMV requirement is met where the compensation paid to the physician does not exceed FMV. Some commenters noted the confusion caused by the regulations' ambiguity on whether an arrangement that is FMV at its inception, but later falls out of FMV, continues to meet the FMV requirement. Long leases should not enjoy exception for years and short leases should not be punished if the lease falls out of FMV in six months. To address this concern, one commenter suggested that Congress could provide that arrangements that are FMV at their inception are presumed or deemed to be FMV throughout their life, up to some maximum period, such as two to three years. Alternatively, if a party obtains an FMV appraisal from a qualified, independent appraisal firm, it is entitled to rely on the appraisal for the life of the appraisal, up to a maximum of two to three years. A variation would be to specify that, in order to gain the protection of the FMV presumption or deeming, the appraisal be obtained before the arrangement begins. The commenter also recommended a similar provision for an appraisal regarding whether an arrangement is commercially reasonable.

A few commenters sought Congress's explicit confirmation that certain practices are acceptable and do not necessarily violate the Stark law. For instance, one commenter suggested that Congress confirm that DHS entities can base compensation on market surveys of similar arrangements without regard to whether those surveys involve actual or potential referral sources – given that the only available surveys involve entities (*e.g.*, medical practices, hospitals and other employers) and physicians who are in a position to make referrals. The commenter also suggested that the Stark law be amended to clearly state that nothing in the law prohibits a DHS entity from developing and using management, financial, and other reports that may include productivity or other data in their internal operations as consistent with typical business practices, so long as such reports are not used in decision-making regarding the compensation to be paid to individual physicians. Several participants at the round table suggested that Congress remove the “commercially reasonable” requirement from the employment and other compensation exceptions or clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.

Others suggested changes to other definitions. One commenter recommended that the definition of “group practice” be revised by removing the current volume or value standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all of the exceptions to the existing Stark law impose restrictions on compensation based on “volume or value” of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance. Another commenter suggested that the Stark law's definitions of remuneration and compensation arrangement be narrowed so that FMV exchanges do not implicate the Stark law.²⁷

²⁷ See [AHLA 2009 White Paper](#), at 12 (similar suggestion that compensation arrangement prohibitions apply only when payments vary with the volume or value of referrals).

Another commenter suggested Congress amend the Stark law to define reasonable safe harbors that would provide predictable refuge for hospitals that reasonably evaluate and document fair market value.

Intent. While not always tying the suggestion to the definition of technical violations, several commenters recommended that an intent requirement be added such that purely accidental omissions were not in violation of the Stark law. Some participants believed this would make the Stark law duplicative of the AKS rather than a payment rule.²⁸ Others recommended adding a harm to programs requirement to limit fines to situations where the prohibited referrals result in some demonstrable harm to the government or the patients served, with the burden of proof on the government.

Create Exception for Technical Noncompliance. One commenter recommended creating an exception for technical noncompliance based on the regulatory exception for certain arrangements involving temporary noncompliance at 42 C.F.R. § 411.353(f), but with fewer restrictions. The commenter did not specify how to differentiate between technical and substantive violations, but emphasized the importance of such an exception.

Determining the Penalty. Some commenters also advocated for the inclusion of mitigating factors when determining the penalties associated with technical violations, sometimes referring to the factors in the legislation creating the SRDP. Some commenters suggested that Congress give the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and those commenters also recommended that certain factors be considered with determining the penalty amount. Suggested factors included: (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance. A variation of a suggestion discussed in the previous section would be for Congress give CMS discretion to determine whether to prohibit billing for technical violations, which would allow CMS to compromise repayment amounts, to impose CMPs, or not to impose any penalty.

VII. GENERAL RECOMMENDATIONS BEYOND MACRA IMPLEMENTATION AND DEFINING TECHNICAL VIOLATIONS

Commenters noted general frustrations with Stark law compliance and explained the difficulties hospitals and other providers face in complying with the law. Several commenters noted that even if a provider fits its arrangements squarely within certain exceptions, the provider could still face lengthy and expensive legal battles because many exceptions are fact-specific. For instance, for challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements. As discussed

²⁸ See [AHLA 2009 White Paper](#), at 12 (similar comments on intent).

above, the same is true of each of the three standards (FMV, volume/value, commercial reasonable). The commenters believe that including requirements of separate laws stacks the deck against hospitals trying to obtain predictability with respect to their Stark law compliance. Although the concerns discussed below are not unique to implementing health reform, they create a chilling effect because both hospitals and physicians are wary not only of the difficulties associated with complying with the Stark law but also of the costs associated with defending even compliant arrangements.

Align Stark Law with AKS. As discussed above, many commenters believe Congress should align the Stark law and AKS. Congress (or for regulatory exceptions, HHS) could accomplish this by replacing certain Stark law exceptions with AKS exceptions. For instance, one commenter suggested that the Stark law bona fide employee exception should be made identical to the AKS bona fide employee exception, which unlike the Stark exception does not include a fair market value component. The commenter reasoned that if the concern giving rise to this exception is that part-time employees are more subject to abuse, then the Stark law's fair market value component could be limited to persons who are dually employed by a provider of DHS and a physician practice, but not be applied to physicians whose only employer is a provider of DHS. The commenter also noted that for all tax-exempt entities, there already are substantial constraints on compensation paid to employees. The commenter suggested that any compensation arrangement that satisfies an AKS safe harbor should also be exempt from the Stark law. Rather than maintaining two parallel, but not identical, sets of regulations that outline permitted practices, the commenter believes it would be better to rely on the AKS safe harbors and eliminate the separate, but not identical, exceptions to the compensation arrangements provisions of the Stark law.

Tax Exempt Exception for Compensation Arrangements. One commenter noted that the Internal Revenue Service (IRS) already limits compensation arrangements entered into by tax exempt entities, and that in light of such limitations, a potential carve out to the Stark law could be an exception applicable to any compensation arrangement that is entered into by a tax exempt enterprise. That commenter suggested that clearer, broader exceptions for bona fide co-management arrangements, professional courtesy, reasonable gifts or rewards for patient referrals, and free screenings would be helpful.

Reverse the Premise and Change the Burden of Proof. One commenter recommended reversing the premise of the Stark law to specify types of particular compensation arrangements that are "strict liability" and place the burden on government to show a violation. The commenter also recommended that penalties be made commensurate with the harm to the Medicare program. Although the structure of the Stark law has long been debated, the main argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.²⁹

Simplify/Clarify. Many of the participants suggested that the Stark law's definitions and exceptions should be streamlined and simplified. Some commenters suggested eliminating or modifying the signature requirement. One commenter recommended removing the limitation on

²⁹ See [AHLA 2009 White Paper](#), at 13.

the number of times a hospital may use the late signature rule, or in the alternative, modifying the signature requirement to simply require evidence of assent between the parties.

Other commenters recommended that the Stark law should be amended to codify CMS policy confirming that payments to physicians for personally performed services are permissible under the Stark law, even if the personally performed services are related to DHS ordered by the physician. These commenters suggest an amendment identifying the following as permissible forms of payment for personally performed services: (1) hours worked in performing such services; (2) revenues billed, collected or collectible for such services; (3) wRVUs for such services; (4) patient encounters; (5) average daily patient census; or (6) any other approach that measures the clinical or administrative services actually furnished by the physician. For every physician (whether or not in a group practice), services that are billable as “incident to” the physician’s services are deemed to be personally performed by the physician.

VIII. CONCLUSION

The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models. Although the FFS payment model still exists, the comments show that the Stark law and its regulations have presented challenges to providers attempting to implement health care reform. Many commenters cited the Stark law’s strict liability standard and significant penalties as serious obstacles to implementing MACRA and other alternative payment reforms. The Committee appreciates all of the comments submitted and will be considering them all as we evaluate and develop potential changes to the Stark law.

Greer, Leslie

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, November 08, 2016 2:17 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila; 'klg1@aol.com'
Subject: OCHA Docket No. 16-32117- CON Completeness Responses
Attachments: COS Completeness Answers 11.3.16.docx; Exhibit R.pdf; Combined Docs 11.3.16.pdf

Dear Ms. Riggott and Mr. Fernandez:

Attached please find the word version of the COS Responses to OHCA's Completeness Questions which were dated September 21, 2016 and a copy of Exhibit R. A copy of the completeness responses in pdf format is also attached, which consists of the responses, a revised Index, a cover sheet for Exhibit R, and the pdf version of the Exhibit R.

Please note that I have copied, Attorney Pat Gerner in on this email. I would appreciate it if Attorney Gerner could be included in all future communication between COS & OCHA regarding this application.

Please let me know if you need anything further. Thank you.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Docket Number 16-32117-CON
Completeness Questions Responses

- Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Essex Service Area

Fiscal Year: 2015

Provider Name and Address	Number of Patients Referred	Distance from Essex
Middlesex Hospital dba Shoreline Medical Center ED 250 Flat Rock Place Westbrook, CT 06498	639	4.5 miles
Middlesex Hospital Outpatient Center 534 Saybrook Road Middletown, CT 06457	78	19 miles
Middlesex Hospital 28 Crescent Street Middletown, CT 06457	49	22 miles
Open MRI of Middletown 140 Main Street #7 Middletown, CT 06457	48	22 miles
Guilford Radiology 1591 Boston Post Road 106 Guilford, CT 06437	29	18 miles
Groton MRI 565 Long Hill Road Groton, CT 06340	11	23 miles
Middlesex Hospital dba Marlborough Medical Center 12 Jones Hollow Road Marlborough, CT 06447	5	26 miles
Yale MRI 801 Howard Avenue New Haven, CT 06510	6	30.7 miles
Lawrence and Memorial 196 Waterford Parkway S # 102 Waterford, CT 06385	3	17 miles
Radiology Associates of Wallingford 67 Masonic Avenue #7 Wallingford, CT 06492	3	41 miles

Provider Name and Address	Number of Patients Referred	Distance from Essex
Jefferson Radiology 1260 Silas Dean Highway Wethersfield, CT 06109	5	31 miles
Radiology Associates of Middletown 57 S Main Middletown, CT 06457	4	23 miles
Open MRI of Branford 1208 Main Street Branford, CT 06405	3	24 miles
Open MRI of Glastonbury 123 Hebron Avenue Glastonbury, CT 06033	3	36 miles
Radiology Associates of Hartford 31 Sycamore Street #102 Glastonbury, CT 06033	2	27.5 miles
Whitney Imaging 2200 Whitney Avenue #120 Hamden, CT 06518	1	38 miles
Backus Hospital 326 Washington Street Norwich, CT 06360	1	30 miles
Day Kimball Hospital 320 Pomfret Street Putnam, CT 06260	1	63 miles
Naugatuck Valley Radiology 1389 West Main Street Waterbury, CT 06708	1	46 miles
Hartford Hospital 85 Seymour Street #200 Hartford, CT 06106	1	38 miles
Madison Radiology 2 Samson Park Drive Madison, CT 06443	1	13 miles
MRI of New Britain 100 Grand Street New Britain, CT 06052	1	34 miles
St. Francis MRI 114 Woodland Street Hartford, CT 06106	1	39 miles
Manhattan Diagnostic Radiology 400 E 66 Street New York, NY 10066	1	104 miles

The above table provides information for all patients (951) who were referred by Shoreline Orthopedic and Sports Medicine to a non-COS MRI scanner in 2015. Please note that this information could not be extracted electronically from the medical records, and was compiled manually from each patient record. As a result, there is a 12 person difference between the total number of patients reported here and what was reported in Exhibit L of the CON application (963).

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?

Accessibility is more than just having an open time slot in another MRI provider schedule. COS improves our patient accessibility by working directly with each patient to accommodate to their personal schedule. COS has early morning hours at 7 am so patients can be seen before work and they are open until 9 pm for after work hours. Likewise, if a patient cannot be seen during the week, COS will open on a weekend to accommodate the patient. If a patient presents with an acute injury and there is an emergent need for MRI, COS holds daily stat slots to accommodate these patients, again providing improved accessibility over traditional radiology centers. If the patient is in pain or in a position where the injury is made worse by moving around, traveling to another office creates a situation where having the MRI scan at a different location is not as accessible as walking (or being wheeled) down a hallway within the COS office to have the MRI performed. The time delay is also a factor, as orthopedic treatment should be administered as early as possible after the injury.

Currently almost all of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS, and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to non-COS providers for MRI scans. This is due to lack of capacity of the existing scanners in Hamden and Branford, and the geographic distance of these COS scanners from the Shoreline Orthopedic offices. Accessibility will be improved because the COS patients who use the proposed 1.5T mobile MRI will be able to have the MRI scan performed in the doctor's office without having to schedule and travel to another location and without waiting longer for the results.

3. Who will staff the mobile MRI? Will the staff be the same at both locations?

One FTE receptionist and 1 FTE MRI tech will be required for services provided in the mobile MRI unit. It is anticipated that both the receptionist and MRI tech will travel to both locations. Both the receptionist and the MRI tech will be COS employees. COS will continue to utilize Dr. Joseph Gagliardi as our radiologist to read the MRI studies in the two additional locations.

4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.

In numerous locations in the above-referenced CON application, the method of "bundled payments" is discussed. COS has a bundled payment program with 3 major payors for outpatient reconstructive of both total knees and hips, and is working to include all of its payors in this program.

There is a correction that needs to be brought to the attention of OHCA which was only recently discovered as the applicant prepared for OHCA's Completeness Answers. The bundled payment program does not yet include the cost of the MRI. The MRI is often utilized as part of the diagnosis, and currently the bundled payment program does not begin until the injury is diagnosed and treatment begins. As both COS and the payor community become more familiar with the intricacies of bundled payment reimbursement, which includes the collection of data for post-operative complications

and patient outcomes, it is anticipated that more services (including MRI), can be included into the bundle. As both COS and the payor community become more familiar with the intricacies of bundled payments as well as further transformation from fee for service to value based reimbursement, it is anticipated that more services, including MRI will be included in risk based payment models. As the bundle becomes more complete, with both pre-operative and post-operative services, the risk sharing between provider and payor will allow for even greater savings to the delivery system.

The existing bundled payment plan already reduces the cost for the patient and payor. The efficiency of the outpatient total joint procedures (i.e., total hip and knee replacements) has allowed the payor to lower patient deductibles associated with inpatient procedures while lowering the total cost of the surgical event by several thousands dollars as compared to the same procedure done on an inpatient basis. The savings to the patient and the payor that are incurred for these procedures are as follows:

Pre- op visit	\$50
Home visit assessment	\$250
Physical therapy 16 visits @ \$35 / visit	\$560
ASC deductible or co insurance	\$3,000
Professional fee deductible or co insurance	\$1,995
Anesthesia fee deductible or co insurance	\$1,020
Pain block fee deductible or co insurance	\$420
DME deductible or co insurance	<u>\$100</u>
TOTAL	\$7,395

5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.

Presently, the patients in COS who are under the bundled payment program make up approximately 3%. This is due to the fact that bundled payment programs are new and COS is the only practice in CT that is providing outpatient total joint procedures under a bundled payment arrangement. As healthcare reimbursement transitions from fee for service to pay for performance, capitations and bundled payment programs, it is anticipated that the percentage will increase in a dramatic fashion.

6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?

COS accepts Medicaid recipients at all of its offices and facilities; COS does not discriminate patients based on insurance type or ability to pay. The availability of MRI service in Orange and Essex at the physicians' offices will enhance the ability of all patients to access this necessary diagnostic modality. The MRI service is managed by Dr. Gagliardi, a board certified radiologist, who is able to read the MRI scan and report the findings back to the treating physician within the same day, but no later than 24 hours after the scan. The short time between the MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of health care provided. While this service will only be available two days a week in both locations, it will allow more COS patients (Medicaid and all others) to take advantage of a seamless health care service.

7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).

The estimated costs for the installation of the MRI trailer at the Orange and Essex locations were revised subsequent to the publication of the newspaper notice which listed a capital expenditure of \$675,000. At the time of the publication the installation costs were projected to be \$100,000 and the revised estimate increased the costs by \$35,000 to \$55,000. Therefore, the costs now range from \$135,000 to \$155,000. We have used the higher installation estimate in projecting the project costs. Additionally, a clerical error occurred in the completion of Table 3 as submitted in the CON application. The corrected Table 3 follows. Copies of the purchase agreement for the MRI unit and trailer with MedExchange International, Inc., and an estimate for the trailer installation by Kingsbrook Development Corp. are found in Exhibit M of the CON application, starting on page 199.

**REVISED TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$575,000
Land/Building Purchase*	
Construction/Renovation**	\$155,000
Other (specify)	
Total Capital Expenditure (TCE)	\$730,000
Lease (Medical, Non-medical, Imaging)***	0
Total Lease Cost (TLC)	0
Total Project Cost (TCE+TLC)	\$730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

8. Why was there a drop in MRI volume at the Branford facility in FY2013?

The drop in MRI Branford volume at the Branford facility was multi-faceted. Problems existed with the 1T MRI unit that was located in Branford and it was replaced at the end of 2013. There were several significant down time periods throughout 2013 when the unit was out of commission, and patients were either referred to COS MRI unit located in Hamden or other facilities. In December of 2013, the 1T unit was replaced with a refurbished 1.5T GE magnet. This installation took 2 weeks and resulted in additional loss of patient volumes.

9. Why was FY 2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?

Between 2014 and 2015, COS merged with four (4) other orthopedic physician group practices. (See CON App., Q. #1, p.16). This merger expanded the total number of physician offices from 8 to 21 for a practice that now has 49 physicians. Patient volume increased from 6,302 scans in FY 2014 to 7,624 scans in FY 2015. The significant expansion of COS in 2014 - 2015 is the primary reason that a second MRI is needed. This volume is not expected to go down in the future because of the large increase of physicians in the COS practice. Therefore, FY2015 is a true reflection of COS patient volume because it reflects the expanded size of COS. It was selected as the base year because it was the most recently completed FY, and the number of scans is actual, not projected.

The four practices that merged with COS are Center for Orthopedics, Shoreline Orthopedics and Sports Medicine, The Orthopedic Group and Orthopedic Health. The merger and resultant increase in the number of COS physicians resulted in a significant increase in the number of MRI scans in 2014, 2015 and projected for 2016. Both of the existing COS scanners (located in Branford and Hamden) experienced increases in the number of scans, all related to the expansion of COS.

10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI?

There are no articles that speak specifically to mobile MRI units. The reality is that there is no difference between a "fixed" MRI vs. a mobile MRI. Both units are 1.5 T in magnet strength. The only difference is that a mobile unit is located within a tractor trailer and is therefore capable of being moved from one location to another. There is no difference in the resolution of the MRI study. The patient experience is essentially the same because the units are identical in capability.

Both existing COS "fixed" MRI scanners have received accreditation from the American College of Radiology (ACR). ACR accreditation will be obtained for the proposed mobile MRI scanner if approved. (CON App., p. 22 and Exhibit H).

11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark)

The proposal meets the in-office ancillary services ("IOAS") exception that is provided to group practices under the Stark law.

The Stark Law, 42 USC §1395nn(a)(1)(b), prohibits a physician from making a referral to a Designated Health Services entity ("DHS entity") for the furnishing of designated health services that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies 42 USC § 1395nn(a)(1)(b).

The exceptions include the In-Office Ancillary Services (“IOAS”) exception, which allows radiology services such as MRI to be performed within a physician group as long as certain requirements are met. The Applicant, COS, complies with all of the Stark requirements in order to meet the demands of the exception to the general rule.

This is the current law in effect, and there does not appear to be any intent on the part of Congress to eliminate the In-Office Ancillary Services exception. To the contrary, there has been discussion that many of the Stark restrictions are impeding the ability to lower the cost of health care – and as a result, some of the restrictions should be eliminated. In December of 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral rule, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. “Support for Stark law reform has grown in recent years, and following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger.” See Senate Finance Committee Majority Staff Report, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models” Exhibit R, p. 1.

This “white paper”, published after round table discussions on issues related to the physician self-referral law, stated, “The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models.” Exhibit R, p. 2. The case is being made to eliminate the Stark Law completely, not to eliminate the In-Office Ancillary Exception.

While there is still debate about whether to eliminate or restructure the Stark Law in the future, at this time the In-Office Ancillary Service exception is still the law, and the Applicant, COS, conforms to this federal law.

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EXHIBIT R

Why Stark, Why Now?

Suggestions to Improve the Stark Law to Encourage
Innovative Payment Models



A Senate Finance Committee Majority Staff Report

Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

Senate Committee on Finance, Majority Staff
Chairman Orrin Hatch (R-Utah)

I. INTRODUCTION

On December 10, 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral law, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the Stark law.

The Stark law prohibits a physician from referring Medicare patients for “designated health services” (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.¹ Financial relationships include both ownership and investment interests, as well as compensation arrangements. In addition, the law prohibits an entity from billing the Medicare program for services provided pursuant to an impermissible, or tainted, referral.

Support for Stark law reform has grown in recent years, and, following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger. The strict liability regime, huge penalties, and the breadth, complexity, and ambiguities of the Stark law and its regulations have created what is often referred to as a minefield for the health care industry. With this backdrop, attempts by Congress, the Centers for Medicare & Medicaid Services (CMS), and the private sector to encourage value-based payment models have not effected change as quickly as some had hoped. While many providers would like to move toward alternative payment models, most are reluctant to do so because they must contend with the tension between the Stark law and alternative payment models and the possibility of devastating penalties if they guess wrong.

The round table participants discussed whether changes to the law were necessary to implement MACRA and, if so, what options would work best in a system that includes both the fee-for-service (FFS) payment model and alternative payment models. After the meeting, the Committees invited the round table participants and others to share their views on the Stark law.²

The round table participants and the groups that submitted comments for the Committees’ review included Stark law experts, academics, attorneys in private practice who work with

¹ Section 1903 of the Social Security Act, 42 U.S.C. § 1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.

² In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a “Convener on Stark law” (Convener Session) held on April 24 and June 30, 2009, in Washington, D.C. A white paper was published entitled, [A Public Policy Discussion: Taking the Measure of the Stark Law](#), which summarizes the discussion and proposals for changing the

hospitals and/or physicians, attorneys in the private sector who previously served in government regulatory and enforcement agencies, hospital systems, electronic health record providers, as well as associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.

II. EXECUTIVE SUMMARY

Congress enacted the Stark law to limit the influence of financial relationships on physician referrals. If a physician (or an immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of DHS under Medicare and, to some extent, Medicaid, unless an exception applies. 42 U.S.C. § 1395nn; 42 U.S.C. § 1396b. A “financial relationship” is defined as any direct or indirect (1) ownership or investment interest or (2) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS. An entity may not bill for DHS provided as the result of a tainted referral.

Congress intended the Stark law to provide a bright line test to curb physician self-referral. But despite CMS’s efforts to provide clear rules and interpretations to address the strict liability regime, the Stark law’s breadth, complexity, and impenetrability have created a minefield for the health care industry. As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted last year, “even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.” [United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.](#), No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Before Congress passed health care reform, the health care industry recognized that the Stark law would be an obstacle to hospitals’ and other providers’ efforts to align incentives with physicians for certain alternative payment models, including pay-for-performance, gainsharing, bundled payment or outcomes measures. During the American Health Lawyers Association’s (AHLA) 2009 Stark discussion, many participants noted that alternative payment programs inevitably link physician payments to

law itself or its administration or enforcement. Although the topics covered do not overlap precisely, our December 2015 round table was an effort to look at what changes had taken place since 2009, given the passage of the Affordable Care Act in 2010 and MACRA in 2015. The views shared by the round table participants and subsequent commenters reflect the changing legal landscape between 2009 and the present, but they also echo many of the underlying issues discussed in the 2009 AHLA session.

the volume or value of physician referrals³ – a payment formula that generally will not pass muster under the compensation arrangement exceptions to the Stark law.⁴

Congress also recognized that alternative payment models would be difficult or impossible to establish in the current FFS enforcement environment. As a result, the Affordable Care Act (ACA) included an authorization for the Health and Human Services (HHS) Secretary to issue regulatory waivers from the Stark law and other fraud and abuse laws for innovative payment and service delivery models.⁵ Under that authority, the Secretary has issued waivers from fraud and abuse laws for participants in the Medicare Shared Savings Programs (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI), the Comprehensive Care for Joint Replacement (CJR), and other Accountable Care Organization (ACO) programs.

MACRA's modification of the Civil Monetary Penalties (CMP) law, 42 U.S.C. § 1320a-7a, (specifying that the gainsharing prohibition applies only to inducements made to reduce or limit medically necessary services to beneficiaries) has removed some barriers to gainsharing and pay-for-performance programs. Nevertheless, as the waivers for CMS demonstrations illustrate, the Stark law continues to pose significant risks for implementation of such programs. Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

The Committees invited the round table participants to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

Although the comments that we received were wide-ranging, there were many recurring themes. To implement health care reform, many comments focused on potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS's regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety. Comments also concentrated on other important non-MACRA issues, including changes to standard Stark law definitions, like fair market value, the volume and value of referrals, and commercial reasonableness. In distinguishing technical and substantive violations, comments centered on documentation requirements and harm to beneficiaries or federal health care programs.

³ Reducing unnecessary FFS procedures or services reduces costs but increases profit (*i.e.*, value).

⁴ AHLA, [A Public Policy Discussion: Taking the Measure of the Stark law](#), at 9 (2009) (hereinafter, [AHLA 2009 White Paper](#)).

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, (2010).

Some commenters submitted other suggestions for improving the law, including changes or clarifications to in-office ancillary services exception, the physician-owned hospital exception, documentation requirements, and others. This white paper focuses on potential changes to the Stark law to remove hurdles to implementing health care reform and on how to distinguish technical and substantive violations. The other issues that are not addressed in detail in this white paper may be considered by the Committee at a future point in time.

III. STARK LAW BACKGROUND

Under an FFS payment model, physicians have a financial incentive to provide more services. When a physician has a financial interest in an entity to which he or she refers patients, the incentive extends to ordering tests, procedures, or referring patients to that entity. The issue received attention in the 1980s, and, by 1989, the HHS Office of Inspector General found that physician self-referral related to laboratory tests was associated with a marked increase in utilization.⁶

That year, Congress passed the Ethics in Patient Referrals Act of 1989 (Stark I) prohibiting a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. Stark I also prohibited the lab from billing for any services furnished pursuant to a tainted referral. To prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership, Congress also prohibited circumventions schemes and compensation arrangements. Stark I became effective January 1, 1992. Congress soon expanded the clinical laboratory prohibition to ten “designated health services” in the Omnibus Budget Reconciliation Act of 1993 (Stark II), which became effective January 1, 1995. Stark I and Stark II each included exceptions to the general prohibition.

CMS has published a series of regulations implementing the Stark law, beginning in 1992.⁷ The final rules, listed below, are codified at 42 C.F.R. § 411.350–411.389.⁸

- Stark I regulations, August 14, 1995.
- Stark II Phase I regulations, January 4, 2001 (interim final rule).
- Stark II Phase II regulations, March 26, 2004 (interim final rule).
- Stark II Phase III regulations, September 5, 2007.
- Stark II Phase IV, Inpatient Prospective Payment System (IPPS) regulations, August 19, 2008.
- Stark II Phase V, IPPS regulations, October 30, 2015.

⁶ OIG-Office of Analysis and Inspections, Report to Congress, [Financial Arrangements Between Physicians and Health Care Businesses](#), 3 (May 1989).

⁷ AHLA’s [2009 White Paper](#) includes a chart with a helpful description of the regulatory changes from 1992 through 2009, at pages 4-5.

⁸ The CMS website has a list detailing the Stark law’s [significant regulatory history](#).

Several commenters stated that the Stark law is not a “fraud” statute, but a regulation of payment. There is no requirement of an intent to violate the statute and compliance is a straightforward condition of payment. These commenters noted that Congress intended to provide a bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.

Even with regulatory exceptions and guidance, the result has been an extremely broad prohibition on physician referrals. If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions.⁹ But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, “takes into account” volume or value of referrals, and commercially reasonable—are factual, which means parties must prove that their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes. The unpredictability is especially frustrating given the enormous penalties under the Stark law, which can be much higher than penalties for fraudulent activity.¹⁰

Commenters also noted the high cost and difficulty of complying with the Stark law. Even tracking non-monetary compensation issues can cause headaches for hospitals and physicians. For instance, if a physician agrees to join an ACO, it makes sense to provide access to the same electronic health record system used by the rest of the network. While the current MSSP waivers address this concern, if the physician leaves the ACO, or when the waivers expire, the physician may face Stark liability, which is just one additional hurdle to physicians joining ACOs and other integrated health care entities.

Some participants noted the law’s inflexibility, as it prohibits any financial arrangement with a physician that does not fit within an exception. This inflexibility is underscored as providers attempt to implement alternative payment models like ACOs, pay-for-performance, shared savings, and bundled payments, which do not always fit into existing exceptions. Participants and commenters generally agreed that the Stark law does not have a place in the pay-for-value world because it was created to address overutilization in an FFS environment. Many participants and commenters believe that the law is disruptive to the development and implementation of value-based models.

⁹ The requirement that the financial relationship fit within an exception is different than the option to fit a relationship within a safe harbor to the Anti-Kickback Statute (AKS). Under the AKS, financial relationships that do not fit squarely within a safe harbor do not necessarily violate the AKS.

¹⁰ If a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services from that physician are “overpayments” and must be returned, regardless of the amount of the “tainted” transaction or nature of the payment. In contrast, even the new authority in the ACA expanding the false claims liability for violations of the AKS is limited to claims “resulting from” the kickback.

Although many areas for improvement were discussed, especially those to usher in health care reform, round table participants and commenters also recognized that the Stark law has been effective in restricting physician ownership and investment in entities such as free-standing imaging centers and other providers of ancillary services. The law has also encouraged the industry to focus on compliance because of the need to closely scrutinize physician relationships, but several commenters noted that in practice the burden of compliance falls upon hospitals. Round table participants praised the establishment of the Self-Referral Disclosure Protocol, which enables providers to disclose Stark violations and permits CMS to compromise repayment amounts. Some participants noted that the settlements under the Protocol have been fair and reasonable. But several participants believe that the process is too time consuming and does not provide certainty to disclosing parties. Some commenters point to exceptionally high settlements for disclosures of technical violations based on documentation issues alone.

IV. STARK LAW IN CONTEXT

Round table participants and commenters discussed the Stark law in the context of other enforcement authorities and reimbursement rules that may also address physician self-referral practices.

Anti-Kickback Statute. Many commenters noted the imperfect and often confusing overlap between the Anti-kickback statute (AKS), 42 U.S.C. § 1320a-7b, and the Stark law.¹¹ Relationships that are permissible under the Stark law may violate the AKS, which some commenters said means the Stark law occasionally undermines the enforcement of the AKS. When Congress passed the Stark law, there was no civil liability for anti-kickback violations under the CMP law, and it was unclear whether the government could use an anti-kickback violation as a predicate for a False Claims Act (FCA) case.

With the expansion of the scope and application of the AKS over the years, however, many participants and commenters argue that the Stark law is no longer needed. The AKS can now be enforced in the civil context through the FCA and the CMP law. Not all participants agreed that the Stark law was no longer needed, in part because the FFS payment model would still be used to some extent for years to come.

Compounding the complicated overlap between these two statutes, is the disproportion in penalty levels. Penalties are smaller for AKS violations, which require knowing and willful intent, meaning the underlying conduct is arguably much more egregious.

False Claims Act. The FCA has become the primary enforcement mechanism of the Stark law. 31 U.S.C. § 3729–3733. While the Stark law prohibits physician referrals to an entity based on non-compliant financial relationships, from an FCA perspective, the focus is on the prohibition on billing for services furnished pursuant to a tainted referral. FCA exposure is created if the claims were submitted with the requisite intent (reckless disregard or deliberate

¹¹ While this may be an area that would benefit from further examination by Congress, the AKS is outside the Finance Committee's jurisdiction, and while we may refer to comments that mention the AKS, we are unable to address those concerns at this time.

ignorance of their truth or falsity). The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the potential for FCA exposure by revising the definition of a claim to include the knowing and improper retention of an overpayment.¹² 31 U.S.C. § 3729(a)(1)(G). In 2010, the ACA added the “60-day rule” requiring providers to “report and return” a Medicare or Medicaid overpayment within 60 days “after the date on which the overpayment was identified.” 42 U.S.C. § 1320a-7k(d)(1)–(3). Thus, under the FCA’s reverse false claims provision, an entity that submits a claim with no knowledge that it may be prohibited by the Stark law may face FCA exposure if (1) the entity later discovers the Stark violation and (2) fails to report and return any reimbursement associated with the tainted claim within the 60-day period.¹³

Some commenters expressed concerns with recent FCA litigation, noting that certain aspects of the Stark law have led to a number of recent FCA settlements that threaten the development of integrated delivery systems. The commenters pointed to several recent FCA settlements based on a *qui tam* theory that an accounting loss for hospital-owned physician practices is *ipso facto* evidence that the employed physicians are paid more than fair market value and that the arrangement is not commercially reasonable. The commenters acknowledge that the complaints for some of the recent settlements may involve extreme facts but are nonetheless concerning as potential examples of bad facts making bad law.

Reimbursement. Some round table participants noted that reforming reimbursement rules may address the Stark law’s underlying concern of overutilization. Some suggestions included decreasing reimbursement for ancillary services provided through a physician’s group practice, bundling the payment for physician office visits and ancillary services, and adopting bundled payment plans that promote shared risk among providers involved in an episode of care.¹⁴ Although we did not receive comments in direct opposition to these suggestions, we received numerous comments both in favor of and against any changes to the in-office ancillary services exception which could serve as an alternative to payment changes for such services.

V. IMPLEMENTING MACRA AND OTHER ALTERNATIVE PAYMENT MODELS

As noted above, the Committees invited round table participants and others to share their perspectives on what changes to the Stark law might be necessary to implement health care reforms promoting alternative payment models, such as MACRA. Participants were asked to

¹² Prior to FERA, liability for retention of an overpayment required an affirmative step to evade repayment through a false record or statement and only if it could be established that repayment was an “obligation.” This provision became known as a reverse false claim.

¹³ In rejecting two motions to dismiss, the District Court for the Southern District of New York recently addressed what it means to “identify” an overpayment and start the clock for the 60-day rule under the FCA. *U.S. ex rel. Kane v. Healthfirst, Inc., et al.*, No. 11 CIV 2325, 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

¹⁴ For additional reimbursement suggestions shared during AHLA’s Convener Session, see, [AHLA 2009 White Paper](#), at 12.

include in their suggestions options that would work in a payment environment that includes both FFS and alternative payment models.

The comments generally focused on potential new waivers or exceptions, expansions of existing waivers or exceptions, changes to standard Stark law definitions, broadening the Secretary's authority, or repealing the law or the compensation arrangement prohibition. The relevant comments are summarized by category below.

Repeal. Many commenters suggested that the Stark law has outlived its utility. These commenters argue that the AKS in its current form can address the conduct that the Stark law seeks to curtail. However, some commenters noted that the Stark law addresses conduct that may not fall under the AKS. Additionally, while the FFS payment model is being phased out, it will continue in some form for many years. With this in mind, some commenters advocating repeal recommended that the Stark law be sunset once Medicare had transitioned to alternative payments to a meaningful extent.

Repeal Compensation Arrangement Prohibitions. A larger group of commenters believed that repealing the compensation arrangement requirements would address many of the concerns not only with implementing health care reform but with the Stark law's most difficult provisions. They recommend limiting the Stark law to ownership and investment interests, which they believe was Congress's original intent. However, as some commenters noted, prohibitions on compensation arrangements have been in the law from the beginning and were included to avoid schemes to circumvent the law with creative arrangements that would give physicians the benefits, and dangers, of ownership but that did not involve equity.¹⁵ Other commenters argued that the compensation arrangement prohibitions are no longer necessary because the AKS can now be enforced in a civil context through both the FCA and the CMP law.

New Risk Revenue Waiver/Exception. To lessen the burden of health care entities making the transition from FFS to alternative payment models, two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. Health care entities receiving such a waiver would be required to meet certain criteria, for example, having the governing board of the ACO entity approve applicable financial relationships through a process that validated Triple Aim¹⁶ principles and shows no motivation to increase utilization. Noting that some health care entities would never reach this level of risk based revenue, one of the commenters acknowledged that entities that did not reach such a level of risk engagement would still be required to meet a Stark

¹⁵ [AHLA 2009 White Paper](#), at 12.

¹⁶ See Donald M. Berwick, et al., [The Triple Aim: Care, Health, And Cost](#), Health Affairs, May/June; 2008, 27(3) at 759-769. "The Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the "Triple Aim": Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care." IHI website, [Triple Aim Initiative](#).

exception for certain arrangements. The other commenter framed the exception in terms of health care systems that derive no less than 50 percent of their health care revenue from alternative payment methodologies, and recommended that such systems receive a broad waiver from the Stark law similar to those now in effect for ACOs.

The commenters believe that enforcement agencies could use the AKS and the gainsharing CMP to address problematic arrangements. This idea accommodates the incremental transition to value-based payment models. However, some round table participants questioned how health care entities could reach a threshold percentage without being at risk, arguing that this type of fix would simply shorten the period of exposure for a subset of providers.

Create New or Expand Currently Restricted Waivers. Most commenters suggested extending the waivers that are currently highly limited to CMS-run programs to all payers. Many commenters believed that expanding the waivers for the MSSP to qualifying alternative payment model participants would be the best solution.¹⁷ Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current Center for Medicare & Medicaid Innovation (CMMI) waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority.

Commenters agreed not only that Congress should create waivers to address the problem but also that Congress should give HHS broader authority to create regulatory waivers. While commenters generally agreed that some new waivers could be created through existing but limited CMS rulemaking authority, most agreed that Congress should give CMS express authority to create broader waivers than currently authorized by law.¹⁸

Some commenters argued for consistency in fraud and abuse laws' applicability to ACO programs for all government-supported innovative payment models. One suggestion to accomplish such consistency was the creation of a new Stark law exception at 42 U.S.C. § 1395nn(b) that would apply to MIPS, physician-focused payment models, and payments associated with alternative payment models. Another suggestion was to create a waiver that would apply to MIPS, alternative payment models, and ACOs, modeled on current Stark exceptions for Medicare prepaid plan enrollees. These type of waivers could address issues in an environment that includes both FFS (MIPS) and alternative payment models.

¹⁷ CMS and OIG, HHS, [Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66,726](#) (Oct. 29, 2015) (codified at 42 C.F.R. Chs. IV and V).

¹⁸ Recommendations to expand the Secretary's authority to create waivers and exceptions are discussed below.

Create New Exceptions. Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the “APM Exception”) apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a fair market value requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals.

Other commenters stated that a new exception should be available for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care (referring to integrated delivery systems, accountable care, team-based care, or value-based payment arrangements). Some commenters, concerned that an exception may focus on institutional providers, expressed the need for an exception that took into account the breadth and scope of providers and entities necessary for truly integrated health care. Other commenters emphasized that the new exception should be available for truly clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. Commenters also noted the need to protect shared savings and incentive programs, as well as any arrangement start-up or support contribution, when certain conditions are met.

One commenter suggested an approach to accommodate alternative payment models, either under MACRA or more broadly, that would involve adding an additional statutory exception for alternative payment models that promote and advance accountability for quality, cost/risk, care coordination, patient experience, and outcomes. To qualify for the exception, which could be added to the compensation arrangement exceptions at 42 U.S.C. § 1395nn(e), arrangements would need to meet conditions that are already used to qualify ACOs and other risk-sharing arrangements under the Stark law and AKS. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

Special Compensation Rule. The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA alternative payment model financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

Modify Existing Exceptions. Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives.

Most Stark law exceptions protect a “financial relationship” and except the relationship from triggering the prohibition on DHS referrals. Other exceptions, like the prepaid plan exception at 42 U.S.C. § 1395nn(b)(3), only protect the services that would otherwise be

prohibited DHS referrals. The prepaid plan exception, for example, only protects referrals of services to the prepaid plan but still prohibits FFS referrals to the same party. Several commenters recommended Congress broaden the statutory prepaid plan exception so that the prohibition on referrals for DHS would not apply to services rendered by an entity that has a contract with CMS or its agent that contemplates the use of alternative payment models. Alternatively, the exception could be framed so that it protects DHS furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO, or any other ACO model established by CMS or tested under CMMI. Either scenario should protect services that would otherwise be prohibited DHS referrals; FFS referrals to the same party would still be prohibited. These commenters argue that this would provide more certainty for the regulated community than an extension of the regulatory waiver approach for ACO arrangements.

Several commenters recommended Congress expand the risk-sharing exception at 42 C.F.R. § 411.357(n) to apply to Medicare and Medicaid FFS programs. Other commenters would expand the exception to incentive payment arrangements between a DHS entity and a physician participating in a qualified alternative payment model (others framed this as applying to compensation arrangements involving integrated care organizations). Some commenters recommended that a new exception be created based on the risk-sharing exception that would apply to MSSP, Pioneer, Next Generation ACO, or other CMS or CMMI ACO models, as long as the arrangement is reasonably related to one of the purposes of the respective program. The exception would explicitly cover payment arrangements that are downstream of bundled payments, shared savings, and other alternative payment programs implemented by governmental or private payers. Commenters advocated for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, as amended by MACRA, specifically the modifications to the gainsharing prohibition. They also recommended a clarification that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to the hospital.

One commenter recommended Congress codify the existing exception applicable to services furnished by an organization (or its contractors or subcontractors) to enrollees set forth at 42 C.F.R. § 411.355(c), and modify it to incorporate alternative payment models, including those involving integrated care organizations, as being eligible for protection.¹⁹

Another commenter noted that although the current Stark rules do not pose major obstacles for parties to enter into bundled payment or gainsharing arrangements, some legislative changes or clarifications to the Stark law could provide much needed comfort for parties who are uncertain how to proceed or fear inappropriate enforcement efforts.

One area the commenter identified for clarification is the definition of an indirect compensation arrangement, which, along with the exception for indirect compensation

¹⁹ For purposes of consistency, the commenter recommended that the definitions of health plan and enrollees under 42 C.F.R. § 1001.952(1) be modified to contemplate ownership and compensation relationships arising out of alternative payment models.

arrangements, is one of the most complex and frustrating areas of Stark regulation. The definition includes three components. One of those components is based on the referring physician's receipt of aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. *See* 42 C.F.R. § 411.354(c)(2)(ii). The commenter recommends that Congress clarify that where the physician's compensation from an entity with which he or she has a direct compensation arrangement does not necessarily rise as a direct result of more referrals or higher paying referrals, the aggregate compensation test is not met.

Additionally, the commenter notes that although arrangements where physicians are paid a percentage of savings are common, CMS has never expressly recognized that a percentage of savings can be fair market value and commercially reasonable. To resolve uncertainty and to promote non-abusive shared savings arrangements, the commenter recommended that Congress adopt CMS's deeming provision for per-click compensation arrangements, 42 C.F.R. § 411.354(d)(2), and extend it to percentage compensation arrangements. The commenter also recommended that Congress amend the Stark law to state that an arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception. Alternatively, Congress could provide that an arrangement under which a physician would receive a percentage of savings realized by the hospital or other provider or supplier will be presumed (or deemed) to satisfy the fair market value and commercial reasonableness requirements of an applicable exception if the parties relied in good faith on an opinion from a nationally recognized appraisal firm. To prevent opinion shopping, the statute must provide that all opinions (draft or otherwise) of fair market value and commercial reasonableness would be taken into account when determining whether the parties relied in good faith on a favorable opinion. One commenter suggested that such a change should include some standard to govern the amount that can be shared with physicians, such as a cap or threshold.

Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions. Some commenters noted that the Stark law and regulations are payment regulations that providers must comply with to receive payment. An effective regulatory regime requires that the regulated community be able to obtain timely and clear guidance. Commenters offered a number of suggestions in this regard.

Commenters generally agreed that Congress should expand the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

The Stark law permits the Secretary to create regulatory exceptions that the Secretary determines do "not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). CMS has taken a cautious approach in issuing Stark exceptions.²⁰ Commenters believe that many of

²⁰ Although CMS recently provided additional guidance on the Stark law, [Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885](#), 71300-71341 (Nov. 16, 2015), at least one commenter

the existing exceptions are too narrow or complicated to be useful but that more practical exceptions could be issued if the Secretary were given authority to create exceptions where an arrangement does not pose an undue or significant risk of program or patient abuse. Commenters also noted that HHS has greater authority and flexibility to create safe harbors to the AKS, a criminal statute, than it has to create exceptions to the Stark law, a regulation of Medicare payment.

Several commenters also urged Congress to strengthen the Secretary's authority to issue Stark advisory opinions and promote timely agency guidance. One commenter noted that if an exception for innovation arrangements were adopted, it could permit the submission of a request through the CMS advisory opinion process, which would provide added comfort to both CMS and the industry. The commenter noted that Congress could direct CMS to modify its current regulations to accommodate the review process and set forth other requirements CMS considers necessary to organize, facilitate, and fund the analysis and the timely issuance of advisory opinions dealing with innovation arrangements that promote the Triple Aim. This commenter noted that such advisory opinions should not be required, but that they should be available to provide added comfort to the industry in a time of innovation and change.

The participants and commenters agreed that the creation of the Self-Referral Disclosure Protocol (SRDP) and the expansion of the Secretary's authority to compromise Stark repayment obligations were positive developments in Stark law enforcement. Nevertheless, some said the process was too lengthy and left providers in limbo while they waited for a disposition. Many commenters argued Congress should give CMS more discretion to settle Stark law violations, such as providing CMS with the explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount.²¹ One commenter suggested Congress give CMS discretion to determine whether to prohibit billing for violations, which could have far-reaching implications, including taking Stark law violations out of the realm of FCA litigation.

Some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex. These commenters also believed it would not be effective to simply strengthen the Secretary's advisory opinion authority to promote timely agency guidance because, based on 25 years' worth of rule-making, they believe Congress should revise the law entirely. In their view, advisory opinions only help at the margins, and, in almost all cases, very slowly.

VI. DEFINING TECHNICAL VIOLATIONS

Commenters generally agreed that "technical" violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment

believed that the agency could be more hesitant to issue exclusions after the recent decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). This concern underscores the importance of consideration of an explicit grant of authority to the Secretary.

²¹ Recommendations concerning a revised penalty structure are discussed below.

liability.²² Several commenters noted that Congress recognized the disparity between technical and substantive violations when it created the SRDP and authorized the Secretary to reduce amounts owed. In distinguishing technical and substantive violations, comments focused on documentation requirements, adherence to fair market value, the volume or value of referrals, or harm to beneficiaries or federal health care programs. But some commenters questioned whether drawing such a distinction would be helpful because it would be difficult to determine penalty provisions and enforcement priorities in an already hyper-technical environment. Their solution to the complexity would be to eliminate the compensation arrangements prohibition. As for penalties for technical violations, all commenters recommended that CMPs be assessed in lieu of penalties or that no penalty be assessed. Some commenters recommended further reducing the CMP if a party self-disclosed a violation within 60 days of discovery.

Documentation Requirements. Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement. Commenters and round table participants pointed to Representative Charles Boustany’s proposed legislation, the Stark Administrative Simplification Act of 2015, as a move in the right direction, specifically in terms of its definition of technical violations.²³ The proposed legislation defines “technical noncompliance” as arrangements that violate the law’s prohibition of self-referral “only because (i) the arrangement is not set forth in writing; (ii) the arrangement is not signed by 1 or more parties to the arrangement; or (iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.”²⁴

Several commenters added that technical violations are those that pose a low risk of affecting the Medicare fisc and are unlikely to result in increased use of medically unnecessary services.

Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making. In describing technical violations, some commenters included along with documentation requirements violations that are irrelevant to whether an arrangement incentivizes referrals. Outside the context of ownership, they only consider “substantive” violations of the Stark law to be compensation structures that induce or reward referrals (*i.e.*, the physician is paid for referrals). Some of these commenters recommended eliminating any technical violations that do not harm patients or Medicare and authorizing the Secretary to impose a CMP for each arrangement to reduce the impact of technical violations. One commenter suggested that a financial arrangement that a reasonable person would conclude creates a significant incentive to a physician to refer to a particular entity is substantive.

Fair Market Value. Some commenters suggested dividing violations into two categories: (1) those where compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume

²² [AHLA 2009 White Paper](#), at 16.

²³ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

²⁴ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

or value of referrals; and (2) those where compensation is not. However, commenters recognized that the division is not clear cut in practice due to the technical nature of the rules on fair market value and volume or value of referrals. Many commenters and participants agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.²⁵ One suggestion was to define technical violations to include any violation that does not involve fair market value (and perhaps commercial reasonableness) or the volume or value prohibition; and that, depending on the facts and circumstances, technical violations may include violations that involve fair market value, commercial reasonableness, or the volume or value prohibition.

Compensation Arrangements That Do Not Violate the AKS. Several commenters recommended defining technical violations as compensation arrangements that do not otherwise violate the AKS. In other words, as suggested above, prohibited ownership violations would be substantive noncompliance, and problematic compensation arrangements would be enforced through the AKS or the CMP law. One commenter suggested that any arrangements that do not confer a financial benefit to the referring physician should not be considered substantive and that technical violations should not carry Stark penalties.

Create Bright Line Requirements For Substantive Noncompliance. One commenter suggested first creating bright line requirements to improve clarity and then considering all noncompliance with those bright line requirements to be substantive. The commenter recommended that Congress direct CMS to specify, on a regular basis (*e.g.*, through Medicare Physician Fee Schedule rule making), compensation practices that are not permitted based on the agency’s experience. Only noncompliance with such specifically non-permitted compensation practices should be viewed as substantive noncompliance. As discussed below, concerns have been raised about Congress’s or CMS’s ability to create a list that would effectively cover all financial arrangements that may involve self-referral concerns.

Clarify Compensation Arrangement Terms. Several commenters recommended clarification of the three key terms in the compensation arrangement exceptions: fair market value (FMV), “takes into account” the “volume or value” of referrals, and commercially reasonable. The comments we heard echoed those raised during the AHLA discussion, including concerns about the difficulty of establishing and documenting FMV.²⁶

Some commenters recommended allowing physician compensation for providing high-quality and efficient care without violating the Stark law’s FMV standard, even if the compensation is related to the volume or value of the referrals. These commenters argue that the statutory definition of FMV simply reflects the clear rule that arrangements must reflect arm’s length bargaining and that the “volume or value” standard was a regulatory addition created by CMS. Another commenter also rejected CMS’ definition of FMV and recommended that Congress clarify that intent is not material in the strict liability law, and bar CMS from defining

²⁵ We received many comments recommending changes to terms associated with compensation arrangement exceptions. They are discussed in Section VI, below.

²⁶ See [AHLA 2009 White Paper](#), at 11-12.

essential terms (*i.e.*, FMV, commercially reasonable and volume or value of referral standards) in a purportedly circular, interconnected manner.

One commenter suggested amending the statute to provide that the FMV requirement is met where the compensation paid to the physician does not exceed FMV. Some commenters noted the confusion caused by the regulations' ambiguity on whether an arrangement that is FMV at its inception, but later falls out of FMV, continues to meet the FMV requirement. Long leases should not enjoy exception for years and short leases should not be punished if the lease falls out of FMV in six months. To address this concern, one commenter suggested that Congress could provide that arrangements that are FMV at their inception are presumed or deemed to be FMV throughout their life, up to some maximum period, such as two to three years. Alternatively, if a party obtains an FMV appraisal from a qualified, independent appraisal firm, it is entitled to rely on the appraisal for the life of the appraisal, up to a maximum of two to three years. A variation would be to specify that, in order to gain the protection of the FMV presumption or deeming, the appraisal be obtained before the arrangement begins. The commenter also recommended a similar provision for an appraisal regarding whether an arrangement is commercially reasonable.

A few commenters sought Congress's explicit confirmation that certain practices are acceptable and do not necessarily violate the Stark law. For instance, one commenter suggested that Congress confirm that DHS entities can base compensation on market surveys of similar arrangements without regard to whether those surveys involve actual or potential referral sources – given that the only available surveys involve entities (*e.g.*, medical practices, hospitals and other employers) and physicians who are in a position to make referrals. The commenter also suggested that the Stark law be amended to clearly state that nothing in the law prohibits a DHS entity from developing and using management, financial, and other reports that may include productivity or other data in their internal operations as consistent with typical business practices, so long as such reports are not used in decision-making regarding the compensation to be paid to individual physicians. Several participants at the round table suggested that Congress remove the “commercially reasonable” requirement from the employment and other compensation exceptions or clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.

Others suggested changes to other definitions. One commenter recommended that the definition of “group practice” be revised by removing the current volume or value standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all of the exceptions to the existing Stark law impose restrictions on compensation based on “volume or value” of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance. Another commenter suggested that the Stark law's definitions of remuneration and compensation arrangement be narrowed so that FMV exchanges do not implicate the Stark law.²⁷

²⁷ See [AHLA 2009 White Paper](#), at 12 (similar suggestion that compensation arrangement prohibitions apply only when payments vary with the volume or value of referrals).

Another commenter suggested Congress amend the Stark law to define reasonable safe harbors that would provide predictable refuge for hospitals that reasonably evaluate and document fair market value.

Intent. While not always tying the suggestion to the definition of technical violations, several commenters recommended that an intent requirement be added such that purely accidental omissions were not in violation of the Stark law. Some participants believed this would make the Stark law duplicative of the AKS rather than a payment rule.²⁸ Others recommended adding a harm to programs requirement to limit fines to situations where the prohibited referrals result in some demonstrable harm to the government or the patients served, with the burden of proof on the government.

Create Exception for Technical Noncompliance. One commenter recommended creating an exception for technical noncompliance based on the regulatory exception for certain arrangements involving temporary noncompliance at 42 C.F.R. § 411.353(f), but with fewer restrictions. The commenter did not specify how to differentiate between technical and substantive violations, but emphasized the importance of such an exception.

Determining the Penalty. Some commenters also advocated for the inclusion of mitigating factors when determining the penalties associated with technical violations, sometimes referring to the factors in the legislation creating the SRDP. Some commenters suggested that Congress give the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and those commenters also recommended that certain factors be considered with determining the penalty amount. Suggested factors included: (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance. A variation of a suggestion discussed in the previous section would be for Congress give CMS discretion to determine whether to prohibit billing for technical violations, which would allow CMS to compromise repayment amounts, to impose CMPs, or not to impose any penalty.

VII. GENERAL RECOMMENDATIONS BEYOND MACRA IMPLEMENTATION AND DEFINING TECHNICAL VIOLATIONS

Commenters noted general frustrations with Stark law compliance and explained the difficulties hospitals and other providers face in complying with the law. Several commenters noted that even if a provider fits its arrangements squarely within certain exceptions, the provider could still face lengthy and expensive legal battles because many exceptions are fact-specific. For instance, for challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements. As discussed

²⁸ See [AHLA 2009 White Paper](#), at 12 (similar comments on intent).

above, the same is true of each of the three standards (FMV, volume/value, commercial reasonable). The commenters believe that including requirements of separate laws stacks the deck against hospitals trying to obtain predictability with respect to their Stark law compliance. Although the concerns discussed below are not unique to implementing health reform, they create a chilling effect because both hospitals and physicians are wary not only of the difficulties associated with complying with the Stark law but also of the costs associated with defending even compliant arrangements.

Align Stark Law with AKS. As discussed above, many commenters believe Congress should align the Stark law and AKS. Congress (or for regulatory exceptions, HHS) could accomplish this by replacing certain Stark law exceptions with AKS exceptions. For instance, one commenter suggested that the Stark law bona fide employee exception should be made identical to the AKS bona fide employee exception, which unlike the Stark exception does not include a fair market value component. The commenter reasoned that if the concern giving rise to this exception is that part-time employees are more subject to abuse, then the Stark law's fair market value component could be limited to persons who are dually employed by a provider of DHS and a physician practice, but not be applied to physicians whose only employer is a provider of DHS. The commenter also noted that for all tax-exempt entities, there already are substantial constraints on compensation paid to employees. The commenter suggested that any compensation arrangement that satisfies an AKS safe harbor should also be exempt from the Stark law. Rather than maintaining two parallel, but not identical, sets of regulations that outline permitted practices, the commenter believes it would be better to rely on the AKS safe harbors and eliminate the separate, but not identical, exceptions to the compensation arrangements provisions of the Stark law.

Tax Exempt Exception for Compensation Arrangements. One commenter noted that the Internal Revenue Service (IRS) already limits compensation arrangements entered into by tax exempt entities, and that in light of such limitations, a potential carve out to the Stark law could be an exception applicable to any compensation arrangement that is entered into by a tax exempt enterprise. That commenter suggested that clearer, broader exceptions for bona fide co-management arrangements, professional courtesy, reasonable gifts or rewards for patient referrals, and free screenings would be helpful.

Reverse the Premise and Change the Burden of Proof. One commenter recommended reversing the premise of the Stark law to specify types of particular compensation arrangements that are "strict liability" and place the burden on government to show a violation. The commenter also recommended that penalties be made commensurate with the harm to the Medicare program. Although the structure of the Stark law has long been debated, the main argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.²⁹

Simplify/Clarify. Many of the participants suggested that the Stark law's definitions and exceptions should be streamlined and simplified. Some commenters suggested eliminating or modifying the signature requirement. One commenter recommended removing the limitation on

²⁹ See [AHLA 2009 White Paper](#), at 13.

the number of times a hospital may use the late signature rule, or in the alternative, modifying the signature requirement to simply require evidence of assent between the parties.

Other commenters recommended that the Stark law should be amended to codify CMS policy confirming that payments to physicians for personally performed services are permissible under the Stark law, even if the personally performed services are related to DHS ordered by the physician. These commenters suggest an amendment identifying the following as permissible forms of payment for personally performed services: (1) hours worked in performing such services; (2) revenues billed, collected or collectible for such services; (3) wRVUs for such services; (4) patient encounters; (5) average daily patient census; or (6) any other approach that measures the clinical or administrative services actually furnished by the physician. For every physician (whether or not in a group practice), services that are billable as “incident to” the physician’s services are deemed to be personally performed by the physician.

VIII. CONCLUSION

The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models. Although the FFS payment model still exists, the comments show that the Stark law and its regulations have presented challenges to providers attempting to implement health care reform. Many commenters cited the Stark law’s strict liability standard and significant penalties as serious obstacles to implementing MACRA and other alternative payment reforms. The Committee appreciates all of the comments submitted and will be considering them all as we evaluate and develop potential changes to the Stark law.

Greer, Leslie

From: Fernandes, David
Sent: Thursday, December 08, 2016 2:35 PM
To: Glenn F. Elia; 'klg1@aol.com'
Cc: Riggott, Kaila; Greer, Leslie
Subject: 2nd Completeness Letter for CON 16-32117
Attachments: 16-32117-Completeness Letter 2 Final.docx

Good afternoon Mr. Elia and Ms. Gerner,

Please see the attached completeness letter in the matter of the proposed acquisition of a mobile 1.5T MRI. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by February 6, 2017.

Email to OHCA@ct.gov and cc: David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact David Fernandes at (860) 418-7032.

Please confirm receipt of this email.

Thank You,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Acting Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

December 8, 2016

VIA EMAIL ONLY

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialists, P.C.
2408 Whitney Avenue
Hamden, CT 06518

Ms. Patricia A. Gerner
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057

RE: Certificate of Need Application; Docket Number: 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Completeness Letter

Dear Mr. Elia and Ms. Gerner:

On November 8, 2016, OHCA received responses to the first completeness letter in the above referenced matter. OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). Please electronically confirm receipt of this email as soon as you receive it. Provide responses to the questions below in both a Word document and PDF format as an attachment to a responding email. **Please email your responses to all of the following email addresses: OHCA@ct.gov, David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.**

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **February 6, 2017**, otherwise your application will be automatically considered withdrawn.

Paginate and date your response (i.e., each page in its entirety). Repeat each OHCA question before providing your response. Information filed after the initial CON application submission



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Affirmative Action/Equal Opportunity Employer

(e.g., completeness response letter, prefiled testimony, late file submissions, etc.) must be numbered sequentially from the Applicant’s preceding document. Begin your submission using **Page 249** and reference “**Docket Number: 16-32117-CON.**”

1. Why were the majority of COS referrals made to Shoreline Medical Center, (e.g., proximity, joint agreement, etc.)?
2. Please clarify what is meant by “currently *almost all* of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to *non-COS providers* for MRI scans,” as found on page 221. Also, please reconcile this statement with the table below, created using information on pages 26-27 of the application, which appears to indicate the majority of patients were referred to another COS facility. Please explain any corrections.

	Patients Referred to Non-COS Facility	Patients Referred to a COS Facility
Essex Service Area	563	950
Orange Service Area	447	1,041

3. How will MRI results from the mobile MRI be conveyed to Dr. Gagliardi?
4. Please update Table 5 on page 42 with year-to-date volume for the most recently completed fiscal year and explain any increases or decreases.
5. Based on the Applicant’s assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location?

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7032, or Kaila Riggott at (860) 418-7037.

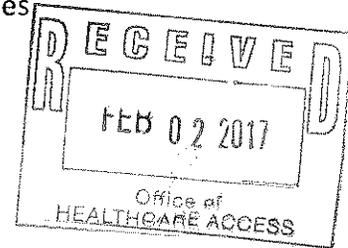
Sincerely,

David Fernandes
Planning Analyst (CCT)

User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Thursday, February 02, 2017 12:03 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila
Cc: 'klg1@aol.com'
Subject: OHCA Docket No. 16-32117- CON 2nd Completeness Responses from COS
Attachments: Exhibit List R2.docx; COS Completeness #2 1.26.17.pdf; COS Completeness #2 1.26.17.docx; Exhibit List R2.pdf

From: Glenn F. Elia gelia@ct-ortho.com
To: OHCA@ct.gov., David.Fernandes@ct.gov. kaila.riggott@ct.gov, klg1@aol.com
Subject: OHCA Docket No. 16-32117- CON 2nd Completeness Responses to OHCA Questions dated December 8, 2016.
Date: February 2, 2017



Dear Ms. Riggott and Mr. Fernandes,

Attached please find the Word version of the COS Responses to OHCA's Completeness Questions dated December 8, 2016, which includes four (4) new exhibits. A copy of the same Completeness Responses, with four (4) Exhibits is also attached in pdf format. The Revised Exhibit List is attached in both word and pdf format.

Please let me know if you need anything further. I would also appreciate knowing that you have received this email transmission with the four attached files. Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Exhibit List

Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 - 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae.	75 - 91
E	Scholarly Articles.	92 - 122
F	Letters of Support.	123 - 130
G	COS Standard of Practice Guidelines.	131 171
H	American College of Radiology Accreditation for Existing MRI Scanners.	172 - 174
I	COS Charity Care Policy.	175 - 176
J	Target Populations: Patient Zip Codes.	177 - 193
K	FY2015MRI Scans in the Essex Area for COS Patients.	194 - 196
L	FY2015MRI Scans in the Orange Area for COS Patients.	197 - 198
M	Capital Expenditures for Mobile MRI and Quotation for Trailer Installations.	199 - 203
N	Funding or Financial Resources for the Project	204 - 208

O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015.	209 - 213
P	Financial Worksheet.	214 - 215
Q	Assumptions Used in Financial Worksheet.	216 - 218
R	Senate Finance Committee Majority Staff Report, 'Why Stark, Why Now?'	228-248
	COS Completeness Responses #2 dated February 2, 2017	249 - 256
S	COS Disclosure Form used in the COS offices within the Shoreline Orthopedic & Sports Medicine practice disclosing other locations for a MRI scan in the geographic area.	257 258
T	Payer Mix for COS for FY2016.	259 - 260
U	Ohsfeldt, Robert L, Pengxiang, Li and Schneider, John E, <u>Health Economics Review</u> "In-Office Magnetic Resonance Imaging (MRI) Equipment Ownership and MRI Volume Among Medicare Patients in Orthopedic Practices", 2015.	261 - 271
V	2016 MRI Non-Operating Hours for the Hamden and Branford MRIs.	272 -274

**CON Application: OHCA Docket Number 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T MRI Scanner
Completeness Responses #2: February 2, 2017**

□

1. Why were the majority of COS referrals made to Shoreline Medical Center, (e.g., proximity, joint agreement, etc.)?

Response: There is a list available to COS patients who are patients of the Shoreline Orthopedics & Sports Medicine practice as to where the patient can have the required MRI scan performed. The patients decide where to go. (See Exhibit S). Patients are not referred to a specific facility. It is assumed that proximity was the reason patients chose the Shoreline Medical Center rather than other facilities which are at a greater distance. There is not now, nor has there ever been, a joint agreement between Shoreline Orthopedics & Sports Medicine and the Shoreline Medical Center.

2. Please clarify what is meant by “currently *almost all* of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to *non-COS providers* for MRI scans,” as found on page 221. Also, please reconcile this statement with the table below, created using information on pages 26-27 of the application, which appears to indicate the majority of patients were referred to another COS facility. Please explain any corrections.

	Patients Referred to Non-COS Facility	Patients Referred to a COS Facility
Essex Service Area	563	950
Orange Service Area	447	1,041

Response: The information found on p. 221 is specific to the Shoreline Orthopedic & Sports Medicine offices only, whereas the above table refers to the “Essex Service Area”. It does not include patients who live in the Essex service area who were treated at another COS facility and had a MRI scan at a COS facility. Virtually all of the patients from the Shoreline Orthopedic & Sports

Medicine practice (which does not include all COS patients in the Essex service area) went to a non-COS facility for their MRI scan because of the lack of existing MRI capacity at both of the existing COS MRIs in Hamden and Branford. The total number of Shoreline Orthopedics & Sports Medicine patients who had the MRI scan done at a non-COS facility was 963 (569 of this number are residents of the Essex service area and another 394 patients came from outside of the Essex service area.).

But an additional 950 patients who live in the Essex service area, and were treated by an orthopedic physician in a COS office other than Shoreline Orthopedics & Sports Medicine in 2015 were referred to a COS facility for their needed MRI (COS in Branford or Hamden). Therefore, approximately the same number of patients in the Essex service area use COS for their MRI scanning (950) as the total number seen at Shoreline Orthopedics & Sports Medicine who have to go to another facility (963). (See CON App., Exhibit J1, p.181 and supporting statistics on pp. 178-180, and Exhibit K, pp. 194-196).

The majority of the patients who see COS physicians in the 6 COS offices in Orange, Milford and Shelton utilize the COS scanners in Branford and Hamden for their MRI scans. The information found on pp. 26-27 of the CON application refers to both the Orange and Essex service areas. The majority of the COS patients in the Orange area use one of the two existing COS MRIs for MRIs scanning.

The Essex service area is very different than the Orange service area.

Essex:

The statement that almost all of the patients from COS Shoreline Orthopedics & Sports Medicine were sent to a non-COS facility for the MRI scan is accurate. In 2015, of the 963 COS Shoreline Orthopedics & Sports Medicine patients who had a MRI scan at a non-COS facility, 569 of them reside in the Essex service area. (See pp. 26-27 of the CON application.) Another 394 patients came from outside of the Essex service area to be treated at the one of the COS Shoreline Orthopedics & Sports Medicine offices. Therefore, the number of patients referred to a non-COS facility in the chart should be 569, but only from the 3 Shoreline Orthopedic & Sports Medicine offices. (See chart below). As stated above, almost all patients from the Shoreline Orthopedics & Sports Medicine offices (residents and non-residents of the Essex service area) had to go to a non-COS facility for the MRI scan, because there is no MRI scanner available at any of the Shoreline Orthopedics & Sports Medicine offices, the two COS MRI scanners in Branford and Hamden are a long distance from Essex, and the two COS scanners have no additional capacity to accommodate the Shoreline Orthopedic & Sports Medicine patients.

Essex Service Area

	Patients Referred to a Non-Cos Facility	Patients Referred to a COS Facility
COS patients living in the Essex Service Area treated by Shoreline Orthopedic & Sports Medicine	569	0
COS patients living outside the Essex Service Area treated by Shoreline Orthopedic & Sports Medicine	394	0
Patients living in the Essex Service Area treated by COS (other than the Shoreline Orthopedic & Sports Medicine practice).	0	950
Totals in Essex Service Area	569 *	
Total of Shoreline Orthopedic & Sports Medicine Referrals	963	

*Correction: The number 563 in the chart included in Question #1 as the number of patients in the Essex service area treated by physicians of the Shoreline Orthopedics & Sports Medicine practice should have been 569. This was a typographical error (See CON application, page 26).

As noted above, 950 patients who live in the Essex service area, are being seen by a physician at a COS office other than one of the Shoreline Orthopedics & Sports Medicine offices. These are the patients who currently have MRI scanning done at the either of the two existing COS MRI scanners in Hamden or Branford. It is anticipated that a majority of the 950 patients who have used

the COS MRI in Hamden or Branford, but live in the Essex service area, will use the mobile MRI in Essex, if it is approved. Having the mobile MRI within the physician practice in Essex should be much more accessible for these patients than Branford or Orange. This shift will reduce the number of scans done at the COS offices in Hamden and Branford, freeing up extra capacity for those patients who live closer to those two offices.

Orange

The statement on page 221 of the CON application that is specific to the Orange, Milford and Shelton COS offices is accurate that “many of the patients from the 6 COS offices in Orange, Milford and Shelton” were referred to non-COS providers for MRI scans in 2015. This happened due to the addition of 3 new COS offices in the Orange service area in the last few years, in addition to the three existing COS offices in the area (1 in Milford, 1 in Orange, and one in Shelton). COS has run out of capacity on both its MRI scanners and has had to refer patients to other providers. However, most of the COS patients from the 6 COS offices in the Orange service area used the existing COS MRI in either Hamden or Branford.

Orange Service Area

	Patients Referred to a Non-COS Facility	Patients Referred to a COS Facility
COS Patients living in the Orange Service Area	447	1,041

In 2015, 1,041 patients seeing a COS physician at one of the six offices in the Orange service area were referred to the COS MRI either in Hamden or Branford. Only 447 patients received a MRI study at a non-COS facility. Therefore, it is accurate to state that the majority of COS patients (1,041) in the Orange service area have their MRI scan done at a COS facility (Branford or Hamden), while the minority (447) had to have their MRI scan done at a non-COS facility. For those patients who prefer to choose to have a MRI scan done at a COS facility, it is expected than many patients who would have traveled to Branford or Hamden will choose to use the proposed mobile MRI at the COS office in Orange, if it is approved.

3. How will MRI results from the mobile MRI be conveyed to Dr. Gagliardi?

Response:

COS uses Greenway Prime Suite as our Electronic Medical Records (“EMR”) provider. Greenway uses an order-based interface with our PACS system, Ambra Healthcare. Ambra is a cloud based PACS upon which all of the COS MRI studies are directly uploaded and stored via a secure interface. The COS radiologist, Dr. Gagliardi, is able to log into the COS web portal with a secure log-in and view all MRI studies for his review. His report is loaded directly back into the COS EMR, Greenway, under the patient account. This happens within 24 hours of the MRI study being performed. Treating physicians can access the MRI study by logging into the COS / Ambra portal, just like the radiologist. The report from the radiologist is likewise available to the treating physician both from the clinic and remotely by logging into the secure portal for treating physicians. Patients who wish to access their MRI study can do so by requesting that COS give them a secure log-in to a patient portal in the Ambra website. Patients can only access their own study. This access is provided by COS only upon the request of the COS patient.

4. Please update Table 5 on page 42 with year-to-date volume for the most recently completed fiscal year and explain any increases or decreases.

Response:

Table 5 has been updated to include actual data for FY 2016. The volume on the COS Branford MRI increased by 847 scans (from 3,851 in FY 2015 to 4,698 in FY2016), which was an increase of 20%. *See* CON App., Table 5, p. 42. The volume at the COS Hamden MRI increased from 3,773 scans in FY2015 to 4,410 scans in FY2016, an increase of 637 scans. This amounts to a 17% increase in volume. COS increased the number of scans at both Branford and Hamden from a combined total of 7,624 scans in FY2015 to 9,108 scans in FY2016.

COS traditionally had a 3% increase in MRI scans per year prior to the addition of the new practices which joined COS between 2014 and 2015. *See* CON App., Table 5, p. 42. The numbers increased dramatically after the new offices joined COS, but have now leveled off. However, new patients are continuing to seek medical help at COS offices, as evidenced by the growth over the last year. Instead of hoping for additional patients (or additional physicians) in the future to utilize a new MRI, COS already has the patients who are ready to begin using the proposed mobile scanner in Orange and Essex.

**TABLE 5
HISTORICAL UTILIZATION BY SERVICE
MRI Scans**

MRI Service	Actual Volume (Last 5 Completed FYs)				
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	2,886	2,095	2,577	3,851	4,698
Connecticut Orthopaedic Specialists 2416 Whitney Ave Hamden, CT (MRI)	2,214	3,141	3,725	3,773	4,410
Total	5,100	5,236	6,302	7,624	9,108

In addition to updating the utilization for the most recently completed fiscal year, COS examined the payer mix for COS services for the same time period.

COS became a Medicaid provider in 1977. However, St. Raphael's Hospital absorbed most of these patients in the Hamden/New Haven area. It has only been since the closure of St. Raphael's that COS has seen an influx of Medicaid patients. This began in 2014 with a very few patients, and has grown each year since St. Raphael's closed. While the payer mix showed only a .7% Medicaid use of COS MRI scanners in FY 2015 and the first 6 months of 2016 (See CON App. Table 7, p. 42), that volume increased in FY2016 to .86%. (See Exhibit T). Also, for all COS practices in FY 2016,, the volume of Medicare patients seen in general (not a count of MRI scans) was 28% (excluding Shoreline Orthopedic & Sports Medicine, "Shoreline"). The Shoreline payer mix in FY2016 was 5.2% for Medicaid patients and 18.7 % Medicare patients. (See Exhibit T.)

COS believes that it will fully utilize the mobile MRI four days a week within the next 3 years. The Medicaid population is expected to increase as part of the 3% increase in volume COS has projected over the next 3 years because COS had been experiencing a 3% increase in volume in the years prior to the addition of the new physician practices that joined COS in 2014 and 2015. See CON App., Table 6, p. 43. And the increase in MRI volume on the existing COS scanners in Branford and Hamden in the last year also easily supports 3% growth per year See Table 5 above.

In-office MRI scanning is allowed under the federal Stark law. There is evidence that physicians who have in-office MRI scanning have not been found to order more MRI scans than if they sent the patient to a radiologist's office or another facility for the MRI scan. Health Economics Review produced a study entitled "In-office Magnetic Resonance Imaging (MRI) Equipment Ownership and MRI Volume Among Medicare Patients in Orthopedic Practices" (Exhibit U) which used Medicare data that substantiated the fact that orthopedic physician practices acquiring on-site MRI scanners did not significantly increase the volume of MRI scans performed once the MRI was owned by the physician practice.

The authors in this study compared orthopedic practices without MRI capability with other orthopedic practices which acquired a MRI after having been in practice at least one full year without MRI capacity in-house. Three years of Medicare Part B utilization data were obtained for 2007, 2008 and 2009 from the physician practices which had acquired in-office MRI, and those orthopedic physician practices with no in-house scanning who referred their patients to other providers for a MRI scan. By analyzing the data of the physicians during the year prior to acquiring an in-office MRI, the authors found that "the physicians in practices acquiring onsite MRI capacity had higher MRI volume before MRI acquisition than physicians in similar practices that did not subsequently acquire onsite MRI capacity." (Exhibit U, p. 8).

The article stated that, "None of our model results suggest any substantive change in Medicare MRI volume one-year post on-site MRI-acquisition and one-year pre-onsite MRI acquisition for physicians in MRI-acquiring practices relative to physicians in the non-MRI comparison practices. This finding is inconsistent with results reported in much of the literature focused on the issue of "self-referral" for imaging services. (Exhibit U, p. 8.)

The article concluded that:

"In all of the Medicare MRI volume change models estimated, the estimated impact of onsite MRI acquisition on the change in Medicare MRI volume is consistently small and not statistically significant. Thus, our data analysis provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period."
(Exhibit U, p.12)

- 5. Based on the Applicant's assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location?**

Response:

Each of the MRI scanners currently are in operation 13 hours per day Monday through Friday and 10 hours on Saturday, for a total of 75 hours per week. The average MRI scan takes 45 minutes, which results in a total of 98 scans per week (17 scans per weekday and 13 scans on Saturday). The scanners are closed for 8 holidays (New Year's Day, Good Friday, Memorial Day, July 4, Labor Day, Thanksgiving and the day after, and Christmas) which results in a reduction of 136 scans (17 scans x 8 days). This results in a maximum of 4,960 scans annually.

The COS scanner in Hamden was out of operation 18.5 hours in 2016 due to machine maintenance, 14 hours due to weather cancellation and 4.5 hours due to ACR testing. The COS scanner in Branford was closed 44 hours for machine maintenance, 14 hours for weather cancellation and 4.5 hours for ACR testing and 10.5 hours for air conditioning repair. (See Exhibit V). These factors vary by year and were not included in the calculation of maximum number of scans, but such factors have an impact on the number of scans that could be performed.

In 2016 4,698 MRI scans were performed in Branford which results in a 94.7% utilization rate based on 4,960 scan annual capacity. During the same period 4,410 scans were performed in Hamden which results in an 88.9% utilization rate based on a 4,960 scan annual capacity.

General Note: The COS Shoreline Orthopedics & Sports Medicine practice closed its office in Guilford after the CON application was submitted. All COS Shoreline Orthopedics & Sports Medicine patients are now seen by the same physicians either in the Shoreline Orthopedics & Sports Medicine facility in Essex or in Madison. There has been no change in the number of physicians in the Shoreline Orthopedics & Sports Medicine practice, and the specific physicians remain the same as listed in Exhibit A of the CON application.

EXHIBIT S



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

Diagnostic Imaging Disclosure Statement

Connecticut Orthopaedic Specialists provides advanced imaging services such as MRI for patient convenience. New regulations within the Affordable Care Act, however, require physicians to notify patients of alternate MRI locations within their area. You may have your MRI done at COS or any of the following locations:

<i>Location</i>	<i>MRI Phone</i>	<i>MRI Fax</i>
Middlesex Hospital dba Shoreline Medical Center	(860) 358-2600	(860) 358-2626
Middlesex Hospital Outpatient Center	(860) 358-2600	(860) 358-2626
Middlesex Hospital	(860) 358-2600	(860) 358-2626
Open MRI of Middletown	(860) 346-7400	(860) 347-7900
Guilford Radiology	(203) 453-5123	(203) 458-0427
Groton MRI	(860) 448-6736	(860) 448-6215
Connecticut Orthopaedic Spec. (Branford)	(203) 407-3500	
Connecticut Orthopaedic Spec. (Hamden)	(203) 407-3500	

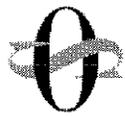
We are also required to obtain your signature as acknowledgement that you have received this form.

Patient Printed Name: _____

Patient Signature: _____

Date: _____

EXHIBIT T



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics



SHORELINE ORTHOPEDICS & SPORTS MEDICINE

The payer mix numbers for Medicare and Medicaid that reflect COS and Shoreline as a whole for FY2016 are as follows:

COS Practice

(payer mix percentage of new patients in 2016)

	% of Patients
Medicare	28%
Medicaid	2%

Shoreline Practice

(payer mix percentage of new patients in 2016)

	% of Patients
Medicare	18.7%
Medicaid	5.2%

COS MRI units *(payer mix percentage of MRI scans)*

	% of Patients
Medicare	21.345%
Medicaid	0.86%

EXHIBIT U

RESEARCH

Open Access



In-office magnetic resonance imaging (MRI) equipment ownership and MRI volume among medicare patients in orthopedic practices

Robert L. Ohnsfeldt^{1*}, Pengxiang Li² and John E. Schneider³

Abstract

Background: Concerns have been raised about physician ownership of onsite advanced imaging equipment as allowed under Stark laws by the in-office ancillary service exception (IOASE).

Methods: A web-based survey of orthopedic practices in the United States was used to assign a first date of onsite MRI capacity acquisition (if any) to specific orthopedic practices. Medicare claims data for 2006–2010 was obtained for providers in orthopedic practices acquiring onsite MRI capacity and in matched orthopedic practices without an onsite MRI over the same period of time. Multivariate regression was used to estimate the change in provider Medicare MRI volume one year before and one year after the onsite MRI acquisition year for providers in MRI practices compared to providers in propensity-score matched non-MRI practices.

Results: In all of the MRI volume change models estimated, the association between onsite MRI acquisition and the change in provider Medicare MRI volume (one-year post-onsite-MRI-acquisition less one-year pre-acquisition) was consistently small and not statistically significant. This lack of association was robust to changes in model specification in terms of types of MRI exams considered, specific covariates included in the multivariate model, or the process used to confirm individual provider affiliation with study practices in study years.

Conclusions: Our analysis of Medicare claims data provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period.

Keywords: Medicare; Physician self-referral; Orthopedic practice; Transactions costs

Background

Considerable concern has been expressed about the effects of physician ownership of imaging equipment on the use of such services in the United States [1–4]. A series of laws known as “Stark Laws” (named for the law’s primary sponsor, United States Congressman Pete Stark) generally prohibit physicians from referring patients covered by Medicare (a universal public insurance program for persons age 65 or older) for certain “designated health services” if the referring physician or his/her family has a financial relationship with the service provider. The first

of these laws (“Stark I”), effective in 1992, banned referral of Medicare patients to provider-owned clinical laboratories. Effective in 1998, “Stark II” expanded the self-referral ban to a number of additional ancillary health services, and extended the self-referral ban to patients covered by Medicaid (a public insurance program for low income individuals). Finally, effective in 2007, “Stark III” provided additional regulatory guidance for compliance, such as defining specific provider compensation arrangements as analogous to ownership interests [5, 6].

The Stark Law restrictions on physician self-referral were intended to avoid the financial incentives for physicians to increase the volume of referrals for ancillary services, particularly with physician ownership of imaging service capacity [7–17]. However, many factors affect

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decisions about which patients receive imaging services. Carey and Garrett found that the use of CT and MRI exams for low back pain patients was associated with patient characteristics, such as baseline functional status [18]. In a randomized controlled trial of patients with low back pain, Gilbert and colleagues found those who received "early" imaging had better outcomes than those receiving delayed imaging [19]. If onsite imaging advances the timing of imaging or otherwise enhances the appropriate use of imaging in treatment, onsite imaging may improve the quality of care. Some have questioned whether the lower rate of referral among physicians without ready access to imaging capacity represents underuse rather than overuse by physicians with such capacity [20]. Indeed, the rationale for the "In-Office Ancillary Services Exception" (IOASE) to the Stark restriction relates to the potential benefits of onsite ancillary service availability [5].

The incentives for physician practices to acquire onsite imaging capacity extend beyond the indirect payment from a referral to a physician-owned service in a fee-for-service (FFS) payment system. The relationship between a physician practice and ancillary services represents a "vertical relationship," which can be organized through market-based contractual arrangements or through vertical integration [21, 22], i.e., direct practice ownership as permitted by IOASE. Orthopedic practices without an onsite MRI typically refer patients to a shared MRI facility, often offered through a hospital outpatient department (HOPD) proximate to the practice location, but practices relying on shared facilities have less control over the scheduling of MRI exams.

Thus, the choice of using onsite or shared MRI equipment is a variant of the classic "make or buy" decision in organizational economics, which is mainly influenced by scope economies and transaction economies [23–29]. The make-or-buy decision has been studied extensively in the context of transaction cost economics, which posits that the boundaries of organizations are in large part a function of the nature of the business transacted, where relatively complex transactions are more efficiently organized in settings that feature stronger administrative controls, such as ownership [23, 27, 29]. In the market for medical care, consumer transaction costs are the costs incurred to the consumer to complete a transaction, including the time necessary to implement informed choice, such as evaluating, choosing and locating a care provider, as well as the time spent directly obtaining the services [22]. Consumer transaction costs are expected to be lower in the case of onsite MRI availability because patients may be able to economize on identifying, vetting, locating and traveling to a provider [30]. In addition, there are several potential convenience-related benefits associated with onsite availability, including

easier scheduling, enhanced adherence to treatment plans [31, 32], and "one-stop shopping" [33–35]. Likewise, monitoring costs may be reduced via onsite MRI capacity, to the extent it permits practices to improve supervision of the quality of care, and allows for better coordination among patients, physicians, and ancillary services, and to provide incentives for patients to adhere to recommended treatment plans [36].

Opponents of IOASE contend that the purported benefits of onsite availability are non-existent or overstated [37], instead focusing on the role of asymmetrical and imperfect information, which may allow providers to "induce" demand for ancillary services [8–17]. The potential impact on the extent of demand inducement resulting from physician ownership of imaging services under FFS payment relates to the magnitude of the indirect payment to providers from imaging service ownership, which would be analogous to an equivalent increase in the direct provider payment for professional services [22]. The impact of this incentive is muted by payer policy which often requires pre-authorization or pre-certifications, thus limiting provider discretion over the provision of imaging services [38, 39].

Those advocating an end to IOASE point to a number of studies concluding the financial incentives from physician self-referral causes an increase in the volume of services provided under FFS payment so large as to outweigh any benefits [8–17], though some suggest that movement away from FFS payment would be a superior solution compared to ending IOASE [40]. However, most of these studies do not provide adequate adjustment for incentives beyond self-referral for practices to acquire onsite services, which is a likely source of bias toward finding a positive association between MRI acquisition and MRI volume.

The present study addresses this methodological limitation in the existing literature by using Medicare claims data to assess the extent of differences in MRI exams for Medicare patients among providers in orthopedic practices before and after their practice acquired onsite MRI capacity, compared to physicians in matched orthopedic practices without onsite MRI over the same period of time.

Methods

A persistent challenge in the literature on this subject is the limited data on the extent and timing of physician practice acquisition of imaging capacity. The present study used a web-based survey of orthopedic practices in the United States to determine the date of onsite MRI capacity acquisition, or the absence of onsite MRI capacity, to facilitate a comparison of MRI use with/without onsite MRI capacity. A practice-level propensity score (PS) matching approach was used to match orthopedic

practices with onsite MRI to non-MRI practices. Multivariate regression models were used to examine the change in Medicare MRIs per Medicare patient one year before and one year after the onsite MRI acquisition year for providers in MRI practices compared to providers in non-MRI comparison practices.

Practice survey data

A survey of orthopedic practices in the United States was initiated in July 2012 with the support of the American Academy of Orthopaedic Surgeons (AAOS) to determine the date of first acquisition onsite MRI equipment (if any), and general information about the practice. Details about the administration of the AAOS practice survey have been reported elsewhere [41].

For practices reporting onsite MRI capacity, respondents were asked to report the number of practice providers (and their UPIN/NPI numbers) authorized to order an MRI as of the year of their first onsite MRI acquisition. All non-MRI practice respondents reported the number of current providers in the practice authorized to order MRI exams (and their UPIN/NPI numbers).

By September 2012, the orthopedic practice survey was closed with a total of 770 responses received. Eliminating duplicate and incomplete responses yielded 740 practice responses. An additional 185 practices did not report provider ID numbers (167 [90 %] of these reported no onsite MRI capacity) and thus were excluded from the practice sample used for PS matching of onsite MRI and comparison non-MRI practices.

Selection of MRI and non-MRI practices

At the time of this study, the most recent full year of Medicare claims data available was for 2010. To assure a full year of Medicare claims data before and after MRI acquisition, 63 practices which reported a first MRI acquisition in 2007, 2008, or 2009 were classified as MRI "case" practices. Similarly, 465 practices without an onsite MRI by December 31, 2010, or practices which acquired an onsite MRI after January 1, 2011, were classified as non-MRI practices.

Preliminary confirmation of the respondent-reported physician ID numbers was obtained by using the survey-reported physician ID numbers to the NPI/UPIN crosswalk file to get a UPIN number (for physicians with an NPI in the survey) or NPI number (for physicians with a UPIN in the survey). Next, we merged the survey physician UPIN/NPI numbers with the CMS National Plan and Provider Enumeration System (NPPES) Full Replacement Monthly NPI File [42] for the MRI acquisition year (for MRI practices) or 2012 (for non-MRI practices).

Comparing the city and state of the provider's business mailing address from NPPES to the survey reported city

and state of practice address revealed the states did not match for more than 50 % of the physician ID numbers for 195 of the survey practices. These 14 MRI practices and 181 non-MRI practices were excluded from the practices considered for inclusion in the final sample of practices (see Table 1). In addition, we excluded 172 practices not serving Medicare beneficiaries and all providers without valid UPIN/NPI.

For the resulting sample of 32 MRI practices and 129 non-MRI practices, we used a propensity score (PS) approach to identify specific non-MRI (comparison) practices to be matched to specific MRI (case) practices. The PS matching approach was originally developed in part to enhance the efficiency of sampling comparison observations to be included in the study sample over random sampling from a large pool of potential observations [43]. The first step in the PS matching approach is to estimate a model to predict the likelihood of onsite MRI acquisition for individual practices based on various practice characteristics – specifically practice characteristics that might also affect the volume of MRI exams performed by practice providers.

We used a logistic regression model predicting the likelihood of onsite MRI acquisition which included as predictor variables the number of providers in the practice, practice payer mix (Medicare revenue share), number of Medicare beneficiaries they served, number of providers with valid UPIN or NPI, percentage of providers in the same city during our study years, and dummy variables for Census region (model results not reported). The Hosmer–Lemeshow χ^2 test statistic for the model is 21.8 ($p < 0.01$), with a c-statistic of 0.827 and McFadden's R-squared of 0.30. The common support for the PS model (in terms of predicted probabilities) covers the range of 0.056 to 0.921, with 76 % of practices (123 out of 161) in this range. Only the practice size variables (number of providers in the practice, number of Medicare beneficiaries served, and number of

Table 1 Survey practices and sample physicians

A. Number of survey practices and physicians by cohort			
MRI acquisition year	Number of practices	Practices with >50 % physician ID match	Number of physicians
Comparison			
Without MRI thru 2010	442	263	1790
2011-2013	23	19	720
Total	465	284	2510
Treatment			
2007	30	21	226
2008	15	12	206
2009	18	16	283
Total	63	49	715

Sources: AAOS Survey Data, 2012; CMS NPPES Downloadable File [39], see text

providers with valid UPIN or NPI) were statistically significant in the model ($p < 0.01$)

The logistic regression index value (i.e., $X\beta$) for each practice was used as a practice-level propensity score for onsite MRI acquisition. For PS matching of MRI to non-MRI practices, there is a classic trade-off between the degree to which PS matching achieves “balance” across covariates for case and comparison practices and the number of case practices retained in the PS-matched sample to be used in the analysis [44]. In this case, because MRI practices are fundamentally different from non-MRI practices in terms of a key practice characteristic (specifically, practice size), restricting the matching of non-MRI practices to comparable MRI practices based on an exact or near exact PS would have resulted in a very small sample of matched case-comparison practices. Adding more covariates to the PS model would not enhance the prospects for more precise PS matches given the predominance of practice size in predicting MRI acquisition.

To address the trade-off between covariate balance and sample size, we used PS caliper matching to avoid selecting a non-MRI practice as a match for an MRI practice when the practices were too dissimilar to constitute a reasonable match, while retaining a reasonable sample size. Specifically, we used one-to-one PS caliper matching (without replacement), with the caliper restricting the acceptable difference in PS to be less than 25 % of the standard deviation of the PS distribution across all practices [45]. By imposing this PS caliper restriction, 23 MRI practices and 23 matched non-MRI comparison practices were identified, with a total of 252 and 181 affiliated providers, respectively (Table 2).

Medicare claims data

Three years of Medicare Part B utilization data were obtained for each of the 433 physicians from the three MRI “treatment” cohorts (2007, 2008, and 2009) and the three matched non-MRI comparison cohorts. For example, for each of the 100 physicians in the 2007 MRI treatment group and each of 67 physicians in the 2007 non-MRI comparison group, we accumulated all Medicare claims

containing each individual UPIN/NPI for one year before and one year after the MRI acquisition cohort year. Specifically, we obtained all patient claims from Medicare carrier files for 2006 and 2008 associated with 167 physician UPIN/NPIs. With duplicate UPIN/NPIs associated with physicians with multiple practice locations, there were a total of 287 physician IDs (UPIN/NPIs) in the “finder file” (used to link providers to their claims) for calendar years 2006 and 2008 (i.e., one year before and one year after 2007), with 631,510 claims and 452,108 Medicare patient visits in the Medicare carrier file with one of the 287 UPIN/NPIs. Among these 287 UPIN/NPIs, 182 UPIN/NPIs had a business zip code in Medicare carrier file that matched the practice zip code in the AAOS survey (see Fig. 1). The sample of physicians with UPIN/NPI zip codes that match the AAOS survey zip code are used as the principal sample for the analysis of patterns of MRI use in the Medicare claims data.

An analogous approach was used to aggregate Medicare claims data for the physicians in the 2008 and 2009 cohorts. Specifically, the pre-MRI year Medicare claims data are for the calendar year 2007 and 2009 for the 2008 and 2009 cohorts, respectively, and the post-MRI year Medicare claims data are for the calendar year 2009 and 2010 respectively.

Despite our efforts to use all available CMS data to confirm the practice affiliation of providers obtained from the AAOS practice survey data, the possibility of errors in the assignment of specific providers to specific practices at the time of first onsite MRI acquisition remains. To assess the extent of any assignment errors, all 46 practices included in the final sample of matched onsite MRI and non-MRI practices were re-surveyed. The MRI practices were asked to confirm that the practice acquired its first onsite MRI in the indicated MRI year (e.g., 2008 for MRI practices in the 2008 cohort), and non-MRI practices were asked to confirm that the practice did not have onsite MRI capacity in any of the study years for that practice (e.g., 2007–2009 for a non-MRI practice in the 2008 cohort). The re-survey instrument also provided a list of UPIN/NPI numbers specific to each of the 46 practices (obtained from the initial survey). Practices were asked to confirm whether the listed providers were affiliated with the practice during all of the specific study years for that practice (e.g., 2007–2009 for a practice with MRI year 2008, or a non-MRI practice matched to a 2008 MRI practice).

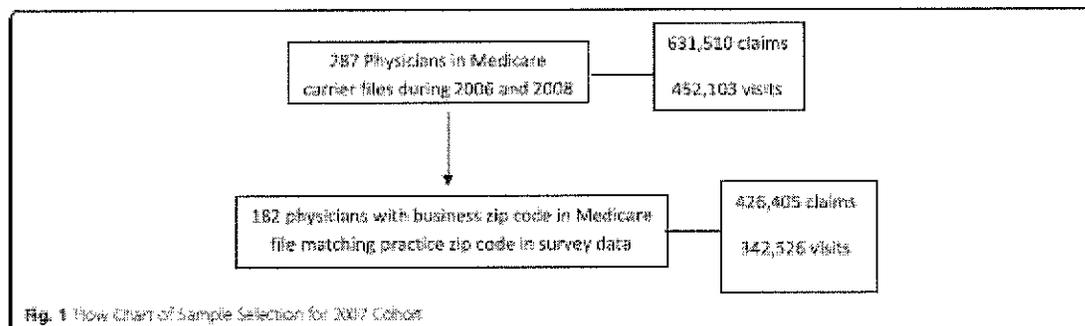
A total of 20 of the 46 practices responded to the re-survey (46 % response rate). All of the responding practices confirmed that the MRI or non-MRI status in the survey was correct. The respondents also confirmed that about 90 % of the provider ID numbers from the original survey were affiliated with the practice in both the pre- and post-MRI year for the practice. While the results of

Table 2 Survey practices and sample physicians

ii Number of physician and practice among treatment and control group

	Number of practices			Number of physicians		
	Comparison	Treatment	Total	Comparison	Treatment	Total
2007	11	11	22	67	100	167
2008	4	4	8	17	35	52
2009	8	8	16	97	117	214
Total	23	23	46	181	252	433

Source: AAOS Survey Data, 2012; CMS NPES Downloadable File (39) see text



the re-survey suggest that provider timing assignment errors in the principal provider sample were not common, all regression models using the principal provider sample were re-estimated using a restricted sample of providers with a confirmed practice affiliation for the pre- and post-MRI years.

Analytic approach

The unit of analysis for the Medicare claims data analysis is the individual physicians affiliated with the MRI treatment practices and the matched non-MRI comparison practices. The analysis focuses on the difference in the volume of MRI exams ordered by each physician during the calendar year after the year of onsite MRI acquisition and the volume of MRI exams ordered by the same physician during the calendar year before MRI acquisition. The intent is to assess the “steady state” volume of MRI exams with and without onsite MRI, as the volume of MRI exams immediately after the acquisition of onsite MRI capacity may be atypical if practices work off “pent up” demand for MRI exams when the onsite MRI capacity first becomes available.

The analytic approach makes use of a multivariate regression model of the general form

$$\begin{aligned} \Delta MRI_{i,j,r} &= (MRI_{i,j,r,t} - MRI_{i,j,r,t-1}) \\ &= \alpha + \beta \text{Onsite}_{j,r,t} + \phi \text{Practice}_{j,r,t} \\ &\quad + \psi \text{Area}_{r,t} + \epsilon_{i,j,r} \end{aligned} \tag{1}$$

In Eq. (1), the term “ $\Delta MRI_{i,j,r}$ ” indicates the difference in the volume of MRI exams in the Medicare claims data for an individual physician (i) in a specific practice (j) located in a specific county (r) for one year post-onsite-MRI acquisition ($t + 1$) and one year pre-onsite-MRI acquisition ($t - 1$). For physicians in the matched non-MRI comparison practices, the MRI acquisition year for the matched MRI practice (t) is used as a pseudo-MRI year to define the pre- and post-MRI-year volume of MRI exams. The term “ $\text{Onsite}_{j,r,t}$ ” is a binary variable equal to one for physicians in practices acquiring onsite MRI

capacity in year t and zero for physicians in the matched non-MRI practices.

The modeling approach is a variant of the familiar “differences in differences” approach [46]. By focusing on the change in the volume of MRI exams for individual physicians, each physician acts as his or her own “control,” in that any specific characteristics of the individual physician (e.g., practice style, patient case mix) that might influence the physician’s use of MRI exams but remain essentially constant over the 3 year pre/post period will “difference out” when examining the change in the volume (post-pre) onsite MRI acquisition. Thus, the dependent variable is only affected by factors that vary over time. Beyond the change in onsite MRI status, general market conditions for orthopedic services could have changed over the pre- and post-MRI periods. Thus, a multivariate model is estimated that also adjusts for differences between MRI and non-MRI practices in practice characteristics (“ $\text{Practice}_{j,r,t}$ ”) and county-level practice area characteristics (“ $\text{Area}_{r,t}$ ”) that remains after PS matching. Finally, α , β , ϕ , and ψ in Eq. (1) represent parameters to be estimated by the regression model, and $\epsilon_{i,j,r}$ represents an error term. The estimation procedure used accounts for the likely correlation in errors among physicians in the same practices.

As noted, a PS matching procedure was used to provide a rationale for the selection of the MRI and comparison non-MRI practices to be used to collect Medicare claims data for the providers in the selected MRI and non-MRI practices. If PS matching had achieved an exact or near exact match between case and comparison practices, differences in observed practice characteristics between the physicians in the treatment and comparison groups might have been negligible, making covariate adjustment for practice characteristics in a multivariate regression unnecessary. However, PS matching of MRI practices to non-MRI practices is approximate in this application. Coupled with the fact that the level of analysis is the individual providers in the matched practices, some significant differences between the practice characteristics of the physicians in the MRI practices and physicians in matched non-MRI

practices remain, as shown in Table 3. Physicians in MRI-acquiring practices had higher Medicare MRI volume than physicians in non-MRI practices both one year before and one year after the MRI acquisition year. The MRI-acquiring practices were larger (in terms of number of providers) and were located in areas experiencing growth in per capita income, compared to non-MRI practices. Given these differences, some covariate adjustment in a multivariate regression model may be needed [47]. Thus, we estimate alternative specifications of Eq. (1) with and without different categories of covariates included in the model.

Table 3 Sample means for physician practice samples, by on-site MRI status

	All (n = 493)	MRI (n = 252)	No MRI (n = 181)
<i>MRI volume^a (% Medicare visits)</i>			
Pre-MRI year	1.151	1.460	0.585
Post-MRI year	1.312	1.530	0.919
ΔPost-Pre	0.161	0.071	0.324
<i>Ortho-MRI volume^b (% Medicare visits)</i>			
Pre-MRI year	1.066	1.391	0.480
Post-MRI year	1.239	1.428	0.809
ΔPost-Pre	0.173	0.037	0.327
<i>MRI Year (%)</i>			
2006	38.55	44.72	27.43
2007	36.54	31.21	18.14
2008	34.91	24.08	54.42
<i>Number of providers (%)</i>			
1-2	2.57	1.47	3.90
3-5	6.64	5.90	7.96
6-10	26.86	12.53	52.65
>10	64.14	80.10	35.49
<i>Practice Payer Mix (%)</i>			
Medicare	27.07	36.13	38.77
Private insurance	46.90	47.83	45.72
Workers' Comp	12.30	12.10	13.64
Other	13.74	13.94	13.88
<i>Area Characteristics (Post-Pre)</i>			
ΔPer capita income (\$1000s)	1.211	1.916	-0.058
ΔTop age 65+ (%)	0.619	0.467	0.817
ΔUnemployment (%)	2.850	2.461	3.578
ΔMMDs/1000 Population	-0.0018	-0.0045	0.0032

Sources: Medicare Claims Data, AAS Survey Data, 2012; Area Resource File (see text)

^aHCPCS codes: 71252, 73278, 73718, 74183, 77089, 70543, 70551, 70553, 72141, 72146, 72148, 72156, 72157, 72158, 72165, 72169, 73220, 73221, 73223, 73225, 73720, 73721, 73722, 73723, 70316, 70340, 70342, 70342, 71550, 71551, 72142, 72147, 72149, 72196, 73219, 73719, 74181, 74182, or 77084
^bHCPCS codes: 72141, 72146, 72148, 72156, 72157, 72158, 72169, 73220, 72197, 73223, 73720, 73721, 73722, 73723, 70316, 70340, 70342, 70342, 71550, 71551, 73220, 73221, 73223, 73720, 73721, 73722, or 73723

The primary measure of “AMRI_{it}” is the difference in the total number of Medicare MRI exams (post-pre) ordered by each physician as a percentage of all Medicare outpatient visits for each physician. (See Table 3 for specific HCPCS codes defining MRI exams.). An alternative measure focuses on the post/pre difference in MRI exams with diagnosis codes indicative of orthopedic conditions (“Ortho-MRI”) as a percentage of all Medicare outpatient visits for each physician (see Table 3). We also analyze the post-pre difference in the absolute (total) number of Medicare MRI exams and Medicare orthopedic-MRI exams for each physician.

All multivariate regression models were estimated using Stata Version 13 (<http://www.stata.com/stata13/>), employing the “cluster” option (to account for physicians in the sample affiliated with the same practice) and the “robust” standard error option (to account for other potential departures from homoscedasticity by using the Huber-White robust standard error estimator).

Results

Table 4 provides model estimates of the effect of onsite MRI acquisition (“Onsite MRI”) on the change in total Medicare MRI exams as a percentage of total Medicare outpatient visits for specific physicians over the post/pre MRI year period. Column 1 of Table 4 reports the estimated impact onsite MRI capacity acquisition on the change in Medicare MRI volume as a percentage of Medicare visits in a regression model with no covariate adjustment (other than MRI cohort year). The model specification in column 2 adds measures of practice size as covariate adjusters, column 3 also includes practice payer mix variables, and column 4 adds the post-pre change in levels of county-level practice area characteristics.

The point estimate for the coefficient of the onsite MRI variable in each of these alternative regression model specifications is negative, which suggests the change in Medicare MRI volume for providers in MRI practices was lower than the change for non-MRI practices over the same time period, but all of the estimated coefficients are small in magnitude and not statistically significant ($p > 0.05$).

Focusing briefly on estimated coefficient values for other covariates included in the model reported in column 4, the estimated coefficients of the MRI cohort year variables suggest that the change in MRI volume for providers in the 2008 cohort was 2.2 percentage points greater than the change for providers in the reference-category 2007 cohort ($p = 0.038$), adjusting for other variables included in the model. A 1 percentage point greater Medicare share in the practice payer mix was associated with a 0.09 percentage point greater change in provider Medicare MRI volume ($p = 0.010$), and a 1 percentage point greater private insurance share in the

Table 4 Estimated difference in percent medicare visits for MRI exams for physicians Post/Pre Onsite MRI acquisition relative to physicians without onsite MRI, 2007–2009 cohorts

AMRIs as % Visits	Model 1		Model 2		Model 3		Model 4	
	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value
Onsite MRI	-0.330	0.486	-0.139	0.753	-0.237	0.307	-0.468	0.161
MRI Year								
2007	Reference	-	Reference	-	Reference	-	Reference	-
2008	1.565	0.063	1.570	0.060	0.817	0.125	2.175	0.038
2009	0.424	0.454	0.567	0.323	0.227	0.533	1.157	0.067
Number of providers								
1-2	-	-	Reference	-	Reference	-	Reference	-
3-5	-	-	-1.930	0.080	-1.121	0.398	-1.086	0.448
6-10	-	-	-2.199	0.037	-2.143	0.076	-1.852	0.095
>10	-	-	-2.395	0.073	-2.015	0.072	-1.907	0.083
Practice Payer Mix (%)								
Medicare	-	-	-	-	0.0734	0.006	0.0926	0.010
Private insurance	-	-	-	-	0.0660	0.004	0.0634	0.006
Worker Comp	-	-	-	-	0.0289	0.511	0.0442	0.353
Other	-	-	-	-	Reference	-	Reference	-
Aged Characteristics								
Age per cap inc (\$1000)	-	-	-	-	-	-	0.072	0.278
Age age 65+ (%)	-	-	-	-	-	-	0.516	0.198
All-employment (%)	-	-	-	-	-	-	-0.246	0.216
AMCs/1000 Pop	-	-	-	-	-	-	-1.215	0.418
F-Statistic (p-value)	1.37	0.266	1.81	0.125	2.80	0.013	2.93	0.007

Sources: see text

practice payer mix was associated with a 0.06 percentage point greater change in provider Medicare MRI volume ($p = 0.006$). None of the remaining estimated coefficients were statistically significant at the $p < 0.05$ level.

To assess whether the finding of a lack of association between onsite MRI acquisition and changes in the volume of Medicare MRI exams is robust to model specification changes, models were estimated using four alternative measures of the change in provider MRI exam volume: 1) the change in MRI exams as a percentage of all Medicare patient visits; 2) the change in orthopedic-related MRI exams as a percentage of all Medicare

patient visits; 3) the absolute change in the number of MRI exams; and 4) the absolute change in the number of orthopedic-related MRI exams.

We also estimated models using the principal study sample and an alternative subsample of providers confirmed by the AAOS practice re-survey to have been practicing in the study practices during both study years. Point estimates of the coefficient of the onsite MRI variable and their associated p -values (for a two-tailed test of the null hypothesis that the true coefficient equals zero) across these alternative model specifications are summarized in Table 5. [Full model results are available on request].

Table 5 Summary of estimated coefficient for "Onsite MRI" for alternative measures of the difference in medicare MRI volume and alternative provider samples

MRI volume change measure	Principal provider sample (N = 433)		Confirmed provider sample (N = 371)	
	"Onsite MRI"	p-value	"Onsite MRI"	p-value
ΔMIRs as % Visits	-0.468	0.161	-0.604	0.273
ΔOrtho MIRs as % Visits	-0.399	0.210	-0.287	0.128
ΔNumber of MIRs	2.165	0.420	1.591	0.310
ΔNumber of Ortho-MIRs	0.102	0.977	0.152	0.507

Sources: see text

None of the point estimates of the onsite MRI coefficient are statistically significant ($p > 0.1$) across all of alternative model specifications reported in Table 5. Results using the principal provider sample are similar (in terms of coefficient point estimates) to results using a sample restricted to providers with their practice location during the study years confirmed by the practice re-survey. Thus, any potential errors in the assignment of specific physicians to specific practices appear to be too infrequent to have a substantive impact on model results.

Discussion

Economic theory predicts, and our results confirm, practices using imaging more intensively were more likely to acquire onsite MRI capacity (i.e., acquiring practices had higher MRI volume than non-MRI practices before MRI acquisition). This creates a sample selection (or endogeneity) issue when attempting to assess the causal impact of onsite MRI acquisition on MRI volume. By using a differences-in-differences model focusing on the change in MRI volume for individual physicians, any individual physician or practice characteristics (observed or unobserved) potentially affecting MRI volume that are invariant over the pre- and post- time periods "difference out" when analyzing the change in MRI volume. Covariate adjustment using proxy measures of physician "practice style" is not needed. Our model also adjusts for changes in observable practice area characteristics over time. To the extent unobservable time-varying factors exist, such factors are likely to affect the demand for imaging services and the likelihood of onsite MRI acquisition in the same direction. Thus, any remaining bias in our analysis relating to the sample selection issue would be toward finding a positive association between MRI acquisition and MRI volume.

None of our model results suggest any substantive change in Medicare MRI volume one-year post- onsite-MRI-acquisition and one-year pre- onsite-MRI-acquisition for physicians in MRI-acquiring practices relative to physicians in the non-MRI comparison practices. This finding is inconsistent with results reported in much of the literature focused on the issue of "self-referral" for imaging services.

The differences in findings may relate to differences in research designs, particularly as they relate to sample selection issue, and the specific measures of MRI acquisition used across studies. Some existing studies rely on proxy measures of the existence or size of ownership interests in specific ancillary services for individual physicians due to a lack data for specific provider interests. For example, close to a dozen published studies (e.g., Hughes et al. [12], Mitchell [13]) use an individual physician's referral patterns to "impute" physician ownership status for individual physicians. Specifically, physicians

with a relatively high share of their overall referrals going to a physician-owned facility are simply assumed to have ownership interest in the facility. These studies provide little or no evaluation of the validity of this imputation process for identifying individual physician ownership status, but even if approximately valid, the use of an imputed ownership status indicator based on patterns of referrals to predict patterns of referrals presents what should be a rather obvious and substantial threat to the validity of any resulting inferences about the causal effect of ownership status on referral volume. In contrast, our analysis uses direct and verified measures of access to onsite MRI capacity for individual providers.

A simple cross-sectional design is used in close to a dozen published studies, including Hillman et al. [10] and Paxton et al. [16]. These studies compare imaging volume for physicians with and without ownership interest in imaging capacity, not before and after the acquisition of ownership interest. Our results indicate that the physicians in practices acquiring onsite MRI capacity had higher MRI volume before MRI acquisition than physicians in similar practices that did not subsequently acquire onsite MRI capacity. Thus, simple cross-sectional comparisons are likely to yield a spurious positive association between onsite MRI acquisition and MRI volume owing to the endogeneity of onsite MRI capacity acquisition.

Still other past studies, such as Sharpe et al. [17], focus on imaging volume within practices acquiring imaging capacity over time, without an appropriate contemporaneous comparison group. Our results indicate that MRI volume increased over time for both MRI and non-MRI practices. Without an appropriate comparison group, our results might have suggested (incorrectly) that MRI acquisition per se was associated with an increase in MRI volume.

Finally, much of the early literature examining physician self-referral for imaging services focused on the general issue of physician investment interests in imaging facilities, including free-standing (off-site) imaging centers. As noted, organizational economics theory suggests that there are likely to be advantages (in terms of lower monitoring and transactions costs) associated with the ownership of imaging capacity for providers making more extensive use of imaging in their practices, compared to less imaging-intensive providers. However, these advantages are likely to more substantive for onsite capacity compared to off-site capacity. In other words, the degree of organizational control may be somewhat greater for owned off-site capacity compared to non-owned offsite capacity, but the degree of organizational control is likely to be far greater for owned onsite capacity compared to owned off-site capacity. Thus, the process of physician self-selection into

ownership of onsite imaging capacity reflected in our data may be different than the process of self-selection into imaging capacity ownership overall present in older studies.

Limitations

Although we used a web-based survey of orthopedic surgery practices to identify specific providers affiliated with practices at the time the practice first acquired onsite MRI capacity, and then used the CMS National Plan and Provider Enumeration System (NPPES) Full Replacement Monthly NPI File data and a re-survey of the final sample of practices included in the analysis to confirm that physicians identified as affiliated with an MRI practice in the survey data actually were affiliated with the practice one year before and one year the practice's MRI-year, the potential for errors in assignment of specific physicians to specific practices remains. If these assignment errors are common, the results of the claims data analysis of the change in MRI volume would be biased toward a finding of "no effect" of onsite MRI capacity.

While the practice re-survey confirmed 90 % of provider practice affiliations, the re-survey response rate was 43 %, so a similar rate of confirmation might not have been obtained from practices not responding to the re-survey. However, the fact that model results restricted to a sample of providers with confirmed practice affiliations produced results similar to results using the full (principal) provider sample provides some assurance that the potential for provider assignment errors is not a substantial limitation of the study.

The sample of providers included in the study was derived from a PS matching approach applied at the practice level using a specific caliper intended to provide a reasonable trade-off between covariate balance and the number of MRI practices retained in the final sample. Selection of a smaller caliper would have produced fewer matches, and thus fewer providers in our analysis sample, whereas a larger caliper would have produced more matches, and thus a larger provider sample. It is possible that a different practice-level PS matching approach yielding a different sample of providers in MRI and non-MRI practices would have produced different results. However, the fact that model results using the full (principal) provider sample were similar to model results using a sample of providers with re-survey confirmed practice affiliations suggests that the results are not highly sensitive to sampling approach used to select the specific providers included in the analysis.

Obviously, our analysis of Medicare claims data only provides information about patterns of MRI use within the Medicare segment of each physician's patient population. No inference about whether onsite MRI acquisition affects patterns of MRI use for other payers is possible. Past studies have shown that geographic variation in the

use of specific services for Medicare patients is not always reflective of patterns of use in non-Medicare populations [48]. Orthopedic surgery practices on average derive about one-third of their total practice revenues from Medicare. While this is not an inconsequential share, this study cannot assess the impact of onsite MRI capacity on use patterns for about two-thirds of the typical orthopedic surgery practice population. Even so, an assessment of the impact of onsite MRI capacity on use patterns for Medicare patients has direct relevance for public policy, as the Stark laws only apply to Medicare and Medicaid patients.

Moreover, commercial payers, especially managed care plans, typically employ stricter MRI utilization controls and incentives than the Medicare program [49]. Thus, rather than a limitation, our choice of examining the Medicare population could alternatively be viewed as a conservative decision; if provider ownership in onsite imaging capacity has a causal impact on imaging volume, we would expect the magnitude of the effect to be larger in the comparatively "less managed" Medicare population relative to more active care management in managed care markets. Our null finding for the Medicare population suggests the likelihood of a null finding in managed care population.

Conclusion

Our analysis of Medicare claims data employed outpatient claims data for the 2007, 2008, and 2009 cohorts of physicians in practices which acquired onsite MRI capacity and physicians in matched non-MRI practice. The claims analysis focused on the change in Medicare MRI volume one-year post-onsite-MRI-acquisition and one-year pre-onsite-MRI-acquisition for physicians in MRI practices relative to physicians in the non-MRI comparison practices. In all of the Medicare MRI volume change models estimated, the estimated impact of onsite MRI acquisition on the change in Medicare MRI volume is consistently small and not statistically significant. Thus, our data analysis provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period.

Competing interests

This research was conducted by Oxford Outcomes, Inc. (now ICON gk) through a contract with the American Academy of Orthopaedic Surgeons (AAOS). No additional competing interests to report.

Authors' contributions

All three authors confirm that we have made individual contributions to the completion of this manuscript to qualify as authors under ICMJE guidelines. Specifically, all of us: 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to

be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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EXHIBIT V



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Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

2016 MRI Non Operating Hours

Hamden MRI	ACR Tests	Weather Cancellation	Machine Maintenance	Air Conditioner Repair
Jan 23rd		14		
Feb 5th			6	
Feb 6th			2	
Feb 7th			2	
Mar 8th			3.5	
Mar 31st			1	
Apr 1st			1	
Apr 18th	1.5			
Apr 19th	3			
May 31st			1	
Jun 1st			1	
Aug 11th			1	
TOTAL HAMDEN	4.5	14	18.5	

2016 MRI Non Operating Hours

Branford MRI	<i>ACR Tests</i>	<i>Weather Cancellation</i>	<i>Machine Maintenance</i>	<i>Air Conditioner Repair</i>
Jan 13th			5.5	
Jan 23rd		14		
Feb 17th				1.5
Feb 26th			2.5	
Mar 4th			4	
Apr 11th			3	
Apr 12th			4	
Apr 18th	1.5			
Apr 19th	3			
Apr 20th			3	
Jun 7th			1.5	2.25
Aug 9th				2.5
Sep 22nd			4	
Sep 23 rd				2.25
Nov 8th				2.25
Nov 30th			5	
Dec 13th			3	
Dec 20th			5	
Dec 21st			3.5	
TOTAL BRANFORD	4.5	14	44	10.75

Combined Branford and Hamden MRI Non Operating Hours

Total number of non operating
hours:

110.25

User, OHCA

From: Fernandes, David
Sent: Thursday, February 02, 2017 1:02 PM
To: Glenn F. Elia; User, OHCA; Riggott, Kaila
Cc: 'klg1@aol.com'
Subject: RE: OHCA Docket No. 16-32117– CON 2nd Completeness Responses from COS

Good Afternoon Mr. Elia,
Confirming receipt of your responses to the Completeness Letter.

Thank you,

David Fernandes
Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



From: Glenn F. Elia [mailto:gelia@ct-ortho.com]
Sent: Thursday, February 02, 2017 12:03 PM
To: User, OHCA <OHCA@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>
Cc: 'klg1@aol.com' <klg1@aol.com>
Subject: OHCA Docket No. 16-32117– CON 2nd Completeness Responses from COS

From: Glenn F. Elia gelia@ct-ortho.com
To: OHCA@ct.gov., David.Fernandes@ct.gov. kaila.riggott@ct.gov, klg1@aol.com
Subject: OHCA Docket No. 16-32117– CON 2nd Completeness Responses to OHCA Questions dated December 8, 2016.
Date: February 2, 2017

Dear Ms. Riggott and Mr. Fernandes,

Attached please find the Word version of the COS Responses to OHCA's Completeness Questions dated December 8, 2016, which includes four (4) new exhibits. A copy of the same Completeness Responses, with

four (4) Exhibits is also attached in pdf format. The Revised Exhibit List is attached in both word and pdf format.

Please let me know if you need anything further. I would also appreciate knowing that you have received this email transmission with the four attached files. Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

March 3, 2017

Via Email Only

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518
gelia@ct-ortho.com

Ms. Patricia A. Gerner
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057
Klg1@aol.com

RE: Certificate of Need Application; Docket Number: 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Completeness Letter

Dear Mr. Elia and Ms. Gerner:

On February 2nd, 2017, the Department of Public Health ("DPH"), Office of Health Care Access ("OHCA") received completeness responses from Connecticut Orthopedic Specialist, P.C. ("COS") seeking authorization to acquire a Mobile 1.5T Magnetic Resonance Imaging Scanner.

OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). *Please "reply all" to electronically confirm receipt of this email as soon as you receive it.* Provide responses to the questions below in both a Word document and PDF format as an attachment to a responding email. *Please email your responses to each of the following email addresses:* OHCA@ct.gov and kaila.riggott@ct.gov.

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer

May 2, 2017 at 4:30p.m., otherwise your application will be automatically considered withdrawn.

Repeat each question before providing your response and paginate and date your response, (i.e., each page, in its entirety). Information filed after the initial CON application submission (e.g., completeness response letter, prefiled testimony, late file submissions and the like) must be numbered sequentially from the applicant’s document preceding it. Please begin your submission using **Page 275** and reference **“Docket Number: 16-32117-CON.”**

1. Please provide projected fiscal year 2020 information for the tables below.

COS’ PROJECTED NUMBER OF SCANS

	FISCAL YEAR		
	2018	2019	2020
Number of Scans by Scanner:			
Branford MRI	3,870	3,986	
Hamden MRI	3,870	3,986	
Orange MRI	1,545	1,591	
Essex MRI	1,577	1,624	
Total	10,862	11,187	

COS’ CURRENT & PROJECTED PAYER MIX

Payer	Fiscal Year 2017		Projected by Fiscal Year					
			2018		2019		2020	
	Discharges	%	Discharges	%	Discharges	%		
Medicare	1,898	18%	1,955	18%	2,014	18%		
Medicaid	74	.70%	76	.70%	78	.70%		
CHAMPUS & TriCare	0	0%	0	0%	0	0%		
Total Government	1,972	18.70%	2,031	18.70%	2,092	18.70%		
Commercial Insurers	7,276	69%	7,495	69%	7,719	69%		
Uninsured	42	.40%	43	.40%	45	.40%		
Workers Compensation	1,255	11.90%	1,293	11.90%	1,331	11.90%		
Total Non-Government	8,573	81.30%	8,831	81.30%	9,095	81.30%		
Total Payer Mix	10,545	100%	10,862	100%	11,187	100%		

COS’ PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2018	FY 2019	FY 2020
Revenue from Operations	\$992,096	\$1,187,746	
Total Operating Expenses	\$525,314	\$554,975	
Gain/Loss from Operations	\$466,782	\$632,771	

2. Please complete an updated Financial Worksheet B and provide any related assumptions used for fiscal year 2020.

If you have any questions concerning this letter, please feel free to contact Kaila Riggott at (860) 418-7037.

Olejarz, Barbara

From: Fernandes, David
Sent: Friday, March 03, 2017 1:07 PM
To: Glenn F. Elia; 'klg1@aol.com'
Cc: Greer, Leslie; Olejarz, Barbara; Riggott, Kaila
Subject: 16-32117 CON 3rd Completeness Letter
Attachments: 16-32117 Completeness Letter 3 Final.docx

Good afternoon Mr. Elia and Ms. Gerner,

Please see the attached completeness letter in the matter of the proposed acquisition of a mobile 1.5T MRI. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by May 2, 2017.

Email to OHCA@ct.gov and cc:Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



User, OHCA

From: mail@sf-notifications.com on behalf of Glenn Elia <mail@sf-notifications.com>
Sent: Wednesday, April 19, 2017 12:02 PM
To: User, OHCA
Subject: OCHA Docket No. 16-32117-CON 3rd Completeness Responses to OCHA Questions dated March 3, 2017



Glenn Elia has sent you files.

Expires 5/19/17

A note from Glenn :

April 18, 2017

Dear Ms. Riggott and Mr. Fernandes,

Attached please find the Word version of the COS Responses to OHCA's Completeness Questions dated March 3, 2017, which includes one (1) new exhibit and the Revised Index List. A copy of the same Completeness Responses, with one (1) exhibit and the Revised Exhibit List is also attached in PDF format.

Please let me know if you need anything further. I would also appreciate knowing that you have received this email transmission with the two attached files.

Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

[Download](#)

Trouble with the above link? You can copy and paste the following URL into your web browser:
<https://ct-ortho.sharefile.com/d/e859e676205c4d61>

ShareFile is a tool for sending, receiving, and organizing your business files online. It can be used as a password-protected area for sharing information with clients and partners, and it's an easy way to send files that are too large to e-mail.

Powered By Citrix ShareFile 2017

Exhibit List

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V	2016 MRI Non-Operating Hours for the Hamden and Branford MRI	271 - 274
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**CON Application: OHCA Docket Number 16 – 32117 – CON
Connecticut Orthopaedic Specialists, P. C.
Acquisition of a Mobile 1.5 T MRI Scanner
Completeness Response # 3: xxx, 2017**

1. Please provide projected fiscal year 2020 information for the tables below. (The Question)

COS' PROJECTED NUMBER OF SCANS

	FISCAL YEAR		
	2018	2019	2020
Number of Scans by Scanner:			
Branford MRI	3,870	3,986	
Hamden MRI	3,870	3,986	
Orange MRI	1,545	1,591	
Essex MRI	1,577	1,624	
Total	10,862	11,187	

COS' CURRENT & PROJECTED PAYER MIX

Payer	Fiscal Year 2017		Projected by Fiscal Year					
			2018		2019		2020	
	Discharges	%	Discharges	%	Discharges	%		
Medicare	1,898	18%	1,955	18%	2,014	18%		
Medicaid	74	.70%	76	.70%	78	.70%		
CHAMPUS & TriCare	0	0%	0	0%	0	0%		
Total Government	1,972	18.70%	2,031	18.70%	2,092	18.70%		
Commercial Insurers	7,276	69%	7,495	69%	7,719	69%		
Uninsured	42	.40%	43	.40%	45	.40%		
Workers Compensation	1,255	11.90%	1,293	11.90%	1,331	11.90%		
Total Non-Government	8,573	81.30%	8,831	81.30%	9,095	81.30%		
Total Payer Mix	10,545	100%	10,862	100%	11,187	100%		

COS' PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2018	FY 2019	FY 2020
Revenue from Operations	\$992,096	\$1,187,746	
Total Operating Expenses	\$525,314	\$554,975	
	\$466,782	\$632,771	

Response

Unless otherwise indicated, the assumptions presented on pages 34 and 35 of the CON application are valid.

COS' PROJECTED NUMBER OF SCANS

	FISCAL YEAR		
	2018	2019	2020
Number of Scans by Scanner:			
Branford MRI	3,870	3,986	3,986
Hamden MRI	3,870	3,986	3,986
Orange MRI	1,545	1,591	1,591
Essex MRI	1,577	1,624	1,624
Total	10,862	11,187	11,187

Assumptions:

The MRI utilization for the four locations for 2020 is projected to be the same as that experienced in 2019. By 2020 the MRI service at Hamden and Branford will be a mature service with little or no increase in volume expected.

Additionally, the two mobile locations (Orange and Essex) will be operating at close to 100% utilization for the two days per week they are authorized; Orange will operate at 95% capacity and Essex at 97.5% capacity.

COS' CURRENT & PROJECTED PAYER MIX

Payer	Fiscal Year 2017		Projected by Fiscal Year					
			2018		2019		2020	
	Patients	%	Patients	%	Patients	%	Patients	%
Medicare	1,998	21.3%	2,314	21.3%	2,383	21.3%	2,383	21.3%
Medicaid	84	0.9%	98	0.9%	101	0.9%	101	0.9%
CHAMPUS & TriCare	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Government	2,083	22.2%	2,411	22.2%	2,484	22.2%	2,484	22.2%
Commercial Insurers	6,351	67.7%	7,354	67.7%	7,574	67.7%	7,574	67.7%
Uninsured	9	0.1%	11	0.1%	11	0.1%	11	0.1%
Workers Compensation	938	10.0%	1,086	10.0%	1,119	10.0%	1,119	10.0%
Total Non-Government	7,298	77.8%	8,451	77.8%	8,703	77.8%	8,703	77.8%
Total Payer Mix	9,381	100.0%	10,862	100.0%	11,187	100.0%	11,187	100.0%

Assumptions:

The patient population mix has been revised to reflect the 2016 actual payer mix. The actual 2016 percentage of Medicare and Medicaid patients, which increased from 2015, was reported in the responses to the second completeness letter, Exhibit T page 260.

Based on the legal requirements of the CON review process, the anticipated start of the project has been revised to January 2018. Since it appears that the mobile scanner will not be in

operation, the number of patients for FY 2017 has been revised to reflect a 3% increase in actual 2016 volume at both the Branford and Hamden locations (please see page 254 of the CON application for 2016 utilization data).

The projected FY 2107 utilization is 4,839 scans at the Branford location and 4,542 scans at the Hamden location for a total of 9,381 MRI scans. It should be noted that this represents 98% capacity at Branford and 92% capacity at Hamden based on scheduled hours of operation; it does not provide for any reductions in MRI availability due to machine maintenance, weather cancellation, ACR testing, or machine repair. There is no volume projected for the Essex or Orange locations in FY 2017.

COS' PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2018	FY 2019	FY 2020
Revenue from Operations	\$ 875,271	\$ 1,067,346	\$ 1,067,346
Total Operating Expenses	\$ 543,694	\$ 568,420	\$ 572,939
	\$ 331,577	\$ 498,926	\$ 494,407

2. Please complete an updated Financial Worksheet B and provide any related assumptions used for fiscal year 2020.

Please see Exhibit W which contains an updated Financial Worksheet B. The revised assumptions are as follows:

Assumptions for Financial Worksheet

Overall assumptions

The mobile scanner will begin operation in FY 2018. If authorization is received earlier than anticipated and the mobile MRI service begins in 2017, revised utilization projections and financial statements will be submitted.

The FY 2017 utilization is based on FY 2016 data for the existing Hamden and Branford MRI scanners (9,108 total MRI scans) with a 3% rate of increase.

There is no volume projected for the Essex or Orange locations in FY 2017.

The MRI utilization for the four locations for 2020 is projected to be the same as that experienced in 2019. By 2020 the MRI will be a mature service with little or no increase in volume expected.

Revenue assumptions

For projections without CON, it is assumed that number of scans would remain constant from 2017 levels since current units are at nearly full capacity.

Payer mix assumptions for number of scans and per scan reimbursements by payer are based on FY 2016 actual data.

Salaries & Wages

Includes MRI technicians, support staff and authorizations staff as well as supervisor for business unit. Assume 3% annual cost of living increases for existing staff. Assumes addition of 1.0 FTE in 2017 for increased number of authorizations, patient scheduling and follow up.

With addition of new unit to be utilized in Essex and Orange, 2.0 FTE's would be added to support additional locations.

Fringe benefits

Includes payroll taxes, health and dental coverage for staff members, disability and life insurance and retirement plan contributions.

Physician fees

Includes radiologist expense based on annual number of scans.

Depreciation and amortization

Includes depreciation expense for existing units. Assumes addition of 5 year depreciation on capital expenditure of \$730,000 for purchase of new unit and installation costs.

Interest expense

Includes interest on existing two units. Projected incremental assumes 4% interest rate on \$730,000 loan for purchase of additional unit and installation.

Malpractice Expense

Includes malpractice expense for two radiologists supporting MRI units. Currently 1 full-time radiologist and 1 part-time radiologist support the two existing units. It is anticipated that the part-time radiologist will be able to increase his hours with us to assist in handling the incremental volume of scans.

Other Operating Expenses

Includes rent, utilities, property taxes and other real estate operating costs for existing equipment and locations.

Includes equipment maintenance expenses as well as repairs and maintenance for locations.

Includes IT support expenses, and office supplies expense as well as billing and collections staff and corporate administrative support including accounting, human resources and management team supervision.

Without the proposal and not taking into account any increase for inflation, it is assumed that 2017 levels will remain constant with the exception of billing and collections expense, which will increase based on volume of scans. Projected incremental increases also includes moving

expense for mobile unit, two moves per week and increased utilities costs at the two proposed locations.

EXHIBIT W

User, OHCA

From: Lazarus, Steven
Sent: Friday, May 12, 2017 8:36 AM
To: klg1@aol.com; Fernandes, David
Cc: gelia@ct-ortho.com; User, OHCA; Riggott, Kaila
Subject: Re: OHCA Docket No. 16-32117-CON

Thank you Pat. David is out of the office until Wednesday and will return this coming Wednesday and can follow up with you if he has any questions.

Steve

From: klg1@aol.com <klg1@aol.com>
Sent: Friday, May 12, 2017 8:25:02 AM
To: Fernandes, David
Cc: Lazarus, Steven; gelia@ct-ortho.com
Subject: OHCA Docket No. 16-32117-CON

David,

I am sending this email on behalf of Connecticut Orthopaedic Specialists. On Monday, May 9th, I sent an email to update the information on page 33 of the CON application regarding the minimum number of units to show an incremental gain for 2020. Based on the information that was submitted in the original application, that information is accurate.

However, the application was filed in 2016, and the 3 year period for projected utilization, revenue, expenses and units required to show a gain included 2017, 2018 and 2019. Since it is now 2017, the 3 year period for the projected financials has changed to include 2018, 2019 and 2020. In the COS response to OHCA's Completeness Questions #3, on pages 278 and 279 and Exhibit W of the CON application, projections for utilization, payer mix, incremental revenues and expenses were all revised. As a result, the minimum number of units required to show an incremental gain also changed.

The revised numbers for each year for the minimum number of units required to show an incremental gain are as follows:

2018:	920 scans (units)
2019:	962 scans (units)
2020	969 scans (units)

Thank you,

Patricia A. Gerner

The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Email: klg1@aol.com

User, OHCA

From: Fernandes, David
Sent: Friday, May 19, 2017 8:46 AM
To: gelia@ct-ortho.com; klj1@aol.com
Cc: User, OHCA; Greer, Leslie; Lazarus, Steven; Riggott, Kaila
Subject: 16-32117-CON Deemed Complete
Attachments: 16-32117-CON Notification of Application Deemed Complete.pdf

Good Morning Mr. Elia and Ms. Gerner,

Please see the attached letter deeming the above-referenced application complete. Please confirm receipt of this email and corresponding attachment.

Sincerely,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

May 19, 2017

Via Email Only

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518
gelia@ct-ortho.com

Ms. Patricia A. Gerner
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057
Klg1@aol.com

RE: Certificate of Need Application, Docket Number 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

Dear Mr. Elia and Ms. Gerner:

This letter is to inform you that, pursuant to Section 19a-639a (d) of the Connecticut General Statutes, the Office of Health Care Access has deemed the above-referenced application complete as of May 19, 2017.

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7032.

Sincerely,

David Fernandes
Planning Analyst (CCT)



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer



User, OHCA

From: Fernandes, David
Sent: Monday, May 22, 2017 8:15 AM
To: User, OHCA
Subject: FW: OHCA Docket No. 16-32117-CON
Attachments: COS Letter to OHCA 5.22.17.pdf

Please place on the record.

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



From: klg1@aol.com [mailto:klg1@aol.com]
Sent: Monday, May 22, 2017 8:04 AM
To: Fernandes, David <David.Fernandes@ct.gov>
Cc: gelia@ct-ortho.com
Subject: OHCA Docket No. 16-32117-CON

Dear Mr. Fernandes,

Attached please find a letter confirming receipt of your notice dated May 19, 2017 that the CON application of Connecticut Orthopaedic Specialists, P.C. in OHCA Docket No. 16-32117-CON was deemed complete on May 19, 2017.

Sincerely,

Pat Gerner
klg1@aol.com

The Law Office of Patricia A. Gerner, LLC

240 Ramstein Road: P.O. Box 209

New Hartford, CT 06057

Phone: (860) 794-1907 Fax: (860) 489-9380

May 22, 2017

Mr. David Fernandes
Planning Analyst
Office of Health Care Access
410 Capitol Avenue
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application: Docket No. 16-32117-CON

Dear Mr. Fernandes,

This is to acknowledge receipt of your letter dated May 19, 2017 confirming that the application of Connecticut Orthopaedic Specialists, P.C. to acquire a mobile 1.5T magnetic resonance imaging scanner was deemed complete by the Office of Health Care Access on May 19, 2017.

Thank you for this notification.

Sincerely,



Patricia A. Gerner

User, OHCA

From: Yoder, Clark <Clark.Yoder@adrad.com>
Sent: Wednesday, May 31, 2017 10:19 AM
To: User, OHCA
Cc: Riggott, Kaila; Jennifer Groves Fusco
Subject: Connecticut Orthopaedic Specialists: Docket No. 16-32177-CON
Attachments: OCHA Docket#16-32117-CON COS Public Hearing Request 5.31.17.pdf

Dear Deputy Commissioner Addo,

Please find the attached letter pertaining to Docket# 16-32117-CON – Connecticut Orthopaedic Specialists.

If you have any questions, please do not hesitate to contact me or Jennifer Fusco, Esq.

Thank you.

Clark Yoder, M.B.A.
Chief Executive Officer
Advanced Radiology Consultants
3 Enterprise Drive Ste 220
Shelton CT 06484-4696



May 31, 2017

VIA ELECTRONIC & REGULAR MAIL

Yvonne T. Addo, M.B.A.
Deputy Commissioner
Department of Public Health
410 Capitol Avenue, P.O. Box 340308
Hartford, CT 06134-0308

Re: Public Hearing Request
Docket No. 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of 1.5 Tesla Mobile MRI Unit

Dear Deputy Commissioner Addo,

In accordance with Section 19a-639a(e) of the Connecticut General Statutes, Advanced Radiology Consultants, LLC ("ARC") hereby requests that the Office of Health Care Access hold a public hearing on Docket No. 16-32117-CON. This docket concerns a proposal by Connecticut Orthopaedic Specialists, P.C. to acquire a 1.5 Tesla mobile MRI unit for use in Orange and Essex.

ARC is a private radiology practice headquartered in Shelton. ARC has more than five (5) employees and is therefore entitled to request a public hearing under Section 19a-639a(e).

Thank you in advance for your consideration of this request.

Very Truly Yours,

A handwritten signature in blue ink, appearing to read 'Clark Yoder', with a long, sweeping underline.

Clark Yoder
Chief Executive Officer

cc: Jennifer G. Fusco, Esq.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Raul Pino, M.D., M.P.H.
Commissioner

Office of Health Care Access

TO: Kevin Hansted, Hearing Officer

FROM: Raul Pino MD/MPH, Commissioner 

DATE: June 7, 2017

RE: Certificate of Need Application: Docket Number: 16-32117-CON
Connecticut Orthopaedic Specialist, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

I hereby designate you to sit as a hearing officer in the above-captioned matter to rule on all motions and recommend findings of fact and conclusions of law upon completion of the hearing.



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410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

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Olejarz, Barbara

From: Olejarz, Barbara
Sent: Thursday, June 08, 2017 11:09 AM
To: 'gelia@ct-ortho.com'; 'klg1@aol.com'
Subject: Notice of Public Hearing
Attachments: 16-32117 Applicant.pdf; 16-32117 New Haven Register.pdf; 16-32117 Hartford Courant.pdf

Tracking:	Recipient	Delivery	Read
	'gelia@ct-ortho.com'		
	'klg1@aol.com'		
	Lazarus, Steven		
	Fernandes, David		Read: 6/8/2017 11:33 AM
	Riggott, Kaila		
	Martone, Kim	Delivered: 6/8/2017 11:09 AM	
	Salton, Henry A.		
	Casagrande, Antony A	Delivered: 6/8/2017 11:09 AM	
	Hansted, Kevin		
	Furniss, Wendy (Wendy.Furniss@ct.gov)	Delivered: 6/8/2017 11:09 AM	
	Downes, Maura	Delivered: 6/8/2017 11:09 AM	Read: 6/8/2017 11:28 AM
	Kennedy, Jill	Delivered: 6/8/2017 11:09 AM	
	Stan, Christopher	Delivered: 6/8/2017 11:09 AM	
	'daniels@chime.org'		
	Addo, Yvonne		Read: 6/8/2017 11:59 AM
	Foreman, Rebecca		
	Rebecca.Foreman@ct.gov	Delivered: 6/8/2017 11:09 AM	
	Kevin.Hansted@ct.gov	Delivered: 6/8/2017 11:09 AM	
	Yvonne.Addo@ct.gov	Delivered: 6/8/2017 11:09 AM	
	Steven.Lazarus@ct.gov	Delivered: 6/8/2017 11:09 AM	
	David.Fernandes@ct.gov	Delivered: 6/8/2017 11:09 AM	
	Kaila.Riggott@ct.gov	Delivered: 6/8/2017 11:09 AM	
	Henry.Salton@ct.gov	Delivered: 6/8/2017 11:09 AM	

6/8/17

Please see the attached notice of public Hearing scheduled for July 11, 2017 regarding Connecticut Orthopaedic Specialist, PC. Also attached are the two newspaper notices that will be published noticing the hearing.

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access

Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

June 8, 2017

Glenn F. Elia
Chief Executive Officer
Connecticut Orthopaedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518

RE: Certificate of Need Application, Docket Number 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Applicant Hearing Notice

Dear Mr. Elia:

With the receipt of the completed Certificate of Need ("CON") application, submitted by Connecticut Orthopaedic Specialist, P.C. ("Applicant") on May 19, 2017, the Office of Health Care Access ("OHCA") has initiated its review of the CON application identified above.

Pursuant to General Statutes § 19a-639a (f)(2), OHCA may hold a hearing with respect to any Certificate of Need application.

This hearing notice is being issued pursuant to General Statutes § 19a-639a (f)(2)

Applicant(s): Connecticut Orthopaedic Specialist, P.C

Docket Number: 16-32117-CON

Proposal: Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner



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Jun 8, 2017

Notice is hereby given of a public hearing to be held in this matter to commence on:

Date: July 11, 2017

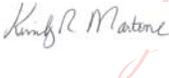
Time: 9:00 a.m.

Place: Department of Public Health, Office of Health Care Access
410 Capitol Avenue, Third Floor Hearing Room
Hartford, CT 06134

The Applicant is designated as a party in this proceeding. Enclosed for your information is a copy of the hearing notice for the public hearing that will be published in the *Hartford Courant and the New Haven Register*, pursuant to General Statutes § 19a-639a (f)(2).

All Applicants and Intervenors are reminded that The Office of Health Care Access division of the Department of Public Health follows the Rules of Practice under section 19a-9-1, et seq., of the Regulations of Connecticut State Agencies.

Sincerely,

 Digitally signed by
Kimberly Martone
Date: 2017.06.08
10:54:20 -04'00'

Kimberly R. Martone
Director of Operations

Enclosure

cc: Henry Salton, Esq., Office of the Attorney General
Antony Casagrande, Department of Public Health
Kevin Hansted, Department of Public Health
Wendy Furniss, Department of Public Health
Maura Downes, Department of Public Health
Jill Kennedy, Department of Public Health
Chris Stan, Department of Public Health
Marielle Daniels, Connecticut Hospital Association

KRM:DF:SWL:bko

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

June 8, 2017

P.O. #54772

Hartford Courant
285 Broad Street
Hartford, CT 06115

Gentlemen/Ladies:

Please make an insertion of the attached copy, in a single column space, set solid under legal notices, in the issue of your newspaper by no later than Friday, **June 9, 2017**. Please provide the following within 30 days of publication:

- Proof of publication (copy of legal ad. acceptable) showing published date along with the invoice.

If there are any questions regarding this legal notice, please contact Kaila Riggott at (860) 418-7001.

KINDLY RENDER BILL IN DUPLICATE ATTACHED TO THE TEAR SHEET.

Sincerely,

Handwritten signature of Kimberly R. Martone in blue ink.

Digitally signed by Kimberly
Martone
Date: 2017.06.08 12:40:13
-04'00'

Kimberly R. Martone
Director of Operations

Attachment

cc: Danielle Pare, DPH
Marielle Daniels, Connecticut Hospital Association

KRM:DF:SWL:bko



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Hartford, Connecticut 06134-0308
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PLEASE INSERT THE FOLLOWING:

Office of Health Care Access Public Hearings

Statute Reference: 19a-638
Applicant: Connecticut Orthopaedic Specialist, P.C.
Towns: Essex and Orange
Docket Number(s): 16-32117-CON
Proposal: Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Date: July 11, 2017
Time: 9:00 a.m.
Place: Department of Public Health, Office of Health Care Access
410 Capitol Avenue, Third Floor Hearing Room
Hartford, CT 06134

Any person who wishes to request status in the above listed public hearing may file a written petition no later than July 6, 2017 (5 calendar days before the date of the hearing) pursuant to the Regulations of Connecticut State Agencies §§ 19a-9-26 and 19a-9-27. If the request for status is granted, such person shall be designated as a Party, an Intervenor or an Informal Participant in the above proceeding. Please check OHCA's website at www.ct.gov/ohca for more information or call OHCA directly at (860) 418-7001. If you require aid or accommodation to participate fully and fairly in this hearing, please phone (860) 418-7001.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

June 8, 2017

P.O. #54772

New Haven Register
40 Sargent Street
New Haven, CT 06531-0715

Gentlemen/Ladies:

Please make an insertion of the attached copy, in a single column space, set solid under legal notices, in the issue of your newspaper by no later than Friday, **June 9, 2017**. Please provide the following within 30 days of publication:

- Proof of publication (copy of legal ad. acceptable) showing published date along with the invoice.

If there are any questions regarding this legal notice, please contact Kaila Riggott at (860) 418-7001.

KINDLY RENDER BILL IN DUPLICATE ATTACHED TO THE TEAR SHEET.

Sincerely,


Digitally signed by Kimberly
Martone
Date: 2017.06.08 12:39:37
-04'00'

Kimberly R. Martone
Director of Operations

Attachment

cc: Danielle Pare, DPH
Marielle Daniels, Connecticut Hospital Association

KRM:DF:SWL:bko



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PLEASE INSERT THE FOLLOWING:

Office of Health Care Access Public Hearings

Statute Reference: 19a-638
Applicant: Connecticut Orthopaedic Specialist, P.C.
Towns: Essex and Orange
Docket Number(s): 16-32117-CON
Proposal: Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Date: July 11, 2017
Time: 9:00 a.m.
Place: Department of Public Health, Office of Health Care Access
410 Capitol Avenue, Third Floor Hearing Room
Hartford, CT 06134

Any person who wishes to request status in the above listed public hearing may file a written petition no later than July 6, 2017 (5 calendar days before the date of the hearing) pursuant to the Regulations of Connecticut State Agencies §§ 19a-9-26 and 19a-9-27. If the request for status is granted, such person shall be designated as a Party, an Intervenor or an Informal Participant in the above proceeding. Please check OHCA's website at www.ct.gov/ohca for more information or call OHCA directly at (860) 418-7001. If you require aid or accommodation to participate fully and fairly in this hearing, please phone (860) 418-7001.

User, OHCA

From: Lazarus, Steven
Sent: Wednesday, June 14, 2017 2:00 PM
To: KLG1@aol.com; gelia@ct-ortho.com
Cc: User, OHCA; Riggott, Kaila; Hansted, Kevin; Fernandes, David
Subject: DN: 16-32117-CON, Request for Prefile Testimony
Attachments: 16-32117 Request for Prefile Testimony FINAL 6 14 17.pdf

Good Afternoon Attorney Gerner and Mr. Elia,

Please see the attached document requesting Applicant's prefile testimony for the hearing schedule for July 11, 2017, in the above referenced matter. If you have any questions, please don't hesitate to contact our office.

Thank you,

Steven

Steven W. Lazarus

Associate Health Care Analyst
Division of Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7012
Fax: 860-418-7053



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

June 14, 2017

Via Email Only

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518
gelia@ct-ortho.com

Ms. Patricia A. Gerner
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057
Klg1@aol.com

RE: Certificate of Need Application, Docket Number 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Request for Prefiled Testimony

Dear Mr. Elia and Ms. Gerner:

The Office of Health Care Access (“OHCA”) will hold a public hearing on the above docket number on July 11, 2017. The hearing is at 9:00 am, at the Department of Public Health, Office of Health Care Access 410 Capitol Avenue, third floor hearing room Hartford, CT 06134. Pursuant to the Regulations of Connecticut State Agencies § 19a-9-29(e), any party or other participant is required to prefile in written form all substantive, technical, or expert testimony that it proposes to offer at the hearing. OHCA requests that Connecticut Orthopaedic Specialist (“Applicant in this matter”) submit prefiled testimony **by 4:00 p.m. on June 27, 2017.**

All persons providing prefiled testimony must be present at the public hearing to adopt their written testimony under oath and must be available for cross-examination for the entire duration of the hearing. If you are unable to meet the specified time for filing the prefiled testimony you



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must request a time extension in writing, detailing the reasons for not being able to meet the specified deadline.

Please contact Kaila Riggott at (860) 418-7037, if you have any questions concerning this request.

Sincerely,



Digitally signed by Kevin T.
Hansted
Date: 2017.06.14 13:52:33 -04'00'

Kevin T. Hansted
Hearing Officer

User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, June 27, 2017 10:56 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: 'klg1@aol.com'
Subject: Subject: OHCA Docket No. 16-32117-CON Prefile Testimony & CVs
Attachments: COS Final Pre-File of Glenn Elia, CEO.docx; COS Final Pre-File of Dr. Gagliardi 6.23.17.docx; COS Final Prefile of Dr. Lorenze 6.23.17.docx; COS Final Prefile of Dr. Ruwe 6.23.17.docx; Glenn Elia prefile testimony.pdf; Joseph Gagliardi prefile testimony.pdf; Mark Lorenze prefile testimony.pdf; Patrick Ruwe prefile testimony.pdf; J Gagliardi CV.pdf; P Ruwe CV.pdf; M Lorenze CV.pdf; B Foraker CV.pdf

Date June 23, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find the prefile testimony for myself (Glenn Elia), Dr. Ruwe, Dr. Gagliardi, and Dr. Lorenze. Also there are three CVs that were not included in the application (Drs. Ruwe, Lorenze and Ms. B. Foraker) and one CV that has been revised (Dr. Gagliardi's) to include his employment with COS.

Please let me know if you need anything further. I would also appreciate knowing that OHCA has received this email transmission with its 12 attachments.

Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF THE OFFICE OF	:	DOCKET NO. 16-32117-CON
HEALTH CARE ACCESS	:	
	:	
	:	
IN RE: CONNECTICUT ORTHOPAEDIC	:	JUNE 27, 2017
SPECIALISTS, P.C., ACQUISITION OF A	:	
1.5 T MOBILE MRI	:	

PRE-FILE TESTIMONY OF GLENN F. ELIA, CEO

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Glenn Elia, and I am the CEO of Connecticut Orthopaedic Specialists (“COS”). At this time, I hereby adopt my prefile testimony. With me today are, Dr. Joseph Gagliardi, the COS board certified staff orthopedic radiologist, two orthopedic specialists; Dr. Patrick Ruwe, President of COS and Dr. Mark Lorenze, Billie Jo Foraker, the Director of Clinical Services & Radiology of COS Radiology, and Susan Bader, Chief Financial Officer of COS.

Connecticut Orthopaedic Specialists (COS) is a multi-specialty musculo skeletal practice with a concentration in orthopedic care. Our main office is located in Hamden, CT. The practice has been serving Connecticut patients for over 50 years. COS earned its reputation as of being an innovative practice which offers outstanding treatment for our patient population. COS was the first single specialty orthopedic group in CT to obtain a CON for an outpatient surgical center. This center is now a 4-room environment and has achieved national recognition for the quality of care it delivers. The COS surgical center is the first center in the State to offer outpatient total joint procedures under a bundled payment program. COS was also the first orthopedic practice to obtain payer contracts for its MRI. COS now operates two 1.5 T MRI units and is contracted with all insurers. All of our ground-breaking developments have enhanced the patient experience while lowering the

overall cost of care. Each COS orthopedic physician is board certified in a specific orthopedic area of expertise; for example- back, foot and ankle, shoulder, hip and athletic injuries, to name a few. Our practice is growing annually since our patients are drawn to COS because of the quality of its practitioners, the innovative comprehensive delivery of services we offer and most importantly the overall total patient experience. It is the mission of COS to meet the orthopedic needs of our patient community while working to reduce the cost of care within the healthcare delivery system.

We are here today to request that you approve our CON application for a mobile 1.5 Tesla MRI for use 4 days a week – 2 days in Essex and 2 days in Orange. This is not a request to offer a new service: COS has been providing MRI scans to its patients for many years. COS currently has a 1.5 Tesla MRI in its Hamden office and a 1.5 Tesla MRI on its Branford campus. There is no facility fee charged at COS MRI scanning offices.

COS believes that its CON application has met all the requirements in Section 19-639 of the CT General Statutes and the criteria for additional MRI service as set forth in the CT Statewide Health Care Facilities and Services Plan. This morning I will touch on the highlights of our application, and the physicians will have some brief testimony as well.

Consistent with our innovative and cost effect approach, we have applied for permission for a mobile MRI rather than ask for a fixed MRI in one location. A mobile MRI will allow us to add just 2 days of scanning per week in each of the two most critical locations where it is needed, Orange and Essex. All our planning is centered around a value-based model where we offer the highest quality of health care at the lowest possible cost. The mobile MRI will make the process of MRI scanning as streamlined and cost-effective as possible. The mobile MRI will be linked directly to a COS physician office in Orange and in Essex. The MRI service is not available to patients who are not being treated by a COS orthopedic physician;

we are not in direct competition with radiology practices which offer many types of testing - from ultrasound to bone density, to mammograms and vascular imaging, as well as nuclear medicine and PET/CT. The utilization of MRI scans is integral to the delivery of a comprehensive orthopedic care service. As we all know, healthcare has undergone significant changes in the past few years. Consolidation of medical practices has begun to be essential for the survival of private practices. The predatory behavior of some healthcare systems has forced COS to merge with several other smaller orthopedic groups in order to maintain our viability.

We would not be here today if other orthopedic practices had not become a part of COS in 2014 and 2015. Over the past few years, four (4) orthopedic private-practice physician groups, which have twelve (12) existing offices, have joined with COS. As a result of these mergers, there are now 49 orthopedic physicians in 20 COS offices in Connecticut.¹ The 12 new locations include offices in Hamden, Branford, Orange, Essex and Madison. With all of the new offices and the patient demand for MRI service within COS, we looked first at where we could locate the mobile scanner so that it would ease the existing demand in Branford and Hamden. Both of those facilities are currently at maximum capacity even with overtime hours. To locate the proposed scanner two days a week in Orange, which is reasonably close to both Hamden and Branford, would allow existing COS patients to continue to have access to a COS MRI scanner. Patients who use the Shoreline Orthopedic & Sports Medicine offices have not had access to the COS MRI scanners in Branford or Hamden. Locating the scanner in Essex for two days a week would improve access to MRI services for these patients.

It was in 2014 that we saw new demand for MRI services as patients from the newly affiliated offices began to rapidly fill up the available time slots in Hamden and Branford, at our 2 existing COS MRIs. At that time, we expanded the hours at both

¹ When this application was filed, there were 21 offices with 13 orthopedic physicians, but one of the Shoreline Orthopedic & Sports Medicine offices (the Guilford office) closed after the application was filed with OHCA. (Record, p. 256 fn.)

MRI sites, which are now operating 13 hours a day on weekdays, 10 hours a day on Saturdays, and flexible hours in Hamden on Sundays for emergencies. We are currently open 75 hours a week at both locations, which does not include hours on Sunday in Hamden. Exhibit B in our application (Record, p.70) is a graph where the growth in volume from FY2013 through the first 6 months of FY2016 is detailed.

In our initial filing of this CON application, our utilization calculations were based on the Statewide Health Care Facilities and Services Plan which considers 4,000 scans per MRI unit as a maximum, operating at 85% capacity, taking into consideration time for repair, bad weather etc., or 3,400 scans maximum per year. In 2015, the MRI scanner in Hamden had performed 3,773 scans which was 94% utilization of current capacity, and was projected to have a 110% utilization of current capacity in 2016 (4,428 scans). (Record, p. 42). The actual number of scans performed by COS in FY2016 in Hamden was 4,410, a difference of 18 scans from the forecast. (Record, p. 254, 2nd Completeness).

Similarly when the application was filed, and using the Statewide Health Care Facilities and Services Plan methodology, in FY2015 the MRI scanner in Branford performed 3,851 scans which was 96% utilization of the current capacity, and was projected to have a 120% utilization of current capacity in FY2016 (4,786 scans). (Record, p. 42). The actual number of scans performed by COS in Branford in FY2016 was 4,698 which represents a total of 117% utilization. (Record. p. 254, Completeness #2).

In Question #5 of the 2nd Completeness Question dated February 2, 2017 OHCA asked the following:

“Based on the Applicant’s assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location? “ (Record, p, 254).

Given that our existing scanners are now functioning at these levels, they meet the standard set forth in the CT Statewide Health Care Facilities and Services Plan, which requires that an existing MRI be at 85% of capacity in order to seek additional MRI service. COS meets that guideline.

COS responded that the maximum number of scans that can be performed in Hamden and Branford, based strictly on the hours per week and the minutes per scan is 4,960 scans. (Record, p. 256). This number is overstated because it does not include time out for weather cancellation, ACR testing or MRI maintenance because those factors vary from year to year. Looking at the utilization of each of the MRI scanners based on the maximum number of scans that could be done at each location, as requested in Completeness #2, Question No. 5, COS determined that in FY2016, 4,410 scans were performed on the Hamden MRI which is an 89% utilization rate. The Branford MRI performed 4,698 scans in FY 2016, which is a 95% utilization rate. (Record, p. 254). Using either methodology (either the Statewide Health Care Facilities and Services methodology of assuming 4,000 scans or the capability of each specific MRI which in this case is higher at each of the COS location), COS has met the standard of reaching 85% utilization as required to apply for additional MRI capacity.

COS does not need to rely on adding any new physicians to support the additional MRI capacity being requested in this CON application. That being said, we continue to recruit new physicians to meet the growing demands of our growing patient volumes. The current MRI volume already exists, and as a result, both locations in Orange and Essex will start with a substantial number of new patients who will no longer be able to use Branford and Hamden due to the existing volumes, but who want to stay within the comprehensive COS delivery system.

As you know from our application, if it is approved, COS will reduce the hours in Hamden and Branford so that they operate at a more reasonable and efficient level. Since it is more expensive to operate on nights and weekend days because of the

overtime cost for technicians, this reduction, which can only occur if the mobile MRI is approved, will be a more efficient way to operate the MRIs at Hamden and Branford. Currently, both of these offices offer MRI scanning 75 hours a week (which includes 13 hours per day every weekday and 10 hours every Saturday). Hamden has accepted appointments on Sundays of up to 10 hours per day. When this happens, the MRI scanners are operating 85 hours per week. Weekdays will be cut back from 13 hours a day to 12 hours per day, and Saturday hours will be reduced from 10 hours a day to 4 hours a day, which means that some of those COS patients who would have been scanned on either of the 2 COS MRIs will cause the volume to go up in other facilities.

While we expect that some of this overflow of COS patients will use the COS mobile scanner in Orange or in Essex, a great deal depends upon the patient's residence. For the patients who want one provider to manage the entire course of orthopedic treatment, they will most likely go to the closest COS MRI scanner, mobile or fixed.

The anticipated maximum volume for both Branford and Hamden will be 3,870 scans at each location, which is a drop of 916 patient scans from FY2016 levels in Branford, and a drop of 540 patients scans in Hamden compared to the volume in FY 2016. It is anticipated that the mobile scanner will handle 1,577 scans in Orange and Essex at each mobile location, operating only 2 days per week. (See R., p. 278, 3rd Completeness). The proposed mobile MRI will operate a total of 4 days a week, 12 hours a day at 45 minutes per scan for a maximum of 3,328 scans (1,664 scans per year at each location).

The proposed mobile MRI scanner in Orange will be available to COS patients who are now using Hamden or Branford, as those patients can shift over to the mobile MRI where there will be more room to accommodate them if they so choose. Due to the proximity of Hamden and Orange, COS anticipates that a significant number of patients who are currently using the COS Hamden MRI will use the mobile MRI in Orange. Also, there are 6 COS offices in the Orange area (3 original and 3 from the

new affiliations). COS conducted an internal analysis which demonstrated that in FY2015, 447 COS patients in the Orange service area were referred to non-COS MRIs. (Record, p. 198). We anticipate that a majority of these patients will use the mobile MRI when it is located in Orange.

There are now more COS patients in the Essex service area who require MRI scanning due to the two offices of Shoreline Orthopedic & Sports Medicine that have affiliated with COS. There has been no COS MRI service available in either of the two towns where the newly affiliated COS offices are located. The COS patients in Essex and Madison have been using a variety of MRI providers. In FY2015, the internal records for the Shoreline Orthopedic & Sports Medicine practice indicated that a total of 963 patients were referred to external, non-COS providers for MRI scans. Of the 963 patients, 569 patients reside in the Essex primary service area for the proposed mobile MRI. Virtually no patients were referred to the COS scanners in Branford or Hamden due to lack of capacity, and the distance between the existing COS scanners and the patients living in the Essex area. Also, there had been no COS physician treating patients in the Essex area prior to the affiliation with Shoreline Orthopedics & Sports Medicine.

In 2015, 950 patients who lived in Essex were treated at a COS facility outside of Essex and had their MRI scan performed at the COS MRI either in Hamden or Branford. CON App., Exh. (J-1). It is anticipated that these patients will use the proposed mobile MRI in Essex.

Since there is currently no space within COS for this MRI growth to occur with the existing scanning capacity, there is no doubt that there is a need for the mobile MRI service for COS patients who want all of their treatment coordinated with one provider. There are hospitals available in both service areas involved in this CON application as there are outpatient hospital departments and free-standing radiology practices. Allowing physician practices which have the resources and capability to offer MRI services within their practice keeps the diversity of health

care providers and patient choice in both geographic regions alive. Patients have a choice of how they want their health care provided, and this is appropriate. COS has no problem with their patients asking to have their MRI scan done at a different location, and continues to work with the patient in terms of recovery from an orthopedic accident or ailment. COS does not charge a facility fee. This application keeps alive the single-specialty physician owned practice which is quickly vanishing from the Connecticut health care landscape as large institutions and companies grow their businesses with physicians who used to be in private practice. One of the goals of the State Healthcare Facilities and Services Plan is to keep the diversity of health care models alive and make sure that they are all available to any patient who needs their services.

COS is a Medicare provider and also accepts Medicaid patients. The COS physician practice is open and accessible to all patients who want COS care. That care includes the MRI service if it is necessary. Indigent persons can take advantage of the COS Charity Care policy that is part of the application. (Record, Exhibit I, p. 176). The volume of Medicaid patients has been small until the last couple of years when it started to increase. There appears to be a connection to the closing of St. Raphael's Hospital in New Haven, leaving Medicaid patients without providers. As word has spread that COS accepts Medicaid, the volume has started to increase.

A COS physician is currently on site in both Hamden and Branford when MRI scanning is being done, and can be reached immediately if there is a problem. COS has 2 radiologists available any time scanning is being conducted for consultation by the tech performing the scan. Dr. Gagliardi, who reads all of the COS scans electronically, will call the orthopedic physician to discuss any issue as well. This is all handled electronically with the MRI report reaching the treating physician very rapidly, but no later than twenty four hours after the scanning process is completed.

With the added volume of patients that COS now has, it will allow the COS physicians to drive down the internal cost of MRI scans in the future. Given the fact

that reimbursement for MRI services is going downward, this is important in order for COS to be able to maintain operations. Allowing COS to remain viable is good for healthcare delivery in the State of CT, as we represent a private practice alternative to the healthcare system-owned alternative in New Haven. COS contracts with all insurers in the State. We also see Medicare and Medicaid patients without discrimination. True to our culture, COS has already begun the active process of dealing with its payers and insurers to partner with them in abiding by the Patient Protection and Affordable Care Act of 2010 which encourages bundled payments. COS has bundled payment contracts with Anthem BC/BS, Ct Care and Aetna. In our core application, due to a misunderstood communication, it is stated that bundled payments currently include all MRI scanning, without mentioning the exclusion of the initial MRI. Language to this effect is present in numerous places in the application. I would like to take this opportunity to retract that mistake, and to apologize for the error.

COS is currently trying to offer MRI services of the highest quality, yet at the lowest price possible. The larger network of physicians will make many things possible, including bundled payments.

The proposal is financially feasible for COS as evidenced by the financial information provided in the application. Our CFO, Susan Bader, is present this morning if you have any questions in this regard. With the large footprint that COS MRI scanning has, and the efficiencies it has incorporated into its MRI operations, it is anticipated that COS MRI scanning will operate in Orange and Essex without losses, from the beginning, if the proposal is approved. The financial details are available in the application. (Record, p. 277, 3rd Completeness).

The application also meets the guidelines required as to quality. The existing MRI units in Branford and Hamden are accredited by the American College of Radiology, as will be the new proposed mobile MRI. The scans in Hamden and Branford are now being read by the COS radiologist, Dr. Gagliardi who is a board certified

radiologist specializing in orthopedic radiology. He will continue to be the COS radiologist after the new MRI begins operation, if this proposal is approved. He will testify as to the requirements set forth in the Statewide Health Care Plan as to the method used to transmit the MRI scan both to him, and the report of the MRI scan back to the physician.

While patients are always given a choice of where to have the MRI scan performed, having it done under the supervision of a COS orthopedic physician who is either the treating physician or in the same practice as the treating physician is always the better alternative medically because of the speed with which the MRI can be done, and the fact that the patient does not have to make another appointment, register with that new facility, and receive results from a radiologist who is not part of the same practice, and is not familiar with the patient,

I want to thank you, on behalf of all of the COS physicians and our supporting staff, for the time you have spent on consideration of this application.

And now I would like to introduce Dr. Joseph Gagliardi, our COS radiologist.

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IN RE: CONNECTICUT ORTHOPAEDIC : **JUNE 27, 2017**
SPECIALISTS, P.C., ACQUISITION OF A :
1.5 T MOBILE MRI :

**PRE-FILE TESTIMONY OF DR. JOSEPH GAGLIARDI
ORTHOPEDIC RADIOLOGIST FOR COS**

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Dr. Joseph Gagliardi, and I am a board certified radiologist and an American Board of Radiology Examiner in the musculoskeletal section. I am submitting an updated curriculum vitae with my prefile testimony. As you will see, the majority of my career has been devoted to the practice of orthopedic radiology; research in the area, presentations and lectures as an assistant clinical professor of diagnostic radiology at Yale School of Medicine and staff radiologist at the West Haven VA hospital. I am also the radiologist for Connecticut Orthopaedic Specialists (“COS”). At this time, I hereby adopt my prefile testimony.

My qualifications to read orthopedic MRI scans are set forth in my C.V. which is part of the record. I have been working with COS since May of 2007. I know all of the doctors in the practice and together we have worked out a very reliable way to get the results of an MRI scan back to the physician who is treating the patient very quickly. This is all electronically, using the COS EMR system, Greenway, as well as verbally in emergent cases. The results of the scan are available wherever it is needed. There is an interface with Epic, and COS is on the cusp of moving to a cloud-based system. Access to the information for the COS orthopedic specialist, the patients and any other physicians involved in the patient’s treatment is effortless.

The physicians know that they can reach me at almost any time of the day or night. I do not limit my time to regular office hours because I know that a COS orthopedic specialist might need to discuss a patient with me at any time of the day.

We have never had a problem with the quality of the scans. The frequency of positive findings is very high. I have never been asked to do a second scan when I did not think it was necessary. To do so would be unprofessional. And there is not a single doctor within COS who is not very professional. These are physicians who work very hard for every patient, and their sole focus is to give patients the best treatment possible.

Because COS is a single specialty orthopedic practice, the scanning process is more homogeneous, and therefore can be handled more quickly than if I had to read scans for different medical practices. I am as familiar with the musculoskeletal system as most of the orthopedic doctors. This gives me an added advantage in terms of reading the scans, because my experience is all in orthopedic MRI scanning.

The proposed 1.5 Tesla mobile scanner is necessary because the existing COS MRIs in Hamden and Branford have reached maximum capacity. The orthopedic practices that have merged with COS in the last 3 years have created a huge increase in volume, and the mobile scanner is needed to handle those additional COS patients. The amount of capacity requested is entirely justifiable given the volumes. We only need two days in the Orange area and two days in the Essex area to handle the COS patients we have, and to keep up with a 3% increase we will need over the next few years.

COS currently uses the 1.5 Tesla MRI, and plans to use a 1.5 Tesla in the proposed mobile scanner. In general, the 1.5 T MRI is the common MRI for orthopedic scanning. If any of our patients needs to be scanned on a 3.0 T MRI, we regularly inform patients in the Orange area that Advanced Radiology Consultants has a 3.0 T MRI unless the patient specifically requests to use another provider. In general, COS

currently sends patients to Advance Radiology Consultants when the 3.0 T is needed, and will continue to do so in the future. I hope that OHCA finds that we have met all of the criteria necessary for the additional scanning capacity we have requested.

I will be happy to answer any questions OHCA may have. Thank you for your time and consideration of the COS propos

Mark David Lorenze, M.D.
Connecticut Orthopedic Specialists
12 Bokum Road Essex, CT 06426
Tel: 860-767-9053
Fax: 203-672-0833

Education:

- 1992-1997 Yale University
New Haven, CT
1992-1993 General Surgery Internship
1993-1997 Orthopaedic Surgery Residency
1996-1997 Chief Orthopaedic Resident
- 1988-1992 Tufts University Medical School
Boston, Ma
Degree: M.D.
Alpha Omega Alpha member 1992-present
- 1984-1988 Yale University
New Haven, CT
Major – Biology
Degree – BA, Cum Laude

Professional Positions:

- Chief of Surgery, Middlesex Hospital
Chief of Orthopedic Surgery, Middlesex Hospital
Treasurer, Connecticut Orthopaedic Specialist, P.C.

Professional Affiliations:

- 2014- present Shoreline Orthopedics and Sports Medicine,
A Division of Connecticut Orthopaedic Specialists, P.C.
12 Bokum Road
Essex, CT 06426
- 2000-2014 Shoreline Orthopedics And Sports Medicine, LLC
12 Bokum Road
Essex, CT 06426
- 1997-2000 Wildwood Orthopaedics, P.C.
Wildwood Medical Center
Essex, Ct 06426
- 1999- present Middlesex Hospital
Attending, Orthopedic Surgery

22 Crescent Street
Middletown, Ct 06457

Relevant Experience:

2016-present	Chief of Surgery Middlesex Hospital, Middletown, CT
2014- 2016	Chairman, Orthopaedic Department, Middlesex Hospital, Middletown, CT
1999- present	Attending, Orthopaedic Surgery Middlesex Hospital, Middletown, CT
1999-present	Member, Middlesex Hospital O.R. Committee
1997-1998	Tufts University Combined Hand & Upper Extremity Surgery Fellowship
1994-1997	Chairman, Resident Education Committee (Resident Representative) Yale University
1996-1997	Chief Resident, Yale University

Honors/Achievements:

Board Certified Orthopaedic Surgeon, Abos, Exp. 12/2020
Board Member, Eastern Orthopaedic Association
Social Committee Chairman 1988- Tufts Medical School
Outstanding Senior – Men’s Varsity Golf 1988
Captain, Men’s Varsity Golf – Yale University 1987-1988

Clinical Interests:

Occupational Injuries
Carpal Tunnel Syndrome
Dequervain’s Syndrome
Lateral/Medial Epicondylitis
Cubital Tunnel Syndrome
Upper Extremity/Hand Fractures/Trauma
Flexor/Extensor Tendon Injuries
CMC Arthritis/Instability
Total Joint Replacement
Rotator Cuff Disease
Wrist/Shoulder/Knee Arthroscopy

Research:

- a. Lorenze, M.D, Keggi, K.J., Huo, M.: Simultaneous Bilateral Total Hip Arthroplasty:

Is It More Cost Effective? Presented as poster at Eastern Orthopaedic Association meeting, Rome 1995 and at AAOS meeting, Atlanta 1996. Also presented at Yale

Orthopaedic Grand Rounds, Yale-New Haven Hospital, 1994. Published in "Orthopaedics" January, 1999.

- b. Lorenze, M.D., Wolfe, S.W.: The Reverse Bennett's Fracture and Its Relationship To The Anatomy of the Hamate. Presented as poster for the American Society For Surgery of the Hand, San Francisco 1995.

3. Lorenze, M.D., Mermelstein, L.E., Sella, E.: Dislocation of the Medial Cuneiform Treated With a Femoral Distractor and Cannulated Screws: A Case Report. Recently submitted to "The Journal of Foot and Ankle" for publication.

- a. Lorenze, M.D. & Wolfe, S.W.: Worker's Compensation and Its Effect on Recovery For Carpal Tunnel Surgery. Presented at Yale Orthopaedic Grand Rounds, Yale-New Haven Hospital, 1996.

- b. Wolfe, S.W., Lorenze, M.D., & Austin, G.: Biomechanical Comparison of Different External Fixators for Distal Radius Fractures. Accepted as Scientific Program Abstract for American Society for Surgery of the Hand, 1997. Published in "Journal of Hand Surgery," May 1999.

- c. Slade, J. Gutow, A., Lorenze, M.D., & Wolfe, S.W.: Flexor Tendon Repairs Augmented With Internal Dermal Splints. Accepted as Scientific Program Abstract

for American Society for Surgery of the Hand and AAOS, 1997.

Presented as disputation project, Yale Orthopaedic Association, 5/30/97.

Research, Continued:

- d. Lorenze, M.D., Wolfe, S.W., & Weisman, S.: The Use of Oral Fentanyl Citrate For Fracture Reduction in Children. Current research in progress, Yale-New Haven Hospital; Pediatric Emergency Department.

- e. Wolfe, S.W., Lorenze, M.D & Austin, G.: The Use of a Dorsal Outrigger K-Wire In a Partially Healed Distal Radius Fracture Model. Accepted as paper presentation

For Eastern Orthopaedic Association meeting, 1997. Also accepted as poster presentation, ASSH/AAOS 1997-98. Published in "Journal of Hand Surgery," March 1999.

- f. Cassidy, C., Lorenze, M.D., Conner, J., Ruby, L.K.: The Breaking Strength of Partially Healed Scaphoid Fractures. Accepted as presentation to New England Hand Society, 1997. Submitted for publication to "The Journal of Hand Surgery, 1998.

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**PRE-FILE TESTIMONY OF DR. JOSEPH GAGLIARDI
ORTHOPEDIC RADIOLOGIST FOR COS**

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Dr. Joseph Gagliardi, and I am a board certified radiologist and an American Board of Radiology Examiner in the musculoskeletal section. I am submitting an updated curriculum vitae with my prefile testimony. As you will see, the majority of my career has been devoted to the practice of orthopedic radiology; research in the area, presentations and lectures as an assistant clinical professor of diagnostic radiology at Yale School of Medicine and staff radiologist at the West Haven VA hospital. I am also the radiologist for Connecticut Orthopaedic Specialists (“COS”). At this time, I hereby adopt my prefile testimony.

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1.5 T MOBILE MRI	:	

PRE-FILE TESTIMONY OF DR. MARK D. LORENZE

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Mark Lorenze and I am an orthopedic surgeon working in the COS offices in Essex, Connecticut 4 days a week and Madison, Connecticut one day a week. At this time, I hereby adopt my prefile testimony.

I am a board certified Orthopedic Surgeon by the American Board of Orthopedic Surgery. I specialize in sports medicine, hand surgery and upper extremity surgery. I perform arthroscopic upper extremity surgery, endoscopic carpal tunnel surgery and I also treat work related injuries with cumulative trauma. I also perform general orthopedic surgery and joint replacement surgery. In addition to my clinical responsibilities, I also serve as the Chief of Surgery at Middlesex Hospital in Middletown, Connecticut. I am honored to hold the position I do at Middlesex Hospital, but I also recognize the great medical care that is being provided today by many institutions and physician groups, both large and small, and all very diverse.

Several years ago, my partners and I in Shoreline Orthopedic & Sports Medicine, with offices in Essex, Madison and Branford, joined COS. Previously, we were a relatively small practice with three physicians. We

joined COS because of the increasing difficulties that we encountered as a small private practice in a rural community. We believe that by joining COS there is a greater economy of scale and efficiency. We also envied the way the COS physicians took care of their patients in an efficient and outstanding manner. Knowing the quality of care provided by Connecticut Orthopaedic Specialists, when Shoreline Orthopedic and Sports Medicine merged with COS, I expect my patients to have the same quality of care that COS is known for.

Currently, when I refer a patient to Middlesex Hospital for an MRI scan the MRI scan is read by a variety of different radiologists. There is really no consistency with regard to who is reading the MRI scan. Often times, I have to make additional phone calls to make sure that a radiologist I can trust reads my orthopedic MRI scan. This can be very time consuming and also effects efficiency of my practice. I could be using that time for patient care and treatment. It also becomes very inconvenient for the patient who has to wait until I can contact a radiologist to review the MRI scan. The patient therefore has to wait longer for treatment to begin. I prefer to have the MRI scans done within COS because I can call Dr. Gagliardi and know that I can easily speak with him during that process. I am intimately involved in the MRI process before I make a diagnosis and begin treatment. Without the proposed mobile scanner in Essex, I am constrained from recommending that any of my patients consider using the COS MRI in Branford or Orange as one of the possible MRI providers due to the current capacity restraints in these two locations. With the proposed mobile MRI scanner in Essex, most of the COS patients living in the Essex area will be able to stay right in Essex if they so choose, providing the patient with a geographically

accessible service. For the patient, a mobile MRI scan in Essex would require no admission to another facility, no additional paperwork to be filled out, and no facility fee for the MRI.

In 2015, prior to the merger between Shoreline Orthopedics and Sports Medicine, there were 950 patients living in the Essex service area who chose a COS orthopedic specialist for their orthopedic care outside of the Essex area. They drove all the way to Branford or Hamden in order to have an MRI scan because a COS physician was handling their care. They did not choose to use a radiology provider in the Essex area even though they could have. (Record, p. 34-35, p.45 and Exhibit J (1), p.181). In that same year, 963 Shoreline Orthopedic & Sports Medicine patients were referred out to a provider other than COS. Of those patients, 569 lived in the Essex area. (Record, p. 45, Table 8B). Now that my physician group practice has merged with COS, I am confident that those Essex patients would be happy to find COS care in this part of the State, and will choose to have an MRI in Essex if this application is approved. (See Letters of Support, Exhibit F, Record pp. 123 – 130.

Since my orthopedic practice is now part of COS, I see that the need for MRI scanning with a COS radiologist can be provided in the Essex service area with this proposal. Some of the MRI volume of patients will be transferred from the larger COS MRI scanner in Orange and Hamden by patients who live in the Essex area, simply because there is no space. The remainder will be some of the patients who were in my practice at Shoreline Orthopedics and Sports Medicine who choose to use the

mobile scanner in Essex, and other new patients who seek out COS care in the area.

While all COS patients have the choice of where to have an MRI scan performed, I will be more closely connected to the patient's course of care if the scan is done right in the office where I have office hours 4 days a week. Middlesex Hospital is wise in their understanding that physicians want to practice medicine where they can be most effective. For many of us, that means that we have a private practice where we get to know patients who rely on us, and use our expertise with the knowledge that I know who they are, and am familiar with their history.

Whenever my patients need hospital care, I recommend Middlesex Hospital because that is where I have privileges. So the relationship between COS and Middlesex Hospital is not a competitive one; it is more one of collaboration. When my patients need major surgery, which they often do, they usually go to Middlesex Hospital. When they just need an office visit, they come to my COS office and do not pay a facility fee. This arrangement leaves the hospital with the ability to charge for the most expensive part of the treatment process, but it leaves me with the trust of my patients and the knowledge that I have been a big part of their recovery. I am very happy with my new affiliation with COS, and I hope that the Office of Health Care Access will be able to approve our application for a mobile scanner which can serve the residents of Essex and its surrounding towns.

Thank you for the work you have had to do to review our Application,
and I thank you for your time this morning.

I will be happy to answer any questions.

Curriculum Vitae

Billie Foraker
101 Bailey Road
North Haven, CT
(203) 619-2607

EDUCATION:

Gateway Community College, New Haven, CT

- Certified Nurse Assistant 1989
- Associate Degree in Science 1995
- Radiological internship YNH 1993-1995
- Radiological certification & CT State license granted 1995

EMPLOYMENT:

2015- present: Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Director of Clinical & Radiological Operations
 - Responsible for clinical and front desk operations, and scheduling for all COS locations
 - Management of all COS radiology services office x-ray, Fluoroscopy, MRI
 - Responsible for clinical staff resource and scheduling allocations

2008 - 2015 : Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Medical Administrative Assistant for Dr. Philip Minotti
 - Instrumental in development Dr. Minotti patient practice
 - Responsible for management of all patient communication, including lab, imaging results and surgical equipment
 - Pre cert and booked surgical cases for joint reconstruction cases performed at YNH
 - Managed referral relationship(s) into Dr. Minotti from outside primary care referral physicians

1989 to 2008: New Haven Orthopaedic Group P.C.
Connecticut Orthopaedic Specialists, P.C.,

- Receptionist & clinical floater 1989-1995
- Billing & Collections 1989-1993
- Physical Therapy aide 1993-1995
- X Ray Technician 1995- 2008
 - Lead X Ray Tech Hamden, responsible for managing all supplies for clinical rooms and x-ray suite

LICENSES / CERTIFICATIONS / COURSE WORK :

Certified Nursing Assistant 1989
Connecticut X Ray License 1995
Certified Medical Assistant June 2013
Greenway Practice Management training program 2015
PC and Apple Software formats

OUTSIDE INTERESTS :

- Freelance photographer
- Equestrian
 - Horse owner & trainer
 - Member of Cheshire Horse Counsel

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PREFILE TESTIMONY OF PATRICK A. RUWE, M.D.

PRESIDENT OF CONNECTICUT ORTHOPAEDIC SPECIALISTS

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Dr. Patrick Ruwe, and I am the President of COS and one of the COS physicians practicing in Orange, CT. My specialities are sports medicine, arthroscopy, shoulder and knee injuries. I am here this morning to support the COS application that is before you to allow COS to add a mobile 1.5T MRI to our practice.

We are the largest group of single orthopedic specialists in Connecticut. We have practiced as a group for over 50 years. Our orthopedic specialists are outstanding and experienced clinicians, and we are the team orthopedic physicians for the Quinnipiac Bobcats and 16 area high schools. We consider the MRI scan, when it is necessary, to be a critical part of our patient's treatment. It is an invaluable diagnostic tool for our orthopedic specialists.

All of our COS physicians put patient care above everything else, and that means we demand quality in every aspect of the practice. We are proud of our reputation and expect to continue to be among the best orthopedic physicians in Connecticut. We believe that the patient should have the

initial MRI scan wherever it is best for the patient. If a patient is injured on a football field and calls to see one of our physicians, that doctor might well advise the patient to go directly to a hospital and have the initial MRI done there. If a patient has had a relationship with a radiologist or radiologist group that they trust, we have no problem with that request. We do not require patients to have their scanning done in a COS facility. But if a patient comes to us first for our expert opinion because they want COS care, our schedulers tell them that we can do the MRI scan at our facility, but also inform them of the other entities within the immediate geographic area that provide MRI scans.

Having MRIs read by our own board-certified orthopedic radiologist is important because we function as a unit. Dr. Gagliardi has worked with many of us for years, and has gotten to know the new physicians who have joined COS between 2014 and 2016. He is accustomed to what we are looking for when we order a scan. We communicate easily with him, and are always pleased with the results. Part of the reason for this is because we interact with Dr. Gagliardi as necessary while he is reading the scan, or after the scan is completed and we are reviewing his report. Not infrequently, we will actually call him before a scan is performed to discuss the specifics of the case. Conversations can be done quickly because Dr. Gagliardi is so familiar with each of us, saving the physicians more time for actual patient care. Emergent cases are discussed, often at night. It is not uncommon for us to look at images simultaneously where we discuss the case on our cell phones.

For each patient scanned in Orange, their specific COS orthopedic specialist will always be available by phone to speak with Dr. Gagliardi. If there is an emergency situation during the scanning process, there will be an

orthopedic specialist available to speak with the technician who is performing the scan, as is our practice in all of our COS offices.

Because of the many new orthopedic specialists who have merged with COS during the past 3 years, the COS physician pool is larger than it is been. We were reaching the point of maximum capacity in Hamden and Branford before the new affiliations, but now we are over that point. And from this point forward, we anticipate that COS will grow 3% every year as it was growing prior to the mergers. COS has acquired an outstanding reputation, and patients seek us out as their treating orthopedic specialists. We believe that diagnosing the orthopedic problem is the foundation for the treatment that follows. There is why we employ Dr. Gagliardi, who we know will live up to our high standards.

Before doctors become employees of hospitals, all doctors had the sense of pride and accomplishment in taking direct care of their patients because they practiced usually as sole practitioners or as part of a small group. With the cost of medical care constantly escalating, medical professionals have found that they have to collaborate and work together to save the patients from ever-rising medical bills. COS is trying to do this by creating a large enough group practice that it can offer programs such a bundled payments, which help to keep payments under control.

For all of the reasons I have just set forth, I ask that you approve the COS application for one additional mobile MRI to be operated 4 days a week. Thank you for the time you have spent reviewing all of the documents in this file, and for your time in considering the application. I will be happy to answer any questions you may have.

DEPARTMENT OF PUBLIC HEALTH :
DIVISION OF THE OFFICE OF : **DOCKET NO. 16-32117-CON**
HEALTH CARE ACCESS :
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: :
IN RE: CONNECTICUT ORTHOPAEDIC : **JUNE 27, 2017**
SPECIALISTS, P.C., ACQUISITION OF A :
1.5 T MOBILE MRI :

PREFILE TESTIMONY OF PATRICK A. RUWE, M.D.

PRESIDENT OF CONNECTICUT ORTHOPAEDIC SPECIALISTS

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Dr. Patrick Ruwe, and I am the President of COS and one of the COS physicians practicing in Orange, CT. My specialities are sports medicine, arthroscopy, shoulder and knee injuries. I am here this morning to support the COS application that is before you to allow COS to add a mobile 1.5T MRI to our practice.

We are the largest group of single orthopedic specialists in Connecticut. We have practiced as a group for over 50 years. Our orthopedic specialists are outstanding and experienced clinicians, and we are the team orthopedic physicians for the Quinnipiac Bobcats and 16 area high schools. We consider the MRI scan, when it is necessary, to be a critical part of our patient's treatment. It is an invaluable diagnostic tool for our orthopedic specialists.

All of our COS physicians put patient care above everything else, and that means we demand quality in every aspect of the practice. We are proud of our reputation and expect to continue to be among the best orthopedic physicians in Connecticut. We believe that the patient should have the

initial MRI scan wherever it is best for the patient. If a patient is injured on a football field and calls to see one of our physicians, that doctor might well advise the patient to go directly to a hospital and have the initial MRI done there. If a patient has had a relationship with a radiologist or radiologist group that they trust, we have no problem with that request. We do not require patients to have their scanning done in a COS facility. But if a patient comes to us first for our expert opinion because they want COS care, our schedulers tell them that we can do the MRI scan at our facility, but also inform them of the other entities within the immediate geographic area that provide MRI scans.

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REVISED
CURRICULUM VITAE

PERSONAL DATA:

Joseph Anthony Gagliardi
DOB: May 20, 1959
Place: New Haven, CT
Citizenship: USA

EDUCATION:

Yale University, BS, Psychobiology, 1978-82
New York Medical College, Valhalla, NY, M.D., Medicine, 1982-86

TRAINEESHIP:

Internship: St. Vincent's Medical Center, Bridgeport, CT, Transitional, 1986-87
Residency: St. Vincent's Medical Center, Bridgeport, CT, Diagnostic Radiology, 1987-91
Chief Resident, 1990-1991

LICENSURE:

Connecticut #029458, 1988
Hawaii #7589, 1991-1995
DEA #BG2862374, 1989

MILITARY SERVICE:

Active Duty US Army M.C., Tripler A.M.C., Honolulu, HI, 1991-1995

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

Radiological Society of North America
Hawaii Radiologic Society 1991-1995
American Roentgen Ray Society
Connecticut Radiologic Society 1995-2010
Association of Program Directors in Radiology 2004-2010

ACADEMIC APPOINTMENTS:

Associate Clinical Professor, Department of Radiology, University of Hawaii, Manoa, 1992-1997
Assistant Clinical Professor, Department of Radiology, New York Presbyterian Healthcare, 1999-present
Clinical Adjunct Associate Professor, Quinnipiac University School of Health Sciences, 2004-present
Assistant Clinical Professor, Department of Diagnostic Radiology, Yale School of Medicine, 2010-present

HOSPITAL APPOINTMENTS:

Chief, Musculoskeletal Radiology, Tripler Army Medical Center, Honolulu, HI, 1991-1992

Chief, Genitourinary Radiology, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Academic Council/Surgical Case Review, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Chief, Musculoskeletal Radiology, St. Vincent's Medical Center, Bridgeport, CT, 1995-2009

Residency Program Co-Director, St. Vincent's Medical Center, Bridgeport, CT, 1999-2003

Vice Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2001-2005

Residency Program Director, St. Vincent's Medical Center, Bridgeport, CT, 2003-2009

Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2006-2009

Veterans Administration Medical System, West Haven, CT, 2010-present

REGULAR TEACHING ACTIVITIES:

St. Vincent's Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

Yale University Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

PROFESSIONAL ACTIVITIES:

Manuscript Reviewer, Consultant Magazine, Cligott Publishing Co., 55 Holly Hill Lane, Greenwich, CT 06831, 1998-present.

FDA Investigational New Drug Number 48,354 issued for Magnetic Resonance Imaging research of musculoskeletal disorders following intra-articular administration of Gadolinium.

American Board of Radiology, Board Examiner, Musculoskeletal Section, 1999-present.

Board Member, Musculoskeletal Section, Mediaworks, Inc. Electronic journal: *Radiology web.Com*. 1999-present.

Professional Liability Committee member, St. Vincent's Medical Center. 2001-2009.

Medical Executive Committee Member, St. Vincent's Medical Center, 2004-2009.

American Board of Radiology Item Writing Task Force for Written Board Exam, 2005-present.

American College of Radiology, 2006-2010.

Radiologist Connecticut Orthopaedic Specialists, 2007-present.

Manuscript Reviewer, Journal of Neuroimaging, Blackwell Publishing, 2008 – present.

Manuscript Reviewer, Case Reports in Radiology, Hindawi Publishing Corporation, 2014- present.

Yale Diagnostic Radiology:

1. Clinical competency committee 2012 – present
2. Curriculum mentorship committee 2013 - present
3. Programmatic evaluation committee 2014 – present
4. Residents selection committee 2016 - present

PUBLICATIONS:

A. Original Articles

1. Gagliardi JA, Interventional Radiology Complication Rates. *Administrative Radiology* 1992; 11:90-99
2. Chandnani VP, Yeager TD, DeBerardino TM, Christensen K, Gagliardi, JA, Heitz DR, Baird DE, Hansen MF. Glenoid Labral Tears: Prospective Evaluation with MR Imaging, MR Arthrography and CT Arthrography. *AJR* 1993; 161:1229-1235
3. Chandnani VP, Harper MT, Ficke J, Gagliardi JA, Rolling L, Christensen K, Hansen MF. Chronic Ankle Instability. Evaluation with MR Arthrography, MR Imaging, and Stress Radiography. *Radiology* 1994; 192:189-94
4. Gagliardi, JA, Chung EM, Chandnani VP, Kesling KL, Christensen KP, Null RN, Radvany MG, Hansen MF. Detection and Staging of Chondromalacia Patella: Relative Efficacies of Conventional MR Imaging, MR Arthrography and Computed Arthrography. *AJR* 1994; 163: 629-636
5. Chandnani VP, Gagliardi JA, Murnane TG, Bradley YC, DeBerardino TM, Spaeth J, Hansen MF. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. *Radiology* 1995; 196:27-32
6. Bradley YC, Chandnani VP, Gagliardi JA, Reeves TQ. Partial Thickness Supraspinatus Tears; Diagnosis by Magnetic Resonance Arthrography. *Australas Radiol* 1995; 39(2): 124-127
7. Riccio GJ, Gagliardi JA. Pitfalls in Hysterosalpingographic Interpretation. *Postgraduate Radiology* 1997; 17:190-208
8. Gagliardi JA, Nunberg SM, Fisher T. Fracture Detection: A Possible Method to Aid in Diagnosis and Improve Reporting Accuracy. *Radiologyweb.com*. April Issue 2001

B. Case Reports

1. Gagliardi, JA, Chaddha, SKB. CNS Toxoplasmosis. *Consultant* 1991; 31: 45-48
2. Gagliardi JA, Torstenson G. Fibrous Dysplasia in the Skull Base. *Applied Radiology* 1991; 20: 42-43
3. Gagliardi JA, Chaddha SKB. Mid Gut Volvulus with Computed Tomography. *Applied Radiology* 1992; 21: 58-59

4. Gagliardi JA, Posch R. Flare Response in Nuclear Medicine Secondary to Chemotherapy Toxicity to the Kidneys. *Applied Radiology* 1992; 21:24-25
5. Gagliardi JA, Eline MJ. Minimal Plain Film Findings of a Femoral Neck Osteoid Osteoma Diagnosed by Radionuclide Bone Scintigraphy and MRI. *Clinical Nuclear Medicine* 1993; 18:446-447
6. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Cancer Investigation* 1993; 11:306-309
7. Shanley DJ, Gagliardi JA, Daum-Kowalski R. Choledochal Cyst Complicating Pregnancy: Antepartum Diagnosis with MRI. *Abdom Imaging* 1994; 19: 61-62
8. Radvany MG, Shanley DJ, Gagliardi JA. Magnetic Resonance Imaging with Computed Tomography of a Renal Leiomyoma. *Abdom Imaging* 1994; 19:67-69
9. Quan SS, Gagliardi JA*, Russo RD. Neurofibromatosis. *Applied Radiology* 1994; 23: 35-26
10. Samlaska CP, Gagliardi JA. Diffuse Venous Malformation with Intraosseous Involvement. *Hawaii Medical Journal* 1994; 53: 218-221
11. Gagliardi JA, Evans EM, Chandnani VP, Myers JB, Pacheco CM. Osteogenesis Imperfecta Complicated by Osteosarcoma. *Skeletal Rad* 1995; 24(4): 308-310
12. Munter FM, Gagliardi JA, Russo RD. Familial Hyperphosphatasemia. *Applied Radiology* 1995; 25(7): 44-45
13. Eclavea A, Gagliardi JA, Jezior J, Burton B, Donahue J. Pheochromocytoma with Central Nervous System Manifestations. *Australasian Radiology* 1997 41(4): 373-376
14. Lustberg H, Gagliardi JA, Lawson JP. Digital Enlargement in Tuberous Sclerosis. *Skeletal Radiology* 1999; 28:116-118
15. Gagliardi JA. Musculoskeletal Involvement of Sarcoidosis in the Hands. Electronic Journal: *Radiologyweb .Com*. December Issue, 1999
16. Gagliardi JA. Silicone Implant Arthropathy of the Wrist. Electronic Journal: *Radiologyweb.Com*. September Issue, 2000
17. Gagliardi JA, Duff MK, Callahan T, Pannese JR. Abnormal Dilatation to the Internal Carotid Artery on Angiography without Abnormal Finding at Craniotomy: *Connecticut Medicine* 2004; 68:3-5
18. Hyo-Jeong Lee, Gagliardi JA. Diffuse pigmented villonodular synovitis. *Applied Radiology* 2004; 33(12):41-43
19. Udeshi M, Gagliardi JA. Foreign body giant cell reaction to polytetrafluoroethylene used as interposition material in scaphoid-trapezium arthroplasty. *Australasian Radiology* 2006; 50:233-236
20. Martinez F, Gagliardi JA, Olsavsky TD. Gastrointestinal stromal tumor originating in the stomach. *Applied Radiology* 2006; 35(7): 43-46.
21. Gripp M, Gagliardi JA. Calciphylaxis On Technetium Bone Scan: Two Case Reports. *Radiology Case Reports* 2007; 2(2):30-32.

22. Rastogi P, Gagliardi JA, Bharucha R. Manifestations of Von Hippel-Lindau disease. *Applied Radiology* 2007; 36(11):62-65.
23. Swain FR, Udeshi M, Gagliardi JA, Armm M. Fracture of the Penis: MR Imaging with Surgical Correlation. *Radiology Case Reports Epub* 2007; 2 (3).
24. Werder GM, Razdan RS, Gagliardi JA, Chaddha SKB. Conservatively managed pineal apoplexy in an anticoagulated patient. *Radiography* 2008; 14:69-72.
25. Tagg W, Woods S, Razdan R, Gagliardi J, Steenbergen P. Hemoperitoneum after Colonoscopy. Endoscopy. *Accepted for publication ID ENDOS -2008-1226.R1*
26. Martinez F., Cho Y., Gagliardi JA, Razdan R. Spontaneous Pneumomediastinum. *Applied Radiology* 2008;37(4):40-44.
27. Werder GM, Tangri RK, Gagliardi JA. Bleeding diathesis with hemophilic arthropathy. *Applied Radiology* 2008;37(9):35-36.
28. Chirindel A, Martinez F, Gagliardi JA, Armm MF. Testicular Tuberculosis without epididymitis simulating neoplasm. *Radiology Case Reports* 2008;3(3):1-6.
29. Cho Y, Gagliardi JA, Chaddha SK. Cystic Meningioma. *Applied Radiology* 2009; 38(5):29-30.
30. Khan AA, Agarwal A, Chaddha SK, Gagliardi JA. Histiocytic sarcoma of the Terminal Ileum Presenting as a Large Ulcerating Lesion: CT Diagnosis. *Radiology Case Reports*, 2009; 4(2):262
31. Singhal A, Torstenson GE, Gagliardi JA. Celiac Artery Dissection on Computed Tomography. *Clinical Challenges and Images in GI. Gastroenterology* 2010; 139(3):733.
32. Gagliardi JA and Agarwal A. Gamekeeper's Thumb (Skier's thumb). [http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-\(Skier's-thumb\).aspx](http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-(Skier's-thumb).aspx)
33. Gagliardi, JA and Carino, M. Glenoid Bare Spot. *Applied Radiology* 2013; 42(10):29-30.

C. Reviews and Book Chapters

1. Gagliardi JA, Freestone KA, Shanley DJ. Testicular Microlithiasis: Ultrasound Appearance and Associated Complications. *Hawaii Medical Journal* 1993; 452:192-193
2. Gagliardi JA, Lengyel RJ. A Review of the Radiographic Manifestations of Gout. *Hawaii Medical Journal* 1994; 53: 40-43
3. Gagliardi JA, Radvany MG, Kilkenny TE, Russo RD. Colonic Sphincters Revisited: Simulator's of Organic Disease. *Hawaii Medical Journal* 1994; 53:278-282
4. Wilbur MJ, Gagliardi JA, Riccio GJ, Vincent NR, Haber S, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. *Applied Radiology* 1997; 26(12): 30-37
5. Meyer NR, Gagliardi JA, Lawson JP. Musculoskeletal Radiology. Practical Guide of Diagnostic Imaging, CV Mosby Co., 1998, page 220-279
6. Wilbur MJ, Gagliardi JA, Lawson JP, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. *Postgraduate Radiology* 1999; 19:3-12

7. Lustberg H, Gagliardi JA, Lawson JP, Fugate M, Micalizzi GJ, Specht NT. Intramedullary Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiologyweb.Com*. December Issue, 1999
8. Lustberg H, Gagliardi JA, Lawson JP, Lawson AJ, Fugate M, Specht NS, Micalizzi GJ. Surface Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiology web.com*. January Issue, 2000
9. Lustberg H, Gagliardi JA, Lawson JP, Specht NS, Fugate M, Micalizzi GJ. Secondary Osteosarcoma. *Radiologyweb.com*. February Issue, 2000
10. Lustberg H, Gagliardi JA, Lawson JP, Kilkenny TE, Donkor D, Fugate M, Micalizzi GJ, Specht NS. Extraskeletal and Gnathic Osteosarcoma. *Radiologyweb.com*. March-April Issue, 2000
11. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part One: Benign Lesions. *Radiologyweb.com*. January Issue, 2001
12. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part Two: Malignant Lesions. *Radiologyweb.com*. February Issue, 2001
13. Gagliardi JA, Ibrahim S, Kumar M. Paget's Disease: Radiologic Findings. *Rheumatologyweb.com*. July Issue, 2002
14. Swain FR, Martinez F, Gripp M, Razdan R, Gagliardi JA. Traumatic complications from placement of thoracic catheters and tubes. *Emergency Radiology* 2005; 12: 11-18
15. Tagg WG, Razdan RS, Swain FR, Gagliardi JA, Chaddha SKB. Posterior Reversible Encephalopathy Syndrome Following a Cesarean Delivery: Case Report and Literature Review. *Connecticut Medicine* 2008 (72) 5: 267-269.

D. Abstract:

1. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Connecticut Medicine* 1992; 56:623

E. Presentations:

1. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrotomography. Society of Skeletal Radiology, Marco Island, FL. 1993
2. Chandnani VP, Harper MT, Gagliardi JA, Ficke J, Rolling L, Christensen K. Chronic Ankle Instability: Evaluation by Stress Radiography, Magnetic Resonance Imaging and Magnetic Resonance Arthrography. Society of Skeletal Radiology, Marco Island, FL. 1993
3. Chandnani VP, Yeager TD, DeBaradino TM, Christensen K, Heitz DR, Gagliardi JA, Hansen MF. Glenoid Labral Tears: A Comparison of the Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrotomography. American Roentgen Ray Society, San Francisco, CA. 1993
4. Gagliardi JA. Reading Chest Radiographs: The Secrets. Fifth Annual Aloha Medical Conference, Honolulu, HI. 1993
5. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. Radiological Society of North America, Chicago, IL. 1993

6. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrography. Radiological Society of North America, Chicago, IL. 1993
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8. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. 18th International Congress of Radiology, Singapore. 1994
9. Bradley YC, Chandnani VP, Gagliardi JA, Yeager TD, Harper MT, Hansen MF. Magnetic Resonance Arthrography of the Musculoskeletal System. 18th International Congress of Radiology, Singapore. 1994
10. Harper MT, Chandnani VP, Evans EM, Gagliardi JA, Hansen MF. Chronic Ankle Injuries: Evaluation with MR Arthrography, MR Imaging and Conventional Imaging Techniques. Annual 42nd meeting of the Association of University Radiologists, Boston, MA. 1994
11. Chandnani VP, Spaeth J, Bradley YC, Radvany MG, DeBerardino TM, Gagliardi JA. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. Radiological Society of North America, Chicago, IL. 1994
12. Gagliardi JA, Chung EM, Chandnani VP, Hansen MF. Chondromalacia Patellae: Prospective Evaluation of Relative Efficacies of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrography. USARPAC Asia-Pacific Military Medical Conference, New Delhi, India. 1995
13. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. European Congress of Radiology, Vienna, Austria. 1995
14. Harper MT, Murnane TG, Chandnani VP, Gagliardi JA, Spaeth JH, Boutin R. MR Imaging of Musculoskeletal Ganglia: A Pictorial Essay. European Congress of Radiology, Vienna, Austria. 1995
15. Chandnani VP, Murnane TG, Harper MT, Gagliardi JA, Bradley YC. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. European Congress of Radiology, Vienna, Austria. 1995
16. Chandnani VP, Gagliardi JA, Harper MT. Glenohumeral Ligaments and Capsular Mechanism: Evaluation with MR Arthrography. The First Kuwait International Conference of Radiology and Nuclear Medicine, Kuwait. 1995
17. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. American Roentgen Ray Society, Washington, DC. 1995
18. Chandnani VP, Bradley YC, Gagliardi JA, Murnane TG, DeBerardino TM. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. Roentgen Centenary Congress, Birmingham, England. 1995
19. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. 43rd Annual J. C. Kimbrough Urological Seminar, Washington, DC. 1995
20. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. 19th International Congress of Radiology, Beijing, China. 1996

21. Gagliardi JA, Riccio GJ, Eclavea A. Pitfalls in Hysterosalpingographic Interpretation. 19th International Congress of Radiology, Beijing, China. 1996
22. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. 19th International Congress of Radiology, Beijing, China. 1996
23. Gagliardi JA, Riccio GJ. Pitfalls in Hysterosalpingographic Interpretation. . Radiological Society of North America, Chicago, IL. 1996
24. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1996
25. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. Western Section of American Urological Association, San Diego, CA. 1996
26. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. American Roentgen Ray Society, Boston, MA. 1997
27. Gagliardi JA, Lawson JP, Bonnet AL, Fugate MJ, Micalizzi GJ. Parosteal Lipoma: A Review of the Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1997
28. Gagliardi JA. Genitourinary System Trauma: Classification and Management Strategies. St. Vincent's College, Bridgeport, CT. 1998
29. Gagliardi JA, Lustberg H, Lawson JP, Specht N, Fugate MJ, Micalizzi GJ. Osteosarcoma: The Radiologic Appearances and Imaging Strategies. American Roentgen Ray Society, New Orleans, LA. 1999
30. Gagliardi JA. One Week Genitourinary and Musculoskeletal Review. Visiting Consultant: Tripler Army Medical Center, Honolulu, HI. March 20-24, 2000
31. Gagliardi JA. Magnetic Resonance Imaging of the Knee. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. September 25, 2002
32. Gagliardi JA. X-Ray Callbacks in the Emergency Department. Emergency Medicine Grand Rounds, St. Vincent's Medical Center, Bridgeport, CT. March 19, 2003
33. Gagliardi JA. Breast Calcifications on Mammography: Characterization and Management. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
34. Gagliardi JA. Understanding the BI-RADS Lexicon in Mammography. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
35. Gripp MJ, Coleman B, Tangri R, Udeshi M, Gagliardi JA. Review of Iatrogenic Trauma to the Thorax. American Roentgen Ray Society, Miami FL. 2004
36. Gripp MJ, Gagliardi JA, Russo G, Callahan T. A Patterned Approach for Evaluating Patients with Arthritis. International Congress of Radiology, Montreal, Canada. 2004
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DEPARTMENT OF PUBLIC HEALTH	:	
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IN RE: CONNECTICUT ORTHOPAEDIC	:	JUNE 27, 2017
SPECIALISTS, P.C., ACQUISITION OF A	:	
1.5 T MOBILE MRI	:	

PRE-FILE TESTIMONY OF GLENN F. ELIA, CEO

Good morning Hearing Officer Hansted and members of the OHCA panel. My name is Glenn Elia, and I am the CEO of Connecticut Orthopaedic Specialists (“COS”). At this time, I hereby adopt my prefile testimony. With me today are, Dr. Joseph Gagliardi, the COS board certified staff orthopedic radiologist, two orthopedic specialists; Dr. Patrick Ruwe, President of COS and Dr. Mark Lorenze, Billie Jo Foraker, the Director of Clinical Services & Radiology of COS Radiology, and Susan Bader, Chief Financial Officer of COS.

Connecticut Orthopaedic Specialists (COS) is a multi-specialty musculo skeletal practice with a concentration in orthopedic care. Our main office is located in Hamden, CT. The practice has been serving Connecticut patients for over 50 years. COS earned its reputation as of being an innovative practice which offers outstanding treatment for our patient population. COS was the first single specialty orthopedic group in CT to obtain a CON for an outpatient surgical center. This center is now a 4-room environment and has achieved national recognition for the quality of care it delivers. The COS surgical center is the first center in the State to offer outpatient total joint procedures under a bundled payment program. COS was also the first orthopedic practice to obtain payer contracts for its MRI. COS now operates two 1.5 T MRI units and is contracted with all insurers. All of our ground-breaking developments have enhanced the patient experience while lowering the

overall cost of care. Each COS orthopedic physician is board certified in a specific orthopedic area of expertise; for example- back, foot and ankle, shoulder, hip and athletic injuries, to name a few. Our practice is growing annually since our patients are drawn to COS because of the quality of its practitioners, the innovative comprehensive delivery of services we offer and most importantly the overall total patient experience. It is the mission of COS to meet the orthopedic needs of our patient community while working to reduce the cost of care within the healthcare delivery system.

We are here today to request that you approve our CON application for a mobile 1.5 Tesla MRI for use 4 days a week – 2 days in Essex and 2 days in Orange. This is not a request to offer a new service: COS has been providing MRI scans to its patients for many years. COS currently has a 1.5 Tesla MRI in its Hamden office and a 1.5 Tesla MRI on its Branford campus. There is no facility fee charged at COS MRI scanning offices.

COS believes that its CON application has met all the requirements in Section 19-639 of the CT General Statutes and the criteria for additional MRI service as set forth in the CT Statewide Health Care Facilities and Services Plan. This morning I will touch on the highlights of our application, and the physicians will have some brief testimony as well.

Consistent with our innovative and cost effect approach, we have applied for permission for a mobile MRI rather than ask for a fixed MRI in one location. A mobile MRI will allow us to add just 2 days of scanning per week in each of the two most critical locations where it is needed, Orange and Essex. All our planning is centered around a value-based model where we offer the highest quality of health care at the lowest possible cost. The mobile MRI will make the process of MRI scanning as streamlined and cost-effective as possible. The mobile MRI will be linked directly to a COS physician office in Orange and in Essex. The MRI service is not available to patients who are not being treated by a COS orthopedic physician;

we are not in direct competition with radiology practices which offer many types of testing - from ultrasound to bone density, to mammograms and vascular imaging, as well as nuclear medicine and PET/CT. The utilization of MRI scans is integral to the delivery of a comprehensive orthopedic care service. As we all know, healthcare has undergone significant changes in the past few years. Consolidation of medical practices has begun to be essential for the survival of private practices. The predatory behavior of some healthcare systems has forced COS to merge with several other smaller orthopedic groups in order to maintain our viability.

We would not be here today if other orthopedic practices had not become a part of COS in 2014 and 2015. Over the past few years, four (4) orthopedic private-practice physician groups, which have twelve (12) existing offices, have joined with COS. As a result of these mergers, there are now 49 orthopedic physicians in 20 COS offices in Connecticut.¹ The 12 new locations include offices in Hamden, Branford, Orange, Essex and Madison. With all of the new offices and the patient demand for MRI service within COS, we looked first at where we could locate the mobile scanner so that it would ease the existing demand in Branford and Hamden. Both of those facilities are currently at maximum capacity even with overtime hours. To locate the proposed scanner two days a week in Orange, which is reasonably close to both Hamden and Branford, would allow existing COS patients to continue to have access to a COS MRI scanner. Patients who use the Shoreline Orthopedic & Sports Medicine offices have not had access to the COS MRI scanners in Branford or Hamden. Locating the scanner in Essex for two days a week would improve access to MRI services for these patients.

It was in 2014 that we saw new demand for MRI services as patients from the newly affiliated offices began to rapidly fill up the available time slots in Hamden and Branford, at our 2 existing COS MRIs. At that time, we expanded the hours at both

¹ When this application was filed, there were 21 offices with 13 orthopedic physicians, but one of the Shoreline Orthopedic & Sports Medicine offices (the Guilford office) closed after the application was filed with OHCA. (Record, p. 256 fn.)

MRI sites, which are now operating 13 hours a day on weekdays, 10 hours a day on Saturdays, and flexible hours in Hamden on Sundays for emergencies. We are currently open 75 hours a week at both locations, which does not include hours on Sunday in Hamden. Exhibit B in our application (Record, p.70) is a graph where the growth in volume from FY2013 through the first 6 months of FY2016 is detailed.

In our initial filing of this CON application, our utilization calculations were based on the Statewide Health Care Facilities and Services Plan which considers 4,000 scans per MRI unit as a maximum, operating at 85% capacity, taking into consideration time for repair, bad weather etc., or 3,400 scans maximum per year. In 2015, the MRI scanner in Hamden had performed 3,773 scans which was 94% utilization of current capacity, and was projected to have a 110% utilization of current capacity in 2016 (4,428 scans). (Record, p. 42). The actual number of scans performed by COS in FY2016 in Hamden was 4,410, a difference of 18 scans from the forecast. (Record, p. 254, 2nd Completeness).

Similarly when the application was filed, and using the Statewide Health Care Facilities and Services Plan methodology, in FY2015 the MRI scanner in Branford performed 3,851 scans which was 96% utilization of the current capacity, and was projected to have a 120% utilization of current capacity in FY2016 (4,786 scans). (Record, p. 42). The actual number of scans performed by COS in Branford in FY2016 was 4,698 which represents a total of 117% utilization. (Record. p. 254, Completeness #2).

In Question #5 of the 2nd Completeness Question dated February 2, 2017 OHCA asked the following:

“Based on the Applicant’s assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location? “ (Record, p, 254).

Given that our existing scanners are now functioning at these levels, they meet the standard set forth in the CT Statewide Health Care Facilities and Services Plan, which requires that an existing MRI be at 85% of capacity in order to seek additional MRI service. COS meets that guideline.

COS responded that the maximum number of scans that can be performed in Hamden and Branford, based strictly on the hours per week and the minutes per scan is 4,960 scans. (Record, p. 256). This number is overstated because it does not include time out for weather cancellation, ACR testing or MRI maintenance because those factors vary from year to year. Looking at the utilization of each of the MRI scanners based on the maximum number of scans that could be done at each location, as requested in Completeness #2, Question No. 5, COS determined that in FY2016, 4,410 scans were performed on the Hamden MRI which is an 89% utilization rate. The Branford MRI performed 4,698 scans in FY 2016, which is a 95% utilization rate. (Record, p. 254). Using either methodology (either the Statewide Health Care Facilities and Services methodology of assuming 4,000 scans or the capability of each specific MRI which in this case is higher at each of the COS location), COS has met the standard of reaching 85% utilization as required to apply for additional MRI capacity.

COS does not need to rely on adding any new physicians to support the additional MRI capacity being requested in this CON application. That being said, we continue to recruit new physicians to meet the growing demands of our growing patient volumes. The current MRI volume already exists, and as a result, both locations in Orange and Essex will start with a substantial number of new patients who will no longer be able to use Branford and Hamden due to the existing volumes, but who want to stay within the comprehensive COS delivery system.

As you know from our application, if it is approved, COS will reduce the hours in Hamden and Branford so that they operate at a more reasonable and efficient level. Since it is more expensive to operate on nights and weekend days because of the

overtime cost for technicians, this reduction, which can only occur if the mobile MRI is approved, will be a more efficient way to operate the MRIs at Hamden and Branford. Currently, both of these offices offer MRI scanning 75 hours a week (which includes 13 hours per day every weekday and 10 hours every Saturday). Hamden has accepted appointments on Sundays of up to 10 hours per day. When this happens, the MRI scanners are operating 85 hours per week. Weekdays will be cut back from 13 hours a day to 12 hours per day, and Saturday hours will be reduced from 10 hours a day to 4 hours a day, which means that some of those COS patients who would have been scanned on either of the 2 COS MRIs will cause the volume to go up in other facilities.

While we expect that some of this overflow of COS patients will use the COS mobile scanner in Orange or in Essex, a great deal depends upon the patient's residence. For the patients who want one provider to manage the entire course of orthopedic treatment, they will most likely go to the closest COS MRI scanner, mobile or fixed.

The anticipated maximum volume for both Branford and Hamden will be 3,870 scans at each location, which is a drop of 916 patient scans from FY2016 levels in Branford, and a drop of 540 patients scans in Hamden compared to the volume in FY 2016. It is anticipated that the mobile scanner will handle 1,577 scans in Orange and Essex at each mobile location, operating only 2 days per week. (See R., p. 278, 3rd Completeness). The proposed mobile MRI will operate a total of 4 days a week, 12 hours a day at 45 minutes per scan for a maximum of 3,328 scans (1,664 scans per year at each location).

The proposed mobile MRI scanner in Orange will be available to COS patients who are now using Hamden or Branford, as those patients can shift over to the mobile MRI where there will be more room to accommodate them if they so choose. Due to the proximity of Hamden and Orange, COS anticipates that a significant number of patients who are currently using the COS Hamden MRI will use the mobile MRI in Orange. Also, there are 6 COS offices in the Orange area (3 original and 3 from the

new affiliations). COS conducted an internal analysis which demonstrated that in FY2015, 447 COS patients in the Orange service area were referred to non-COS MRIs. (Record, p. 198). We anticipate that a majority of these patients will use the mobile MRI when it is located in Orange.

There are now more COS patients in the Essex service area who require MRI scanning due to the two offices of Shoreline Orthopedic & Sports Medicine that have affiliated with COS. There has been no COS MRI service available in either of the two towns where the newly affiliated COS offices are located. The COS patients in Essex and Madison have been using a variety of MRI providers. In FY2015, the internal records for the Shoreline Orthopedic & Sports Medicine practice indicated that a total of 963 patients were referred to external, non-COS providers for MRI scans. Of the 963 patients, 569 patients reside in the Essex primary service area for the proposed mobile MRI. Virtually no patients were referred to the COS scanners in Branford or Hamden due to lack of capacity, and the distance between the existing COS scanners and the patients living in the Essex area. Also, there had been no COS physician treating patients in the Essex area prior to the affiliation with Shoreline Orthopedics & Sports Medicine.

In 2015, 950 patients who lived in Essex were treated at a COS facility outside of Essex and had their MRI scan performed at the COS MRI either in Hamden or Branford. CON App., Exh. (J-1). It is anticipated that these patients will use the proposed mobile MRI in Essex.

Since there is currently no space within COS for this MRI growth to occur with the existing scanning capacity, there is no doubt that there is a need for the mobile MRI service for COS patients who want all of their treatment coordinated with one provider. There are hospitals available in both service areas involved in this CON application as there are outpatient hospital departments and free-standing radiology practices. Allowing physician practices which have the resources and capability to offer MRI services within their practice keeps the diversity of health

care providers and patient choice in both geographic regions alive. Patients have a choice of how they want their health care provided, and this is appropriate. COS has no problem with their patients asking to have their MRI scan done at a different location, and continues to work with the patient in terms of recovery from an orthopedic accident or ailment. COS does not charge a facility fee. This application keeps alive the single-specialty physician owned practice which is quickly vanishing from the Connecticut health care landscape as large institutions and companies grow their businesses with physicians who used to be in private practice. One of the goals of the State Healthcare Facilities and Services Plan is to keep the diversity of health care models alive and make sure that they are all available to any patient who needs their services.

COS is a Medicare provider and also accepts Medicaid patients. The COS physician practice is open and accessible to all patients who want COS care. That care includes the MRI service if it is necessary. Indigent persons can take advantage of the COS Charity Care policy that is part of the application. (Record, Exhibit I, p. 176). The volume of Medicaid patients has been small until the last couple of years when it started to increase. There appears to be a connection to the closing of St. Raphael's Hospital in New Haven, leaving Medicaid patients without providers. As word has spread that COS accepts Medicaid, the volume has started to increase.

A COS physician is currently on site in both Hamden and Branford when MRI scanning is being done, and can be reached immediately if there is a problem. COS has 2 radiologists available any time scanning is being conducted for consultation by the tech performing the scan. Dr. Gagliardi, who reads all of the COS scans electronically, will call the orthopedic physician to discuss any issue as well. This is all handled electronically with the MRI report reaching the treating physician very rapidly, but no later than twenty four hours after the scanning process is completed.

With the added volume of patients that COS now has, it will allow the COS physicians to drive down the internal cost of MRI scans in the future. Given the fact

that reimbursement for MRI services is going downward, this is important in order for COS to be able to maintain operations. Allowing COS to remain viable is good for healthcare delivery in the State of CT, as we represent a private practice alternative to the healthcare system-owned alternative in New Haven. COS contracts with all insurers in the State. We also see Medicare and Medicaid patients without discrimination. True to our culture, COS has already begun the active process of dealing with its payers and insurers to partner with them in abiding by the Patient Protection and Affordable Care Act of 2010 which encourages bundled payments. COS has bundled payment contracts with Anthem BC/BS, Ct Care and Aetna. In our core application, due to a misunderstood communication, it is stated that bundled payments currently include all MRI scanning, without mentioning the exclusion of the initial MRI. Language to this effect is present in numerous places in the application. I would like to take this opportunity to retract that mistake, and to apologize for the error.

COS is currently trying to offer MRI services of the highest quality, yet at the lowest price possible. The larger network of physicians will make many things possible, including bundled payments.

The proposal is financially feasible for COS as evidenced by the financial information provided in the application. Our CFO, Susan Bader, is present this morning if you have any questions in this regard. With the large footprint that COS MRI scanning has, and the efficiencies it has incorporated into its MRI operations, it is anticipated that COS MRI scanning will operate in Orange and Essex without losses, from the beginning, if the proposal is approved. The financial details are available in the application. (Record, p. 277, 3rd Completeness).

The application also meets the guidelines required as to quality. The existing MRI units in Branford and Hamden are accredited by the American College of Radiology, as will be the new proposed mobile MRI. The scans in Hamden and Branford are now being read by the COS radiologist, Dr. Gagliardi who is a board certified

radiologist specializing in orthopedic radiology. He will continue to be the COS radiologist after the new MRI begins operation, if this proposal is approved. He will testify as to the requirements set forth in the Statewide Health Care Plan as to the method used to transmit the MRI scan both to him, and the report of the MRI scan back to the physician.

While patients are always given a choice of where to have the MRI scan performed, having it done under the supervision of a COS orthopedic physician who is either the treating physician or in the same practice as the treating physician is always the better alternative medically because of the speed with which the MRI can be done, and the fact that the patient does not have to make another appointment, register with that new facility, and receive results from a radiologist who is not part of the same practice, and is not familiar with the patient,

I want to thank you, on behalf of all of the COS physicians and our supporting staff, for the time you have spent on consideration of this application.

And now I would like to introduce Dr. Joseph Gagliardi, our COS radiologist.

PATRICK A. RUWE, M.D.

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Education: Yale University School of Medicine
New Haven, Connecticut
Doctor of Medicine cum laude 1987

University of London School of Medicine
Royal Free Hospital

Yale University
Bachelor of Science 1983
Major: Environmental Biology

Eisenhower High School
Decatur, IL
Valedictorian, 1979

Academic
Affiliation: Assistant Professor
Section of Sports Medicine
Department of Orthopaedics and Rehabilitation
Yale University School of Medicine 1993-99

Fellowship: Sports Medicine: Kerlan-Jobe Orthopaedic Clinic 1992-93

Residency: Orthopaedic Surgery Resident, Chief Resident 1988-92
Yale-New Haven Hospital, New Haven, Connecticut.

Occupation: Orthopaedic Surgeon, Sports Medicine Specialist
Connecticut Orthopaedic Specialists, P.C.

Sports
Coverage: Head Orthopaedic Team Physician 2001-2014
Yale University

Team Physician 1993- 1999
Yale University.

Assistant Team Physician 1988-1993
Yale University Intramural Athletics, Los Angeles Dodgers,
Angels, Rams, Kings, Lakers
Southern CT State University Varsity Football
University of Southern California Men's Varsity Volleyball.

Academic

Honors:

Yale University School of Medicine
Doctor of Medicine cum laude (top 10%)
Alpha Omega Alpha Medical Honor Society
Donjoy Orthopaedic Research Prize, 1992
James M. Cary Orthopaedic Research Prize, 1990
Community Orthopaedic Anatomy Prize, 1990, 1992
Louis G. Welt Graduate Prize
Lange Medical Publication Award
Thesis Day Presentation Prize

Yale College
Thomas A. Yawkey Scholarship
Chester J. LaRoche Memorial Scholarship
CoSIDA Academic All-American Football Player
106th Yale Varsity Football Captain.
George HW Bush Lifetime of Leadership Award Winner, 2016

Medical

Societies:

American Academy of Orthopaedic Surgeons
National Orthopaedic Educational Society
American Orthopaedic Society for Sports Medicine
Alpha Omega Alpha Medical Honor Society
American Medical Association
Connecticut Medical Society
New Haven County Medical Society
Yale Orthopaedic Association

Associations/

Societies:

Yale Football Association
Phelps Association
Ladies Aid Society
Yale Hockey Association
Yale Alumni Schools Committee
Hotchkiss School Parent Agent
Hammonasset Fishing Association
USSGA

Leadership

President, Connecticut Orthopaedic Specialists, PC
Medical Director, COS Surgical Center
President, Yale Football Association 1996-Present
Positions: President, National Orthopaedic Educational Society

Vice President, Yale Sports Federation
Orthopaedic Representative, Temple Surgical Center Board,
1993-2006
Head Team Orthopaedic Surgeon, Yale University 2001-2014
Head Orthopaedic Consultant, Yale Health Services 2001-2014
Phelps Association, Board of Governors
Chair 2007 Blue Leadership Ball, Yale University
Selection Committee, George H.W. Bush Leadership Award
Chair, Alumni Selection Committee, Yale Football Head Coach,
2008,2011

Member, University Football Head Coach Selection Committee,
2011
Member, Alumni Football Head Coach Selection Committee,
1995
Yale University Presidents Committee on Athletics
Member, Mory's Council

Family: Stacy S. Ruwe, MBA: CFO, EDUCAUSE

Patrick A. Ruwe II: BA Yale College 2011

Brian C. Ruwe: BA Yale College 2013

Katelyn Ruwe: Yale College 2017

Boards: National Board of Medical Examiners, 7/1/88
American Board of Orthopaedic Surgeons, 7/13/95

License: California Medical License G 073816.
Connecticut Medical License 033031

Chairs: Chairman: Orthopaedic Consensus and Controversies in
the Desert. 6th Meeting of the Yale
Orthopaedic Association. Phoenix, AZ April
14-17, 1997

 Chairman: Yale Orthopaedics in the Millennium - Minus
One. 7th Meeting of the Yale Orthopaedic
Association. Bermuda, March 25-28, 1999

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Ruwe PA, Pink M, Jobe FW, Perry J, Scovazzo ML: The Normal and Painful Shoulder During the Breaststroke: An EMG and Cinematographic Analysis of Twelve Muscles. AOSSM/JOSSM Trans Pacific Meeting, March, 1993.

Ruwe PA, Klein I, Shields CL: The Effect of Intra-articular Injection of Morphine and Bupivacaine on Post-arthroscopic Pain Control. AOSSM Annual Meeting, June, 1994.

Regional Presentations: Ruwe PA, Trumble TE: Fresh Vs. Cryopreserved Peripheral Nerve Autografts: VA Surgical Meeting, Northpoint, New York, March 1987.

Ruwe A, Gage GR, Ozonoff MB, DeLuca PA: Clinical Determination of Femoral Anteversion: A Comparison to Established Methods: Newington Children's Hospital 28th Annual Orthopaedic Conference, Newington, CT, November 2, 1990.

Ruwe PA, Pink M, Jobe FW, Perry J, Scovazzo ML: The Normal and Painful Shoulder During the Breaststroke: An EMG and Cinematographic Analysis of Twelve Muscles. Kerlan-Jobe Orthopaedic Clinic Annual Fellows Conference, July, 1993.

Ruwe PA, Klein I, Shields CL: The Effect of Intra-articular Injection of Morphine and Bupivacaine on Post-arthroscopic Pain Control. Kerlan-Jobe Orthopaedic Clinic Annual Fellows Conference, July, 1993.

Local Presentations: Ruwe PA, Baumgaertner MJ: Fractures of the Tibial Plafond. The Pilon Fracture Orthopaedic Grand Rounds, Yale University School of Medicine, New Haven, CT, July 1989.

Ruwe PA, Lynch JK: The Physiologic Basis for Meniscal Repair: Orthopaedic Grand Rounds, Yale University School of Medicine, New Haven, CT, May 1990.

Ruwe PA: Hand Fractures in the Growing Child: Combined Orthopaedic and Plastic Surgery Hand Conference, Yale University School of Medicine, New Haven, CT, Oct 1989.

Ruwe PA, Wolfe SW: Soft Tissue Infections of the Hand:
Combined Orthopaedic and Plastic Surgery Hand Conference,
Yale University School of Medicine, New Haven, CT, Nov 1990.

Ruwe PA, Gage GR, Ozonoff MB, DeLuca PA: A Clinical
Method For the Determination of Femoral Anteversion:
Newington Children's Hospital Residents' Research Day,
Newington, CT, June 1990.

Ruwe PA, Jokl P: Ruptures of the Tendo Achilles: The Yale
Experience: Orthopaedic Grand Rounds, Yale University School
of Medicine, New Haven, CT, December, 1991.

Ruwe PA, Lombardo SJ: Allograft and Prosthetic ACL
Reconstruction: Centinela Hospital Orthopaedic Grand Rounds,
Inglewood CA, November, 1992.

User, OHCA

From: Jennifer Groves Fusco <jfusco@uks.com>
Sent: Tuesday, June 27, 2017 2:22 PM
To: Lazarus, Steven; Hansted, Kevin; Riggott, Kaila; Fernandes, David; User, OHCA
Cc: Yoder, Clark (clark.yoder@adrad.com); KLG1@aol.com; Glenn F. Elia
Subject: Advanced Radiology Consultants -- Petition for Status & Prefiled Testimony (Docket No. 16-32117-CON)
Attachments: DOCS-#1596401-v1-ARC_COS_OHCA_COVER_LETTER.PDF; DOCS-#1596366-v1-ARC_COS_APPEARANCE_(FINAL).pdf; DOCS-#1596369-v1-ARC_COS_PETITION_FOR_STATUS_(FINAL).pdf; DOCS-#1596370-v1-ARC_COS_YODER_PREFILE_(FINAL).pdf; DOCS-#1596506-v1-ARC_COS_KAROL_PREFILE_(FINAL).pdf

All:

Attached please find the following on behalf of Advanced Radiology Consultants, LLC:

- Cover Letter;
- Notice of Appearance;
- Petition For Status;
- Prefiled Testimony of Clark G. Yoder, M.B.A.; and
- Prefiled Testimony of Ian G. Karol, M.D.

Please let me know if you have any questions.

Thanks,
Jen

Jennifer Groves Fusco, Esq.
Principal
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June 27, 2017

VIA ELECTRONIC MAIL

Yvonne T. Addo, M.B.A.
Deputy Commissioner
Office of Health Care Access Division
Department of Public Health
410 Capitol Avenue
Post Office Box 340308
Hartford, CT 06134-0308

**Re: *Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5 Tesla Magnetic Resonance Imaging Scanner
Docket No. 16-32117-CON***

Dear Deputy Commissioner Addo:

This office represents Advanced Radiology Consultants, LLC (“ARC”). Enclosed are an original and four (4) copies of the following:

- Notice of Appearance of Updike, Kelly & Spellacy, P.C.;
- Petition of Advanced Radiology Consultants, LLC To Be Designated As An Intervenor With Full Rights Including The Right of Cross-Examination;
- Prefiled Testimony of Clark G. Yoder, M.B.A., Chief Executive Officer, Advanced Radiology Consultants; and
- Prefiled Testimony of Ian G. Karol, M.D., Chief Medical Officer, Advanced Radiology Consultants.

These documents are being submitted in connection with the public hearing on the above matter scheduled for July 11, 2017 at 9:00 a.m. Mr. Yoder and Dr. Karol will be present at the hearing to adopt their prefiled testimony under oath and for cross-examination.

Yvonne T. Addo
June 27, 2017
Page 2

Should you require anything further, please feel free to call me at (203) 786-8316.

Very truly yours,



Jennifer Groves Fusco

Enclosures

cc: Clark G. Yoder (w/enc)
Patricia A. Gerner, Esq. (w/enc)

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION**

.....)
IN RE: CONNECTICUT ORTHOPAEDIC)
SPECIALISTS, P.C. ACQUISITION OF A)
MOBILE 1.5 T MAGNETIC RESONANCE)
IMAGING SCANNER)
.....)

DOCKET NO. 16-32117-CON

JUNE 27, 2017

**PREFILED TESTIMONY OF IAN G. KAROL, M.D.,
RADIOLOGY EXECUTIVE COMMITTEE MEMBER,
ADVANCED RADIOLOGY CONSULTANTS, LLC,
IN OPPOSITION TO THE CON REQUEST OF
CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.**

Good morning Hearing Officer Hansted and members of the Office of Health Care Access (“OHCA”) staff. My name is Ian Karol and I am a physician partner with Advanced Radiology Consultants, LLC (“ARC”). I am a board-certified radiologist with a subspecialty in body imaging and musculoskeletal MRI. I am ARC’s Chief Medical Officer (“CMO”) and a member of the Radiology Executive Committee. In addition, I am a member of the Radiology Society of North American and the Radiological Society of Connecticut. A copy of my Curriculum Vitae is attached for your reference (see Exhibit A).

Thank you for this opportunity to testify in opposition to the Certificate of Need (“CON”) Application filed by Connecticut Orthopaedic Specialists, P.C. (“COS”) for acquisition of a third MRI unit. My testimony will focus primarily on the quality of the MRI unit that COS is proposing to acquire and how COS’s radiology service compares with full-service radiology practices such as ARC. I will also speak about the lack of need for “same day” MRI in most instances and how ARC is in a position to provide that services, at an office less than half-a-mile

from COS's proposed Orange MRI site, on those rare occasions when it is necessary. Lastly, I will discuss the issue of physician self-referral and how this practice can lead to overutilization of MRI services and increased costs for healthcare payers and consumers.

COS has failed to establish that the proposed MRI unit will improve the quality, accessibility and cost-effectiveness of healthcare delivery in the Orange and Essex service areas (Conn. Gen. Stat. §19a-639(4)). For these reasons, and as discussed in greater detail below, ARC respectfully requests that COS's CON Application be denied.

The Proposed COS MRI Unit is of Lesser Quality than ARC's Scanners

COS is proposing to acquire a mobile MRI unit to be utilized at office locations in Orange and Essex. The proposed unit is a 2000 Mobile GE 1.5 T Excite (11X) 8 Channel MRI System (CON Application, p. 51). The unit was manufactured in 2000, meaning it will be at least 17 years old by the time it is put into service. MRI technology evolves rapidly. New pulse segments are continually being designed and older units cannot always perform them. Pathology can also be missed on older MRI units. Also, older units tend to be less reliable and vendors stop supporting them after a certain point.

The proposed office locations in Orange and Essex are approximately 36 miles apart and connected by a major interstate highway, I-95. The unit will travel between the offices via trailer at least once each week. Vibrations associated with this amount of travel can damage the unit and compromise the quality of the images it produces. This type of travel is not typical of MRI services in Connecticut and is not optimal. The only reasons to purchase a mobile MRI unit are the reduced purchase price (\$575,000 vs. \$1.5 - \$2 million) and to maximize COS's ability to "recapture" MRI volume from existing providers in multiple areas of the state (CON Application, p. 37).

Compare this with the newer, fixed units being operated by ARC in the Orange service area and elsewhere. ARC's MRI units are all 1.5 Tesla or 3.0 Tesla units, including a 3.0 Tesla MRI operated in our Orange office. We find that many orthopedists only want their patients scanned on a 3.0 Tesla unit given the superior image quality and its benefits in diagnosing and determining course of treatment. ARC has invested considerable capital in making this technology available for patients and OHCA should not approve a CON for an inferior MRI unit that will certainly adversely impact our practice given COS's ability to redirect referrals.

ARC's Offers Superior Professional Radiology Services

COS provides more than 9,000 MRI scans each year, with that number projected to increase to more than 11,000 by FY 2020 if a third unit is approved for the practice (CON Application, p. 278). It appears that a majority of those scans are read by Dr. Joseph Gagliardi, a radiologist employed by COS (CON Application, p. 15). According to his CV, Dr. Gagliardi is a general radiologist without fellowship training (CON Application, p. 77). In contrast, each and every one of ARC's 34 radiologists is subspecialty trained. In order to be a subspecialist, a radiologist must complete fellowship training beyond his or her medical residency.

We currently have 15 radiologists who are subspecialty trained at reading various types of MRI scans. And most importantly, every scan performed at ARC is interpreted by a subspecialist with training in that particular type of scan. For example, if an orthopedic patient is referred for an MRI of the knee, that scan will always be read by a musculoskeletal MRI subspecialist. Spine MRI's are read by subspecialty trained neuroradiologists. With only Dr. Gagliardi reading scans for COS, the practice is not offering this level of sub-specialization to its patients.

In addition, ARC has sufficient radiologists on staff to ensure that MRI scans are read in a timely fashion without overburdening any particular radiologist and risking incomplete or inaccurate results. COS projects performing 11,187 MRI scans by FY 2020 if this proposal is approved (CON Application, p.278). Considering vacation and downtime, COS's units are presumably operating 50 weeks each year. Weekend hours are limited, so Dr. Gagliardi is likely reading scans no more than 5 ½ day each week or 275 days each year. If the practice performs 11,187 scans in a year, and Dr. Gagliardi reads those scans over 275 days that is 41 scans per day on average. Depending upon how much time Dr. Gagliardi spends fulfilling his duties at the Veterans Administration Medical System in West Haven, he may have even less time to read COS scans (CON Application, p. 78). Assuming Dr. Gagliardi has another radiologist assisting him, the number of scans being reviewed by each radiologist is still significant. Also, we do not know the credentials of any other radiologists reading for COS and whether they are subspecialty trained in MRI.

Having an MRI Unit In-house Does Not Mean Timelier or Better Care

COS claims that providing its patients with MRI services in-house results in higher quality care, quicker diagnosis, better care coordination, and greater convenience for patients (CON Application, pp. 15, 16, 23, & 29). There are several flaws with COS's reasoning. First, it is extremely unlikely that a COS patient will receive an MRI scan on the same day that a COS physician orders the scan. MRI scans require preauthorization from a patient's insurance and this typically takes days to obtain (and often requires that months of conservative therapy take place before an MRI is ordered). Based on my 20 years of experience as a radiologist, I would estimate that emergent MRIs account for a small fraction of all MRI scans. A National Health Statistics Report from 2010 found that only .7% of all emergency department visits resulted in an

MRI scan, and only .3% resulted in a non-brain MRI scan (see Exhibit B). Presumably even fewer individuals in need of emergent MRI present in an outpatient physician office setting. Accordingly, having in-office MRI at an orthopedic practice is neither a convenience nor a diagnostic necessity like having in-office x-ray where patients do, in fact, have exams in conjunction with office visits.

Moreover, the chances that a COS patient requiring same-day MRI will have his or her physician appointment in the Orange or Essex office on a day that the mobile unit is parked at that office are low. And if a patient from the COS Orange office needs a same-day MRI scan, ARC has emergency slots held at each of its offices every day, including our Orange office which is .2 miles away. ARC also understands that the quicker an MRI scan is scheduled the earlier a diagnosis can be made and treatment started. For non-emergent scans, ARC can schedule a patient on its Orange and Stratford MRI units the next day and in Shelton within two days.

In addition, the ability to coordinate care is no better when an orthopedic practice owns its own MRI unit. COS claims that having in-house MRI means the exam results are returned to the orthopedists “much faster” than if the scans were referred to a non-COS provider (CON Application, p. 29). This is not true. While Dr. Gagliardi promises turnaround within 24 hours, ARC turns around MRI scans Monday through Friday within 1 hour, with a slightly longer turnaround time on the weekends. To the best of our knowledge, ARC has the capability of interfacing with COS’s EMR system so that our delivery of results would be identical to those provided by Dr. Gagliardi. Our images and results are also accessible by physicians, and patients themselves, from virtually anywhere via ARC’s image sharing network.

As far as cost is concerned, ARC likely charges similar rates for MRI services and like COS, there is no facility fee involved. COS makes frequent mention of the cost-effectiveness of bundled payments in its CON submission, however it concedes that the cost of MRI is not included in any of its bundles (CON Application, p. 221). Incidentally, ARC participates in bundled payment contracts but has never been approached by COS about participating in such an arrangement to try to maximize the cost-effectiveness of imaging and other services for patients.

Moreover, because ARC does not self-refer patients for studies, there is less risk of overutilization and increased costs for patients and payers. As I discuss in greater detail below, studies have shown that providers who refer patients to scanners in which they have a financial interest tend to refer at higher rates than those who send their patients to unaffiliated imaging providers.

Impact of Self-Referral on Utilization, Cost-effectiveness & Quality of Imaging Services

I would like to conclude by discussing how providing imaging services, in this case MRI, in an office such as COS where the providers themselves both decide whether a patient needs an exam, and make referral for that exam to a unit in which they have a financial interest, results in overutilization and increased cost. Based on the findings of numerous imaging self-referral studies, COS's existing volume and projected "need" for MRI services within its practice may be overstated. Moreover, authorizing the acquisition of a third scanner by COS is not the most cost-effective means of meeting MRI demand and it may adversely impact quality of care.

Put simply, self-referral is when a provider refers a patient to a facility for healthcare services and that provider has a financial interest in, or arrangement with, the facility that allows the potential for financial gain from the referral. The MRI service operated by COS is a perfect example – two scanners owned by an orthopedic group and the referral of patients for "in-office"

MRI services by physicians in that group. The physicians at COS who make these referrals stand to benefit from the revenues generated by the MRI units. They therefore have a financial incentive to maximize referrals to their existing scanners.

Compare this with private radiology practices, which only perform examinations referred by non-affiliated providers. These providers make MRI referrals for one reason only, their need for information to take care of their patients, including preventative, interventional, diagnostic, and staging studies, as well as determinations of efficacy of treatment. There is no personal incentive on the part of referring providers to send patients for procedures or scans and there is certainly no financial gain realized in doing so.

On the other hand, as our experience demonstrates and study after study unequivocally show, the volume and cost of care increases substantially when providers who refer patients for imaging tests own the machines on which the examinations are performed. Early studies, which led to initial attempts at curtailing self-referral, showed that providers engaged in self-referral ordered imaging studies at a much higher rate than their colleagues who sent patients to dedicated imaging facilities (Exhibit C). They also showed that self-referral increased the cost of care considerably (Exhibit C). Many subsequent studies showed similar results. For example, analysis of Medicare data published in 2002 showed that growth in the use of radionuclide myocardial perfusion imaging between 1996 and 1998 was 10 times higher among cardiologists (self-referred) than radiologists (Exhibit D). Recently, a review of Medicare claims from 2005 to 2015 showed that, although the number of private office MRI claims submitted by radiologists remained relatively unchanged or even decreased, MRI claims submitted by orthopedic surgeons increased by 53% (Exhibit E). According to the physician who will present these findings at the 2017 meeting of the Radiological Society of North America, this raises concerns about self-

referral, particularly given the fact that the orthopedist-referred studies were virtually all related to musculoskeletal conditions (Exhibit E).

There is no obvious explanation for the higher rate of use except the financial benefits of self-referral for providers making the referrals. Self-referral accounts for a majority of imaging growth. The issues regarding self-referral and its adverse impact on cost of care are so well known that many advocacy groups (i.e. American Association of Retired Persons¹), the GAO (Exhibit G), and President Obama's 2017 budget (Exhibit H) have all called for reform of the system to close any loopholes in the law that allow it.

Much of the evidence cited in opposition to self-referral is in the context of Medicare patients and shows the staggering financial implications of the practice. Now consider that private insurers typically reimburse physician practices 2 to 3 times what Medicare pays for MRI scans, and only 21% of COS's MRI scans are Medicare (CON Application, p.278). If one were to apply the COS situation (commercial rates higher than Medicare) to the OMB formula for the budgetary savings from eliminating self-referral, the savings would be multiplied.

If OHCA allows COS to acquire an unprecedented third MRI unit there can be no assurances that the scanner will be used to fulfill only the legitimate healthcare needs of area patients. COS physicians have everything to gain financially from ordering MRI scans. It would not be far-fetched to wonder whether every scan referred by COS and performed on its MRI unit is entirely necessary. Research tells us that physicians who own imaging equipment refer patients for studies at a higher rate than those who do not self-refer. This certainly calls into

¹ In a 2014 letter to U.S. Rep. Speier, the AARP stated as follows: "The in-office ancillary services exception was intended to allow physicians to perform services which can be completed in the physician's office while the patient is present and which aid in the diagnosis of the patient in order to minimize delays in patient care. Unfortunately, the exception has contributed to overutilization and rapid growth of certain services, particularly in radiation oncology, anatomic pathology, advanced imaging, and physical therapy. Closing the loophole will better serve patients and preserve Medicare's resources by saving approximately \$6 billion over ten years for these services" (Exhibit F).

question the true need for these examinations and whether they are artificially driving up the cost of care.

Note also that self-referral can have an adverse impact on the quality of imaging services. The former editor of the New England Journal of Medicine wrote that self-referral situations deprive patients of independent judgment on the part of their doctor and of peer review, factors that are inherent in any exam referred from one physician to another, and thereby undermine the integrity and trust of the medical profession and its social contract with patients (Exhibit I).

The current in-office ancillary services exception was intended to facilitate the imaging studies necessary for an office visit, like an x-ray that can be performed while you are waiting to be seen by the doctor. Allowing providers to own advanced imaging equipment like an MRI unit, and to refer patients to that unit for reasons other than the convenience associated with same-day ancillary services, was not the original intent of the law. In point of fact, while “convenience” may come into play for some examinations, like x-rays in the case of suspected fracture, as previously mentioned it is impractical and uncommon to perform advanced imaging, like MRI, on the same day. Those examinations are almost universally scheduled in advance; they almost always require pre-authorization from insurance companies; and commonly require preparation protocols. A 2010 article in Health Affairs, the most prestigious journal of health economics and policy, showed the following:

Proponents of such self-referral argue that the practice offers patients convenient same-day, one-stop service and allows treatment to start sooner. Our analysis of 2006 and 2007 Medicare data showed that self-referral provided same-day imaging for 74 percent of straightforward x-rays, but for only 15 percent of more-advanced procedures such as computed tomography and magnetic resonance imaging (Exhibit J).

While legislators work to close this massive and costly loophole, we implore OHCA to look critically at whether approval of self-referred major imaging equipment is in the best interest of

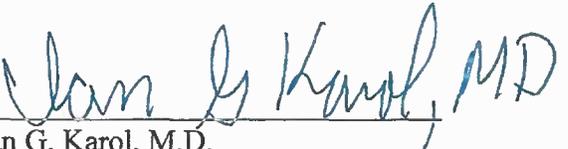
healthcare consumers and payers in our state. Our understanding is that the state's Health Care Cabinet will be looking closely at self-referral during the next year. This could result in recommendations for legislation that bans the practice altogether. We urge OHCA to deny COS's request for a third self-referral MRI unit pending further clarification of the law and policy.

Conclusion

Based on the foregoing, ARC respectfully requests that COS's application for authorization to acquire a third MRI unit be denied. COS has not shown that the quality, accessibility or cost-effectiveness of care will be enhanced by the proposal. Rather, they are proposing to acquire an older mobile MRI unit and to have scans interpreted by a general radiologist instead of the subspecialty radiologists that read for other providers in the area. COS's claims regarding the benefits of in-house MRI in terms of access, quality and cost are therefore overstated. This is particularly true given the risks associated with self-referral of MRI services.

Thank you again. Mr. Yoder and I are available to answer any question that you have.

The foregoing is my sworn testimony.



Ian G. Karol, M.D.

EXHIBIT A

CURRICULUM VITAE

NAME: Ian. G. Karol, M.D.

HOME ADDRESS: 2A Woodhill Road
Westport, CT 06880

HOME TELEPHONE: (203) 254-8668

CELL TELEPHONE: (203) 258-9343

EMAIL ADDRESS: NSIK44@gmail.com

MARITAL STATUS: Married (wife is physician in Internal Medicine)

CHILDREN: Three (Alex 22, Josh 19, Zach 15)

POST GRADUATE TRAINING:

1997 - 1998
Fellowship in Abdominal Imaging
Yale New Haven Hospital
New Haven, CT

1993 – 1997
Residency in Diagnostic Radiology
Albert Einstein College of Medicine and Montefiore
Medical Center
Bronx, NY
Distinction: Chief Resident

1992 - 1993
Internship in Internal Medicine
Greenwich Hospital/Yale University School of Medicine
Greenwich, CT

GRADUATE EDUCATION: 1988 – 1992
Albert Einstein College of Medicine
Degree: M.D.

UNDERGRADUATE EDUCATION: 1984 – 1988
University of Pennsylvania
Philadelphia, PA
Degree: BA

Curriculum Vitae
Ian G. Karol, M.D.
Page 2 of 3

EMPLOYMENT:

1999 – present
Advanced Radiology Consultants
Shelton, CT

Distinction: Member Advanced Radiology Exec Committee
Chief Medical Officer – Advanced Radiology

Chairman Radiology Department-Active - Bridgeport
Hospital

1998 – 1999
Radiology Affiliates of Central New Jersey
Hamilton, NJ

STAFF APPOINTMENTS:

2010 – present
Radiology Attending
St Vincents Medical Center

1999 - present
Associate Attending
Bridgeport Hospital
Distinction: Chief of CT Body Imaging

LICENSURE:

Connecticut #036164

BOARD CERTIFICATION:

Diplomate , American Board of Radiology, 1997

HONORS AND AWARDS:

2002 Bridgeport Hospital Housestaff Teacher of the Year Award
1997 Milton Elkin Outstanding Graduating Resident Award
1990 American Cancer Society Research Fellowship Award
1988 – 1992 Faculty Student Senate – Albert Einstein College of Medicine

PUBLICATIONS:

Hayashi D, Sharma P, Kaye A, Karol I. Prostatosymphyseal fistula as a complication of transurethral resection of prostate (TURP). American College of Radiology (ACR) Case in Point. 2017.

Hayashi, Kumar, Bhatt, Karol, I. "Calf Muscle Herniation presenting twelve months after dog bit injury: Case report; Connecticut Medicine, Volume 80, November/December 2016; Number 10.

Thawait, S, Karol, I. "Traumatic Lipohearthrosis of the wrist joint due to a Scaphoid fracture" RCR July 2012

Golia JS, Vossen JA, Chamarthy M, Thawait SK, Lam C, Karol I. The Many Faces of Superior Mesenteric Artery Aneurysms. RSNA 98th Scientific Assembly and Annual Meeting 2012. Chicago, IL (abstract accepted).

Jain M, Singh R, Karol I; "Alternative Pathologies on Unenhanced Helical CT Scan in Patients Presenting with Flank Pain," The Radiologist, March 2003, 10 (2): 55-61.

Singh R, Jain M, Karol I, Choy O, Zinn K; "Helical Non-Contrast CT in Evaluation of Acute Appendicitis: A Bridgeport Hospital Experience"

Karol I, Szarnecki G, Khalil H; "Gallbladder Carcinoma," eMedicine Journal, December 2001, 2 (12)

Curriculum Vitae

Ian G. Karol, M.D.

Page 3 of 3

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Karol,I, Townsend-Watts,M, Pinto, A, "Testicular Microlithiasis" Applied Radiology, December 2008, Vol 37, Number 12: 34-36

PRESENTATIONS:

"Alternative Pathologies in Clinically Suspected Renal Colic Patients on Unenhanced Helical CT Scan," Presented at the 16th Annual Bridgeport Hospital Science Symposium, April, 2002

"Alternative Pathologies in Clinically Suspected Renal Colic Patients on Unenhanced Helical CT Scan," Presented at the RSNA 2001, Chicago, IL.

"Helical Non-Contrast CT in the Evaluation of Acute Appendicitis: A Spectrum of Findings," Karol I, Singh R, Jain M, Patel K, Choy O., AUR, May 2001.

"Spontaneous Renal Artery Dissection: Limitation of Abdominal Helical Non-Contrast CT for Flank Pain and Review of Literature: A Case Report," Karol I, Jain M, Singh R, Patel K, Butler D, Kaye A, Presented at the 64th Annual Scientific Meeting of Canadian Association of Radiologists; Vancouver, Canada.

“Retroperitoneum Perforation of Duodenal Ulcer: An Unusual Cause of Acute Abdomen,” Karol I, Jain M, Singh R, Patel K, Shah S; Bridgeport Hospital Annual Science Symposium 2001.

“Web Based Musculoskeletal Ultrasound Atlas of Normal and Abnormal Anatomy with MRI Correlation” - Accepted as Power Hour Presentation (on Monday, April 27th at 8am) and Electronic Exhibit during the April 2009 American Roentgen Ray Society meeting in Boston, MA. Developed by Bruce Kovalenko M.D., Contributing authors: Ian Karol, and Steven Cohen

“Case Report: 54 Year Old Woman with Chronic Lithium Induced Nephropathy” – Confirmed with MRI. Bruce Kovalenko M.D., Ian Karol M.D.
Approved by ACR and submitted to ACR: Case in Point – 8/2009

“Web Based Musculoskeletal Ultrasound Anatomy Atlas” at the 109th Annual Meeting of the American Roentgen Ray Society held April 26-May 1, 2009 in Boston, MA. Presented by Bruce Kovalenko, M.D. entitled Preceptor: Ian Karol, M.D.

Kumar Y, Hooda K, Chamarthy MK, Gupta M, Weiland D, Karol I. Morel-Lavallee Lesion: A Case of American Football Player Injury. Poster presentation at the 26th Annual Bridgeport Hospital Science Symposium, April 26, 2012.

Golia JS, Vossen JA, Chunwang L, Karol I. The Many Faces of Superior Mesenteric Artery Aneurysms. Poster presentation at the 26th Annual Bridgeport Hospital Science Symposium, April 26, 2012.

“Traumatic Liophemarthrosis of the Wrist Joint Due to a Scaphoid Fracture.” Thawait SK, Karol I. Poster presentation at Bridgeport Hospital’s 25th Annual Science Symposium, Bridgeport, CT; April 28, 2011. Awarded 3rd Place for Scientific Merit.

“MR Imaging of Non-obstetric Pelvic Pain in the Pregnant Patient.” Karol, K, L. Miller, D. Fedele, F. Lu, and J. Vossen. Presented at ECR 2014 Vienna, Austria

"Ulnar Artery Aneurysm and the Hypothenar Hammer Syndrome" Case report Kumar, Yogesh; Hooda, Kusum; Lo, Lawrence; Karol, Ian, BMJ.com accepted 11-2015

Do We Really Need Open or Upright MRI scanner?

Our Technique for Imaging the Wrist in Obese and Claustrophobic Patients Using a Standard MRI scanner. Y Kumar, MD; D Hayashi, MBBS, PhD; B Rapillo, RT; K Hooda, MBBS; S Sharma, MD; I G Karol, MD, Department of Radiology Yale New Haven Health System at Bridgeport Hospital, CT Science Symposium 2015 and pending RSNA presentation 2015.

SOCIETY MEMBERSHIPS:

Radiological Society of North American
American College of Radiology

EXHIBIT B

National Health Statistics Reports

Number 26 ■ August 6, 2010

National Hospital Ambulatory Medical Care Survey: 2007 Emergency Department Summary

by Richard Niska, M.D., M.P.H., F.A.C.E.P.; Farida Bhuiya, M.P.H.; and
Jianmin Xu, M.S.; Division of Health Care Statistics

Abstract

Objective—This report presents data on U.S. emergency department (ED) visits in 2007, with statistics on hospital, patient, and visit characteristics.

Methods—Data are from the 2007 National Hospital Ambulatory Medical Care Survey, which uses a national probability sample of visits to emergency departments of nonfederal general and short-stay hospitals in the United States. Sample data were weighted to produce annual national estimates.

Results—In 2007, there were about 117 million ED visits in the United States. About 25 percent of visits were covered by Medicaid or the State Children's Health Insurance Program (SCHIP). About one-fifth of ED visits by children younger than 15 years of age were to pediatric EDs. There were 121 ED visits for asthma per 10,000 children under 5 years of age. The leading injury-related cause of ED visits was unintentional falls. Two percent of visits resulted in admission to an observation unit. Electronic medical records were used in 62 percent of EDs.

Keywords: boarding • electronic medical records • emergency department visits • overcrowding

Introduction

The National Hospital Ambulatory Medical Care Survey (NHAMCS) has been gathering, analyzing, and disseminating information about hospital outpatient and emergency departments (EDs) since 1992. NHAMCS and the National Ambulatory Medical Care Survey (NAMCS) are parts of the ambulatory component of the National Health Care Surveys, a family of surveys that measure health care utilization across various types of

providers. More information about the National Health Care Surveys can be found at the following website: <http://www.cdc.gov/nchs/nhcs.htm>.

NHAMCS and NAMCS data have been used in articles examining important topics of interest in public health and health services research. For a list of publications, see: <http://www.cdc.gov/nchs/data/ahcd/publist-9-4-2009.pdf>. In addition to the ED report, other reports highlight visits to outpatient departments (OPDs) (1) and

physician offices (2). Annual reports are available from: http://www.cdc.gov/nchs/ahcd/ahcd_reports.htm. Public-use data files are available from: http://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm. Data from NHAMCS 2007 will also be available on CD-ROM. These and other products can be obtained from the National Center for Health Statistics (NCHS), Office of Information Services, Information Dissemination Staff at 1-800-232-4636, the Ambulatory and Hospital Care Statistics Branch at 301-458-4600, or by e-mail at CDCINFO@cdc.gov.

This 2007 report begins with a summary of major issues in emergency medicine as articulated by the Institute of Medicine (IOM), the American College of Emergency Physicians (ACEP), and the Healthy People 2010 (HP-2010) objectives of the U.S. Department of Health and Human Services. The report then highlights key data elements on EDs from NHAMCS that are relevant to those issues.

In 2006, IOM identified several key issues affecting U.S. emergency medicine, including overcrowding of EDs, lack of critical specialists to whom EDs could refer patients, and gaps in emergency pediatric care. On overcrowding, the IOM noted an increase in ED visits along with a



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decrease in the number of EDs. The visit increase was tied not only to provision of medical care to uninsured patients, but also to evening and weekend care of insured patients whose regular physicians were unavailable (3). There has been concern about increasing enrollment in Medicaid as an indicator of stress on the safety net system in which EDs play a major part (4). Data on ED visit rates, Medicaid and uninsured status of those using EDs, and the use of EDs for care in the evening and on weekends are presented in this report.

According to the Government Accountability Office (GAO), the main issue contributing to overcrowding of EDs has been delays in moving the sickest patients to inpatient beds (5). Admitted patients have often been boarded in EDs or hospital hallways for hours to days, resulting in overcrowding and diversion of incoming ambulances to other hospitals (6). IOM recommended adopting systems to even out the flow of patient admissions and implementing 23-hour observation units (3). This report presents data on boarding and systems to address patient flow.

On specialist availability, IOM found that approximately 75 percent of hospitals had difficulty providing consultants to take calls for emergencies. On pediatric care, IOM observed that most children received care in general EDs, rather than pediatric facilities with optimal expertise and equipment to handle their unique needs (3). Included in this report are data on visits involving on-call physicians and pediatric EDs.

In its 2009 National Report Card, ACEP rated emergency department quality of care, including patient safety, with respect to a scoring system based on 15 quality indicators. Quality of care was rated as a C+ nationally, but individual state scores varied widely. Hospital crowding, ED boarding, ambulance diversion, and high rates of uninsured individuals were key issues impacting quality of care (7).

Data from NHAMCS are used as a national standard for health care estimates in the HP-2010 objectives.

NHAMCS ED visit data have been used to establish baseline estimates for two objectives related to reducing ED visits for asthma and nonfatal dog bite injuries. The asthma objective breaks the population into three age groups and identifies separate targets for reduction in each group (8). This report includes data on visit rates for asthma for each of these age groups, for injuries in general, and for dog bites in particular.

Methods

Data source

This report presents data on ED visits in terms of hospital, patient, and visit characteristics. These data are from the 2007 NHAMCS, a national probability sample survey of nonfederal, general, and short-stay hospitals conducted by the Division of Health Care Statistics, NCHS, Centers for Disease Control and Prevention (CDC). The survey was conducted from January 1, 2007, through December 30, 2007. The multistage design involves sampling geographic primary sampling units (PSUs), hospitals that have EDs or OPDs within PSUs, clinics within OPDs, and then patient visits within emergency service areas (ESAs) in EDs and clinics in OPDs. Within EDs, types of ESAs included general, adult, pediatric, fast track, psychiatric, and trauma. The sample of 112 PSUs comprised a probability subsample of PSUs used in the 1985–1994 National Health Interview Surveys (NHIS). In 2007, a sample of 482 hospitals was selected from a sampling frame constructed from hospitals listed in the 1991 Verispan Hospital Database updated using hospital data from Verispan, L.L.C., specifically its “Healthcare Market Index, Updated July 15, 2006” and “Hospital Market Profiling Solution, Second Quarter, 2006.” These products were formerly known as the SMG Hospital Database. Using the 2006 data to update the 2007 sample allowed for the inclusion of hospitals that had opened or changed their eligibility status since the previous sample was updated for 2003.

Hospital staffs or field representatives from the Bureau of the Census completed a Patient Record Form (PRF) for a sample of visits during a 4-week reporting period. Of the sample of 482 hospitals selected for the 2007 NHAMCS, 384 were in scope and had eligible EDs, and 357 of these EDs responded (ED-level response rate of 93.0 percent unweighted and 92.6 percent weighted for the probability of selection). A total of 438 of the 477 ESAs within the participating EDs responded and provided 35,490 PRFs. Of these 438 ESAs, 432 responded fully or adequately by providing at least one-half of their expected forms (ESA-level response rate of 90.6 percent unweighted and 93.1 weighted). The overall response rate, which is the product of the response rates of the EDs and the ESAs, was 84.2 percent unweighted and 86.2 percent weighted. A detailed discussion of methodology may be found in the “Technical Notes.” A sample PRF is included at the end of this report.

New data items

The 2007 survey uses a similar design and data collection forms as the 2006 survey (9), but some items have been expanded or added. New items include respiratory rate and episode of care (initial or follow-up visit). New diagnostic and screening services include prothrombin time/international normalized ratio (INR), blood culture, toxicology screen, rapid influenza test, and wound culture. The computerized tomography (CT) scan and magnetic resonance imaging (MRI) items now differentiate between head and other scans. For procedures, orthopedic care has been replaced by cast and splint or wrap, and wound care by laceration repair, incision and drainage, wound debridement, and foreign body removal. Residents have been added to the on-call attending/fellow checkbox. Left without being seen has been replaced by dual checkboxes for left before and after medical screening exam. Dead on arrival (DOA) and died in ED have been split into separate items. For hospital admission, step-down or telemetry unit

and mental health or detoxification unit have been added, and the operating room and cardiac catheterization lab have been split into separate items. Alive hospital discharge status now has subcategories for home and transferred to another hospital.

Tests of significance

In this report, the determination of statistical significance is based on the two-tailed *t*-test. The Bonferroni inequality was used to establish the critical value for statistically significant differences (0.05 level of significance) based on the number of possible comparisons within a particular variable (or combination of variables) of interest. A weighted least squares regression analysis was used to determine the significance of trends at the 0.05 level. Terms relating to differences such as “greater than” or “more likely” or “less than” or “less likely” indicate that the difference is statistically significant. A lack of comment regarding the difference does not mean that the difference was tested and found to be not significant.

Results

Emergency department utilization

- In 2007, there were 116.8 million ED visits or 39.4 visits per 100 persons (Table 1). There were about 222 visits to U.S. EDs every minute during 2007.
- The annual number of visits to EDs has increased by 23 percent since 1997 (Figure 1), while the annual visit rate increased by 11 percent (data not shown).
- About 18.6 percent of visits by children younger than 15 years of age were to pediatric EDs (data not shown).

Patient characteristics

- The age group with highest annual ED visit rate was infants under 12 months old (88.5 visits per 100 U.S. infants). This represents about 3.8 million visits (Table 2).

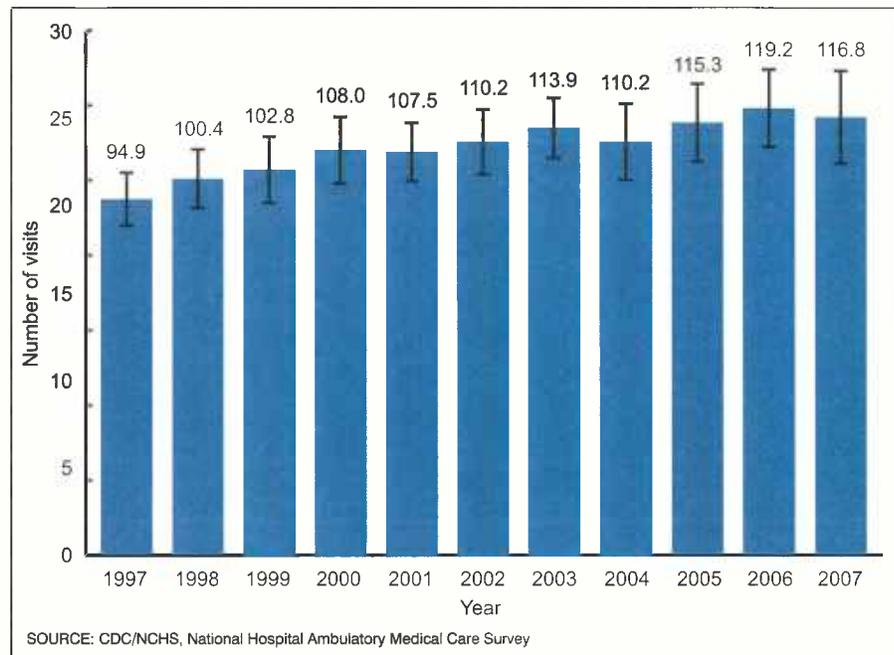


Figure 1. Annual number of emergency department visits (and 95% confidence intervals): United States 1997–2007

- Persons aged 75 years and over had an annual ED visit rate of 62.0 visits per 100 U.S. persons (Table 2).
- The visit rate for persons living in nursing homes was approximately four times higher than for those living in private residences, for the overall population and for persons aged 65 or over (data not shown). Nursing home residents accounted for about 2.3 million visits (Table 2).
- The visit rate for homeless persons was almost twice that of those living in private residences (71.8 compared with 35.9 visits per 100 persons). Homeless persons accounted for 542,000 visits (Table 2).
- Compared with the ED visit rate for white persons (35.9 visits per 100 U.S. white persons), the rate for black persons was more than double (74.6 visits per 100 U.S. black persons), and that for Asian persons was less than one-half (16.0 visits per 100 U.S. Asian persons) (Table 3).

Time of day

- For 64.7 percent of visits, patients arrived in EDs during nonbusiness hours (5:00 p.m. to 8:00 a.m.

Monday through Friday, and on the weekends) (Table 4).

- During two-thirds of visits, a patient spent fewer than 4 hours in the ED (Table 4).

Mode of arrival

- Patients arrived in EDs by ambulance for about 18 million (15.5 percent) visits (Table 5).
- About 44.9 percent of patients 75 years of age or over arrived at EDs by ambulance (Table 5).

Payment source

- Private insurance was an expected source of payment for 39.0 percent of all ED visits (Table 6).
- Other sources of payment included Medicaid or SCHIP (25.2 percent) and Medicare (17.2 percent) (Table 6).
- Uninsured patients, defined as self-pay and no charge or charity, where no other payment source was reported, represented 15.3 percent of visits (Table 6).

Triage

- Patients were triaged as needing to be seen immediately at 4.5 percent of

ED visits and within 1 to 14 minutes (emergent) at 11.3 percent of visits. Patients were triaged as needing to be seen within 15 to 60 minutes (urgent) at 38.5 percent, 1 to 2 hours (semi-urgent) at 21.0 percent, and 2 to 24 hours (nonurgent) at 7.9 percent of visits. At 16.9 percent of visits, no triage was done or triage time was unknown or blank (Table 7). The term “nonurgent” does not imply an unnecessary visit.

- Blood pressure was recorded at 95.8 percent of visits by adults 18 years of age or over (data not shown).
- Temperature was in the febrile range (above 38.0° C or 100.4° F) at 4.8 percent, normal (between 35.1° C and 38.0° C or 95.1° F and 100.4° F) at 87.9 percent, and in the hypothermic range (below 35.0° C or 95.0° F) at 0.4 percent of visits (Table 8).
- Pulse oximetry was recorded at 74.3 percent of visits (Table 8).
- Patients presented with severe pain at 22.4 percent of visits and with moderate pain during 23.3 percent of visits. The pain level was not recorded at 21.5 percent of visits (Table 8).

Reasons for visits

- The leading reasons for visits among children (under age 15 years) were fever, cough, and vomiting (Table 9).
- The leading reasons given by patients aged 15–64 years for visiting the ED were chest pain and abdominal pain (Table 9).
- The leading reasons given by older patients (aged 65 years or over) for visiting the ED were chest pain, shortness of breath, and abdominal pain (Table 9).

Primary diagnoses

- Acute upper respiratory infections and otitis media or Eustachian tube disorders were the leading primary diagnoses in both boys and girls under 15 years of age (Table 10).
- For women between 15 and 64 years of age, abdominal pain and obstetrical

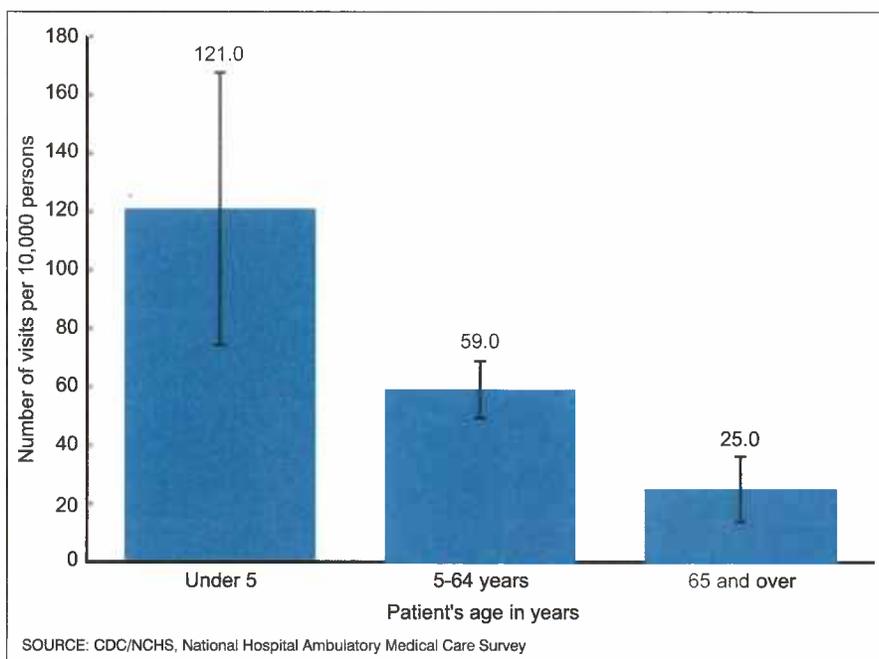


Figure 2. Emergency department visit rates for primary diagnosis of asthma (and 95% confidence intervals) by age group: United States, 2007

- complications were the leading primary diagnoses, while for men, open wounds and contusions were the leading diagnoses (Table 10).
- For adults 65 years of age and over, chest pain and non-ischemic heart disease were leading primary diagnoses for both men and women (Table 10).
 - There were 121.0 ED visits with a primary diagnosis of asthma per 10,000 children under 5 years of age, 59.0 visits per 10,000 persons between 5 and 64 years of age, and 25.0 visits per 10,000 persons 65 years of age or over (Figure 2). The HP-2010 target is to reduce asthma-related ED visits to 80 from the 1997 baseline of 150 visits per 10,000 for children under 5 years old (8).

Injury, poisoning, and adverse effects of medical treatment

- Visits for injury, poisoning, and adverse effects of medical treatment accounted for 39.4 million visits (33.7 percent), or 13.3 visits per 100 persons (Table 11).

- Adults 75 years of age or over (19.1 per 100 persons) had the highest visit rates for injuries, poisoning, and adverse effects of medical treatment, followed by adults 15–24 years of age (17.1 per 100 persons) (Table 11).
- Visit rates for injury, poisoning, or adverse effects of medical treatment for black persons (22.1 visits per 100 U.S. black persons) were almost twice those for white persons (12.6 visits per 100 U.S. white persons) (Table 12).
- Of all injury-related visits, 66.1 percent were for unintentional injuries, 5.1 percent were for intentional injuries, 4.3 percent were due to adverse effects of medical treatment, 4.5 percent were related to alcohol or drug abuse, and the cause or intent of injury was unknown or undetermined for 20.0 percent (Table 13).
- The leading mentioned body sites for injuries were wrist, hand, and fingers (11.6 percent) and face (4.7 percent) (Table 14).
- There were about 365,000 ED visits for dog bites in 2007. There were about 123 ED visits for dog bites per

100,000 persons in 2007 (data not shown in tables).

Diagnostic and screening services

- The leading tests ordered or provided at ED visits were complete blood counts (35.4 percent), x-rays (33.8 percent), and urinalyses (22.5 percent) (Table 15).
- CT scans were ordered or provided at 13.9 percent of visits, of which about one-half were of the head. MRI was ordered or provided at 0.7 percent of visits, of which about one-half were of the head (Table 15).
- Prothrombin times or INR were ordered or provided at 5.2 percent, toxicology screens at 2.7 percent, and rapid influenza tests at 1.3 percent of visits (Table 15).
- Blood cultures were ordered or provided at 3.6 percent, and wound cultures at 0.8 percent of visits (Table 15).

Procedures

- Procedures were performed at 45.5 percent of ED visits. The leading procedure mentioned was intravenous fluid administration (26.6 percent of visits) (Table 16).
- Splints or wraps were applied at 5.7 percent and casts at 0.5 percent of ED visits (Table 16).
- Lacerations were repaired at 4.4 percent of visits. Wound debridement was performed at 1.7 percent, incision and drainage at 1.0 percent, and foreign body removal at 0.4 percent of visits (Table 16).

Medications and immunizations

- Prescription or over-the-counter drugs, immunizations, or desensitizing medications were either given in the ED or prescribed at discharge at 76.3 percent of visits. This represents about 213 million drug mentions, or 1.8 drug mentions per visit (2.4 drug mentions per visit when any medication was given or prescribed) (Table 17).

- The leading therapeutic drug classes mentioned during ED visits were analgesics, including narcotic and nonnarcotic pain medications and nonsteroidal anti-inflammatory drugs (36.3 percent of drug mentions), and antibiotics (15.7 percent) (Table 18). Antibiotics include cephalosporins, penicillins, quinolones, macrolides, sulfonamides, and miscellaneous antibiotics from Table 18.
- Toxoids comprised 1.3 percent of drug mentions at ED visits (Table 18). There were about 1.4 million doses of tetanus toxoid and about 1.3 million doses of tetanus-diphtheria toxoid combinations administered at ED visits in 2007 (data not shown).
- The leading drugs given in the ED were acetaminophen (alone or with hydrocodone or oxycodone) (5.9 percent of drug mentions), ketorolac (3.3 percent), morphine (3.1 percent), and ibuprofen (3.0 percent) (Table 19).
- The leading drugs prescribed at discharge were acetaminophen (alone or in combination with hydrocodone or oxycodone) (8.9 percent of drug mentions) and ibuprofen (4.6 percent) (Table 19).
- Cephalosporins (1.9 percent), including ceftriaxone and cephalexin, were the leading antibiotics given in the ED. Amoxicillin (1.5 percent) was the leading antibiotic prescribed at discharge (Table 19).

Health care providers

- Patients saw physicians at 89.7 percent, physician assistants at 9.2 percent, and nurse practitioners at 4.0 percent of ED visits (Table 20).
- Patients saw an ED attending physician at 86.9 percent; an ED resident or intern at 8.0 percent; and an on-call attending physician, fellow, or resident at 4.7 percent of visits (Table 20).

Disposition

- Patients were referred to an outside physician or clinic at 61.7 percent, advised to return to the ED as needed

or by appointment at 35.4 percent, and referred to social services at 0.8 percent of visits. No follow-up was planned at 5.4 percent of visits (Table 21).

- The patient died in the ED at 0.1 percent of visits. The number of visits at which the patient was DOA was too small to represent a reliable national estimate (Table 21).

Hospital admissions

- Patients were admitted to the same hospital at 12.5 percent of visits (14.6 million); admitted to an observation unit at 2.1 percent of visits (2.5 million); and transferred to a different hospital at 1.8 percent of visits (2.1 million) (Table 21).
- Among visits resulting in admission, 11.5 percent of patients went to a critical care unit and 19.8 percent went to a step-down or telemetry unit (calculated from Table 21).
- Among visits resulting in admission, 4.4 percent of patients went to the operating room (calculated from Table 21). There were too few visits resulting in admission to a cardiac catheterization laboratory to make a reliable national estimate.
- Among visits resulting in admission, about 4.0 percent of patients went to a mental health or detoxification unit (calculated from Table 21).
- The mean length of the hospital stay for patients admitted from the ED was 5.3 days. Nursing home residents admitted from the ED stayed in the hospital for a mean of 7.4 days (Table 22).
- The mean hospital length of stay was 6.0 days for patients with Medicare, 5.4 days for patients with Medicaid or SCHIP, 5.2 days for patients with no insurance, and 4.9 days for patients with private insurance (Table 22).
- Among patients discharged alive from the hospital, 76.9 percent went home, 7.4 percent were transferred, and 5.1 percent were discharged to another location. The discharge disposition was unknown or blank for 10.6 percent of patients discharged alive (Table 22).

- Among those admitted from the ED, the leading principal hospital discharge diagnoses were non-ischemic heart disease (6.3 percent of admissions), chest pain (5.7 percent), pneumonia (3.5 percent), and cerebrovascular disease (3.0 percent) (Table 23).

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Table 1. Number, percent distribution, and annual rate of emergency department visits with corresponding standard errors, by selected hospital characteristics: United States, 2007

Selected hospital characteristics	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹⁻³	(Standard error of rate)
All visits	116,802	(6,293)	100.0	...	39.4	(2.1)
Ownership						
Voluntary	87,511	(5,727)	74.9	(2.8)	29.5	(1.9)
Government	13,828	(1,997)	11.8	(1.8)	4.7	(0.7)
Proprietary	15,463	(3,190)	13.2	(2.5)	5.2	(1.1)
Geographic region						
Northeast	20,484	(1,834)	17.5	(1.6)	38.0	(3.4)
Midwest	25,062	(2,652)	21.5	(2.1)	38.4	(4.1)
South	48,713	(4,418)	41.7	(2.8)	45.0	(4.1)
West	22,543	(3,224)	19.3	(2.4)	32.7	(4.7)
Metropolitan status ²						
Metropolitan statistical area	99,074	(6,371)	84.8	(1.9)	39.8	(2.6)
Nonmetropolitan statistical area	17,728	(2,128)	15.2	(1.9)	37.5	(4.5)
Medical school affiliation						
Yes	62,265	(4,943)	53.3	(3.0)	21.0	(1.7)
No or blank	54,537	(4,414)	46.7	(3.0)	18.4	(1.5)
Trauma center						
Yes	41,276	(4,566)	35.3	(3.4)	13.9	(1.5)
No or blank	75,526	(5,577)	64.7	(3.4)	25.5	(1.9)
Season ⁴						
Winter	34,667	(4,031)	29.7	(2.6)	11.7	(1.4)
Spring	30,939	(3,576)	26.5	(2.6)	10.4	(1.2)
Summer	28,674	(3,885)	24.5	(3.2)	9.7	(1.3)
Fall	22,522	(2,554)	19.3	(2.2)	7.6	(0.9)

... Category not applicable.

¹Visit rates for region are based on the July 1, 2007, set of the estimates of the civilian noninstitutional population of the United States as developed by the Population Division, U.S. Census Bureau. See "Methods" for more details.

²Population estimates of metropolitan statistical area (MSA) status are based on data from the 2007 National Health Interview Survey, National Center for Health Statistics, adjusted to the U.S. Census Bureau definition of core-based statistical areas as of December 2007. See <http://www.census.gov/population/www/metroareas/metrodef.html> for more about MSA definitions.

³For geographic region and MSA, population denominators are different for each category, and thus do not add to total population rate. For other variables, the denominator is the total population for each stratum.

⁴Winter is December 22 to March 19; spring is March 20 to June 20; summer is June 21 to September 22; and fall is September 23 to December 21.

NOTE: Numbers may not add to totals because of rounding.

Table 2. Number, percent distribution, and annual rate of emergency department visits with corresponding standard errors, by patient age, sex, and residence: United States, 2007

Selected patient characteristics	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)
All visits	116,802	(6,293)	100.0	...	39.4	(2.1)
Age						
Under 15 years	22,308	(1,864)	19.1	(1.1)	36.7	(3.1)
Under 1 year	3,766	(426)	3.2	(0.3)	88.5	(10.0)
1–4 years	8,340	(729)	7.1	(0.5)	50.7	(4.4)
5–14 years	10,202	(790)	8.7	(0.4)	25.4	(2.0)
15–24 years	18,983	(1,257)	16.3	(0.4)	45.7	(3.0)
25–44 years	33,485	(1,843)	28.7	(0.5)	41.0	(2.3)
45–64 years	24,491	(1,342)	21.0	(0.5)	32.2	(1.8)
65 years and over	17,535	(1,014)	15.0	(0.5)	48.4	(2.8)
65–74 years	6,908	(412)	5.9	(0.2)	36.2	(2.2)
75 years and over	10,627	(645)	9.1	(0.3)	62.0	(3.8)
Sex and age						
Female	63,170	(3,426)	54.1	(0.5)	41.8	(2.3)
Under 15 years	10,072	(859)	8.6	(0.5)	33.9	(2.9)
15–24 years	11,084	(712)	9.5	(0.2)	54.0	(3.5)
25–44 years	18,698	(1,037)	16.0	(0.4)	45.4	(2.5)
45–64 years	12,776	(728)	10.9	(0.3)	32.7	(1.9)
65–74 years	3,723	(255)	3.2	(0.1)	36.0	(2.5)
75 years and over	6,816	(427)	5.8	(0.2)	65.7	(4.1)
Male	53,632	(2,968)	45.9	(0.5)	37.0	(2.0)
Under 15 years	12,236	(1,047)	10.5	(0.7)	39.3	(3.4)
15–24 years	7,899	(594)	6.8	(0.3)	37.7	(2.8)
25–44 years	14,786	(873)	12.7	(0.3)	36.5	(2.2)
45–64 years	11,715	(661)	10.0	(0.3)	31.7	(1.8)
65–74 years	3,185	(197)	2.7	(0.1)	36.3	(2.2)
75 years and over	3,811	(261)	3.3	(0.2)	56.4	(3.9)
Patient residence						
Private residence	106,436	(5,937)	91.1	(0.5)	35.9	(2.0)
Nursing home	2,323	(175)	2.0	(0.1)	155.7	(11.7)
Other institution	1,077	(126)	0.9	(0.1)	42.3	(5.0)
Other residence	604	(85)	0.5	(0.1)	0.2	(0.0)
Homeless	542	(72)	0.5	(0.1)	71.8	(9.6)
Unknown or blank	5,820	(613)	5.0	(0.5)

... Category not applicable.

¹Visit rates for age, sex, private residence, and other residence are based on the July 1, 2007, set of estimates of the civilian noninstitutionalized population of the United States as developed by the Population Division, U.S. Census Bureau. Visit rates for nursing home residents are based on the 2004 CDC/NCHS National Nursing Home Survey (20). Visit rate for homeless people is based on the Annual Homeless Assessment Report to Congress by the U.S. Department of Housing and Urban Development (21).

NOTE: Numbers may not add to totals because of rounding.

Table 3. Number, percent distribution, and annual rate of emergency department visits with corresponding standard errors, by patient race and age, and ethnicity: United States, 2007

Patient characteristics	Reported plus imputed race or ethnicity				Reported race or ethnicity only					
	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)
All visits	116,802	(6,293)	100.0	...	39.4	(2.1)
Race and age ²⁻⁵										
Reported	99,455	(5,341)	85.1	(1.9)	33.6	(1.8)	100.0	...	33.6	(1.8)
Imputed (missing)	17,347	(2,591)	14.9	(1.9)	5.9	(0.9)
White	85,171	(5,298)	72.9	(1.7)	35.9	(2.2)	73.4	(1.8)	30.7	(2.0)
Under 15 years	15,657	(1,338)	13.4	(0.8)	33.8	(2.9)	12.5	(0.7)	26.8	(2.1)
15-24 years	13,257	(1,020)	11.4	(0.4)	41.3	(3.2)	11.3	(0.5)	35.1	(2.7)
25-44 years	23,807	(1,560)	20.4	(0.7)	36.9	(2.4)	20.6	(0.7)	31.8	(2.2)
45-64 years	17,913	(1,221)	15.3	(0.6)	28.4	(1.9)	15.9	(0.6)	25.1	(1.8)
65-74 years	5,465	(350)	4.7	(0.2)	33.5	(2.1)	4.9	(0.2)	29.8	(2.0)
75 years and over	9,072	(590)	7.8	(0.3)	60.0	(3.9)	8.2	(0.3)	54.1	(3.7)
Black or African American	27,870	(2,229)	23.9	(1.6)	74.6	(6.0)	23.6	(1.7)	63.0	(5.0)
Under 15 years	5,672	(686)	4.9	(0.5)	61.1	(7.4)	4.5	(0.5)	48.3	(5.7)
15-24 years	5,164	(450)	4.4	(0.3)	83.5	(7.3)	4.3	(0.3)	69.0	(5.8)
25-44 years	8,615	(707)	7.4	(0.5)	82.7	(6.8)	7.5	(0.6)	71.9	(6.2)
45-64 years	5,888	(522)	5.0	(0.4)	70.1	(4.8)	5.3	(0.5)	62.3	(5.7)
65-74 years	1,227	(153)	1.1	(0.1)	69.0	(8.6)	1.0	(0.1)	57.9	(7.4)
75 years and over	1,304	(174)	1.1	(0.1)	100.2	(13.4)	1.0	(0.1)	78.5	(12.1)
Asian	2,134	(247)	1.8	(0.2)	16.0	(1.9)	1.6	(0.2)	12.2	(1.5)
Native Hawaiian or Other Pacific Islander	313	(90)	0.3	(0.1)	59.2	(17.0)	*0.3	(0.1)	*54.8	(16.8)
American Indian or Alaska Native	*1,031	(414)	*0.9	(0.4)	*35.7	(14.3)	*0.8	(0.3)	*26.8	(9.7)
Multiple races	284	(83)	*0.2	(0.1)	5.9	(1.7)	*0.3	(0.1)	*5.3	(1.7)
Ethnicity ^{2,3,6,7}										
Reported	87,702	(5,654)	75.1	(2.7)	29.6	(1.9)	100.0	...	29.6	(1.9)
Imputed (missing)	29,100	(3,492)	24.9	(2.7)	9.8	(1.2)
Hispanic or Latino	15,804	(1,364)	13.5	(1.0)	35.1	(3.0)	13.9	(1.1)	27.1	(2.3)
Not Hispanic or Latino	100,998	(5,681)	86.5	(1.0)	40.2	(2.3)	86.1	(1.1)	30.0	(2.1)

... Category not applicable.
¹ Figure does not meet standards of reliability or precision.
² Visit rates are based on the July 1, 2007, set of estimates of the civilian noninstitutionalized population of the United States as developed by the Population Division, U.S. Census Bureau.
³ The race groups of white, black or African American, Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, and multiple races include persons of Hispanic and not Hispanic origin. Persons of Hispanic origin may be of any race. Starting with data year 1999, race-specific estimates have been tabulated according to 1997 Standards for Federal Data on Race and Ethnicity, and are not strictly comparable with estimates for earlier years. The percent of visit records with multiple races indicated is small and lower than what is typically found for self-reported race in household surveys.
⁴ For 2007, race data were missing for 14.9 percent of visits, and ethnicity data were missing for 24.9 percent of visits. Readers are therefore advised to treat these data with caution. In this table, estimates based on imputed race and ethnicity data are shown separately from comparison estimates using unimputed data. Missing race and ethnicity were imputed using a hot deck approach rather than the previously used cold deck strategy. The imputation process is described more fully in the 2007 public-use file documentation (<http://www.cdc.gov/nchs/ahccd.htm>). Research is currently underway to evaluate further changes to the imputation strategy for use with 2008 data.
⁵ Reported plus imputed includes race that was reported directly by emergency departments and imputed values for the 14.9 percent of visits for which race was not reported.
⁶ Reported only calculations are based on 99,455,000 visits with race reported directly by emergency departments. The visits for which race was missing are excluded from the denominator, so that readers may compare differences between estimates that include and exclude imputed race values.
⁷ Reported plus imputed includes ethnicity that was reported directly by emergency departments and imputed values for the 24.9 percent of visits for which ethnicity was not reported.
⁸ Reported only calculations are based on 87,702,000 visits with ethnicity reported directly by emergency departments. The visits for which ethnicity was missing are excluded from the denominator, so that readers may compare differences between estimates that include and exclude imputed ethnicity values.
 NOTE: Numbers may not add to totals because of rounding.

Table 4. Number and percent distribution of emergency department visits with corresponding standard errors, by time spent waiting to see a physician and time spent in the emergency department: United States, 2007

Visit characteristic	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits	116,802	(6,293)	100.0	...
Time spent waiting to see a physician¹				
Fewer than 15 minutes	20,803	(1,537)	17.8	(1.0)
15–59 minutes	41,657	(2,216)	35.7	(1.3)
1 hour, but fewer than 2 hours	16,683	(1,080)	14.3	(0.6)
2 hours, but fewer than 3 hours	5,846	(487)	5.0	(0.3)
3 hours, but fewer than 4 hours	2,272	(247)	1.9	(0.2)
4 hours, but fewer than 6 hours	1,584	(187)	1.4	(0.2)
6 hours or more	906	(132)	0.8	(0.1)
Not seen by a physician	10,236	(1,136)	8.8	(0.7)
Blank	16,815	(2,433)	14.4	(1.7)
Time spent in the emergency department				
Less than 1 hour	13,256	(934)	11.3	(0.6)
1 hour, but fewer than 2 hours	26,959	(1,551)	23.1	(0.5)
2 hours, but fewer than 4 hours	38,732	(2,274)	33.2	(0.6)
4 hours, but fewer than 6 hours	16,456	(994)	14.1	(0.4)
6 hours, but fewer than 10 hours	9,410	(609)	8.1	(0.4)
10 hours, but fewer than 14 hours	1,999	(169)	1.7	(0.1)
14 hours, but fewer than 24 hours	1,538	(177)	1.3	(0.1)
24 hours or more	606	(123)	0.5	(0.1)
Blank	7,845	(1,382)	6.7	(1.1)
Patient arrived in emergency department after business hours²				
Yes	75,565	(4,160)	64.7	(0.4)
No	39,796	(2,111)	34.1	(0.3)
Blank	1,441	(384)	1.2	(0.3)

... Category not applicable.
¹The median waiting time to see a physician was 33.0 minutes.
²Business hours defined as Monday through Friday 8 a.m. to 5 p.m.
 NOTE: Numbers may not add to totals because of rounding.

Table 5. Percent distribution of emergency department visits with corresponding standard errors, by patient mode of arrival according to patient age: United States, 2007

Patient age	Number of visits in thousands	Patient's mode of arrival				
		Total	Walk-in ¹	Ambulance	Public service ²	Unknown ³
Percent distribution (standard error of percent)						
All visits	116,802	100.0	75.2 (1.0)	15.5 (0.6)	2.3 (0.6)	7.0 (0.8)
Age						
Under 15 years	22,308	100.0	87.6 (1.0)	4.2 (0.5)	*1.4 (0.4)	6.8 (0.8)
Under 1 year	3,766	100.0	87.2 (1.4)	4.1 (0.9)	* . . .	7.1 (1.0)
1–4 years	8,340	100.0	88.1 (1.4)	3.6 (0.6)	*1.0 (0.4)	7.3 (1.1)
5–14 years	10,202	100.0	87.4 (1.0)	4.6 (0.5)	1.7 (0.5)	6.3 (0.9)
15–24 years	18,983	100.0	80.3 (1.3)	10.3 (0.7)	*2.5 (0.9)	6.9 (0.9)
25–44 years	33,485	100.0	78.3 (1.1)	11.7 (0.6)	2.8 (0.7)	7.1 (0.9)
45–64 years	24,491	100.0	70.9 (1.1)	19.1 (0.7)	2.6 (0.6)	7.3 (0.9)
65 years and over	17,535	100.0	53.7 (1.5)	37.6 (1.4)	1.8 (0.4)	6.9 (0.9)
65–74 years	6,908	100.0	63.9 (1.5)	26.5 (1.3)	1.6 (0.4)	8.0 (1.2)
75 years and over	10,627	100.0	47.1 (1.8)	44.9 (1.8)	1.9 (0.5)	6.2 (0.9)

... Category not applicable.
 * Figure does not meet standards of reliability or precision.
¹Includes patients arriving by car, taxi, bus, or on foot.
²Includes patients arriving in public service vehicles such as police cars, social service vehicles, beach patrol, or escorted or carried by a public service official.
³The unknown category includes blanks.
 NOTE: Numbers may not add to totals because of rounding.

Table 6. Number and percentage of emergency department visits with corresponding standard errors, by expected sources of payment: United States, 2007

Expected sources of payment	Number of visits in thousands ¹	(Standard error in thousands)	Percent of visits	(Standard error of percent)
All visits	116,802	(6,293)
Private insurance	45,580	(2,864)	39.0	(1.3)
Medicaid or SCHIP ²	29,379	(1,780)	25.2	(1.0)
Medicare	20,133	(1,180)	17.2	(0.6)
Medicare and Medicaid ³	3,478	(276)	3.0	(0.2)
No insurance ⁴	17,926	(1,317)	15.3	(0.8)
Self-pay	17,037	(1,285)	14.6	(0.8)
No charge or charity	1,155	(271)	1.0	(0.2)
Workers' compensation	1,823	(182)	1.6	(0.1)
Other	2,764	(311)	2.4	(0.3)
Unknown or blank	10,484	(2,109)	9.0	(1.7)

... Category not applicable.
¹Total exceeds "all visits" because more than one source of payment may be reported per visit.
²SCHIP is the State Children's Health Insurance Program.
³The visits in this category are also included in both the Medicare and the Medicaid or SCHIP categories.
⁴"No insurance" is defined as having only self-pay, no charge, or charity as payment sources.

Table 7. Percent distribution of emergency department visits with corresponding standard errors, by immediacy with which patient should be seen according to selected patient and visit characteristics: United States, 2007

Patient and visit characteristics	Number of visits in thousands	Total	Immediate ¹	Emergent ²	Urgent ³	Semiurgent ⁴	Nonurgent ⁵	Unknown or no triage ⁶
Percent distribution (standard error of percent)								
All visits	116,802	100.0	4.5 (0.6)	11.3 (0.7)	38.5 (1.4)	21.0 (1.1)	7.9 (0.7)	16.9 (2.0)
Age								
Under 15 years	22,308	100.0	2.3 (0.6)	8.2 (0.9)	33.2 (2.5)	26.0 (2.2)	8.6 (1.0)	21.6 (4.2)
Under 1 year	3,766	100.0	3.5 (0.9)	9.6 (1.5)	32.6 (3.3)	23.9 (3.0)	8.5 (1.2)	21.9 (5.3)
1–4 years	8,340	100.0	*2.4 (0.7)	7.8 (1.1)	32.4 (2.7)	24.4 (2.5)	8.0 (1.1)	25.1 (4.5)
5–14 years	10,202	100.0	*1.9 (0.6)	8.2 (0.9)	34.0 (2.4)	28.1 (2.0)	9.2 (1.1)	18.7 (3.7)
15–24 years	18,983	100.0	3.2 (0.6)	9.3 (0.9)	37.3 (1.8)	23.7 (1.4)	9.3 (0.9)	17.3 (2.2)
25–44 years	33,485	100.0	3.6 (0.5)	10.7 (0.8)	39.8 (1.5)	21.4 (1.2)	9.2 (0.9)	15.2 (1.8)
45–64 years	24,491	100.0	5.4 (0.7)	13.2 (0.8)	40.4 (1.4)	19.3 (1.1)	6.8 (0.7)	15.0 (1.7)
65 years and over	17,535	100.0	8.8 (1.2)	15.7 (1.0)	41.5 (1.7)	13.1 (1.0)	4.4 (0.6)	16.5 (2.2)
65–74 years	6,908	100.0	8.4 (1.2)	14.0 (1.3)	42.0 (1.9)	15.5 (1.4)	4.9 (0.7)	15.1 (2.1)
75 years and over	10,627	100.0	9.1 (1.3)	16.8 (1.2)	41.2 (2.0)	11.6 (1.1)	4.0 (0.6)	17.4 (2.3)
Sex								
Female	63,170	100.0	4.0 (0.6)	10.9 (0.7)	39.8 (1.5)	20.7 (1.1)	7.6 (0.7)	17.0 (2.0)
Male	53,632	100.0	5.0 (0.7)	11.7 (0.7)	36.9 (1.4)	21.4 (1.1)	8.2 (0.8)	16.8 (2.0)
Race ^{7–10}								
Reported	99,455	100.0	4.5 (0.7)	11.8 (0.7)	39.3 (1.4)	21.1 (1.2)	8.1 (0.8)	15.2 (1.8)
Imputed (missing)	17,347	100.0	4.2 (0.9)	8.4 (1.2)	34.2 (3.8)	20.4 (2.1)	6.3 (1.1)	*26.5 (5.9)
Reported plus imputed								
White	85,171	100.0	4.6 (0.6)	11.4 (0.7)	38.6 (1.4)	20.3 (1.1)	7.6 (0.7)	17.5 (2.0)
Black or African American	27,870	100.0	4.1 (0.8)	10.8 (1.0)	38.2 (2.0)	23.1 (1.7)	9.0 (1.2)	14.8 (2.7)
Other	3,762	100.0	2.8 (0.6)	11.1 (1.6)	39.1 (2.0)	21.6 (2.7)	5.4 (1.0)	20.0 (4.2)
Reported only								
White	73,001	100.0	4.6 (0.7)	12.0 (0.8)	39.3 (1.4)	20.4 (1.1)	7.8 (0.8)	15.9 (1.9)
Black or African American	23,513	100.0	4.3 (0.9)	11.1 (1.0)	39.1 (2.3)	23.2 (2.0)	9.4 (1.4)	13.0 (2.7)
Other	2,941	100.0	3.2 (0.7)	12.3 (1.7)	39.1 (2.1)	22.1 (2.8)	5.8 (1.1)	17.4 (3.4)
Ethnicity ^{7,8,11,12}								
Reported	87,702	100.0	4.5 (0.7)	10.9 (0.7)	40.3 (1.5)	21.5 (1.2)	8.4 (0.9)	14.5 (1.8)
Imputed (missing)	29,100	100.0	4.3 (0.8)	12.5 (1.7)	33.1 (2.4)	19.5 (1.9)	6.3 (0.8)	24.3 (4.4)

See footnotes at end of table.

Table 7. Percent distribution of emergency department visits with corresponding standard errors, by immediacy with which patient should be seen according to selected patient and visit characteristics: United States, 2007—Con.

Patient and visit characteristics	Number of visits in thousands	Total	Immediate ¹	Emergent ²	Urgent ³	Semiurgent ⁴	Nonurgent ⁵	Unknown or no triage ⁶
Reported plus imputed								
Hispanic or Latino	15,804	100.0	3.2 (0.5)	8.0 (1.0)	37.2 (2.6)	22.6 (1.9)	7.5 (0.8)	21.5 (3.9)
Not Hispanic or Latino	100,998	100.0	4.6 (0.7)	11.8 (0.7)	38.7 (1.4)	20.7 (1.1)	7.9 (0.8)	16.2 (1.9)
Reported only								
Hispanic or Latino	12,202	100.0	3.3 (0.5)	6.9 (0.9)	38.4 (3.0)	23.1 (2.0)	8.3 (1.0)	20.1 (3.9)
Not Hispanic or Latino	75,500	100.0	4.7 (0.8)	11.5 (0.7)	40.6 (1.4)	21.2 (1.3)	8.4 (0.9)	13.6 (1.8)
Expected sources of payment ¹³								
Private insurance	45,580	100.0	4.0 (0.5)	12.3 (0.8)	40.1 (1.5)	20.8 (1.2)	6.9 (0.7)	15.9 (1.8)
Medicaid or SCHIP ¹⁴	29,379	100.0	3.8 (0.7)	11.7 (1.0)	38.5 (1.7)	22.5 (1.6)	8.5 (0.9)	15.0 (2.2)
Medicare	20,133	100.0	8.4 (1.1)	15.7 (1.0)	40.3 (1.5)	14.4 (1.0)	5.3 (0.6)	15.9 (2.0)
Medicare and Medicaid ¹⁵	3,478	100.0	7.0 (1.4)	16.7 (1.6)	40.2 (2.5)	14.3 (1.7)	6.7 (1.2)	15.1 (2.7)
No insurance ¹⁶	17,926	100.0	4.2 (0.6)	8.9 (0.8)	37.3 (2.0)	22.7 (1.6)	10.0 (1.1)	17.1 (2.5)
Workers' compensation	1,823	100.0	* *	9.6 (1.6)	33.9 (3.5)	25.8 (2.7)	10.4 (2.1)	16.7 (3.2)
Other	2,764	100.0	*8.7 (3.0)	11.7 (1.6)	32.5 (3.0)	19.7 (2.7)	8.9 (1.7)	18.5 (3.1)
Unknown or blank	10,484	100.0	3.4 (0.9)	7.8 (1.2)	32.8 (4.9)	19.4 (2.9)	8.4 (1.9)	*28.2 (8.8)

* Figure does not meet standards of reliability or precision.

¹A visit in which the patient should be seen in less than 1 minute.

²A visit in which the patient should be seen in 1–14 minutes.

³A visit in which the patient should be seen within 15–60 minutes.

⁴A visit in which the patient should be seen within 61–120 minutes.

⁵A visit in which the patient should be seen within 121 minutes–24 hours.

⁶A visit in which there is no mention of triage level or immediacy rating in the medical record, the hospital did not perform triage, or the patient was dead on arrival.

⁷Other race includes Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, and persons of multiple races. All race categories include visits by persons of Hispanic origin and not Hispanic origin. Persons of Hispanic origin may be of any race. Starting with data year 1999, race-specific estimates have been tabulated according to 1997 Standards for Federal Data on Race and Ethnicity and are not strictly comparable with estimates for earlier years. The percentage of visit records with multiple races indicated is small and lower than what is typically found for self-reported race.

⁸For 2007, race data were missing for 14.9 percent of visits, and ethnicity data were missing for 24.9 percent of visits. Readers are therefore advised to treat these data with caution. In this table, estimates based on imputed race and ethnicity data are shown separately from comparison estimates using unimputed data. Missing race and ethnicity were imputed using a hot deck approach rather than the previously used cold deck strategy. The imputation process is described more fully in the 2007 public-use file documentation (<http://www.cdc.gov/nchs/ahcd.htm>). Research is currently underway to evaluate further changes to the imputation strategy for use with 2008 data.

⁹"Reported plus imputed" includes race that was reported directly by emergency departments and imputed values for the 14.9 percent of visits for which race was not reported.

¹⁰"Reported only" calculations are based on 99,455,000 visits with race reported directly by emergency departments. The visits for which race was missing are excluded from the denominator, so that readers can compare differences between estimates that include and exclude imputed race values.

¹¹"Reported plus imputed" includes ethnicity that was reported directly by emergency departments and imputed values for the 24.9 percent of visits for which ethnicity was not reported.

¹²"Reported only" calculations are based on 87,702,000 visits with ethnicity reported directly by emergency departments. The visits for which ethnicity was missing are excluded from the denominator so that readers can compare differences between estimates that include and exclude imputed ethnicity values.

¹³Total exceeds "all visits" because more than one source of payment may be reported per visit.

¹⁴SCHIP is the State Children's Health Insurance Program.

¹⁵The visits in this category are also included in both the Medicare and the Medicaid or SCHIP categories.

¹⁶"No insurance" is defined as having only self-pay, no charge, or charity as payment sources.

NOTE: Numbers may not add to totals because of rounding.

Table 8. Number and percent distribution of emergency department visits with corresponding standard errors, by initial vital signs, episode of care, prior visits, and prior hospital discharges: United States, 2007

Visit characteristic	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits	116,802	(6,293)	100.0	...
Temperature				
Febrile: >38.0 °C or >100.4 °F	5,629	(424)	4.8	(0.3)
Normal: 35.1–38.0 °C or 95.1–100.4 °F	102,622	(5,603)	87.9	(0.6)
Hypothermic: <35.0 °C or <95.0 °F	517	(77)	0.4	(0.1)
Unknown or blank	8,034	(831)	6.9	(0.6)
Pulse oximetry ¹				
95–100%	78,690	(5,133)	67.4	(1.9)
90–94%	5,319	(519)	4.6	(0.3)
90%	2,789	(603)	2.4	(0.5)
Unknown or blank	30,004	(2,485)	25.7	(1.9)
Oriented to time, place, and person				
Yes	85,811	(4,437)	73.5	(1.5)
No	2,541	(209)	2.2	(0.2)
Unknown or blank	28,451	(2,748)	24.4	(1.6)
Presenting level of pain				
None	23,955	(1,382)	20.5	(0.7)
Mild	14,370	(885)	12.3	(0.5)
Moderate	27,187	(1,666)	23.3	(0.8)
Severe	26,196	(1,616)	22.4	(0.6)
Unknown or blank	25,094	(2,389)	21.5	(1.5)
Episode of care				
Initial visit	92,065	(4,965)	78.8	(1.3)
Follow-up visit	8,341	(701)	7.1	(0.4)
Unknown or blank	16,396	(1,722)	14.0	(1.2)
Patient seen in this emergency department within the last 72 hours				
Yes	4,463	(391)	3.8	(0.2)
No	86,681	(5,128)	74.2	(1.9)
Unknown or blank	25,658	(2,742)	22.0	(2.0)
Patient discharged from any hospital within the last 7 days				
Yes	2,701	(228)	2.3	(0.2)
No	65,459	(4,881)	56.0	(2.3)
Unknown or blank	48,642	(3,360)	41.6	(2.3)

. . . Category not applicable.

¹Normal oxygen saturation as measured by pulse oximetry is 95% or more. An oxygen saturation less than 90% is consistent with severe hypoxemia.

NOTE: Numbers may not add to totals because of rounding.

Table 9. Number and percent distribution of visits with corresponding standard errors, by the 10 leading principal reasons for emergency department visits, according to age and sex: United States, 2007

Principal reason for visit and RVC code ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits	116,802	(6,293)	100.0	...
All visits under age 15	22,308	(1,864)	100.0	...
Female	10,072	(859)	45.2	(0.9)
FeverS010	1,637	(215)	7.3	(0.5)
VomitingS530	687	(105)	3.1	(0.4)
CoughS440	614	(84)	2.8	(0.3)
Stomach pain, cramps, and spasmsS545	451	(69)	2.0	(0.3)
Skin rashS860	357	(52)	1.6	(0.2)
Symptoms referable to throatS455	350	(47)	1.6	(0.2)
Earache or ear infectionS355	330	(44)	1.5	(0.2)
Injury, other and unspecified type—head, neck, and faceJ505	247	(41)	1.1	(0.2)
Headache, pain in headS210	202	(38)	0.9	(0.2)
Facial areaJ210	198	(40)	0.9	(0.2)
All other reasons ²	5,000	(434)	22.4	(0.7)

See footnotes at end of table.

Table 9. Number and percent distribution of visits with corresponding standard errors, by the 10 leading principal reasons for emergency department visits, according to age and sex: United States, 2007—Con.

Principal reason for visit and RVC code ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
Male	12,236	(1,047)	54.8	(0.9)
FeverS010	1,888	(212)	8.5	(0.5)
CoughS440	876	(106)	3.9	(0.3)
VomitingS530	668	(96)	3.0	(0.3)
Injury, other and unspecified type—head, neck, and faceJ505	442	(70)	2.0	(0.3)
Earache or ear infectionS355	440	(68)	2.0	(0.3)
Facial areaJ210	368	(44)	1.7	(0.2)
Skin rashS860	350	(50)	1.6	(0.2)
Stomach pain, cramps, and spasmsS545	306	(40)	1.4	(0.1)
Symptoms referable to throatS455	234	(38)	1.1	(0.2)
Labored or difficult breathing (dyspnea)S420	220	(44)	1.0	(0.2)
All other reasons ²	6,445	(594)	28.9	(0.9)
All visits, age 15–64 years	76,959	(4,249)	100.0	. . .
Female	42,559	(2,372)	55.3	(0.6)
Stomach pain, cramps, and spasmsS545	4,585	(331)	6.0	(0.3)
Chest pain and related symptomsS050	2,285	(187)	3.0	(0.2)
Headache, pain in headS210	1,784	(137)	2.3	(0.1)
Back symptomsS905	1,460	(142)	1.9	(0.1)
Problems of pregnancy and the post-partum periodS790	1,303	(130)	1.7	(0.1)
Pain, site not referable to a specific body systemS055	1,260	(109)	1.6	(0.1)
Symptoms referable to throatS455	949	(98)	1.2	(0.1)
Shortness of breathS415	905	(84)	1.2	(0.1)
NauseaS525	815	(102)	1.1	(0.1)
Uterine and vaginal bleedingS755	759	(79)	1.0	(0.1)
All other reasons ²	26,453	(1,443)	34.4	(0.4)
Male	34,400	(1,963)	44.7	(0.6)
Chest pain and related symptomsS050	2,159	(187)	2.8	(0.2)
Stomach pain, cramps, and spasmsS545	2,031	(148)	2.6	(0.1)
Back symptomsS905	1,273	(113)	1.7	(0.1)
Pain, site not referable to a specific body systemS055	1,219	(117)	1.6	(0.1)
Headache, pain in headS210	1,004	(117)	1.3	(0.1)
Lacerations and cuts—upper extremityJ225	971	(88)	1.3	(0.1)
Shortness of breathS415	669	(64)	0.9	(0.1)
Symptoms referable to throatS455	639	(74)	0.8	(0.1)
Low back symptomsS910	633	(71)	0.8	(0.1)
Leg symptomsS920	589	(69)	0.8	(0.1)
All other reasons ²	23,213	(1,332)	30.2	(0.5)
All visits, age 65 years and over	17,535	(1,014)	100.0	. . .
Female	10,539	(643)	60.1	(0.8)
Chest pain and related symptomsS050	894	(92)	5.1	(0.4)
Shortness of breathS415	666	(91)	3.8	(0.4)
Stomach pain, cramps, and spasmsS545	629	(66)	3.6	(0.3)
Accident, not otherwise specifiedJ810	379	(56)	2.2	(0.3)
General weaknessS020	374	(49)	2.1	(0.3)
Vertigo—dizzinessS225	276	(36)	1.6	(0.2)
NauseaS525	256	(39)	1.5	(0.2)
Labored or difficult breathing (dyspnea)S420	246	(44)	1.4	(0.2)
Leg symptomsS920	242	(39)	1.4	(0.2)
CoughS440	223	(35)	1.3	(0.2)
All other reasons ²	6,354	(389)	36.2	(0.9)
Male	6,996	(414)	39.9	(0.8)
Chest pain and related symptomsS050	585	(56)	3.3	(0.3)
Shortness of breathS415	439	(54)	2.5	(0.3)
Stomach pain, cramps, and spasmsS545	391	(57)	2.2	(0.3)
General weaknessS020	266	(41)	1.5	(0.2)
Vertigo—dizzinessS225	218	(34)	1.2	(0.2)
Other urinary dysfunctionsS660	161	(32)	0.9	(0.2)
Accident, not otherwise specifiedJ810	144	(30)	0.8	(0.2)
Labored or difficult breathing (dyspnea)S420	140	(32)	0.8	(0.2)
Lacerations and cuts—upper extremityJ225	138	(35)	0.8	(0.2)
Abnormal pulsations and palpitationsS260	124	(36)	0.7	(0.2)
All other reasons ²	4,390	(277)	25.0	(0.7)

. . . Category not applicable. ¹Based on A Reason for Visit Classification for Ambulatory Care (RVC)(13).²Category includes all other reasons not listed above as well as unknown and blanks.

NOTE: Numbers may not add to totals because of rounding.

Table 10. Number and percent distribution of emergency department visits with corresponding standard errors, by the 10 leading primary diagnosis groups, according to age and sex: United States, 2007

Primary diagnosis group and ICD-9-CM code(s) ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits	116,802	(6,293)	100.0	...
All visits, age under 15 years	22,308	(1,864)	100.0	...
Female	10,072	(859)	45.2	(0.9)
Acute upper respiratory infections, excluding pharyngitis460-461,463-466	929	(137)	4.2	(0.5)
Otitis media and Eustachian tube disorders381-382	614	(92)	2.8	(0.3)
Unspecified viral and Chlamydia infection079.9	503	(124)	2.3	(0.4)
Contusion with intact skin surface920-924	451	(63)	2.0	(0.3)
Pyrexia of unknown origin780.6	433	(67)	1.9	(0.3)
Open wound of head870-873	370	(55)	1.7	(0.2)
Acute pharyngitis462	357	(45)	1.6	(0.2)
Abdominal pain789.0	307	(58)	1.4	(0.2)
Noninfectious enteritis and colitis555-558	264	(62)	1.2	(0.3)
Fractures, excluding lower limb800-819	204	(45)	0.9	(0.2)
All other diagnoses ²	5,640	(482)	25.3	(0.7)
Male	12,236	(1,047)	54.8	(0.9)
Acute upper respiratory infections, excluding pharyngitis460-461,463-466	1,250	(174)	5.6	(0.6)
Otitis media and Eustachian tube disorders381-382	946	(120)	4.2	(0.4)
Open wound of head870-873	651	(71)	2.9	(0.3)
Contusion with intact skin surface920-924	583	(61)	2.6	(0.3)
Pyrexia of unknown origin780.6	541	(62)	2.4	(0.2)
Open wound, excluding head874-897	434	(63)	1.9	(0.2)
Asthma493	375	(62)	1.7	(0.2)
Fractures, excluding lower limb800-819	364	(47)	1.6	(0.2)
Unspecified viral and Chlamydia infection079.9	351	(48)	1.6	(0.2)
Acute pharyngitis462	292	(38)	1.3	(0.2)
All other diagnoses ²	6,450	(618)	28.9	(0.9)
All visits, age 15-64 years	76,959	(4,249)	100.0	...
Female	42,559	(2,372)	55.3	(0.6)
Abdominal pain789.0	2,597	(225)	3.4	(0.2)
Complications of pregnancy, childbirth, and the puerperium630-677	1,794	(145)	2.3	(0.2)
Chest pain786.5	1,572	(158)	2.0	(0.2)
Contusion with intact skin surface920-924	1,503	(102)	2.0	(0.1)
Spinal disorders720-724	1,202	(139)	1.6	(0.2)
Sprains and strains of neck and back846,847	1,187	(129)	1.5	(0.1)
Acute upper respiratory infections, excluding pharyngitis460-461,463-466	1,160	(127)	1.5	(0.1)
Urinary tract infection, site not specified599.0	1,124	(104)	1.5	(0.1)
Cellulitis and abscess681-682	992	(107)	1.3	(0.1)
Sprains and strains, excluding ankle and back840-844,845,1,848	896	(93)	1.2	(0.1)
All other diagnoses ²	28,532	(1,579)	37.1	(0.5)
Male	34,400	(1,963)	44.7	(0.6)
Open wound, excluding head874-897	1,816	(151)	2.4	(0.1)
Contusion with intact skin surface920-924	1,425	(120)	1.9	(0.1)
Chest pain786.5	1,421	(141)	1.8	(0.1)
Cellulitis and abscess681-682	1,118	(102)	1.5	(0.1)
Spinal disorders720-724	1,112	(108)	1.4	(0.1)
Sprains and strains, excluding ankle and back840-844,845,1,848	1,026	(95)	1.3	(0.1)
Abdominal pain789.0	1,009	(104)	1.3	(0.1)
Sprains and strains of neck and back846,847	948	(96)	1.2	(0.1)
Fractures, excluding lower limb800-819	911	(85)	1.2	(0.1)
Drug dependence and nondependence abuse of drugs304-305	690	(74)	0.9	(0.1)
All other diagnoses ²	22,924	(1,314)	29.8	(0.5)
All visits, age 65 years and over	17,535	(1,014)	100.0	...
Female	10,539	(643)	60.1	(0.8)
Chest pain786.5	576	(76)	3.3	(0.3)
Contusion with intact skin surface920-924	548	(67)	3.1	(0.4)
Heart disease, excluding ischemic.391-392.0,393-398,402,404,415-416,420-429	520	(55)	3.0	(0.3)
Urinary tract infection, site not specified599.0	391	(57)	2.2	(0.3)
Abdominal pain789.0	322	(44)	1.8	(0.2)
Fractures, excluding lower limb800-819	293	(46)	1.7	(0.2)
Cerebrovascular disease430-438	266	(41)	1.5	(0.2)
Fracture of the lower limb820-829	233	(41)	1.3	(0.2)
Pneumonia480-486	232	(39)	1.3	(0.2)
Spinal disorders720-724	229	(41)	1.3	(0.2)
All other diagnoses ²	6,929	(425)	39.5	(0.9)

See footnotes at end of table.

Table 10. Number and percent distribution of emergency department visits with corresponding standard errors, by the 10 leading primary diagnosis groups, according to age and sex: United States, 2007—Con.

Primary diagnosis group and ICD-9-CM code(s) ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
Male	6,996	(414)	39.9	(0.8)
Heart disease, excluding ischemic.391-392.0,393-398,402,404,415-416,420-429	461	(60)	2.6	(0.3)
Chest pain786.5	422	(46)	2.4	(0.2)
Pneumonia480-486	225	(37)	1.3	(0.2)
Cellulitis and abscess681-682	206	(39)	1.2	(0.2)
Open wound, excluding head874-897	197	(42)	1.1	(0.2)
Abdominal pain789.0	176	(34)	1.0	(0.2)
Cerebrovascular disease.430-438	171	(32)	1.0	(0.2)
Syncope and collapse780.2	169	(29)	1.0	(0.2)
Contusion with intact skin surface920-924	168	(33)	1.0	(0.2)
Symptoms involving the urinary system.788	163	(31)	0.9	(0.2)
All other diagnoses ²	4,638	(285)	26.5	(0.8)

. . . Category not applicable.

¹Based on the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) (14). However, certain codes have been combined in this table to better describe the use of ambulatory care services.

²Category includes all other diagnoses not listed above as well as unknown and blanks.

NOTE: Numbers may not add to totals because of rounding.

Table 11. Number, percent distribution, and annual rate of emergency department visits with corresponding standard errors, by injury, poisoning, or adverse effects of medical treatment, according to patient age and sex, hospital ownership, geographic area, and metropolitan status: United States, 2007

Selected patient and hospital characteristics	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)
All injury-related visits ²	39,395	(2,089)	100.0	...	13.3	(0.7)
Patient characteristics						
Age:						
Under 15 years	7,303	(516)	18.5	(0.9)	12.0	(0.8)
Under 1 year	405	(62)	1.0	(0.1)	9.5	(1.5)
1–4 years	2,429	(198)	6.2	(0.4)	14.8	(1.2)
5–14 years	4,469	(324)	11.3	(0.5)	11.1	(0.8)
15–24 years	7,112	(466)	18.1	(0.5)	17.1	(1.1)
25–44 years	11,633	(691)	29.5	(0.7)	14.2	(0.8)
45–64 years	8,119	(457)	20.6	(0.6)	10.7	(0.6)
65 years and over	5,227	(328)	13.3	(0.6)	14.4	(0.9)
65–74 years	1,963	(148)	5.0	(0.3)	10.3	(0.8)
75 years and over	3,265	(213)	8.3	(0.4)	19.1	(1.2)
Sex and age:						
Female	18,449	(996)	46.8	(0.6)	12.2	(0.7)
Under 15 years	3,076	(233)	7.8	(0.4)	10.4	(0.8)
15–24 years	3,103	(200)	7.9	(0.3)	15.1	(1.0)
25–44 years	5,082	(331)	12.9	(0.5)	12.3	(0.8)
45–64 years	3,947	(252)	10.0	(0.4)	10.1	(0.6)
65–74 years	1,063	(102)	2.7	(0.2)	10.3	(1.0)
75 years and over	2,178	(161)	5.5	(0.3)	21.0	(1.6)
Male	20,946	(1,141)	53.2	(0.6)	14.4	(0.8)
Under 15 years	4,227	(332)	10.7	(0.6)	13.6	(1.1)
15–24 years	4,009	(301)	10.2	(0.4)	19.1	(1.4)
25–44 years	6,550	(405)	16.6	(0.5)	16.2	(1.0)
45–64 years	4,173	(252)	10.6	(0.4)	11.3	(0.7)
65–74 years	900	(85)	2.3	(0.2)	10.3	(1.0)
75 years and over	1,087	(89)	2.8	(0.2)	16.1	(1.3)
Hospital characteristics						
Ownership:						
Voluntary	29,333	(1,849)	74.5	(3.0)	9.9	(0.6)
Proprietary	5,206	(1,189)	13.2	(2.7)	1.8	(0.4)
Government	4,856	(712)	12.3	(1.9)	1.6	(0.2)
Geographic region:						
Northeast	7,248	(654)	18.4	(1.6)	13.5	(1.2)
Midwest	8,627	(795)	21.9	(1.9)	13.2	(1.2)
South	15,541	(1,382)	39.4	(2.7)	14.4	(1.3)
West	7,980	(1,221)	20.3	(2.6)	11.6	(1.8)
Metropolitan status ³						
MSA ⁴	33,175	(2,129)	84.2	(1.9)	13.3	(0.9)
Non-MSA ⁴	6,220	(687)	15.8	(1.9)	13.2	(1.5)

... Category not applicable.

¹Visit rates for age, sex, and region are based on the July 1, 2007, set of estimates of the civilian noninstitutionalized population of the United States as developed by the Population Division, U.S. Census Bureau.

²Injury-related includes injuries, poisoning, and adverse effects, accounting for 33.7 percent (SE=0.6) of all visits.

³Population estimates of metropolitan statistical area (MSA) status are based on estimates of the civilian noninstitutionalized population of the United States from the 2007 National Health Interview Survey, National Center for Health Statistics, compiled according to the December 2006 Office of Management and Budget definitions of core-based statistical areas. See: <http://www.census.gov/population/www/metroareas/metrodef.html> for more about MSA definitions.

⁴MSA is metropolitan statistical area.

NOTE: Numbers may not add to totals because of rounding.

Table 12. Number, percent distribution, and annual rate of emergency department visits with corresponding standard errors, by injury, poisoning, or adverse effects of medical treatment, according to race and age, and ethnicity: United States, 2007

Patient characteristics	Reported plus imputed				Reported only					
	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)	Percent distribution	(Standard error of percent)	Number of visits per 100 persons per year ¹	(Standard error of rate)
All injury-related visits ²	39,395	(2,089)	100.0	...	13.3	(0.7)
Race and age ³⁻⁶										
Reported	33,478	(1,817)	85.0	(2.0)	11.3	(0.6)	(1,817)	...	11.3	(0.6)
Imputed (missing)	5,917	(893)	15.0	(2.0)	2.0	(0.3)
White	29,894	(1,789)	75.9	(1.5)	12.6	(0.8)	(1,629)	(1.6)	10.8	(0.7)
Under 15 years	5,396	(376)	13.7	(0.6)	11.6	(0.8)	(320)	(0.6)	9.5	(0.7)
15-24 years	5,236	(408)	13.3	(0.6)	16.3	(1.3)	(360)	(0.6)	13.8	(1.1)
25-44 years	8,748	(597)	22.2	(0.7)	13.6	(0.9)	(550)	(0.8)	11.7	(0.9)
45-64 years	6,131	(414)	15.6	(0.6)	9.7	(0.7)	(370)	(0.6)	8.4	(0.6)
65-74 years	1,565	(122)	4.0	(0.2)	9.6	(0.7)	(111)	(0.2)	8.3	(0.7)
75 years and over	2,817	(188)	7.2	(0.4)	18.6	(1.2)	(179)	(0.4)	16.9	(1.2)
Black or African American	8,264	(664)	21.0	(1.4)	22.1	(1.8)	(547)	(1.5)	18.6	(1.5)
Under 15 years	1,656	(207)	4.2	(0.5)	17.9	(2.2)	(173)	(0.5)	14.5	(1.9)
15-24 years	1,639	(152)	4.2	(0.3)	26.5	(2.4)	(117)	(0.3)	22.4	(1.9)
25-44 years	2,519	(205)	6.4	(0.5)	24.2	(2.0)	(182)	(0.5)	20.7	(1.7)
45-64 years	1,721	(166)	4.4	(0.4)	20.5	(2.0)	(143)	(0.4)	17.7	(1.7)
65-74 years	337	(62)	0.9	(0.1)	19.0	(3.5)	(51)	(0.1)	15.7	(2.9)
75 years and over	392	(70)	1.0	(0.2)	30.1	(5.4)	(59)	(0.2)	21.2	(4.6)
Asian	747	(84)	1.9	(0.2)	5.6	(0.6)	(64)	(0.2)	4.1	(0.5)
Native Hawaiian or Other Pacific Islander	76	(21)	*0.2	(0.1)	14.3	(4.1)	(21)	(0.1)	13.6	(4.0)
American Indian or Alaska Native	*328	(125)	*0.8	(0.3)	*11.4	(4.3)	(92)	(0.3)	*9.3	(3.2)
Multiple races	*87	(27)	*0.2	(0.1)	*1.8	(0.6)	(26)	(0.1)	*1.6	(0.6)
Ethnicity ^{3,4,7,8}										
Reported	29,153	(1,825)	74.0	(2.7)	9.8	(0.6)	(1,825)	...	9.8	(0.6)
Imputed (missing)	10,242	(1,243)	26.0	(2.7)	3.5	(0.4)
Hispanic or Latino	4,732	(417)	12.0	(0.9)	10.5	(0.9)	(320)	(1.0)	7.9	(0.7)
Not Hispanic or Latino	34,663	(1,908)	88.0	(0.9)	13.8	(0.8)	(1,691)	(1.0)	10.2	(0.7)

... Category not applicable.
¹Figure does not meet standards of reliability or precision.
²Visit rates are based on the July 1, 2007, estimates of the civilian noninstitutionalized population of the United States as developed by the Population Division, U.S. Census Bureau.
³Injury-related includes injuries, poisoning, and adverse effects, accounting for 33.7 percent (SE=0.6) of all visits.
⁴The race groups of white, black or African American, Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, and multiple races, include persons of Hispanic and not Hispanic origin. Persons of Hispanic origin may be of any race. Starting with data year 1999, race-specific estimates have been tabulated according to 1997 Standards for Federal Data on Race and Ethnicity and are not strictly comparable with estimates for earlier years. The percentage of visit records with multiple races indicated is small and lower than what is typically found for self-reported race in household surveys.
⁵For 2007, race data were missing for 14.9 percent of visits, and ethnicity data were missing for 24.9 percent of visits. Readers are therefore advised to treat these data with caution. In this table, estimates based on imputed race and ethnicity data are shown separately from comparison estimates using unimputed data. Missing race and ethnicity were imputed using a hot deck approach rather than the previously used cold deck strategy. The imputation process is described more fully in the 2007 public-use file documentation (<http://www.cdc.gov/nchs/data/hdm>). Research is currently underway to evaluate further changes to the imputation strategy for use with 2008 data.
⁶Reported plus imputed includes race reported by emergency departments, and imputed values for the 15.0% of injury-related visits for which race was not reported.
⁷Reported only calculations are based on 33,478,000 injury-related visits with race reported directly by emergency departments. The visits for which race was missing are excluded from the denominator so that readers can compare differences between estimates that include and exclude imputed race values.
⁸Reported plus imputed includes ethnicity reported by emergency departments, and imputed values for the 26.0% of injury-related visits for which ethnicity was not reported.
⁹Reported only calculations are based on 29,153,000 visits with ethnicity reported directly by emergency departments. The visits for which ethnicity was missing are excluded from the denominator, so that readers can compare differences between estimates that include and exclude imputed ethnicity values.
 NOTE: Numbers may not add to totals because of rounding.

Table 13. Number and percent distribution of emergency department visits with corresponding standard errors, by injuries, poisoning, and adverse effects of medical treatment according to intent and mechanism of external cause: United States, 2007

Intent and mechanism ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All injury-related visits	39,395	(2,089)	100.0	---
Unintentional injuries	26,036	(1,379)	66.1	(0.9)
Falls	8,898	(536)	22.6	(0.6)
Motor vehicle traffic	3,836	(264)	9.7	(0.5)
Struck against or struck accidentally by objects or persons	3,044	(198)	7.7	(0.4)
Overexertion and strenuous movements	2,116	(130)	5.4	(0.3)
Cutting or piercing instruments or objects	2,089	(147)	5.3	(0.3)
Natural and environmental factors	1,522	(106)	3.9	(0.2)
Foreign body	638	(67)	1.6	(0.1)
Poisoning	486	(64)	1.2	(0.1)
Motor vehicle, nontraffic, and other	451	(46)	1.1	(0.1)
Fire and flames, hot substances or object, caustic or corrosive, and steam	416	(59)	1.1	(0.1)
Caught accidentally in or between objects	359	(48)	0.9	(0.1)
Pedal cycle, nontraffic	330	(48)	0.8	(0.1)
Machinery	280	(42)	0.7	(0.1)
Other transportation	209	(38)	0.5	(0.1)
Other mechanism ²	1,182	(122)	3.0	(0.2)
Mechanism unspecified	179	(28)	0.5	(0.1)
Intentional injuries	1,998	(122)	5.1	(0.2)
Assault	1,447	(98)	3.7	(0.2)
Unarmed fight or brawl, striking by blunt or thrown object	784	(66)	2.0	(0.1)
Cutting or piercing instrument	76	(20)	*0.2	(0.1)
Other and unspecified mechanism ³	587	(57)	1.5	(0.1)
Self-inflicted	472	(51)	1.2	(0.1)
Poisoning by solid or liquid substances, gases, and vapors	294	(40)	0.7	(0.1)
Other and unspecified mechanism ⁴	178	(26)	0.5	(0.1)
Other causes of violence	79	(18)	0.2	(0.0)
Injuries of undetermined intent	293	(54)	0.7	(0.1)
Adverse effects of medical treatment	1,684	(151)	4.3	(0.3)
Medical and surgical complications	968	(110)	2.5	(0.2)
Adverse drug effects	716	(78)	1.8	(0.2)
Alcohol and drug use ⁵	1,766	(152)	4.5	(0.3)
Unknown ⁶	7,618	(559)	19.3	(0.8)

... Category not applicable.

* Figure does not meet standards of reliability or precision.

0.0 Quantity more than zero but less than 0.05.

¹First-mentioned of three possible causes, based on the "Supplementary Classification of External Cause of Injury and Poisoning," International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) (14). A detailed description of the ICD-9-CM E-codes used to create the grouping in this table can be found in the 2003 Advance Data report (15).

²Category includes suffocation, drowning, firearms, and other mechanism.

³Category includes assaults by firearms and explosive, and other mechanism.

⁴Category includes injury by cutting and piercing instrument, and other and unspecified mechanism.

⁵Alcohol and drug abuse are not contained in the "Supplementary Classification of External Causes of Injury and Poisoning," but are frequently recorded as a cause of injury or poisoning.

⁶Category includes illegible entries and blanks.

NOTE: Numbers may not add to totals because of rounding.

Table 14. Number and percent distribution of emergency department visits with corresponding standard errors, by body site of primary injury-related diagnosis: United States, 2007

Body site ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All injury visits.	39,395	(2,089)	100.0	(0.0)
Head and neck	5,411	(355)	13.7	(0.5)
Traumatic brain injury.	373	(48)	0.9	(0.1)
Other head	1,383	(151)	3.5	(0.3)
Face	1,855	(164)	4.7	(0.3)
Eye	454	(43)	1.2	(0.1)
Head, face, and neck unspecified	1,346	(103)	3.4	(0.2)
Vertebral column	2,083	(192)	5.3	(0.4)
Cervical	1,087	(117)	2.8	(0.2)
Thoracic and dorsal.	189	(42)	0.5	(0.1)
Lumbar	765	(88)	1.9	(0.2)
Torso	1,809	(134)	4.6	(0.2)
Chest	732	(70)	1.9	(0.2)
Abdomen	168	(33)	0.4	(0.1)
Pelvis and urogenital	242	(39)	0.6	(0.1)
Trunk	173	(29)	0.4	(0.1)
Back and buttocks.	494	(60)	1.3	(0.1)
Upper extremity.	7,335	(480)	18.6	(0.6)
Shoulder and upper arm	1,326	(122)	3.4	(0.3)
Forearm and elbow	1,008	(93)	2.6	(0.2)
Wrist, hand, and fingers	4,582	(306)	11.6	(0.4)
Other and unspecified upper extremity	418	(64)	1.1	(0.2)
Lower extremity.	5,754	(340)	14.6	(0.4)
Hip	488	(63)	1.2	(0.2)
Upper leg and thigh.	203	(36)	0.5	(0.1)
Knee	507	(58)	1.3	(0.1)
Lower leg and ankle	1,601	(131)	4.1	(0.2)
Foot and toes	1,294	(107)	3.3	(0.2)
Other and unspecified lower extremity	1,661	(136)	4.2	(0.3)
Systemwide	1,316	(110)	3.3	(0.2)
Other and unspecified body site injuries.	1,855	(174)	4.7	(0.3)
Adverse effects and medical complications	1,208	(109)	3.1	(0.2)
All other diagnoses ²	11,735	(639)	29.8	(0.8)
Unknown ³	881	(95)	2.2	(0.2)

. . . Category not applicable.

¹Based on the International Classification of Diseases, Ninth Revision, Clinical Modification (14). A detailed description of the Barell Injury Diagnosis Matrix: Classification by Region of Body and Nature of the Injury can be found in the 2003 Advance Data report (15). Three additional categories were added that were not in the Barell Injury Diagnosis Matrix to account for all injury-related visits: illness diagnoses, supplementary classification, and other adverse effects and medical complications.

²All other diagnoses include musculoskeletal system (710–739), symptoms and ill-defined conditions (780–799), skin and subcutaneous tissue (680–709), mental disorders (290–319), nervous system and sense organs (320–389), other illnesses (001–289, 390–677, 740–779), and supplementary classification (V01–V82).

³Category includes blank, uncodable, and illegible diagnoses.

NOTE: Numbers may not add to totals because of rounding.

Table 15. Number and percentage of emergency department visits with corresponding standard errors, by diagnostic services ordered or provided: United States, 2007

Diagnostic and screening services ordered or provided	Number of visits in thousands ¹	(Standard error in thousands)	Percent of visits	(Standard error of percent)
All visits	116,802	(6,293)
One or more diagnostic or screening service listed ²	77,561	(4,295)	66.4	(0.9)
None	36,071	(2,263)	30.9	(0.9)
Blank	3,169	(508)	2.7	(0.4)
Blood tests				
Complete blood count	41,341	(2,442)	35.4	(0.9)
Blood urea nitrogen or creatinine	25,801	(1,968)	22.1	(1.1)
Glucose	22,836	(1,734)	19.6	(1.0)
Electrolytes	22,752	(1,913)	19.5	(1.2)
Cardiac enzymes	14,177	(1,203)	12.1	(0.7)
Liver function tests	9,226	(895)	7.9	(0.6)
Prothrombin time or international normalized ratio (INR)	6,121	(576)	5.2	(0.4)
Blood culture	4,202	(349)	3.6	(0.2)
Toxicology screen	3,181	(321)	2.7	(0.2)
Arterial blood gases	2,795	(374)	2.4	(0.3)
Blood alcohol concentration	1,910	(203)	1.6	(0.2)
Other blood test	21,061	(1,433)	18.0	(0.8)
Any blood test listed	46,476	(2,700)	39.8	(0.9)
Imaging				
X-ray	39,460	(2,272)	33.8	(0.8)
Computed tomography scan	16,186	(1,052)	13.9	(0.5)
Head	7,839	(553)	6.7	(0.3)
Other than head	7,815	(600)	6.7	(0.4)
Ultrasound	3,537	(308)	3.0	(0.2)
Magnetic resonance imaging scan	763	(92)	0.7	(0.1)
Head	308	(48)	0.3	(0.0)
Other than head	357	(52)	0.3	(0.0)
Other imaging	1,181	(139)	1.0	(0.1)
Any imaging	51,862	(2,984)	44.4	(0.9)
Examinations and tests				
Urinalysis	26,267	(1,494)	22.5	(0.6)
Electrocardiogram	19,435	(1,157)	16.6	(0.5)
Cardiac monitor	9,387	(820)	8.0	(0.5)
Pregnancy test	5,577	(463)	4.8	(0.3)
Rapid flu or influenza test	1,485	(382)	1.3	(0.3)
Wound culture	969	(127)	0.8	(0.1)
Other test or service	13,034	(1,256)	11.2	(1.0)

. . . Category not applicable.

0.0 Quantity more than zero but less than 0.05.

¹Total exceeds "all visits" because more than one service may be reported per visit.²Does not include medical screening and mental status exams, which were removed from the survey in 2005.

Table 16. Number and percentage of emergency department visits with corresponding standard errors, by selected procedures: United States, 2007

Procedure performed	Number of visits in thousands	(Standard error in thousands)	Percent of visits	(Standard error of percent)
All visits	116,802	(6,293)
One or more procedure listed	53,090	(3,219)	45.5	(1.3)
None ¹	57,911	(3,475)	49.6	(1.3)
Blank ²	5,801	(702)	5.0	(0.5)
Intravenous fluids	31,045	(2,021)	26.6	(0.9)
Splint or wrap	6,681	(466)	5.7	(0.2)
Laceration repair	5,125	(319)	4.4	(0.2)
Nebulizer therapy	3,048	(245)	2.6	(0.2)
Bladder catheter	2,576	(279)	2.2	(0.2)
Wound debridement	1,967	(234)	1.7	(0.2)
Incision and drainage	1,174	(127)	1.0	(0.1)
Cast	529	(69)	0.5	(0.1)
Foreign body removal	450	(51)	0.4	(0.0)
Nasogastric tube gastric suction	365	(84)	*0.3	(0.1)
Endotracheal intubation	269	(70)	*0.2	(0.1)
Other	9,706	(1,371)	8.3	(1.1)

... Category not applicable.

* Figure does not meet standards of reliability or precision.

0.0 Quantity more than zero but less than 0.05.

¹The None checkbox was marked on the Patient Record form (PRF).

²No checkboxes were marked on the PRF.

Table 17. Number and percent distribution of emergency department visits with corresponding standard errors, by medications provided or prescribed: United States, 2007

Medication therapy ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits	116,802	(6,293)	100.0	...
Visits with mention of medication ²	89,108	(4,832)	76.3	(0.7)
Number of medications provided or prescribed ³				
1	30,658	(1,752)	26.2	(0.5)
2	25,695	(1,410)	22.0	(0.4)
3	15,775	(975)	13.5	(0.3)
4	8,340	(547)	7.1	(0.2)
5	4,440	(348)	3.8	(0.2)
6	2,052	(190)	1.8	(0.1)
7	1,043	(116)	0.9	(0.1)
8	1,106	(186)	0.9	(0.2)
Visits without mention of medication	27,694	(1,742)	23.7	(0.7)

... Category not applicable.

¹Includes prescription drugs, over-the-counter preparations, immunizations, and desensitizing agents.

²Visits at which one or more medications were provided or prescribed.

³There were 213,387,000 drug mentions at emergency department visits in 2007. The average drug mention rate was 1.8 mentions per ED visit (standard error = 0.04). For visits with at least one drug mention, the average rate was 2.4 drugs per visit (standard error = 0.04).

NOTE: Numbers may not add to totals because of rounding.

Table 18. Number and percentage of drug mentions at emergency department visits, with corresponding standard errors, by the 20 most frequently occurring drug categories: United States, 2007

Drug category ¹	Number of mentions in thousands	(Standard error in thousands)	Percent of drug mentions ²	(Standard error of percent)
Analgesics ³	77,545	(4,631)	36.3	(0.4)
Antiemetic/antivertigo agents	23,234	(1,553)	10.9	(0.3)
Antihistamines	12,100	(775)	5.7	(0.2)
Anxiolytics, sedatives, and hypnotics	9,199	(548)	4.3	(0.1)
Cephalosporins	8,041	(650)	3.8	(0.2)
Minerals and electrolytes	7,684	(794)	3.6	(0.3)
Bronchodilators	7,296	(473)	3.4	(0.2)
Penicillins	7,132	(515)	3.3	(0.2)
Adrenal cortical steroids	6,267	(419)	2.9	(0.1)
Miscellaneous antibiotics	5,899	(403)	2.8	(0.1)
Anticonvulsants	5,581	(384)	2.6	(0.1)
Quinolones	5,105	(342)	2.4	(0.1)
Miscellaneous respiratory agents	5,047	(720)	2.4	(0.3)
Macrolide derivatives	4,231	(310)	2.0	(0.1)
Muscle relaxants	4,066	(297)	1.9	(0.1)
Antiplatelet agents	3,838	(317)	1.8	(0.1)
Dermatological agents	3,417	(322)	1.6	(0.1)
Antiparkinson agents	3,108	(212)	1.5	(0.1)
Sulfonamides	3,053	(266)	1.4	(0.1)
Toxoids ⁴	2,730	(192)	1.3	(0.1)

¹Based on Multum Lexicon second-level therapeutic drug category (see: <http://www.multum.com/Lexicon.htm>).

²Based on an estimated 213,387,000 drug mentions at visits in 2007.

³Includes narcotic and nonnarcotic analgesics and nonsteroidal anti-inflammatory drugs.

⁴Includes tetanus toxoids and combinations containing tetanus and diphtheria toxoids.

Table 19. Number and percent distribution of drug mentions at emergency department visits, with corresponding standard errors, by generic equivalents with therapeutic categories, according to whether the drug was given in the emergency department or prescribed at discharge: United States, 2007

Drug name ¹	Number of drug mentions in thousands	(Standard error in thousands)	Percent distribution	Percent of mentions (Standard error of percent)			Therapeutic drug category ²
				(Standard error of percent)	Given in emergency department	Prescribed at discharge	
All drug mentions	213,387	(12,070)	100.0	...	62.3 (1.1)	44.2 (1.1)	...
Ibuprofen	14,607	(992)	6.8	(0.3)	3.0 (0.1)	4.6 (0.2)	Analgesics
Acetaminophen-hydrocodone	13,114	(1,032)	6.1	(0.3)	2.1 (0.1)	4.9 (0.2)	Analgesics
Acetaminophen	10,430	(717)	4.9	(0.2)	2.8 (0.1)	2.4 (0.2)	Analgesics
Promethazine	7,446	(564)	3.5	(0.2)	2.8 (0.2)	1.1 (0.1)	Antiemetic/antiemetic agents or antihistamines
Ketorolac	7,335	(529)	3.4	(0.2)	3.3 (0.2)	0.2 (0.0)	Analgesics
Morphine	6,747	(523)	3.2	(0.2)	3.1 (0.2)	*0.1 (0.0)	Analgesics
Ondansetron	6,064	(615)	2.8	(0.2)	2.7 (0.2)	0.3 (0.0)	Antiemetic/antiemetic agents
Hydromorphone	5,074	(502)	2.4	(0.2)	2.3 (0.2)	0.1 (0.0)	Analgesics
Sodium chloride	4,940	(721)	2.3	(0.3)	2.2 (0.3)	0.0 (0.0)	Minerals and electrolytes or miscellaneous respiratory agents
Acetaminophen-oxycodeone	4,557	(424)	2.1	(0.2)	1.0 (0.1)	1.6 (0.1)	Analgesics
Albuterol	4,190	(261)	2.0	(0.1)	1.2 (0.1)	1.0 (0.1)	Bronchodilators
Azithromycin	3,591	(259)	1.7	(0.1)	0.7 (0.0)	1.2 (0.1)	Macrolide derivatives
Amoxicillin	3,509	(332)	1.6	(0.1)	0.4 (0.0)	1.5 (0.1)	Penicillins
Aspirin	3,449	(292)	1.6	(0.1)	1.4 (0.1)	0.2 (0.0)	Analgesics or antiplatelet agents
Ceftriaxone	3,369	(302)	1.6	(0.1)	1.5 (0.1)	0.1 (0.0)	Cephalosporins
Cephalexin	3,276	(285)	1.5	(0.1)	0.4 (0.0)	1.3 (0.1)	Cephalosporins
Sulfamethoxazole-trimethoprim	3,008	(265)	1.4	(0.1)	0.4 (0.0)	1.2 (0.1)	Miscellaneous antibiotics or sulfonamides
Diphenhydramine	2,992	(208)	1.4	(0.1)	1.1 (0.1)	0.5 (0.0)	Antiemetic/antiemetic agents or antihistamines; anti-Parkinson agents; or anxiolytics, sedatives, and hypnotics
Lorazepam	2,795	(213)	1.3	(0.1)	1.1 (0.1)	0.2 (0.0)	Anticonvulsants; antiemetic/antiemetic agents; or anxiolytics, sedatives, and hypnotics
Levofloxacin	2,666	(250)	1.2	(0.1)	0.9 (0.1)	0.5 (0.1)	Anticonvulsants; antiemetic/antiemetic agents; or anxiolytics, sedatives, and hypnotics
All other	100,228	(5,444)	47.0	(0.6)	28.0 (0.6)	21.3 (0.7)	Quinolones

... Category not applicable.
 0.0 Quantity more than zero but less than 0.05.
 * Figure does not meet standards of reliability or precision.
¹Based on Multum Lexicon terminology, the drug name reflects the active ingredients of a drug mention.
²Based on Multum Lexicon second-level therapeutic drug category (see: <http://www.multum.com/lexicon.htm>).

Table 20. Number and percentage of emergency department visits with corresponding standard errors, by providers seen: United States, 2007

Type of provider	Number of visits in thousands ¹	(Standard error in thousands)	Percent of visits	(Standard error of percent)
All visits	116,802	(6,293)	100.0	(0.0)
Registered nurse or licensed practical nurse	105,923	(6,002)	90.7	(1.1)
Any physician	104,718	(5,495)	89.7	(0.8)
Emergency department attending physician	101,554	(5,335)	86.9	(1.1)
Emergency department resident or intern	9,290	(1,141)	8.0	(1.0)
Other on-call attending physician, fellow, or resident	5,500	(861)	4.7	(0.7)
Physician assistant	10,717	(1,546)	9.2	(1.1)
Nurse practitioner	4,724	(696)	4.0	(0.5)
Emergency medical technician	10,053	(1,138)	8.6	(0.8)
Other	28,600	(2,814)	24.5	(2.0)
Blank	1,848	(248)	1.6	(0.2)

. . . Category not applicable.

¹Total exceeds all visits because more than one provider may be reported per visit.**Table 21. Number and percentage of emergency department visits with corresponding standard errors, by visit disposition: United States, 2007**

Disposition	Number of visits in thousands ¹	(Standard error in thousands)	Percent of visits	(Standard error of percent)
All visits	116,802	(6,293)	100.0	(0.0)
Admitted, transferred, or died				
Admitted to hospital	14,641	(1,033)	12.5	(0.6)
Stepdown or telemetry unit	2,895	(308)	2.5	(0.2)
Critical care unit ²	1,689	(154)	1.4	(0.1)
Operating room	649	(71)	0.6	(0.1)
Mental health or detoxification unit	581	(80)	0.5	(0.1)
Cardiac catheterization lab	*	*	*	*
Other bed or unit	7,184	(579)	6.2	(0.4)
Unknown or blank	1,551	(244)	1.3	(0.2)
Admitted to observation unit	2,453	(354)	2.1	(0.3)
Transferred to different hospital	2,147	(222)	1.8	(0.2)
Died in emergency department	139	(29)	0.1	(0.0)
Outpatient follow-up				
Return or refer to physician or clinic for follow-up	72,108	(4,050)	61.7	(1.3)
Return to emergency department as needed or by appointment	41,332	(3,079)	35.4	(1.8)
Refer to social services	925	(107)	0.8	(0.1)
No follow-up planned	6,311	(1,033)	5.4	(0.7)
Left or referred out from triage				
Left before medical screening exam	1,928	(183)	1.7	(0.1)
Left against medical advice	1,381	(143)	1.2	(0.1)
Left after medical screening exam	1,289	(200)	1.1	(0.2)
Other	639	(113)	0.5	(0.1)
Blank	1,396	(300)	1.2	(0.3)

. . . Category not applicable.

* Figure does not meet standards of reliability or precision.

0.0 Quantity more than zero, but less than 0.05.

¹Total exceeds all visits because more than one disposition may be reported per visit.²Critical care units include intensive care and coronary care units.

Table 22. Number and percent distribution of emergency department visits resulting in hospital admission, with corresponding standard errors, by selected characteristics: United States, 2007

Selected characteristics	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)	Mean length of stay in days ¹	(Standard error in days)	Admissions as percent of visits	(Standard error of percent)
All admissions	14,641	(1,033)	100.0	...	5.3	(0.1)	12.5	(0.9)
Age								
Under 15 years	663	(107)	4.5	(0.7)	4.7	(0.5)	3.0	(0.5)
15–24 years	838	(94)	5.7	(0.5)	4.5	(0.5)	4.4	(0.5)
25–44 years	2,780	(264)	19.0	(0.9)	4.2	(0.2)	8.3	(0.8)
45–64 years	4,164	(309)	28.4	(0.8)	5.2	(0.2)	17.0	(1.3)
65–74 years	1,917	(152)	13.1	(0.6)	5.9	(0.4)	27.8	(2.2)
75 years and over	4,279	(334)	29.2	(1.0)	6.2	(0.2)	40.3	(3.1)
Residence								
Private residence	12,076	(853)	82.5	(1.0)	5.0	(0.1)	11.3	(0.8)
Nursing home	1,133	(112)	7.7	(0.6)	7.4	(0.6)	48.8	(4.8)
Other institution	200	(35)	1.4	(0.2)	6.8	(1.1)	18.6	(3.3)
Other residence	173	(38)	1.2	(0.2)	6.8	(1.3)	28.6	(6.4)
Homeless	63	(17)	0.4	(0.1)	6.0	(1.4)	11.6	(3.2)
Unknown or blank	996	(152)	6.8	(0.8)	5.7	(0.5)	17.1	(2.6)
Expected sources of payment ²								
Private insurance	5,914	(472)	40.4	(1.9)	4.9	(0.2)	13.0	(1.0)
Uninsured ³	1,650	(271)	11.3	(1.6)	5.2	(0.3)	7.6	(1.2)
Medicare	6,327	(496)	43.2	(1.4)	6.0	(0.1)	31.4	(2.5)
Medicaid or SCHIP ⁴	2,915	(238)	19.9	(1.1)	5.4	(0.2)	9.9	(0.8)
Mode of arrival								
Ambulance	5,692	(461)	38.9	(1.3)	6.0	(0.2)	31.5	(2.5)
Other	8,949	(646)	61.1	(1.3)	4.9	(0.1)	9.1	(0.7)
Triage category								
Immediate or emergent ⁵	5,017	(440)	34.3	(1.8)	5.8	(0.3)	27.3	(2.4)
Other	9,624	(732)	65.7	(1.8)	5.1	(0.1)	9.8	(0.7)
Patient seen in this emergency department within the last 72 hours								
Yes	639	(76)	4.4	(0.4)	6.0	(0.6)	14.3	(1.7)
No, unknown, or blank	14,003	(995)	95.6	(0.4)	5.3	(0.1)	12.5	(0.9)
Patient discharged from any hospital within the last 7 days								
Yes	894	(102)	6.1	(0.6)	6.5	(0.5)	33.1	(3.8)
No, unknown, or blank	13,747	(977)	93.9	(0.6)	5.2	(0.1)	12.0	(0.9)
Length of stay								
1–2 days	2,841	(314)	19.4	(1.3)
3–4 days	4,440	(349)	30.3	(1.2)
5–6 days	2,254	(188)	15.4	(0.8)
7–8 days	1,397	(140)	9.5	(0.7)
9–10 days	624	(75)	4.3	(0.4)
More than 10 days	1,040	(111)	7.1	(0.6)
Unknown or blank	2,045	(362)	14.0	(2.3)
Hospital discharge status								
Alive	12,246	(942)	83.6	(2.2)	5.2	(0.1)
Home or residence	9,411	(683)	76.9	(2.4)	4.9	(0.1)
Transferred to another hospital	904	(107)	7.4	(0.8)	7.1	(0.5)
Other	629	(80)	5.1	(0.6)	8.1	(1.1)
Unknown or blank	1,301	(392)	10.6	(2.8)	4.0	(0.5)
Died	333	(47)	2.3	(0.3)	8.0	(0.8)
Unknown or blank	2,063	(348)	14.1	(2.2)	5.3	(0.5)

... Category not applicable.

¹Denominator for length of stay is 12,596,000 visits where this variable was known. Length of stay was unknown in 14.0 percent of visits resulting in admission.²Total exceeds "all admissions" because more than one source of payment may be reported. Workers' compensation, other, and unknown sources of payment are not included in this table, but account for 10.7 percent of expected sources of payment.³No insurance is defined as having only self-pay, no charge, or charity as payment sources.⁴SCHIP is the State Children's Health Insurance Program.⁵Emergent is needing to be seen within 1–14 minutes.

NOTE: Numbers may not add to totals because of rounding.

Table 23. Number and percent distribution of emergency department visits with corresponding standard errors, by the 20 leading principal hospital discharge diagnosis groups: United States, 2007

Principal diagnosis group and ICD-9-CM codes ¹	Number of visits in thousands	(Standard error in thousands)	Percent distribution	(Standard error of percent)
All visits.	14,641	(1,033)	100.0	0.0
Heart disease, excluding ischemic.391-392.0,393-398,402,404,415-416,420-429	923	(86)	6.3	(0.5)
Chest pain786.5	829	(128)	5.7	(0.7)
Pneumonia480-486	507	(61)	3.5	(0.4)
Cerebrovascular disease.430-438	446	(59)	3.0	(0.3)
Ischemic heart disease.410-414.9	423	(73)	2.9	(0.4)
Psychoses, excluding major depressive disorder290-295,296.0-296.1,296.4-299	357	(57)	2.4	(0.4)
Cellulitis and abscess.681-682	334	(55)	2.3	(0.3)
Malignant neoplasms140-208,230-234	269	(45)	1.8	(0.3)
Fracture of the lower limb820-829	244	(36)	1.7	(0.2)
Syncope and collapse780.2	223	(41)	1.5	(0.2)
Diabetes mellitus.250	218	(39)	1.5	(0.2)
Fractures, excluding lower limb800-819	216	(37)	1.5	(0.3)
Gastrointestinal hemorrhage.578	209	(40)	1.4	(0.3)
Anemia.280-285	208	(39)	1.4	(0.2)
Urinary tract infection, site not specified599.0	203	(40)	1.4	(0.3)
Noninfectious enteritis and colitis.555-558	195	(37)	1.3	(0.2)
Complications of pregnancy, childbirth, and the puerperium630-677	191	(46)	1.3	(0.3)
Abdominal pain789.0	186	(33)	1.3	(0.2)
Disorder of gallbladder and biliary tract574-576	186	(43)	1.3	(0.3)
Asthma.493	158	(30)	1.1	(0.2)
All other diagnoses ²	8,116	(605)	55.4	(1.6)

. . . Category not applicable.

¹Based on the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) (14). However, certain codes have been combined in this table to better describe the use of ambulatory care services.

²All other diagnoses includes blanks and the 16.7 percent of hospital discharges in which the discharge diagnosis was unknown.

NOTE: Numbers may not add to totals because of rounding.

Technical Notes

Data source

The NHAMCS data collection is authorized under Section 306 of the Public Health Service Act (Title 42 U.S. Code), 242k. Participation is voluntary. The U.S. Census Bureau was responsible for data collection. Data collected in NHAMCS are consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). No personally identifying information, such as patient's name, address, or Social Security number, is collected in NHAMCS. All information collected is held in the strictest confidence as referenced by law [Section 308(d) of the Public Health Service Act (42, U.S. Code, 242m (d))] and the Confidential Information Protection and Statistical Efficiency Act (Title 5 of PL 107–347). Approval for the NHAMCS protocol was renewed by the NCHS Research Ethics Review Board in February 2007. Waivers of the requirements to obtain informed consent of patients and patient authorization for release of patient medical record data by health care providers were granted.

The target universe of NHAMCS is in-person visits made in the United States to EDs and OPDs of nonfederal, short-stay hospitals (hospitals with an average stay of fewer than 30 days) and those whose specialty is general (medical or surgical) or children's general. EDs that operate 24 hours a day are considered within the scope of the ED component; EDs that operate fewer than 24 hours are included in the OPD component of NHAMCS.

Data processing and coding

Data processing and medical coding were performed by SRA International, Inc., Durham, North Carolina. As part of the quality assurance procedure, a 10 percent quality control sample of ED survey records was independently keyed and coded, with an error rate of 0.8 percent.

New data definitions used in the 2007 report and verbatim medical data

collected in the survey were coded as follows:

- *Pediatric versus general EDs*—An ED was classified as pediatric if its ESA type was coded as “pediatric” in the NHAMCS Hospital Induction Interview Form. All others including unknowns were classified as general. Since the sample size of children's hospital EDs was too small to permit reliable estimates, pediatric EDs were not further broken down by whether they were located in children's versus general hospitals.
- *Patient's reason for visit*—The patient's main complaint, symptom, or reason for visiting the ED was coded according to “A Reason for Visit Classification for Ambulatory Care” (RVC) (13). Up to three reasons could be coded per visit.
- *Temperature*—Recorded values were coded into febrile, normal, hypothermic, and missing bands. Normal temperature was between 35.0–38.0° C or 95.0–100.4° F. Temperatures greater than normal were febrile (<http://www.nlm.nih.gov/medlineplus/ency/article/003090.htm>). Temperatures less than normal were hypothermic (<http://www.nlm.nih.gov/medlineplus/ency/article/000038.htm>).
- *Injury, poisoning, or adverse effect of medical treatment*—Although there was a separate item on the PRF to indicate whether the visit was for an injury, poisoning, or adverse effect of medical treatment, sometimes an injury reason for visit was specified or an injury diagnosis recorded without the injury item being checked. Therefore, the visit was counted as an injury visit and the checkbox was coded to “yes” if any of the three reasons for visit were in the injury module, or any of the three diagnoses were in the injury or poisoning chapter of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) or any external cause of injury was recorded. The injury intents and mechanisms in Table 13 are from the first-mentioned of three possible causes, based on the “Supplementary Classification of

External Cause of Injury and Poisoning” in the ICD–9–CM (14). A detailed description of the cause of injury codes used to create the grouping in Table 13 can be found in the 2003 Advance Data report (15). The injury body sites in Table 14 are based on the Barell Injury Diagnosis Matrix (16) using ICD–9–CM codes. A detailed description of these codes can also be found in the 2003 Advance Data report (15). Three additional categories were added that were not in the Barell Injury Diagnosis Matrix to account for all injury-related visits: illness diagnoses, supplementary classification, and other adverse effects and medical complications.

- *Diagnosis*—Hospital staff was asked to record the primary diagnosis, and up to two additional diagnoses, associated with the patient's reason for the current visit. The text of the diagnoses was then coded according to the ICD–9–CM (14).
- *Medications including immunizations*—Hospital staff was instructed to record all new or continued medications ordered, supplied, or administered in the ED or prescribed at discharge. This included prescription and nonprescription preparations, immunizations, desensitizing agents, and anesthetics. In this survey, recorded medications are referred to as drug mentions and are coded according to a system developed at NCHS (17). As used in NHAMCS, the term “drug” is interchangeable with the term “medication.” The term “prescribing” is used broadly to mean ordering or providing any medication, whether prescription or over-the-counter. Visits with one or more drug mentions are termed “drug visits” in NHAMCS. Medications, including immunizations, were coded using the Multum Lexicon, a proprietary drug classification system used by NCHS beginning with the 2006 ambulatory care reports. Therapeutic classification of drugs is based on the Multum Lexicon's second-level therapeutic categories,

including any drug mentions coded at third-level therapeutic categories (<http://www.multum.com/Lexicon.htm>). Drugs may have more than one therapeutic application. Although Multum allows up to five therapeutic categories per drug, in this report a maximum of four therapeutic categories for each drug is examined because the number of drugs with five therapeutic categories is small. Generic ingredients of drug mentions were coded according to the drug_id nomenclature included in Multum. Tetanus toxoid was coded as Multum drug_id d01168. Combinations containing both tetanus and diphtheria toxoids included diphtheria/tetanus (d05338), diphtheria/pertussis/tetanus (d03110), Pediarix (a10978), and diphtheria/haemophilus B/acellular pertussis/tetanus (a11631). No other possible diphtheria/tetanus combination in Multum had mentions in the 2007 ED database.

Estimation

Because of the complex multistage design of NHAMCS, a sample weight is computed for each sampled visit that takes all stages of design into account. The survey data are inflated or weighted to produce unbiased national annual estimates. The visit weight includes four basic components: inflation by reciprocals of selection probabilities, adjustment for nonresponse, population ratio adjustments, and weight smoothing. Starting in 2004, changes were made to the nonresponse adjustment factor to account for the seasonality of the reporting period. Extra weights for nonresponding hospitals were shifted to responding hospitals in reporting periods within the same quarter of the year. The shift in nonresponse adjustment did not significantly affect any of the overall annual estimates. Detailed information on NHAMCS estimation can be found elsewhere (18).

The standard error is primarily a measure of the sampling variability that occurs by chance because only a sample rather than an entire universe is surveyed. Estimates of the sampling

variability for this report were calculated using Taylor approximations in SUDAAN, which take into account the complex sample design of NHAMCS. A description of the software and its approach has been published (19). The standard errors of statistics presented in this report are included in each of the tables.

Nonsampling errors

As in any survey, results are subject to both sampling and nonsampling errors. Nonsampling errors include reporting and processing errors as well as biases due to nonresponse and incomplete response. The magnitude of the nonsampling errors cannot be computed. However, these errors were kept to a minimum by procedures built into the operation of the survey. To eliminate ambiguities and to encourage uniform reporting, attention was given to the phrasing of items, terms, and definitions. Also, pretesting of most data items and survey procedures was performed. Quality control procedures and consistency and edit checks reduced errors in data coding and processing.

Nonresponse rates and imputation

Item nonresponse rates in NHAMCS are generally low (5 percent or less). However, levels of nonresponse can vary considerably in the survey. Most nonresponse occurs when the needed information is not available in the medical record or is unknown to the person filling out the survey instrument. Nonresponse can also result when the information is available, but survey procedures are not followed and the item is left blank. In this report, some tables include a combined entry of unknown or blank to display missing data. For items with nonresponse greater than 50 percent, data are not presented. For items where combined item nonresponse is between 30 and 50 percent, percent distributions are not discussed in the text. However, the information is shown in the tables. These data should be interpreted with caution. If nonresponse is random, the

observed distribution for the reported item (i.e., excluding cases for which the information is unknown) would be close to the true distribution. However, if nonresponse is not random, the observed distribution could vary significantly from the actual distribution. Researchers need to decide how best to treat items with high levels of missing responses.

Weighted item nonresponse rates (i.e., if the item was left blank or the unknown box was marked) were 5.0 percent or less for all data items with the following exceptions. Visit-level item nonresponse rates included discharge time (6.2 percent); time spent in the ED (6.7 percent); temperature (6.9 percent); mode of arrival (7.0 percent); expected source of payment (9.0 percent); respiratory rate (10.1 percent); pulse (10.5 percent); systolic blood pressure (13.3 percent); diastolic blood pressure (13.4 percent); episode of care (14.0 percent); length of hospital stay (14.0 percent of admissions); hospital discharge status (14.1 percent of admissions); time spent waiting to see a physician (14.4 percent); race (14.9 percent); hospital discharge diagnosis (16.7 percent of admissions); cause of injury (19.3 percent of injury visits); pain level (21.5 percent); seen in ED within last 72 hours (22.0 percent); time seen by physician (22.8 percent); oriented to time, place, and person (24.4 percent); ethnicity (24.9 percent); and pulse oximetry (25.7 percent).

ED-level item nonresponse rates included boarded outside of ED (5.2 percent), administrative placement of observation unit (7.9 percent), bed coordinator (6.9 percent), ambulance diversion managed on regional or hospital level (15.5 percent), elective surgery days per week (16.3 percent), plans to expand ED physical space in the next 2 years (18.0 percent), elective surgery during ambulance diversion (19.2 percent), and ambulance diversion in 2006 (23.3 percent).

Items with nonresponse rates between 30 and 50 percent included patient discharged from hospital within the last 7 days (41.6 percent) (Table 9), and number of times patient seen in the

ED in the last year (45.7 percent) (not shown). There were no items with nonresponse greater than 50 percent.

For some items, missing values were imputed by randomly assigning a value from a PRF with similar characteristics. Imputations were performed for the following variables: birth year (1.9 percent), sex (0.7 percent), immediacy (3.6 percent), race (14.9 percent), and ethnicity (24.9 percent). Weighted imputation rates are shown.

Imputation for birth year and sex was based on ED volume, geographic region, immediacy with which patient should be seen, and the three-digit ICD-9-CM code for primary diagnosis. Imputation for immediacy with which the patient should be seen was based on ED volume, geographic region, and three-digit ICD-9-CM code for primary diagnosis. (Note that only blank values were imputed for immediacy and imputation included the use of checkbox responses of “unknown” from donor files.)

A new method was used to impute race and ethnicity. Race and ethnicity assignments were based, where possible, on diagnosis and patient's locality (ZIP Code or state or county of residence). A hot deck approach (i.e., filling in missing values on incomplete records using values from similar but complete records of the same dataset) was employed rather than the previously used cold deck strategy (i.e., filling in missing values on incomplete records using values from similar but complete records of the dataset from the previous year), except in cases where a matching record could not be obtained from the current data. When race or ethnicity data could not be assigned using patient locality, the new method attempted to impute within the same facility wherever possible. Failing that, imputation was based on diagnosis, hospital, type of emergency service area, immediacy, and, as a last resort, on a randomly selected record. An internal NCHS evaluation study found that this approach was more likely to correctly identify patients' race and ethnicity than was the previous method. Further refinements to the imputation strategy

are being studied for future use. Because of the high percentages of missing data for race and ethnicity in 2007, readers are advised to treat these data with caution. In the tables, both imputed and nonimputed race and ethnicity data are presented.

Use of tables

The tables present only the first-listed reason for visit and first-listed diagnosis. It should be noted that estimates differing in ranked order may not be significantly different from each other. For items related to diagnostic and screening services, procedures, providers seen, and disposition, hospital staff was asked to check all of the applicable categories for each item. Therefore, multiple responses could be coded for each visit.

In this report, estimates are not presented if they are based on fewer than 30 cases in the sample data; only an asterisk (*) appears in the tables. The relative standard error (RSE) of an estimate is obtained by dividing the standard error by the estimate itself. The result is then expressed as a percentage of the estimate. Estimates based on 30 or more cases include an asterisk if the RSE of the estimate exceeds 30 percent.

In the tables, estimates of ED visits have been rounded to the nearest thousand. Consequently, estimates will not always add to totals. Rates and percentages were calculated from original unrounded figures and do not necessarily agree with figures calculated from rounded data.

Population estimates

Several of the tables in this report present rates of ED visits per population. The population figures used in calculating these rates are based on Census Bureau monthly postcensal estimates of the civilian noninstitutional population of the United States as of July 1, 2007. These population estimates are based on postcensal estimates from the 2000 census and are available from the Census Bureau.

Denominators used in computing estimates of visit rates for nursing home

residents are from the 2004 National Nursing Home Survey (20). Denominators for computing visit rates for homeless people are from a report by the U.S. Department of Housing and Urban Development (21). Estimates presented in the tables and figure for specific race categories reflect visits where only a single race was reported. Denominators used in computing estimates of visit rates by expected source of payment were obtained from the 2007 NHIS. Individuals reporting multiple insurance categories in NHIS were counted in each category they reported, except for Medicaid and SCHIP, which were combined into a single category.

Form Approved 108-10-200-0175 Exp. 03/31/09 2009-02-01 14-10

PHANCE-100(02)
2007 ED

**NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY
2007 EMERGENCY DEPARTMENT PATIENT RECORD**

Assurance of confidentiality: All information which would permit identification of an individual in position or an establishment will be held confidential, will be used only by persons engaged in care for the purpose of the survey and will not be disclosed or released to other persons or used for any other purpose unless consent of the individual or the establishment of occurrence and release (2007) of the Public Health Service Act (42 USC 2423c).

(Number 2462-001 form)

I. PATIENT INFORMATION

a. Date of visit
Month: Day: Year:

b. ZIP Code

c. Date of birth
Month: Day: Year:

d. Time of day
 AM PM
 Night
 Other

e. Patient's sex
 Male Female

f. Race
 White Hispanic or Latino
 Black Indian or Alaska Native
 Asian Other

g. Ethnicity
 Hispanic or Latino
 Other

h. Marital status
 Single Married Widowed Divorced

i. Insurance coverage
 Private insurance Medicare Medicaid
 Other None

II. TRIAGE

a. Initial vital signs
 (1) Temperature: (2) Heart rate:
 (3) Blood pressure: (4) Pulse strength:
 (5) Respiratory rate: (6) Oxygen saturation:

b. Appearance with which patient should be seen
 1-15 minutes 15-30 minutes
 30-60 minutes 60-90 minutes
 90-120 minutes Other

III. PREVIOUS CARE

a. Has patient been in ER within the last 12 hours?
 Yes No

b. Has patient been in ER within the last 7 days?
 Yes No

c. Has patient been in ER within the last 12 months?
 Yes No

IV. REASON FOR VISIT

a. Patient's complaint, symptoms, or chief concern of the visit
 Injury Illness Other

b. Specific injury or illness
 Head injury Neck injury Chest injury
 Abdominal injury Back injury Limb injury
 Other

V. INJURY POSSIBILITIES, SEVERITY, EFFECT

a. Is this visit related to an injury or poisoning?
 Yes No

b. Is this injury poisoning or poisoning effect of medical treatment?
 Yes No

c. Cause of injury, poisoning, or poisoning effect
 Motor vehicle Pedestrian Other

VI. PROVIDER'S DIAGNOSIS FOR THIS VISIT

a. ICD-9-CM diagnosis code

b. Other diagnosis

VII. DIAGNOSTIC/SCREENING SERVICES

a. X-ray
 Head Neck Chest Abdomen
 Pelvis Other

b. Laboratory
 Hematology Chemistry Microbiology
 Immunology Other

VIII. PROCEDURES

a. Wound care
 Suture Laceration repair
 Debridement Other

b. Other procedures
 Cast Splint
 Other

IX. MEDICATIONS & IMMUNIZATIONS

a. Medication
 Analgesic Antibiotic Other

b. Immunization
 Tetanus Other

X. PROVIDERS

a. All providers seen at this visit
 ED physician ED resident
 ED nurse practitioner ED physician assistant
 Other

b. Other providers
 Nurse practitioner Physician assistant
 Other

XI. VISIT DISPOSITION

a. Disposition
 Discharge Hospital admission
 Transfer to another hospital Death

b. Hospital admission
 Admitted Not admitted

XII. HOSPITAL ADMISSION

a. Admitted to
 General ward Outpatient
 Intensive care Other

b. Hospital admission date
 Month: Day: Year:

c. Hospital discharge date
 Month: Day: Year:

d. Principal hospital discharge diagnosis

e. Hospital discharge status
 Discharge Death
 Transfer Other

Figure I. 2007 Emergency Department Patient Record

Suggested citation

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EXHIBIT C



The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Frequency and Costs of Diagnostic Imaging in Office Practice — A Comparison of Self-Referring and Radiologist-Referring Physicians

Bruce J. Hillman, M.D., Catherine A. Joseph, B.A., Michael R. Mabry, B.A., Jonathan H. Sunshine, Ph.D., Stephen D. Kennedy, Ph.D., and Monica Noether, Ph.D.

N Engl J Med 1990; 323:1604-1608 | December 6, 1990 | DOI: 10.1056/NEJM199012063232306

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Abstract

Abstract

To assess possible differences in physicians' practices with respect to diagnostic imaging, we compared the frequency and costs of imaging examinations as performed by primary physicians who used imaging equipment in their offices (self-referring) and as ordered by physicians who always referred patients to radiologists (radiologist-referring).

Using a large, private insurance-claims data base, we analyzed 65,517 episodes of outpatient care by 6419 physicians for acute upper respiratory symptoms, pregnancy, low back pain, or (in men) difficulty urinating. The respective imaging procedures studied were chest radiography, obstetrical ultrasonography, radiography of the lumbar spine, and excretory urography, cystography, or ultrasonography.

For all four clinical presentations, the self-referring physicians obtained imaging examinations 4.0 to 4.5 times more often than the radiologist-referring physicians ($P < 0.0001$ for all four). For chest radiography, obstetrical ultrasonography, and lumbar spine radiography, the self-referring physicians charged significantly more than the radiologists for imaging examinations of similar complexity ($P < 0.0001$ for all three). The combination of more frequent imaging and higher charges resulted in mean imaging charges per episode of care that were 4.4 to 7.5 times higher for the self-referring physicians ($P < 0.0001$). These results were confirmed in a separate analysis that controlled for the specialty of the physician.

Physicians who do not refer their patients to radiologists for medical imaging use imaging examinations more frequently than do physicians who refer their patients to radiologists, and the charges are usually higher when the imaging is done by the self-referring physician. From our results it is not possible to determine which group of physicians uses imaging more appropriately. (N Engl J Med 1990; 323:1604-8.)

Article

THE potential for conflicts of interest and higher costs for health care arising from the ownership by physicians of the diagnostic facilities to which they refer patients has attracted considerable attention recently in the medical literature^{1 2 3 4 5} and lay press^{6 7} and has been the subject of government study and legislation.^{8 9 10} The ownership of imaging centers by physicians has received much of the media attention. However, most self-referral for medical imaging — in which physicians perform and interpret diagnostic imaging examinations of their own patients rather than refer them to imaging specialists — takes place in the physician's office.

The few previous studies investigating the effect of self-referral on the use and costs of imaging have been limited by methodologic flaws, small study populations, and lack of controls. To overcome these limitations, we analyzed a large data base of private insurance claims and evaluated the imaging done in physicians' offices during episodes of outpatient medical care. After controlling for differences in patients' clinical presentations and physicians' specialties, we compared the frequencies

with which the patients underwent imaging examinations during episodes of medical care for acute conditions, according to whether their physicians could perform those imaging examinations themselves. We also compared the resultant charges for the imaging examinations.

We purchased access to a data base (Medstat Systems, Ann Arbor, Mich.) comprising all the health insurance claims of 403,458 employees and dependents of several large American corporations. The insurance programs provided comprehensive coverage, including outpatient imaging services, with no copayments required. The data base was selected for its uniformity and completeness. Seventy-nine percent of the study population lived in the north central United States, 6 percent in the Northeast, 11 percent in the South, and 4 percent in the West. Fifty-one percent were female, and 49 percent male. Fifty-five percent were 0 to 34 years old, 33 percent were 35 to 54 years old, and 12 percent were 55 or older. Ninety-three percent of the physicians making claims for care provided to these patients practiced in metropolitan areas.

Using this data base, we compared the frequency of imaging and the charges for imaging among self-referring physicians and among physicians who instead referred patients to radiologists (radiologist-referring physicians) for four clinical presentations, selected for their variety and the volume of associated imaging procedures. The presentations, with the associated diagnostic inquiry, were as follows: acute upper respiratory symptoms (Was chest radiography performed?), pregnancy (Was obstetrical ultrasonography performed to assess fetal size and gestational age?), low back pain (Was radiography of the lumbar spine performed?), and (in men) difficulty urinating (Was excretory urography, cystography, or ultrasonography performed?).

We surveyed the *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)*,¹¹ selecting all codes that might reasonably represent diagnoses that would be entered by physicians whose patients presented with symptoms related to any of the four clinical presentations. A detailed tabulation of the codes is available elsewhere.*

We developed and applied to the claims data base a computer algorithm, modeled on previous methods, for defining episodes of outpatient medical care occurring in physicians' offices.¹² The date of a claim for an index ICD-9-CM code in an office setting was used to define the starting date of an episode. Episodes were considered to have ended after specified periods — four weeks for upper respiratory infection, nine months for pregnancy, six weeks for low back pain, and six weeks for difficulty urinating. Claims made between the initiation and termination dates of an episode were eligible for inclusion in that episode. Depending on the clinical presentation, a lag period of two to eight weeks followed the termination of each episode, so that follow-up visits for the original episode would not be counted as new episodes of care. The length of the episodes and lag periods was initially proposed on the basis of medical experience. We ensured that these durations were appropriate by evaluating the completeness of 600 randomly selected episodes and determining that the use of alternate durations for the episodes of up to two-thirds longer affected the number of episodes by only 1 to 6 percent in the case of the clinical presentations studied.

To be included in the study, episodes of care had to begin after January 1, 1986, and end before June 1, 1988. Episodes were excluded if the only physician involved in the episode was a radiologist or if the specialty of any physician involved was unknown. Within valid episodes, we deleted any claims for which no charge or payment was made, any claims for supplemental payments, and any claims for which the age or sex of the patient or the physician's identification number was unknown. We also excluded claims that were unrelated in terms of ICD-9-CM coding to the clinical presentations under investigation and claims made by physicians whose specialty codes indicated practices unrelated to the clinical presentations under study. A list of the specialties of the physicians included in the analysis is available elsewhere.*

The physicians who filed the claims included in the episodes studied were distinguished by their physician identification numbers; these numbers were coded to protect confidentiality. With regard to each clinical presentation, the physicians were grouped, according to their involvement in episodes for which they were the only nonradiologist physician to file a claim (one-physician episodes), into the following categories: self-referring physicians, who charged at least once for an index imaging examination; radiologist-referring physicians, who never charged for an index imaging examination and who were involved in at least one one-physician episode in which a radiologist performed such an examination; and physicians whose patients had no imaging in any one-physician episodes. One-physician episodes comprised 92 percent of all valid episodes.

We considered the possibility that some physicians categorized as radiologist-referring might actually be self-referring physicians who happened not to have performed any imaging in the episodes in our sample. We performed a correction to account for this possibility (details available elsewhere*). Since this correction did not alter the results, we report only our unadjusted data here.

The categorization of the physicians who participated in the one-physician episodes was used to develop six categories of similar and dissimilar pairs of physicians for the 7 percent of valid episodes in which two different physicians, neither a radiologist, cared for the patient (two-physician episodes). The 471 valid episodes (0.7 percent) in which more than two nonradiologist physicians were involved were not included in the analysis. We performed separate classifications of the one-physician and two-physician episodes on the basis of the categorization of the physicians and whether a claim for a related imaging examination was filed during the episode, as evidenced by the encountering of an appropriate diagnostic-imaging-procedure code (CPT-4 code; the table of index codes is available elsewhere*).

*See NAPS document no. 04816 for 16 pages of supplementary material. Order from NAPS c/o Microfiche Publications, P.O. Box 3513, Grand Central Station, New York, NY 10163-3513. Remit in advance (in U.S. funds only) \$7.75 for photocopies or \$4 for microfiche. Outside the U.S. and Canada add postage of \$4.50 (\$1.50 for microfiche postage).

For the one-physician episodes, our estimates of the frequency of imaging by the self-referring physicians and the radiologist-referring physicians were based on the observed frequencies for these two categories of physicians. Applying maximum-likelihood methods to the information we derived from our data about the imaging practices of self-referring and radiologist-referring physicians, we adjusted these observed frequencies to account for the episodes attributable to the physicians who had performed no imaging. This adjustment was based on the assumption that the imaging practices of the physicians within each category were homogeneous. However, this was almost certainly not the case. As a result, the correct adjustment of the observed frequencies is uncertain. For this reason, we report here the most likely estimates of the imaging frequencies for the self-referring and the radiologist-referring physicians. In addition, to account for heterogeneity in the physicians' imaging practices, we developed estimates biased upward and downward that show that our results are not affected qualitatively by the choice of the adjustment for the episodes involving the physicians who performed no imaging over the entire range of possible adjustments. The methods we employed, the initial categorization of the physicians and classification of episodes, and the upward- and downward-biased estimations of imaging frequencies are available elsewhere.*

For the analyses of both the one-physician and the two-physician episodes, we assessed the differences between self-referring and radiologist-referring physicians in terms of the proportion of episodes that involved imaging, the charges for imaging performed, and the average imaging charges per episode. To calculate the results for the group, we weighted the results for individual physicians according to the number of episodes in which they were involved. The significance of the differences between self-referring and radiologist-referring physicians was determined by the usual t-statistic for the difference in means between the two groups. We conducted a similar analysis based on the specialties of the physicians involved in the episodes, to compare differences within specialties. The null hypothesis of no difference was rejected at a P level of <0.05.

For each clinical presentation, we compared the complexity of the imaging examinations performed by the self-referring physicians with that of the examinations performed by the radiologists by calculating the mean (\pm SD) relative values of their procedures (i.e., a measure of the complexity of the procedure).¹³

The data base generated 62,880 one-physician episodes for the four study groups. After exclusions (see Methods), there were 60,829 valid episodes involving 6419 physicians. One-physician episodes represented 92 percent of all valid episodes. These were distributed as follows: upper respiratory symptoms, 47,794 episodes involving 3452 physicians; normal pregnancy, 1377 episodes involving 468 physicians; back pain, 9634 episodes involving 2001 physicians; men with difficulty urinating, 2024 episodes involving 498 physicians.

Table 1 shows the frequencies with which imaging was used during the episodes, the charges for imaging, and the charges for imaging per episode for self-referring and radiologist-referring physicians. The mean imaging charges of the self-referring physicians were significantly higher (P for all comparisons, <0.0001) than those of the radiologists for all clinical presentations except difficulty urinating. Depending on the clinical presentation, the episodes involving self-referring physicians resulted in imaging 4.0 to 4.5 times as frequently, with average imaging charges per episode 4.4 to 7.5 times higher than those for the episodes involving radiologist-referring physicians (P<0.0001 for each clinical presentation, for both frequency of imaging and average imaging charges per episode).

There were 4688 valid two-physician episodes, or 7 percent of all episodes. The results for these episodes support the findings in the one-physician episodes. Depending on the clinical presentation, the episodes involving two self-referring physicians were 1.7 to 3.7 times as likely to result in imaging as episodes involving two radiologist-referring physicians (P<0.01 for each presentation). Complete results for all six categories of physician pairs are available elsewhere.*

TABLE 1

Categories of Physicians and Episodes, Frequencies of Imaging, and Imaging Costs in One-Physician Episodes.*

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For each specialty and each clinical presentation, the self-referring physicians performed imaging 2.4 to 11.1 times as often as the radiologist-referring physicians, and at a cost per episode for imaging that was 3.0 to 17.1 times higher, depending on the specialty and clinical presentation (Table 2) ($P < 0.01$ for each specialty studied with regard to each clinical presentation).

The mean (\pm SD) complexity score for chest films was 3.02 ± 0.14 for self-referring physicians, and 3.00 ± 0.20 for radiologist-referring physicians. For obstetrical ultrasonography, the comparison was 11.24 ± 1.14 versus 11.35 ± 0.96 ; for lumbar spine films, 3.98 ± 0.63 versus 4.14 ± 0.52 ; and for the combination of urography, cystography, and ultrasonography, 8.46 ± 0.70 versus 8.35 ± 0.43 . Thus, the differences in complexity ranged from 1 to 4 percent and do not account for the differences identified in the charges for imaging.

For the clinical presentations we studied, patients with similar sets of symptoms were at least four times as likely to have diagnostic imaging performed as part of their evaluation if they sought care from a physician who performed imaging examinations in the office rather than from one who referred patients to a radiologist. Because self-referring physicians performed imaging studies more frequently and generally charged more than radiologists for similar imaging procedures, patients seeking care from self-referring physicians incurred considerably higher charges for diagnostic imaging than patients whose physicians referred them to radiologists. These effects cannot be attributed to differences in the mix of patients, the specialties of the physicians, or the complexity of the imaging examinations performed.

Previously, Childs and Hunter¹⁴ found that physicians other than radiologists who provided imaging services used imaging more frequently than their peers in caring for elderly patients in Northern California. In a 1978 survey of 5447 physicians, Radecki and Steele¹⁵ determined that nonradiologist physicians with imaging facilities either in their offices or at the same site have higher rates of use than physicians without such facilities. A similar study of the effect of the site of imaging facilities used by family practitioners produced a similar result.¹⁶

The differences between our study and those performed previously include the relatively large number of patients and physicians we studied and the emphasis on specific clinical situations and episodes of medical care. Analyzing episodes of care permitted us to focus directly on the issue that seemed most pertinent — whether individual patients with specific symptoms were more likely to receive imaging examinations when their physicians operated imaging equipment. As compared with the global measures used in previous studies, this method controls better for other variables — physicians' specialization, the complexity of examinations, differences in the types of patients seen by physicians, and the number of patient—physician encounters that might occur during the course of a patient's medical care. Finally, the focus on episodes as the unit of analysis allows a more accurate assessment of the activities and costs of medical care, the chief focus of our study.¹²

We have attempted to account for what we perceive to be the major possible biases of our study. After assessing the effect of correcting our results to account for the small percentage of physicians who had probably been miscategorized, and evaluating alternative probabilistic models for assigning the episodes involving physicians whom we could not categorize definitively, we found that these considerations did not affect the results qualitatively (details of these assessments and the adjusted results are available elsewhere*). Our population of patients did not represent the American population, geographically or according to age. However, the geographic concentration tended to lessen the effects of regional differences in practice patterns, and it seems implausible that the large differences we identified in the use of imaging would be related to age. Although there is no assurance that the clinical presentations we studied represent the imaging practices of physicians in other clinical settings, the dimensions and consistency of our findings with regard to four very different clinical presentations and types of imaging examinations suggest that this practice pattern may be widespread.

We based our methods on those used by previous investigators,^{12, 17, 18} but with adaptations to account for the large number of physicians and patients in our data base. Doubtless, the initial visits to physicians that triggered episodes of outpatient care occurred in an undefined context of patients' seeing their personal physicians, being referred by one physician to another, and seeking the specialist they believed to be appropriate. Although the manner in which the patients ended up seeing the physicians they did might potentially have affected the results, it is important to note that the results were uniformly sustained in our analysis of individual specialties. Also, with regard to our means of defining the index symptoms, determining the start of episodes, and including claims in episodes, there is nothing to suggest that our choices unequally biased the probability of imaging or the imaging charges in favor of either self-referring or radiologist-referring physicians. We believe that the differences between these two groups of physicians are so considerable that such issues have little relevance to the results.

TABLE 2

Frequency of Imaging and Costs per Episode in One-Physician Episodes, According to the Specialty of the Physician.*

Our findings of increased use of imaging and increased costs attributable to nonradiologist physicians who operate their own imaging equipment should be of interest to regulatory and reimbursement agencies. It is impossible to determine from our results whether the imaging practices of the self-referring physicians or those of the radiologist-referring physicians represent the more appropriate care. Nor is it possible to determine the extent to which financial incentives are responsible for the higher levels of use and charges among the self-referring physicians. These physicians may perform imaging more frequently because they have financial incentives to do so, because imaging is more convenient when performed in a physician's office, or because physicians who perform imaging more often are more likely to acquire imaging equipment. Nonetheless, the differences between the self-referring and radiologist-referring physicians in the use of imaging are so large that some concern over the role of financial incentives must be invoked. Schroeder and Showstack¹⁹ have detailed the potent financial incentives for a physician to incorporate imaging into an office practice. More recently, Hemenway et al.²⁰ validated this concern by showing an increase in the use of imaging when a group of ambulatory clinics changed to a method of compensation that used the frequency with which physicians ordered imaging examinations as the basis for paying them.

The American Medical Association has stated that the referral of patients to facilities in which physicians have an ownership interest is permissible, provided that patients are apprised of this relation and have other choices, and provided that physicians always act in their patients' best interests.²¹ With respect to diagnostic imaging, however, it is unlikely that patients, even if so apprised, will be able to assess the appropriateness of such referrals accurately or seek imaging elsewhere. Particularly in the office setting, patients cannot be said to have a meaningful choice when their physicians advise them to undergo imaging. The potential to self-refer patients for imaging must surely complicate physicians' decisions and perhaps jeopardize their obligation to place their patients' interests above their own.

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Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population

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Objectives and Rationale.—For 10 common clinical presentations, we assessed differences in physicians' utilization of and charges for diagnostic imaging, depending on whether they performed imaging examinations in their offices (self-referral) or referred their patients to radiologists (radiologist-referral).

Methods.—Using previously developed methodologies, we generated episodes of medical care from an insurance claims database. Within each episode, we determined whether diagnostic imaging had been performed, and if so, whether by a self-referring physician or a radiologist. For each of the 10 clinical presentations, we compared the mean imaging frequency, mean imaging charges per episode of care, and mean imaging charges for diagnostic imaging attributable to self- and radiologist-referral.

Results.—Depending on the clinical presentation, self-referral resulted in 1.7 to 7.7 times more frequent performance of imaging examinations than radiologist-referral ($P < .01$, all presentations). Within all physician specialties, self-referral uniformly led to significantly greater utilization of diagnostic imaging than radiologist-referral. Mean imaging charges per episode of medical care (calculated as the product of the frequency of utilization and mean imaging charges) were 1.6 to 6.2 times greater for self-referral than for radiologist-referral ($P < .01$, all presentations). When imaging examinations were performed—including those performed in both physicians' offices and hospital outpatient departments—mean imaging charges were significantly greater for radiologists than for self-referring physicians in seven of the clinical presentations ($P < .01$). This result is related to the high technical charges of hospital outpatient departments; in office practice, radiologists' mean charges for imaging examinations were significantly less than those of self-referring physicians for seven clinical presentations ($P < .01$).

Conclusions.—Nonradiologist physicians who operate diagnostic imaging equipment in their offices perform imaging examinations more frequently, resulting in higher imaging charges per episode of medical care. These results extend our previous research on this subject by their focus on a broader range of clinical presentations; a mostly elderly, retired population; and the inclusion of higher-technology imaging examinations.

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DURING the last decade, direct payments for physicians' services tripled, from \$41.9 billion to \$125.7 billion.¹ In large part, this has been due to an increase in the number of services provided to patients.^{2,3} One phenomenon promoting greater intensity of care is physicians increasingly adopting more and more complex technologies into their office practices.³ Physicians then can "self-refer" their patients to these technologies. Self-referral has been shown to be associated with higher-technology utilization than when physicians refer their patients to specialists employing these same technologies.^{4,7}

See also p 2055.

Previously, we demonstrated that, for each of four common clinical presentations, self-referring physicians employed diagnostic imaging at least four times as frequently as their colleagues who referred imaging examinations to radiologists. Self-referring physicians also charged significantly more for performing and interpreting imaging studies in their offices than did radiologists.⁷ This investigation employs similar methodology to expand upon our previous work assessing physicians' utilization of and charges for diagnostic imaging by studying a mostly elderly, chronically ill patient population that is of particular interest with regard to Medicare reimbursement; evaluating a broader array of imaging technologies and clinical presentations; more extensively portraying imaging charges; and assessing

patients with 10 common clinical presentations, including three of the four presentations investigated in our previous research.

METHODS

Insurance Claims Database and Clinical Presentations

Access to the insurance claims database used in this investigation was provided without charge by the United Mine Workers of America Health and Retirement Funds (Funds). Reimbursement for physicians' claims and the claims database are administered for the Funds by Alta Health Strategies, Inc (Alta). We investigated the portion of the database representing all physicians' claims for all Funds beneficiaries, regardless of age, rendered during the 2-year period January 1, 1988, through December 31, 1989. The claims history file records the billed charge for all line items for each claim.

Funds beneficiaries and their dependents receive full reimbursement, with no copayments, for outpatient diagnostic imaging examinations. The Funds administers both the Medicare and supplemental insurance components of physician reimbursements for Funds beneficiaries (84% of Funds beneficiaries are covered by Medicare Part B).

The Funds database details the health insurance coverage for their approximately 119 000 beneficiaries. Of these, 79% are 65 years or older. Thirty-four percent are male. Eighty percent live in the Appalachian coal-mining region.

Using this database, we compared the frequency of imaging and the imaging charges accrued during episodes of acute care of self-referring physicians with those of radiologist-referring physicians for 10 clinical presentations. The clinical presentations and their associated imaging examinations were chosen to obtain a broad distribution of anatomic locations, variety of imaging examinations, and sophistication of imaging technology, as well as for their frequency of appearance in the Funds' claims database and the imaging costs they represented to the Funds.

The 10 clinical presentations selected included three of the four clinical presentations investigated in our earlier research,⁷ including (with the associated imaging examinations) acute upper respiratory tract symptoms (plain films, fluoroscopy), men with trouble urinating (excretory urography, cystourethrography, sonography), and low-back pain (plain films, myelography, diskography, computed tomography [CT], magnetic resonance [MR]). Additional clinical presentations investigated in this study

were headache (CT, MR), transient cerebral ischemia (CT, MR, sonography including Doppler studies, angiography), upper gastrointestinal bleeding (plain films, barium studies), knee pain (plain films, arthrography, CT, MR), urinary tract infection (plain films, excretory urography, cystourethrography, sonography, CT, MR), chest pain (plain films, barium studies, radionuclide studies), and congestive heart failure (plain films, echocardiography, real-time and Doppler sonography, angiography, radionuclide studies). A complete list of the radiologic procedure (CPT-4) codes⁸ counted in the analysis for each clinical presentation can be obtained from the National Auxiliary Publications Service (NAPS).

Development of Episodes of Medical Care

We previously have detailed the methods employed to define episodes of outpatient care.⁷ Briefly, for each of the 10 clinical presentations, we defined all diagnostic (ICD-9) codes⁹ that physicians reasonably might enter on their claims for services to these patients. The ICD-9 codes selected for each clinical presentation (index ICD-9 codes) can be obtained from NAPS. Each of the 10 clinical presentations was analyzed separately.

We applied to the database a version of the computerized algorithm we employed in our earlier work.⁷ Briefly, an episode was initiated by a physician's claim for a service related to an index ICD-9 code. The date of this service represented the starting date of the episode; the episode concluded after a fixed period of time, the amount of time depending on the clinical presentation. All claims from physicians with specialties relevant to the clinical presentation (see NAPS deposit), for office and hospital outpatient services, encountered between the beginning and end dates for the episode were eligible for inclusion in the episode. A lag period was observed immediately following each episode, during which neither an index ICD-9 code nor index CPT-4 code either counted as part of the previous episode or initiated a new episode. This restriction prevented the misclassification of a follow-up service as the initiation of a new episode. The durations of episodes and lag periods for each clinical presentation can be obtained from NAPS. The appropriateness of the durations of episodes and lag periods was established and tested by the same methods we have previously described.⁷

Episodes were eligible for inclusion in the analysis if they were triggered by an appropriate index ICD-9 code, with

a service date on or after January 1, 1988, and were completed by December 31, 1989. Because we were unable to determine which of two or more physicians decides whether to perform an imaging examination, we excluded episodes where multiple nonradiologist physicians cared for the patient or where services other than laboratory or radiology were provided in a hospital outpatient department (10% of episodes). Since we could not reliably categorize imaging services as self- or radiologist-referral when multispecialty group practices provided both radiologic and other services, we excluded episodes occurring in clinics and when a provider was involved in numbers of episodes greater than 2 SD from the mean. Following these exclusions, the episode files included 50% to 75% of the original episodes for the 10 clinical presentations.

Individual claims within valid episodes were excluded if the services were unrelated to the clinical indication or provided in nondesignated settings or if there was no charge for the claim.

Designation of Physicians as Self-referring or Radiologist-Referring

Each nonradiologist provider (defined by their primary specialty code and/or having less than 75% of their claims being for imaging procedures) was designated individually as "self-referring," "radiologist-referring," or "unknown," separately, for each clinical presentation in which he or she participated. A self-referring physician was one who at least once during the 2-year period submitted a claim for performing an index imaging study, even if he or she also referred a patient to a radiologist. A radiologist-referring physician never submitted a claim for an index imaging study and at least once participated in a valid episode in which the patient was referred to a radiologist for imaging. An unknown physician did not participate in a valid episode during which either he or a radiologist performed an index imaging examination.

Classification of Episodes and Estimation of the Frequency of Imaging

We classified the episodes of self- and radiologist-referring physicians on the basis of whether imaging was performed. This provided us with the observed frequencies of imaging for these two groups. These observed frequencies overestimate the actual imaging rates of self- and radiologist-referring physicians, since they do not account for physicians who were not involved in episodes where imaging occurred (the "unknown"

Table 1.—Primary Estimates of Imaging Frequency for Self-referring and Radiologist-Referring Physicians*

Clinical Presentation	Imaging Frequencies†		Ratio (95% Confidence Interval)
	Self-referring Physicians (No. of Episodes)	Radiologist-Referring Physicians (No. of Episodes)	
Chest pain	0.31 (4389)	0.16 (12 842)	1.9 (1.8-2.1)
Congestive heart failure	0.25 (13 588)	0.09 (24 840)	2.7 (2.5-2.8)
Difficulty urinating	0.11 (1111)	0.05 (5990)	2.2 (1.5-2.9)
Gastrointestinal bleeding	0.23 (1159)	0.13 (12 074)	1.7 (1.5-2.0)
Headache	0.30 (275)	0.07 (6674)	4.3 (3.3-5.4)
Knee pain	0.40 (2698)	0.05 (5191)	7.7 (6.6-8.7)
Low-back pain	0.21 (7381)	0.06 (21 179)	3.6 (3.4-3.9)
Transient cerebral ischemia	0.60 (334)	0.13 (2531)	4.7 (3.9-5.4)
Upper respiratory tract infection	0.30 (10 781)	0.13 (21 552)	2.3 (2.2-2.4)
Urinary tract infection	0.11 (1731)	0.05 (18 280)	2.4 (1.9-2.8)

*Estimates were rounded to the nearest percentage. All differences between self- and radiologist-referring physicians are statistically significant, $P < .01$.

†Imaging frequency is the number of episodes containing one or more imaging claims divided by the total number of episodes.

group). To correct for this deficiency, we employed the same method of maximum likelihood estimation as in our previous study⁷ (detailed in the NAPS deposit) to estimate the imaging frequencies for all self-referring and radiologist-referring physicians, including those in the unknown group, as the proportion of episodes for each physician group in which imaging was performed. Our method of maximum likelihood estimation is based on the expectation that, within physician designations as self- or radiologist-referring, physicians' imaging practices are uniform. However, this may not strictly be the case. Thus, as in our previous study,⁷ we performed upward and downward biased estimates to represent "worse case" scenarios, embodying the maximum departures from the primary estimate that could result if there were no similarities among the practices of self-referring or radiologist-referring physicians (described in the NAPS deposit).

Comparison of Physicians' Charges and Correction for the Complexity of Imaging Examinations

Our analysis of charges for imaging examinations included all global, professional, and technical charges in both the office and hospital outpatient settings.

We compared the total charges for imaging for all episodes in the database, whether or not imaging occurred. The result, termed "mean imaging charges per episode," is calculated as the product of the mean charges for diagnostic imaging claimed during episodes in which imaging occurred and the frequency of imaging.

To assess the influence of differences in the complexity of examinations on differences in mean imaging charges per episode, we assigned to each imaging service its relative value (in relative value units [RVU]), according to the relative value scale used through 1991 for

payment for imaging services provided to Medicare patients.¹⁰ Dividing the mean charge by the mean RVU provided the measurement "mean charge per RVU," which we used to compare the charges of self- and radiologist-referring physicians for comparable work. Because hospitals apply high technical charges to imaging performed in their hospital outpatient departments and because financial incentives to perform imaging examinations usually differ in office and hospital outpatient practice, we performed this analysis separately for episodes in which imaging solely in physicians' offices.

Analysis

Differences between self- and radiologist-referring physicians' estimated frequency of imaging and imaging charges were tested for statistical significance by unpaired *t* tests of the difference in means between the two groups. Differences were considered statistically significant at $P < .01$.

We also conducted an analysis of imaging utilization for selected individual physician specialties, investigating the imaging practices of a specialty for a clinical presentation if the number of episodes was large enough that the error of the estimate of the frequency of imaging for all physicians of that specialty was less than one fourth the magnitude of the estimate and there were at least 25 self-referring and 25 radiologist-referring physicians in the sample for each such analysis.

RESULTS

The claims database yielded 174 800 episodes for the 10 clinical presentations (Table 1).

The Frequency of Diagnostic Imaging

The primary estimates of imaging frequencies for self-referring physicians were significantly greater than the im-

aging frequencies of radiologist-referring physicians for all 10 clinical presentations (all presentations, $P < .01$). The ratios of the frequency of imaging varied considerably with the clinical presentation. Self-referring physicians employed imaging 7.7 times as frequently as radiologist-referring physicians for knee pain but only 1.7 times as often for gastrointestinal bleeding (Table 1).

Upward biased estimates sustained the essential result of significantly greater imaging by self-referring physicians for all clinical presentations ($P < .01$). However, in three clinical presentations, the downward biased estimate resulted in differences between self- and radiologist-referral that were not statistically significant (difficulty urinating, gastrointestinal bleeding, and transient cerebral ischemia). In two other clinical presentations, the downward biased estimates indicated imaging utilization by radiologist-referring physicians significantly greater than that of self-referring physicians (headache and urinary tract infection). A table of biased estimates is available from NAPS.

Twenty-one clinical presentation-physician specialty combinations met the screening criteria for investigation of specialty-related imaging practices. Six clinical presentations were represented in general practice, four each in internal medicine and family practice, two in general surgery, cardiology, and orthopedic surgery, and one in pulmonology. In all cases, the primary estimates indicated that self-referring physicians employed imaging significantly more frequently than radiologist-referring physicians (all specialty-clinical presentation pairs, $P < .01$) (Table 2). The ratio of the frequencies of imaging (self-referring/radiologist-referring) ranged from 1.5:1 to 4.8:1 for different clinical presentations and specialties. The finding that self-referring physicians employ imaging significantly more frequently than radiologist-referring physicians was sustained

Table 2.—Primary Estimates of Imaging Frequency by Selected Physician Specialties*

Physician Specialty and Clinical Presentation	Imaging Frequency†		Ratio (95% Confidence Interval)
	Self-referring Physicians (No. of Episodes)	Radiologist-Referring Physicians (No. of Episodes)	
Cardiology			
Chest pain	0.38 (390)	0.19 (1327)	2.0 (1.6-2.4)
Congestive failure	0.30 (2195)	0.13 (1314)	2.4 (2.0-2.5)
Family practice			
Chest pain	0.30 (784)	0.16 (2442)	1.8 (1.5-2.1)
Congestive failure	0.20 (2472)	0.10 (5036)	2.1 (1.8-2.3)
Low-back pain	0.20 (1269)	0.05 (4475)	3.8 (3.1-4.5)
Upper respiratory tract infection	0.31 (2834)	0.13 (4216)	2.3 (2.1-2.5)
General practice			
Chest pain	0.30 (2025)	0.16 (5058)	1.9 (1.7-2.1)
Congestive failure	0.25 (4985)	0.09 (10458)	2.7 (2.5-3.0)
Gastrointestinal bleeding	0.20 (618)	0.13 (4081)	1.5 (1.2-1.8)
Knee pain	0.25 (691)	0.05 (1946)	4.8 (3.5-6.1)
Low-back pain	0.19 (2542)	0.05 (8448)	3.5 (3.0-4.0)
Upper respiratory tract infection	0.28 (4352)	0.11 (6721)	2.4 (2.2-2.7)
General surgery			
Low-back pain	0.23 (545)	0.07 (1350)	3.1 (2.3-3.9)
Upper respiratory tract infection	0.30 (726)	0.15 (1660)	1.9 (1.6-2.3)
Internal medicine			
Chest pain	0.33 (990)	0.14 (3633)	2.3 (2.0-2.6)
Congestive failure	0.25 (3715)	0.09 (7856)	2.8 (2.6-3.1)
Low-back pain	0.16 (1274)	0.05 (5693)	2.9 (2.3-3.5)
Upper respiratory tract infection	0.33 (2030)	0.16 (4581)	2.0 (1.8-2.2)
Orthopedic surgery			
Low-back pain	0.28 (1666)	0.12 (511)	2.3 (1.6-3.0)
Knee pain	0.58 (1307)	0.30 (135)	1.9 (1.3-2.5)
Pulmonology			
Upper respiratory tract infection	0.34 (360)	0.20 (184)	1.7 (1.1-2.4)

*Estimates were rounded to the nearest percentage. All differences between self- and radiologist-referring physicians are statistically significant, $P < .01$.
 †Imaging frequency is the number of episodes containing one or more imaging claims divided by the total number of episodes.

in all 21 upward biased estimates and 19 of 21 downward biased estimates ($P < .01$). In two cases—general practitioners seeing patients for gastrointestinal bleeding and internists for patients with low-back pain—the differences in the downward biased estimates were not significantly different.

Imaging Charges

Mean imaging charges per episode—for all episodes, including both office and hospital outpatient department settings and regardless of whether an imaging examination occurred—are detailed in Table 3. For all 10 clinical presentations, mean imaging charges per episode were 1.6 to 6.2 times greater for self-referral than for radiologist-referral ($P < .01$, all clinical presentations).

When all episodes with imaging were considered—including office and hospital outpatient examinations—charges per RVU for self-referral were 0.8 to 1.0 of the charges per RVU referable to radiologist-referral, depending on the clinical presentation. However, the comparison of charge per RVU for examina-

Table 3.—Imaging Charges per Episode of Care*

Clinical Presentation	Charges per Episode, \$†		Ratio
	Self-referral	Radiologist-Referral	
Chest pain	29	19	1.6
Congestive heart failure	41	7	6.2
Difficulty urinating	19	8	2.3
Gastrointestinal bleeding	38	24	1.6
Headache	117	36	3.3
Knee pain	31	5	6.2
Low-back pain	34	13	2.5
Transient cerebral ischemia	242	65	3.7
Upper respiratory tract infection	19	9	2.2
Urinary tract infection	32	13	2.4

*Charges were rounded to the nearest dollar.
 †Charges were calculated as the product of the percentage of episodes in which imaging occurred (ie, imaging frequency) and the mean imaging charge in episodes with imaging.

tions performed in office practice indicates that these differences are attributable to the technical charges billed by hospitals and the fact that almost all imaging examinations in hospital outpatient departments are performed by radiologists. For examinations performed in office practice, self-referral results in charges per RVU 0.9 to 1.3 times the charges per RVU of radiologists.

COMMENT

This investigation both extends and confirms our previous research into how physicians' ownership of diagnostic imaging technology in their office practices affects imaging utilization and charges. The major differences between our previous and current research include the nature of the patient and physician

populations. Also, the present investigation evaluates a broader range of clinical presentations and assesses utilization of both conventional and more advanced imaging technologies. Finally, we were able to extend our evaluation of charges for imaging examinations to include the hospital outpatient setting. Despite these differences, the essential result remains unchanged: physicians who own imaging technology employ diagnostic imaging in the evaluation of their patients significantly more often and, as a result, generate 1.6 to 6.2 times higher average imaging charges per episode of care than do physicians who refer imaging examinations to radiologists. This result is reinforced by the consistent result of significantly greater utilization associated with self-referral in our specialty-based analysis.

In this study, differences in imaging utilization between self- and radiologist-referring physicians were more varied with respect to clinical presentation than in our previous research. Almost certainly, this is attributable to characteristics of the patient population. The Funds' beneficiaries are, overwhelmingly, elderly and, because of their work histories, prone to a variety of chronic ailments. As such, they are very different from the generally healthy, younger, working individuals we evaluated in our initial research.

The large differences between self- and radiologist-referring physicians' mean imaging charges per episode are almost entirely attributable to differences in utilization. Differences in charges for imaging examinations and the complexity of examinations are largely referable to the setting in which the examinations were performed. Examinations performed by radiologists in hospital outpatient departments usually generate higher overall charges be-

cause of the high technical charges filed by hospitals. Medicare, on average, pays 58% of these charges.¹¹ In office practice, self-referring physicians generally charge higher fees than radiologists for comparable examinations.

In recent years, physicians' referral of their patients to medical technologies in which they have a financial interest has gained increasing attention as a significant problem promoting increasing health care costs. Investigations demonstrating that self-referral promotes greater frequency of technology utilization,^{4,7} studies indicating that a financial incentive may motivate the higher frequency of self-referral,¹²⁻¹⁵ and articles in the lay press discussing these findings have negatively affected public perceptions about the medical profession (*Wall Street Journal*, March 1, 1989; *Christian Science Monitor*, December 8, 1988). Although it is difficult to determine what proportion of the higher utilization associated with self-referral might be inappropriate, it has not been shown that more frequent application of office-based ancillary technologies provides a consonant benefit in improving patients' health.

These considerations motivated the United Mine Workers of America Health and Retirement Funds to participate in our continuing research into the costs associated with self-referral for diagnostic imaging. The Funds face a difficult financial future. While the cost of health care for the Funds' beneficiaries continues to increase, contributions to the Funds' financial base from the participating coal companies are declining. Thus, the Funds must identify means of controlling their expenditures that still sustain the high quality of care their beneficiaries receive. This research has provided information that may guide the Funds and other payers in developing

new policies with respect to payment for self-referred imaging. One possible policy would be to deny payment for self-referred imaging, or to deny payment to specific specialties or individual physicians shown to utilize imaging technology at significantly higher rates than other specialties or their peers. The Funds could choose to reduce financial incentives for self-referral by reimbursing self-referred imaging at a lower level than it pays for referred examinations or bundling payment for imaging as part of the reimbursement for an office visit. Alternatively, the Funds might develop standards for image quality and physician training for different examinations, much as standards have been developed for reimbursing claims for mammography under Medicare. Nonqualified practices would become ineligible for reimbursement of their claims.

Each of these alternatives is accompanied by potential political consequences and might potentially affect patient care. The activation of policies regarding self-referral by a payer such as the Funds may provide a demonstration for government and other payers of the effects of restricting self-referral on patient access to diagnostic imaging, the quality of care patients receive, and imaging-related expenditures.

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EXHIBIT D

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Abbreviations:

CPT-4 = Current Procedural
Terminology, 4th Edition
EF = ejection fraction
HCFA = Health Care Financing
Administration
MPI = myocardial perfusion imaging
WM = wall motion

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Guarantors of integrity of entire study, all authors; study concepts and design, all authors; literature research, D.C.L.; data acquisition, L.P., J.H.S.; data analysis/interpretation, all authors; statistical analysis, L.P.; manuscript preparation, D.C.L.; manuscript definition of intellectual content, editing, revision/review, and final version approval, all authors.

Recent Rapid Increase in Utilization of Radionuclide Myocardial Perfusion Imaging and Related Procedures: 1996-1998 Practice Patterns¹

PURPOSE: To evaluate cardiac nuclear medicine practice patterns in different physician specialty groups to better understand a recent rapid increase in utilization of radionuclide myocardial perfusion imaging (MPI) and certain supplementary examinations.

MATERIALS AND METHODS: National Medicare Part B databases from 1996 and 1998 were used to evaluate utilization of four primary procedure codes for radionuclide MPI and two supplementary codes (add-on left ventricular wall motion or left ventricular ejection fraction). Utilization rates were calculated for cardiologists, radiologists, and other physicians. Other cardiac imaging for which radionuclide imaging might be substituted was similarly studied.

RESULTS: Overall utilization rate of radionuclide MPI per 100,000 Medicare beneficiaries increased 19.1%, from 4,046 in 1996 to 4,820 in 1998 ($P < .001$). However, for cardiologists the rate increased from 1,771 to 2,413 (36.3%), whereas for radiologists it increased from 1,958 to 2,031 (3.7%) ($P < .001$ for both changes). Overall utilization rate of add-on codes increased 264% from 1,006 to 3,657 ($P < .001$). By 1998, the ratio of these add-on examinations to primary MPI was 0.94 among cardiologists compared with 0.53 among radiologists (relative risk, 1.77; 95% CI: 1.76, 1.78). Cardiologist-performed stress echocardiography and cardiac catheterization and coronary angiography increased by 24.2% and 8.7%, respectively.

CONCLUSION: Growth in utilization of radionuclide MPI between 1996 and 1998 was almost 10 times higher among cardiologists than radiologists. Utilization of the two add-on codes increased even more dramatically. The greater use of MPI is not a substitute for other cardiac imaging.

In recent years, radionuclide myocardial perfusion imaging (MPI) has become the principal method of noninvasively imaging suspected coronary artery disease. This technique provides greater sensitivity and specificity than does exercise electrocardiographic stress testing alone (1,2). The addition of electrocardiographic gating and technetium 99m-labeled radioisotopes, such as ^{99m}Tc sestamibi and ^{99m}Tc tetrofosmin, have brought further improvements. An important advantage of ^{99m}Tc-labeled compounds, aside from providing better counting statistics for MPI, is that they also allow determination of regional and global left ventricular wall motion (WM) and left ventricular ejection fraction (EF) (2). In 1992, largely as a result of this development, two new codes were incorporated into the nuclear medicine section of the Current Procedural Terminology, 4th Edition (CPT-4) coding manual (3). Codes 78478 and 78480 for left ventricular WM and left ventricular EF, respectively, were specifically designated as "add-on" codes. That is, users of the manual were instructed that these two codes were to be used only in conjunction with one of the four primary codes (78460, 78461, 78464, or 78465) for radionuclide MPI.

Although there is little doubt about the utility of assessing myocardial perfusion and left

TABLE 1
Cardiac Radionuclide Imaging Codes in 1998

CPT-4 Code	Descriptor	Global Relative Value Units*	No. of Examinations Performed†
78460	MPI; (planar) single study, at rest or stress	3.75	11,740
78461	MPI; (planar) multiple studies, at rest and/or stress, and redistribution and/or rest injection	6.80	55,955
78464	MPI; tomographic (SPECT), single study at rest or stress	9.09	139,644
78465	MPI; tomographic (SPECT), multiple studies, at rest and/or stress and redistribution and/or rest injection	14.67	1,329,884
78478	WM (in addition to primary procedure)	2.57	673,050
78480	EF (in addition to primary procedure)	2.57	493,064
78472	CBPI, gated equilibrium; single study at rest or stress, WM plus EF	7.30	100,957
78473	CBPI, gated equilibrium; multiple studies at rest and stress, WM plus EF	10.89	16,403
78481	CBPI, first pass; single study at rest or stress, WM plus EF	6.99	43,126
78483	CBPI, first pass; multiple studies at rest and stress, WM plus EF	10.53	18,252

Note.—CBPI = cardiac blood-pool imaging, SPECT = single photon emission computed tomography.

* Refers to Medicare relative value units in 1998.

† 1998 values.

ventricular WM and EF by using radionuclide imaging techniques, concern has been raised about overutilization. The fiscal year 2000 work plan of the Office of Inspector General of the Department of Health and Human Services identified MPI as a medical service undergoing unusually rapid expansion in utilization, with a 23% increase in billing to the Health Care Financing Administration (HCFA), the administrator of the Medicare program, in just 1 year (4). Among the many thousands of physician services offered to patients, it was the only one specifically targeted by the Office of Inspector General for assessment for medical appropriateness.

The goal of this study was to evaluate cardiac nuclear medicine practice patterns among different physician specialty groups to better understand the rapid increase in utilization of these examinations.

MATERIALS AND METHODS

Our data sources were the HCFA Physician/Supplier Procedure Summary Master Files for 1996 and 1998. These files contain all Medicare Part B services performed nationwide by physicians for beneficiaries enrolled in the traditional fee-for-service Medicare program. In 1996 there were 38.1 million Medicare beneficiaries in the United States—33.2 million in traditional fee-for-service Medicare and an-

other 4.9 million enrolled in Medicare health maintenance organizations, or HMOs. In 1998 there were 38.5 million Medicare beneficiaries—31.9 million in traditional fee-for-service and 6.6 million others in Medicare HMOs. Because services to Medicare HMO patients are generally capitated and not handled directly by Medicare fiscal intermediaries, their records are not included in these files and were therefore not included in this study.

In the files, each physician service is classified in a number of ways. The first is by type of service by using the CPT-4 codes. A second classification is by the location where the service is performed by using one of 27 HCFA location codes. A third classification is by specialty of the physician provider by using one of 107 HCFA specialty codes. For the purposes of this study, physicians were categorized as cardiologists, radiologists (including nuclear medicine physicians), or other physicians.

Table 1 lists the CPT-4 codes that were analyzed and brief descriptors from the coding manual. The first four (78460, 78461, 78464, 78465) are the primary codes used for radionuclide MPI. The next two (78478 and 78480) are the add-on codes for determination of left ventricular WM or EF when used in conjunction with a primary MPI examination. The last four codes (78472, 78473, 78481, and 78483) are "freestanding" codes for WM and EF determination

when these examinations are performed separately and not in conjunction with an MPI. These four codes are used less frequently, usually in patients with some form of heart disease other than coronary disease; aside from determining the total number of these examinations performed, we did not analyze these codes further.

For each of the four primary MPI CPT-4 codes and the two add-on WM and EF codes, we first compared utilization rates during 1996 and 1998 among radiologists, cardiologists, and all other physicians. The difference in proportions for 1996 rates versus 1998 rates was calculated by using the *z* test. Since the rates are complete counts of the entire Medicare population rather than a sample, it might be argued that no inferential statistics are required. However, the particular counts obtained in 1996 and 1998 can be considered theoretically as samples of a superpopulation of samples influenced by various random factors and traditional sampling statistics, such as the *z* test, and can be calculated. Of course, population parameters change systematically from year to year in ways that may be associated with increased utilization—such as the aging of the Medicare population. While it would have been desirable to adjust for age differences, the data set utilized does not contain demographic information, and no adjustment was possible. Because the points are close in time, changes in such parameters are not great, and it is reasonable to treat these years as samples of a superpopulation. Since this confounder could not be eliminated, we caution that our inferential statistics should be considered descriptive rather than true tests of significance. We also calculated the percentages of the examinations performed by each of the three physician groups. We further analyzed the physician utilization rates according to location of the examinations. For this, we used the location codes for (a) hospital inpatient settings, (b) hospital outpatient settings, (c) private offices, and (d) a final group encompassing all other locations. Utilization rates were calculated as the number of examinations per 100,000 Medicare fee-for-service beneficiaries that year. We then calculated the ratios of the add-on WM and EF studies to the primary MPI studies according to physician specialty and location to determine if these variables influenced the utilization of WM and EF studies. The ratios were measures of the risk that a patient undergoing MPI would have a WM and/or EF

TABLE 2
Changes in Utilization Rates of Cardiac Radionuclide Imaging between 1996 and 1998 among Cardiologists, Radiologists, and Other Physicians in All Places of Service

Examination Type and Physician Category	1996*	1998*	Change* (%)
MPI†			
Cardiologists	1,771	2,413	36.3
Radiologists	1,958	2,031	3.7
Other physicians	317	376	18.6
Total	4,046	4,820	19.1
Add-on WM or EF‡			
Cardiologists	603	2,275	277
Radiologists	330	1,080	227
Other physicians	73	302	314
Total	1,006	3,657	264

Note.—For all differences between 1996 and 1998 rates, $P < .001$ (z test).

* Utilization per 100,000 Medicare beneficiaries.

† Four codes.

‡ Two codes.

study added. Relative risks (one ratio divided by another) and CIs were calculated separately for 1996 and 1998 utilization of add-on WM and/or EF studies in all places of service for cardiologists and other physicians versus radiologists.

Because increases in utilization of diagnostic studies like cardiac radionuclide imaging might be offset by decreases in utilization of other imaging tests that provide comparable or supplementary information, we also assessed stress echocardiography and cardiac catheterization. Cardiologists perform the majority of these procedures. We therefore compared 1996 and 1998 utilization rates among cardiologists for stress echocardiography (code 93350) and the seven codes encompassing adult cardiac catheterization and coronary angiographic procedures (codes 93510, 93511, 93526, 93539, 93540, 93543, and 93545).

HCEA uses eight "specialty" codes in which it is not actually possible to determine the medical specialty of the physician who provides the service—multispecialty clinic or group practice, ambulatory surgical center, portable x-ray supplier, clinical laboratory, independent physiological laboratory, skilled nursing facility, intermediate care nursing facility, and other nursing facility. We excluded claims filed under these specialty codes; they ac-

TABLE 3
Cardiac Radionuclide Imaging Performed by Radiologists, Cardiologists, and Other Physicians during 1996 and 1998 in All Places of Service

Examination Type and Physician Category	1996*	1998*
MPI†		
Cardiologists	1,771 (43.8)	2,413 (50.1)
Radiologists	1,958 (48.4)	2,031 (42.1)
Other physicians	317 (7.8)	376 (7.8)
Total	4,046 (100.0)	4,820 (100.0)
Add-on WM or EF‡		
Cardiologists	603 (59.9)	2,275 (62.2)
Radiologists	330 (32.8)	1,080 (29.5)
Other physicians	73 (7.3)	302 (8.3)
Total	1,006 (100.0)	3,657 (100.0)

Note.—Data in parentheses are percentages.

* Utilization per 100,000 Medicare beneficiaries (specialty percentage).

† Four codes.

‡ Two codes.

counted for only 4% of all Medicare fee-for-service claims in 1998.

RESULTS

Data are presented in the Tables. Table 2 demonstrates 1996 and 1998 utilization rates per 100,000 Medicare beneficiaries among cardiologists, radiologists, and other physicians. Total utilization per 100,000 of the four MPI codes increased 19.1% from 4,046 in 1996 to 4,820 in 1998. However, the utilization rate increased 36.3% among cardiologists compared with only 3.7% among radiologists. Utilization of these codes by other physicians was considerably lower but increased 18.6% during the 2-year interval. The total utilization rate of the two add-on WM and EF codes increased 264% from 1,006 in 1996 to 3,657 in 1998. The growth in utilization of the latter two codes during the 2 years was high for all three physician groups—277% among cardiologists, 227% among radiologists, and 314% among other physicians. Differences in utilization rates between 1996 and 1998 reported in Table 2 all show probabilities of less than .001 by using the z-test. As we noted in the Materials and Methods section, these probabilities are to be interpreted descriptively rather than as customary significance tests.

Table 3 is derived from Table 2 and shows the percentages of MPI and add-on WM and/or EF examinations performed by radiologists, cardiologists, and other physicians during 1996 and 1998. During 1996, radiologists performed 48.4% of MPI examinations, while cardiologists performed 43.8%. By 1998, the cardiologists' share had increased to 50.1% while

radiologists' share had decreased to 42.1%. However, during the 2-year interval, the utilization rate among radiologists increased (from 1,958 to 2,031). The shift to the greater utilization proportion by cardiologists thus appears to be due to a much more rapid increase in their utilization (from 1,771 to 2,413), rather than to a shift in procedure volume from radiologists to cardiologists.

Table 4 further demonstrates overall physician utilization by categorizing it according to the place where the service was performed. The three principal places of service where imaging is performed are hospital inpatient settings, hospital outpatient settings, and private offices. All other locations were grouped together as a fourth category, but the table shows that utilization in this category was much less than in the three principal locations. The numeric columns in Table 4 show utilization rates per 100,000 beneficiaries for both 1996 and 1998, as well as the percentage change between them. For hospital inpatients, the utilization rate of MPI increased 21.8% between 1996 and 1998 among cardiologists (from 252 to 307) compared with 6.0% among radiologists (from 581 to 616). In hospital outpatient settings, where the utilization of MPI was considerably higher, the rate increased 18.2% between 1996 and 1998 among cardiologists (from 396 to 468) compared with 2.2% among radiologists (from 1,109 to 1,133). In private offices, cardiologist utilization increased 45.8% (from 1,115 to 1,626) during the period, whereas radiologist utilization increased 8.1% (from 223 to 241). The utilization of the add-on WM and/or EF codes between 1996 and 1998

TABLE 4
Changes in Rates of Utilization of Cardiac Radionuclide Imaging between 1996 and 1998
by Physician Category and Place of Service

Examination Type and Physician Category	Hospital Inpatient	Hospital Outpatient	Office	Other Locations	Total per Physician Category
MPI					
Cardiologists	252/307 (+21.8)	396/468 (+18.2)	1,115/1,626 (+45.8)	9/12 (+33.3)	1,771/2,413 (+36.3)
Radiologists	581/616 (+6.0)	1,109/1,133 (+2.2)	223/241 (+8.1)	45/41 (-8.9)	1,958/2,031 (+3.7)
Other physicians	67/64 (-4.5)	113/115 (+1.8)	134/193 (+44.0)	3/3 (0)	317/376 (+18.6)
Total	900/987 (+9.7)	1,618/1,716 (+6.1)	1,472/2,060 (+39.9)	57/56 (-1.8)	4,046/4,820 (+19.1)
Add-on WM or EF					
Cardiologists	45/182 (+304)	87/302 (+247)	466/1,781 (+282)	5/9 (+80)	603/2,275 (+277)
Radiologists	79/301 (+281)	152/550 (+262)	95/206 (+117)	4/24 (+500)	330/1,080 (+227)
Other physicians	11/38 (+245)	14/54 (+286)	48/207 (+331)	1/2 (+100)	73/302 (+314)
Total	135/521 (+286)	253/906 (+258)	609/2,194 (+260)	10/35 (+250)	1,006/3,657 (+264)

Note.—For all numbers in table, utilization per 100,000 Medicare beneficiaries for 1996/1998; data in parentheses are percentage change.

TABLE 5
Changes in Ratios of Add-on WM and/or EF Studies to Primary MPI Studies between 1996 and 1998

Physician Category	Hospital Inpatient	Hospital Outpatient	Office	Other Locations	Total
Cardiologists	0.18/0.59	0.22/0.65	0.42/1.10	0.56/0.75	0.34/0.94*
Other physicians	0.16/0.59	0.12/0.47	0.36/1.07	0.33/0.67	0.23/0.80†
Radiologists	0.14/0.49	0.14/0.49	0.43/0.85	0.09/0.59	0.17/0.53
Total	0.15/0.53	0.16/0.53	0.41/1.07	0.18/0.63	0.25/0.76

Note.—For all numbers in table, utilization ratios for 1996/1998.

* Relative risk is 2.02 (95% CI: 2.00, 2.04)/1.77 (95% CI: 1.76, 1.78) for cardiologists vs radiologists for all places of service.

† Relative risk is 1.38 (95% CI: 1.35, 1.40)/1.51 (95% CI: 1.49, 1.52) for other physicians vs radiologists for all places of service.

increased proportionately among cardiologists and radiologists in the hospital inpatient and outpatient settings. However, in private offices, utilization of these codes increased 282% among cardiologists compared with 117% among radiologists.

Table 5 shows the 1996 and 1998 ratios of add-on WM and EF studies to primary MPI studies. This ratio indicates the proportion of MPI examinations to which a WM or EF examination is appended. Since the physician performing the examination can elect to add both WM and EF studies to a basic MPI study, the ratio can range from 0 to 2.0. Ratios are shown for cardiologists, radiologists, and other physicians in each of the four place of service categories. The ratios in this table are derived from Table 4. For example, Table 4 shows that in 1996, the total utilization rate of WM or EF studies was 1,006 per 100,000 Medicare beneficiaries, while the total utilization rate of MPI that year was 4,046. The ratio is 1,006/4,046, or 0.25. Because the WM or EF codes can be used only in conjunction with MPI, this indicates that approximately 25% of all MPI studies were accompanied by a WM or EF determination in 1996. In 1998, this ratio was 3,657/4,820, or 0.76, indicating that by then

more than three-fourths of all MPI studies were accompanied by a WM or EF determination. In 1996, the ratio among cardiologists was 0.34 versus 0.17 among radiologists. By 1998, the ratio among cardiologists was 0.94 compared with 0.53 among radiologists. Analysis by location shows that the highest ratios were generally found in private offices. By 1998, the ratios among cardiologists and other physicians in private offices exceeded 1.0. Table 5 shows that for both 1996 and 1998, the relative risk of a patient undergoing WM and/or EF studies is higher for cardiologists and other physicians compared with radiologists.

We noted a different utilization pattern for the four freestanding WM and EF codes (78472, 78473, 78481, and 78483) than for the add-on codes. Claims under the freestanding codes were much less frequent than claims for the WM and EF studies. In 1996 there were 194,585 claims for the four freestanding codes and 333,820 for the two add-on codes; in 1998 there were 178,738 claims for the former and 1,166,114 for the latter. Thus, WM or EF determinations were much more commonly performed along with MPI as part of the evaluation of suspected coronary disease.

The utilization rate for stress echocardiography among cardiologists increased 24.2%, from 727 per 100,000 Medicare beneficiaries in 1996 to 903 in 1998. For the seven cardiac catheterization and/or coronary angiographic codes, the utilization rate among cardiologists in 1996 was 7,318 per 100,000 beneficiaries. By 1998, this rate had increased 8.7% to 7,958. Cardiologists performed 85.3% of all stress echocardiograms and 91.7% of all cardiac catheterization/coronary angiographic procedures in 1998.

DISCUSSION

Our data provide interesting insight into the concerns expressed about MPI in the Medicare program. Between 1996 and 1998 there was a substantial increase (19.1%) in the overall utilization rate of MPI. However, there was a striking difference between the practice patterns of radiologists and cardiologists. The utilization rate increased 3.7% among radiologists during the 2-year interval compared with 36.3% among cardiologists. As shown in Table 4, the most dramatic MPI increase among cardiologists occurred in private offices, with a 45.8%

increase in 2 years. In hospital settings, the utilization increase among cardiologists was more modest (21.8% for inpatients and 18.2% for outpatients). It is thus apparent that a major contributing factor in the increase in Medicare billing for radionuclide myocardial perfusion codes was the rapid increase in utilization of MPI by cardiologists.

Overall utilization of the add-on WM and EF codes increased far more rapidly (264%) than MPI between 1996 and 1998. This is perhaps not surprising, since these studies rely on the use of radioisotopes, nuclear camera improvements, and billing codes that have been developed relatively recently. As shown in the listing of relative value units in Table 1, these studies are considerably less costly than the primary MPI studies. Increases in rates of the WM and/or EF studies during the 2-year period were 277% among cardiologists, 227% among radiologists, and 314% among other physicians. The ratios shown in Table 5 represent a more direct measure of the tendency to utilize these supplementary procedures. This table shows that the ratios for cardiologists were considerably higher than for radiologists in both 1996 and 1998, in all locations. By 1998, the overall ratio for cardiologists was 0.94 compared with 0.53 for radiologists. The relative risk that patients undergoing an MPI examination performed by a cardiologist would also undergo an add-on WM and/or EF exam was 1.77 compared with the risk if the patient was referred for an MPI examination to a radiologist.

The rapid increase in use of cardiac radionuclide imaging might be justified if it was being substituted for other examinations for coronary artery disease. However, at the same time the increases in utilization of cardiac radionuclide imaging were occurring, cardiologists' use of stress echocardiography increased by 24.2%, and their use of cardiac catheterization and coronary angiography increased by 8.7%. Thus there was no evidence that the growth in utilization of radionuclide examinations resulted in lower utilization of these other related diagnostic studies.

MPI and the associated add-on WM and EF studies performed by cardiologists are often self-referred. The opportunity for physicians to self refer has been shown to be a potent stimulus to increased utilization of imaging studies. Hillman et al (5,6) demonstrated that self-referring physicians who operated their own imaging equipment used 2-8 times as many imaging studies as did

physicians who referred their patients to radiologists. Findings of a large-scale General Accounting Office study (7) of the Medicare population in Florida showed substantially the same results. These findings have been confirmed by other study findings as well (8-11). It is not clear whether the increased utilization of imaging among self-referring physicians is due to a belief that their patients are sicker than the norm, to an enthusiasm for technology, to a desire to maximize income, or to some other motivation, but the net effect is increased cost to the health care system.

Some limitations of our study should be noted. First, although it is possible that the MPI utilization increase among cardiologists may be due to self referral within a single practice or group, our database does not allow precise determination of the degree of self referral. Second, we cannot determine whether the rapid growth resulted from higher utilization among a small group of cardiologists, or whether a larger number of cardiologists acquired nuclear cameras and began performing the examinations. Third, the data do not allow us to assess the appropriateness of the imaging examinations. However, there is no reason to assume that the populations of patients studied by radiologists, cardiologists, or other physicians are inherently different or that the latter two populations have greater need for cardiac nuclear imaging examinations. It would be difficult to ascertain whether the increased utilization detected in this study was medically necessary or not. Fourth, this study was conducted among the Medicare population only and may not exactly reflect events occurring in other health insurance databases. Fifth, there are small year-to-year changes in the underlying Medicare population demographics, which may contribute to small changes in utilization and which we are unable to adjust for. Consequently, as noted earlier, probability levels reported should be interpreted as descriptive rather than as traditional significance tests. Finally, the 107 HCFA physician specialty codes are self designated by physician providers and this may lead to minor inaccuracies. For example, in a given hospital, a cardiologist may work in the nuclear medicine section of the department of radiology, and his billings to HCFA might be classified as being from a "radiologist."

In summary, this study has provided insight into the concerns expressed in the Office of Inspector General work plan for 2000 (4). There was sharp growth be-

tween 1996 and 1998 in the utilization rate of MPI; this growth was almost entirely due to increased utilization by cardiologists, particularly in the office setting. There was an even more striking increase in the use of add-on WM and/or EF codes; however, this can be at least partially explained by the fact that these were still relatively new codes, which had been available only for 4 years in 1996. Although the increase in utilization of the add-on WM and/or EF codes was high among all physicians, by 1998 the probability that a patient would undergo one of these examinations was substantially higher if the primary MPI examination was performed by a cardiologist than if it was referred to a radiologist. The recent higher utilization seen in cardiac radionuclide imaging is not being offset by declines in use of other related imaging studies.

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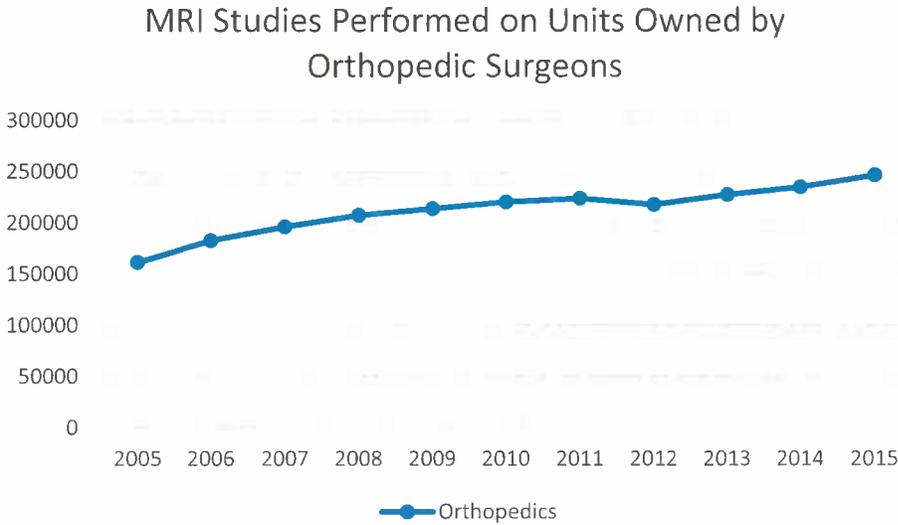
EXHIBIT E

*Ownership of MRI Units by Orthopedic Surgeons:
A Steadily Increasing Trend*

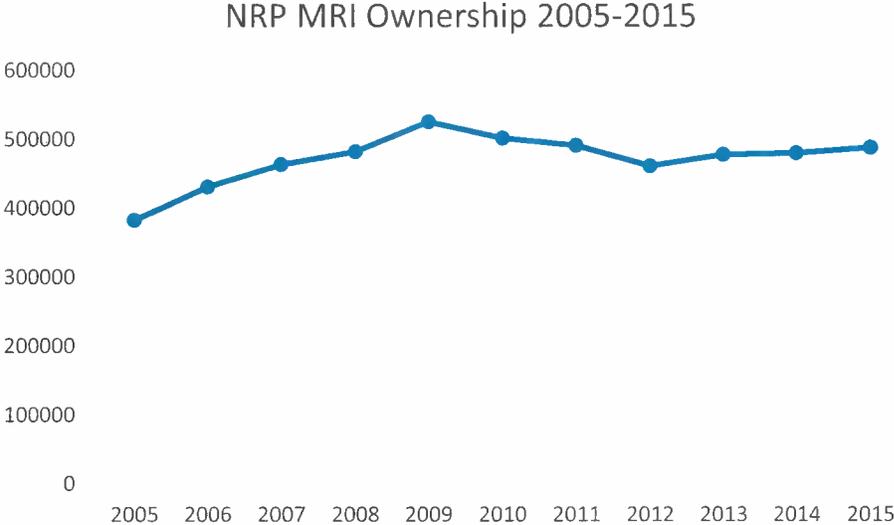
The following is as yet unpublished Medicare data. This is an abstract of a paper to be presented at the annual scientific meeting of the Radiological Society of North America, November, 2017. To be presented by David C. Levin, M.D. (Professor of Radiology at Thomas Jefferson University, Philadelphia, PA) and his colleagues.

Ownership of MRI Units by Orthopedic Surgeons: A Steadily Increasing Trend

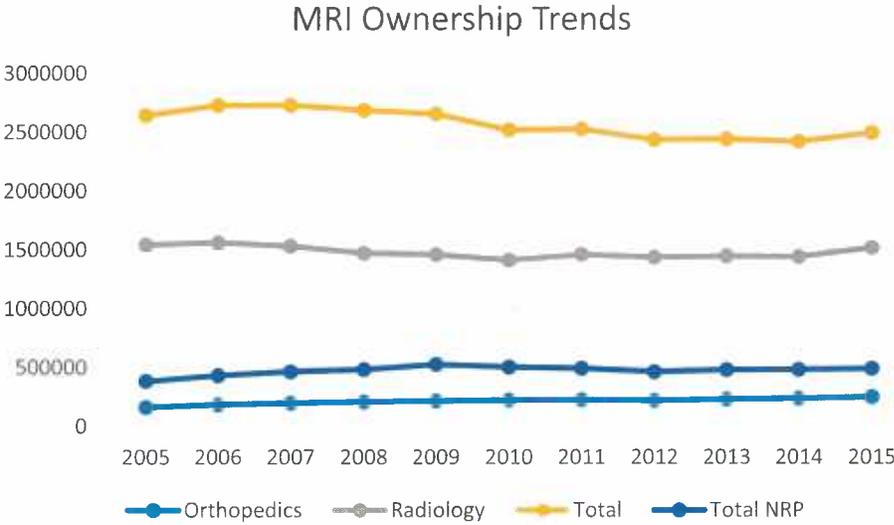
Purpose: To analyze the trend in ownership of MRI facilities by orthopedic surgeons (OSs) and other nonradiologist physicians from 2005-2015. **Methods:** The nationwide Medicare Part B databases for 2005-2015 were reviewed. Medicare’s CPT-4 and place-of-service codes were used to identify all MRI studies performed in private offices. Physician specialty codes were used to identify the specialty of the provider who owned the MRI unit. Ownership was determined by tabulating all approved technical-component and global claims. Trends were examined among OSs, radiologists, and other physicians. **Results:** Total claims for Medicare MRI studies in all private offices were 2,641,812 in 2005, decreasing to 2,491,654 in 2015 (-6%). There were 1,541,922 Medicare MRI claims from private radiology offices in 2005, decreasing to 1,514,372 in 2015 (-2%). Among OS offices, MRI claims increased from 161,296 in 2005 to 246,044 in 2015 (+53%). Among these OS office MRI claims, 98% were musculoskeletal or spine studies. Other specialties with substantial office MRI ownership and their 2005 to 2015 changes were: neurologists (63,363 to 73,083, +15%); primary care physicians (58,574 to 50,541, -14%); and neurosurgeons (20,712 to 19,318, -7%). Another large group was independent diagnostic testing facilities (715,704 to 489,122, -32%) but in these, ownership is usually by a corporate entity. Among all MRIs performed in nonradiologist private physician offices, approximately half were in OS offices in 2015. **Conclusion:** Whereas the number of private office MRI claims submitted by radiologists and most other physicians has remained relatively unchanged or even decreased, MRI claims submitted by OS offices continue to increase. The increase has occurred despite the many reimbursement cuts which appear to have limited the acquisition of MRIs in the offices of other physicians. More private office MRI claims were submitted by OSs than by any specialty other than radiology. This raises a concern about self-referral, especially considering that the studies performed on OS-owned MRI units are almost exclusively related to musculoskeletal conditions. **Clinical Relevance:** n/a.



Nonradiologist trend



Multiple Trends



Orthopedics and Total NRP Trends

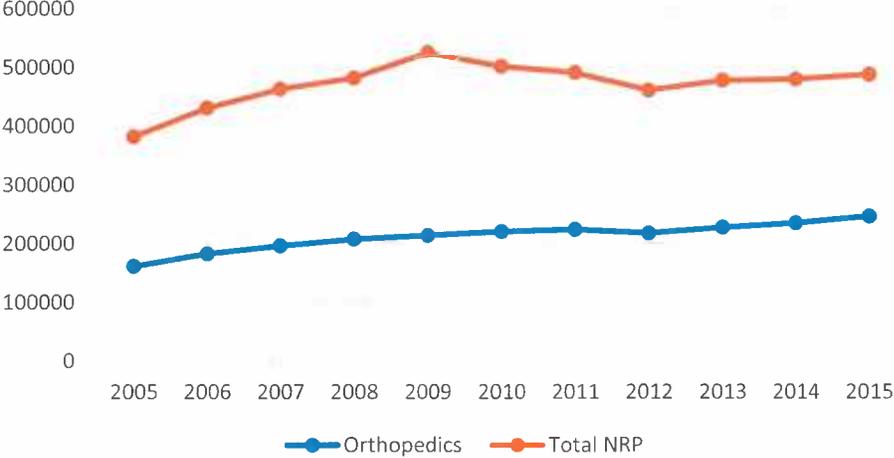


EXHIBIT F



601 E Street, NW | Washington, DC 20049
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December 11, 2014

The Honorable Jackie Speier
House of Representatives
211 Cannon Office Building
Washington, DC 20515

Dear Representative Speier:

On behalf of AARP's nearly 38 million members and the millions more with Medicare, thank you for your continued work to close provider reimbursement loopholes. AARP agrees that restrictions on physician self-referral and provider-kickback schemes must be strengthened. Closing the in-office ancillary services exception for certain services will save taxpayers and Medicare beneficiaries money and reduce unnecessary care.

As you know, the in-office ancillary services exception was intended to allow physicians to perform services which can be completed in the physician's office while the patient is present and which aid in the diagnosis of the patient in order to minimize delays in patient care. Unfortunately, the exception has contributed to overutilization and rapid growth of certain services, particularly in radiation oncology, anatomic pathology, advanced imaging, and physical therapy. Closing the loophole will better serve patients and preserve Medicare's resources by saving approximately \$6 billion over ten years for these services.

We look forward to working with you and your colleagues in both parties to improve Medicare and reduce health care spending. If you have any questions, please contact me or have your staff contact Ariel Gonzalez of our Government Affairs team, at agonzalez@aarp.org or 202-434-3770.

Sincerely,

Joyce A. Rogers
Senior Vice President
Government Affairs

EXHIBIT G



Highlights of GAO-12-966, a report to congressional requesters

MEDICARE

Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions

Why GAO Did This Study

Medicare Part B expenditures—which include payment for advanced imaging services—are expected to continue growing at an unsustainable rate. Questions have been raised about self-referral's role in this growth. Self-referral occurs when a provider refers patients to entities in which the provider or the provider's family members have a financial interest. GAO was asked to examine the prevalence of advanced imaging self-referral and its effect on Medicare spending. This report examines (1) trends in the number of and expenditures for self-referred and non-self-referred advanced imaging services, (2) how provision of these services differs among providers on the basis of whether they self-refer, and (3) implications of self-referral for Medicare spending. GAO analyzed Medicare Part B claims data from 2004 through 2010 and interviewed officials from the Centers for Medicare & Medicaid Services (CMS) and other stakeholders. Because Medicare claims lack an indicator identifying self-referred services, GAO developed a claims-based methodology to identify self-referred services and expenditures and to characterize providers as self-referring or not.

What GAO Recommends

GAO recommends that CMS improve its ability to identify self-referral of advanced imaging services and address increases in these services. The Department of Health and Human Services, which oversees CMS, stated it would consider one recommendation, but did not concur with the others. GAO maintains CMS should monitor these self-referred services and ensure they are appropriate.

View GAO-12-966. For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

From 2004 through 2010, the number of self-referred and non-self-referred advanced imaging services—magnetic resonance imaging (MRI) and computed tomography (CT) services—both increased, with the larger increase among self-referred services. For example, the number of self-referred MRI services increased over this period by more than 80 percent, compared with an increase of 12 percent for non-self-referred MRI services. Likewise, the growth rate of expenditures for self-referred MRI and CT services was also higher than for non-self-referred MRI and CT services.

GAO's analysis showed that providers' referrals of MRI and CT services substantially increased the year after they began to self-refer—that is, they purchased or leased imaging equipment, or joined a group practice that already self-referred. Providers that began self-referring in 2009—referred to as switchers—increased MRI and CT referrals on average by about 67 percent in 2010 compared to 2008. In the case of MRIs, the average number of referrals switchers made increased from 25.1 in 2008 to 42.0 in 2010. In contrast, the average number of referrals made by providers who remained self-referrers or non-self-referrers declined during this period. This comparison suggests that the increase in the average number of referrals for switchers was not due to a general increase in the use of imaging services among all providers. GAO's examination of all providers that referred an MRI or CT service in 2010 showed that self-referring providers referred about two times as many of these services as providers who did not self-refer. Differences persisted after accounting for practice size, specialty, geography, or patient characteristics. These two analyses suggest that financial incentives for self-referring providers were likely a major factor driving the increase in referrals.

Change in Average Number of MRI Services Referred, 2008 and 2010

	Average 2008 referred MRI services	Average 2010 referred MRI services	Percentage change
Switchers	25.1	42.0	67.3
Non-self-referrers	20.6	19.2	-6.8
Self-referrers	47.0	45.4	-3.4

Source: GAO analysis of Medicare data.

Note: Pattern observed for MRI services was similar for CT services. GAO defines switchers as those providers that did not self-refer in 2007 or 2008, but did self-refer in 2009 and 2010.

GAO estimates that in 2010, providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. These additional referrals cost Medicare about \$109 million. To the extent that these additional referrals were unnecessary, they pose unacceptable risks for beneficiaries, particularly in the case of CT services, which involve the use of ionizing radiation that has been linked to an increased risk of developing cancer.

EXHIBIT H

White House Releases FY 2017 Budget Proposal

On February 9, President Obama released his proposed federal budget for the 2017 fiscal year (FY). The FY 2017 budget will be the last of his presidency. The budget is comprised of \$4.1 trillion in spending on receipts of \$3.6 trillion, resulting in a \$503 billion deficit for the year. Although several provisions in the Obama budget may be included throughout the year as separate policies to congressional legislation, due to the Republican majority in Congress, the vast majority of the president's proposals contained in his budget will not be considered or debated.

The President's budget is chock-full of various Medicare-related changes that present both opportunities and threats to radiologists. The American College of Radiology (ACR) is encouraged that the Administration, once again, included provisions to close the in-office ancillary services (IOAS) exception to the Ethics in Patient Referrals Act, commonly referred to as the Stark law, after its author, former Congressman Fortney "Pete" Stark. The budget stipulates that, starting in 2018, advanced imaging, radiation therapy, anatomic pathology and physical therapy services would be removed from the IOAS exception. The Obama Administration would only permit these four services to be self-referred within clinically integrated practices that are required to demonstrate cost containment. In total, closure of the IOAS exception is expected to produce slightly more than \$4.9 billion in savings over 10 years.

However, the ACR continues to be frustrated by the Obama Administration's annual effort to establish a Medicare prior authorization program. Although the Administration did not specifically cite a prior authorization policy strictly for advanced imaging services as it has in past budgets, the president did call for a broader, prior authorization policy that affects all Medicare fee-for-service procedures. The ACR is puzzled as to why the Administration would pursue such a policy for imaging services in light of the passage of a mandatory imaging appropriate use criteria (AUC) consultation policy specifically designed to reduce imaging overutilization. Furthermore, the ACR remains deeply skeptical that a prior authorization policy would generate any savings for Medicare because of the considerable administrative costs associated with implementing the policy. Above all, the ACR continues to hold strong reservations about prior authorization programs limiting patient access to lifesaving imaging services.

In addition to some of the more specific policies the ACR monitors within the President's budget, The White House's medical research funding included a \$33.1 billion budget for the National Institutes of Health (NIH) in fiscal year 2017. Some of the Administration's research priorities include:

Cancer Moonshot

The budget provides \$680 million to the NIH to expand clinical trials for health disparity populations, pursue new vaccine technology and fund exceptional opportunities in cancer research. These investments will drive scientific advances that aim to understand the causes of cancer, discover new prevention strategies, improve early detection and diagnosis and cultivate effective treatments.

Advances the Precision Medicine Initiative

The budget provides the Department of Health and Human Services with \$309 million to continue scaling up the Precision Medicine Initiative. Recent breakthroughs in genomics, computing and molecular medicine have created extraordinary opportunities to advance health care into a new era when many more treatments are based on the genetic characteristics of each patient. Research based on this cohort will lay the foundation for findings for many diseases that can lead to new prevention strategies, novel therapeutics and medical devices.

BRAIN initiative

The budget provides \$195 million within NIH, \$45 million more than FY2016, for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Increased funds in FY 2017 will continue to support basic neuroscience research, human neuroscience, neuroimaging and training initiatives. The funding is also expected to be used on potential projects to collaborate with industry to test novel devices in the human brain, new ways to address big data from the brain, and to develop devices for mapping and tuning brain circuitry.

The ACR will continue to monitor the budget process as it progresses through the legislative process and evaluate any policies that emerge from it that may impact imaging services and/or the practice of radiology.

EXHIBIT I

not detected by current assays may yet be found in both serum and cryoprecipitates.

The possibility that HCV infection is responsible for many or perhaps most cases of Type II and Type III cryoglobulinemia has therapeutic implications. In the past, treatment with plasmapheresis or plasma exchange plus corticosteroids or cytotoxic drugs was reserved for patients with severe manifestations, such as vascular insufficiency, renal failure, and progressive involvement of the peripheral nerves. Combined treatment was often remarkably effective under these circumstances, but it was less effective in patients with smoldering renal or neurologic involvement or painful episodes of cutaneous vasculitis. The favorable results of treatment of mixed cryoglobulinemia with interferon alfa are encouraging⁹; this drug should be subjected to multicenter controlled therapeutic trials to determine its efficacy in mixed cryoglobulinemia due to HCV infection.

Several viruses have also been implicated in the pathogenesis of Sjögren's syndrome,¹⁰ but there is no rigorous proof of an etiologic role for any of them. The finding of HCV RNA in the serum of three of four patients raises this issue anew. Possibly, HCV will prove to be the etiologic agent of Sjögren's syndrome, or perhaps HCV is merely another virus capable of infecting salivary and lacrimal glands to produce a clinical and histologic picture resembling idiopathic Sjögren's syndrome.

Meticulous adherence to the proper methods of collecting and processing samples is essential to the detection of cryoprecipitable substances in serum. At least 20 ml of blood (large amounts enhance the likelihood of detecting small amounts of cryoprecipitate) should be taken from a fasting patient (lipids may interfere with the test by precipitating in the cold). The blood (not treated with an anticoagulant) is placed in tubes in warm water and transported promptly to the laboratory. Once there, it is allowed to clot at 37°C for 1 hour and then separated in a warm centrifuge; the clear serum supernatant is removed and stored at 4°C for 72 hours. The serum is examined daily for cryoprecipitate. If any is detected, the amount of cryoprecipitate (the cryocrit) is determined, and the carefully washed cryoprecipitate is dissolved by warming. Its constituents are then identified by immunodiffusion. Delay in the transport or refrigeration of the sample before processing will lead to the loss of cryoprecipitable substances in the clot, which is discarded when serum is obtained. Hence, in most instances, blood to be examined for cryoprecipitable substances should not be drawn when the laboratory is closed or about to close.

Finally, in view of the demonstration of HCV RNA in the cryoprecipitate from many patients with Type II and Type III cryoglobulinemia, the term "cryoglobulin" no longer accurately describes the cold-precipitable substances recoverable from serum. The phenomenon is once again in search of a name.

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"SELF-REFERRAL" — WHAT'S AT STAKE?

"SELF-REFERRAL" is the term used to describe a physician's referral of patients to an outside facility in which he or she has a financial interest but no professional responsibility. This practice has become particularly prevalent in certain parts of the country, where for-profit imaging centers, diagnostic laboratories, home health care services, radiotherapy centers, physiotherapy units, and other free-standing facilities have been soliciting investments by physicians who can refer patients to them. Self-referral is a prime example of the current and growing encroachment of commercialism on medical practice. The contentious and emotional debate that has been waged over this issue reflects the increasing tension between professional and business values in medicine.¹

In December 1991, the American Medical Association (AMA) seemed finally to have ended years of ambivalence and uncertainty about self-referral when its House of Delegates approved without dissent a report from the Council on Ethical and Judicial Affairs.² Taking a strong stand on the side of professional values, the council advised physicians to avoid self-referral, except when there is a demonstrated need in the community for the facility and alternative financing is not available. The council acknowledged the mounting evidence of excessive costs and rates of use in jointly owned for-profit facilities but emphasized that it was primarily concerned about the integrity of the profession. The following passage from the report expresses its essential message:

At the heart of the Council's view of this issue is its conviction that, however others may see the profession, physicians are not simply business people with high standards. Physicians are engaged in the special calling of healing, and, in that calling, they are the fiduciaries of their patients. They have different and higher duties than

even the most ethical business person. . . . There are some activities involving their patients that physicians should avoid whether or not there is evidence of abuse.²

This admirable statement supports a position I have repeatedly advocated for more than a decade³⁻⁶ — one that was also strongly recommended by the Institute of Medicine in its 1986 report on for-profit enterprise in health care.⁷

Coming on the heels of recent similar statements on self-referral by such other major medical organizations as the American College of Physicians, the American College of Surgeons, and the American College of Radiology, the council's report and its endorsement by the AMA's House of Delegates seemed to have settled the debate once and for all. Unfortunately, that did not prove to be the case. Six months later, in June of this year, the House of Delegates reversed its position. By a close margin, the delegates approved a new resolution introduced by the New Jersey delegation that declared self-referral to be ethical as long as the patient is fully informed about the physician's financial interest in the facility. Although the vote could not change the council's report, which remains part of the AMA's code of ethics, this sudden about-face reveals the confusion and the conflicting interests that still prevent many physicians from recognizing their professional obligations.

The justification offered for the new resolution was unconvincing. Proponents argued that the policy recommended by the council would limit the access of many patients to necessary health services. They also claimed that the great majority of self-referring physicians, who do not abuse their patients' trust, were being penalized because of concern over the few who did. One delegate from New Jersey was quoted in the press as saying, "Sanctions should be applied [to "overutilizers"] when appropriate. . . . But must we always punish the innocent along with the guilty?"⁸

These arguments are transparently spurious. As already noted, the council's report allows for self-referral if the facility is clearly needed by the community and could not be built without physician-investors. As for distinguishing between physicians who abuse self-referral and those who do not, there would be no way to do that without prohibitively expensive and intrusive surveillance of the private practices of all physicians who practice self-referral. Besides, the argument that self-referring physicians should be trusted unless they can be proved to have abused that trust misses an essential point about fiduciary responsibility: people in important positions of trust should not put themselves in situations that inevitably raise questions about their motives and priorities, regardless of whether they actually behave in accordance with that trust.

Physicians are trusted to act as medical purchasing agents for their patients. A doctor who thinks there should be no concern about self-referral as long as it is disclosed and the referrals are monitored is analogous to a purchasing agent for a large corporation who dis-

closes to the chief executive officer (CEO) that he has a vested interest in certain vendors with whom he does business, and who thinks that this disclosure, plus careful surveillance of his purchases by management, should assuage the CEO's concerns. Obviously, it would not do so. In fact, the CEO would probably fire the purchasing agent on the spot. Why should physicians want to apply a lower standard of fiduciary responsibility to themselves than is generally accepted in business?

Two articles in this issue of the *Journal* add to the growing body of evidence that self-referral leads to the overuse of services and excessive cost.^{9,10} In a study of free-standing radiation-therapy facilities in Florida, where at least 40 percent of all practicing physicians are involved in some kind of self-referral,¹¹ Mitchell and Sunshine⁹ report that none of the joint-venture facilities were located in inner-city neighborhoods or rural areas, thus refuting the suggestion that joint ventures often bring needed services to otherwise underserved communities. These authors also found that self-referral in radiation therapy, as already reported for other services, was associated with increased use and costs.⁹ The second study, by Swedlow et al.,¹⁰ reports on self-referral to three different kinds of outside services in California's workers' compensation system. They found that self-referral increased the rate of use and the cost per case of physiotherapy and increased the cost per case of psychiatric evaluation. Even more interesting, they report that the inappropriate use of magnetic resonance imaging was more frequent among the patients cared for by self-referring physicians, although there was no difference in the cost per case. None of this new evidence is particularly surprising, but taken together with the results of earlier studies cited in the council report, it convincingly demonstrates that self-referral adds to the cost of medical care.

No wonder that government has begun to take restrictive action. In September 1991 the U.S. Department of Health and Human Services issued so-called safe-harbor regulations, which allow physicians to refer Medicare and Medicaid patients to facilities in which they have a financial interest only under limited conditions.¹² These regulations are new interpretations of a Medicare and Medicaid anti-kickback statute that has been on the books since 1972, but they may soon become moot as a result of new, more comprehensive laws at the federal and state levels. A law passed by Congress in 1989 that took effect this year bans the referral of Medicare and Medicaid patients to clinical laboratories owned by their physicians. There is discussion about extending the ban to other kinds of facilities, a move favored by the Bush administration as a means of restraining Medicare expenses. The Internal Revenue Service, reversing its previous stance, has announced that not-for-profit hospitals may lose their tax-exempt status if they enter into certain types of financial arrangements with physicians, including those that involve self-referral. The Federal Trade Commission, which had formerly en-

dorsed self-referral as enhancing competitiveness, now thinks the practice may be anticompetitive because it tends to limit the referring physician's choice to the facility in which he or she has invested, and because it keeps prices up. There has also been much activity at the state level. Florida and New Jersey recently banned most self-referrals, and several other states, including California and New York, are considering similar legislation. Thus, it seems evident that still more legislative restrictions are in the offing.

Those who say that ethics cannot and should not be legislated¹³ are right, but for government the issue is clearly economic, not ethical. Voluntary ethical guidelines, although essential for the morale of the profession and for its public image and self-image, cannot establish firm national policy. That requires legislation. Some medical organizations oppose legislation because they fear the indiscriminate banning of referrals to all facilities with which the referring physician has any financial connection — even when the arrangement is in the interest of patients and necessary for good medical practice. This concern is legitimate, but the problem can easily be solved if professional groups work constructively with government to develop laws and regulations that are appropriate. Attempts simply to obstruct corrective legislation are, in my opinion, ill advised. They merely strengthen the public's impression that physicians are more interested in pursuing their own economic interests than in preserving their good name or helping to keep costs down. In any case, as recent history has shown, most efforts to prevent legislative action are likely to fail, leaving a residue of public cynicism and ill will toward organized medicine.

The AMA is worried about the erosion of professionalism in a system of medical care that is becoming increasingly commercialized, and its concern is justified. The reputation of medicine as a trusted profession is at stake, as is the profession's own view of its basic values. The AMA has wisely chosen to make the promulgation and enforcement of ethical standards a major strategic goal. It has sought help from state and local organizations in this task and has asked the Federal Trade Commission to allow physicians more flexibility in self-regulation. These initiatives deserve support, but there is still much more to be done in the profession's struggle against commercialization. In addition to self-referral, the AMA should look closely at the sale of drugs by office-based physicians,¹⁴ deals between physicians and the manufacturers of devices and prostheses, and a wide variety of other kinds of

joint ventures between physicians and the facilities in which they treat their patients.⁵

It would be a major victory for professional values if the AMA could once again endorse a simple precept that stood as one of the beacons of its pre-1980s ethical code: "In the practice of medicine a physician should limit the source of his professional income to medical services actually rendered by him, or under his supervision, to his patients."¹⁵ In today's chaotic medical market, doctors need a few clear guidelines. This is one of the best.

It is hard to predict what our health care system will look like in the year 2000, or what the conditions of medical practice will be. What seems clear, however, is that physicians will have little opportunity to help shape the future if they do not retain their public credibility. That is the real importance of the self-referral debate. If physicians choose to act from self-interest, or even if they merely put themselves in positions that suggest self-interest, they risk damaging their most precious possessions — the trust and respect of their patients and the esteem of the general public.

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EXHIBIT J

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By Jonathan Sunshine and Mythreyi Bhargavan

TECHWATCH

The Practice Of Imaging Self-Referral Doesn't Produce Much One-Stop Service

ABSTRACT Imaging as a result of self-referral—when a physician refers patients for imaging tests at a facility owned or leased by the same physician—is widespread. The practice has come under much scrutiny because it is associated with higher volumes of imaging services. Proponents of such self-referral argue that the practice offers patients convenient same-day, one-stop service and allows treatment to start sooner. Our analysis of 2006 and 2007 Medicare data showed that self-referral provided same-day imaging for 74 percent of straightforward x-rays, but for only 15 percent of more-advanced procedures such as computed tomography and magnetic resonance imaging. Policy makers attempting to make the use of imaging more responsible should consider narrowing Medicare's special provision allowing referrals to a physician's own practice so that the provision covers x-rays only.

Referring a patient for imaging tests to a facility that the physician owns or leases—known as self-referral—is a controversial practice. Proponents say that it has multiple important advantages, most of them arising because it provides what might be called one-stop service.¹⁻³ In other words, in a single trip to a physician's office, the patient can obtain the following: an initial evaluation of his or her health problem; imaging that the treating physician feels is appropriate; and the initiation of well-informed, definitive treatment.

One-stop service purportedly has several advantages. It is more convenient for the patient, who makes just one trip to a provider instead of several. Because patients who are asked to make separate visits to different providers sometimes do not follow through, one-stop service also means that more patients are likely to get appropriate treatment. And episodes of illness are shorter because definitive treatment can start right away and can build on an information base that includes imaging.

Physicians who are not radiologists can bill

and receive payment for self-referred imaging by buying or leasing equipment such as a computed tomography (CT) scanner and either interpreting the images themselves or contracting with others for interpretation.

Opponents of self-referral say that the practice leads to much greater use of imaging, which means that costs are needlessly high and patients are exposed to more radiation than is necessary.^{4,5}

Empirical research has concentrated on the issue of use and does indeed show that self-referral is associated with much higher use of imaging, compared to referrals to radiologists.⁶⁻⁹ This finding has drawn attention because imaging had repeatedly been found to be by far the most rapidly growing component of physician services.¹⁰⁻¹²

As noted, research on self-referred imaging has focused on use. There has been no empirical study of the purported advantages of the practice. To address that knowledge gap, we studied the prevalence of one-stop imaging.

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Study Data And Methods

When self-referral is, in fact, a one-stop process, patients have an office visit and receive an imaging service on the same day. It is easy to ascertain from health care claims whether or not this actually happens. Accordingly, we analyzed claims to ascertain how often self-referred imaging is accompanied by a same-day office visit.

DATA The data primarily came from Medicare's 5 percent Research Identifiable Files for 2007 (the latest year available at the time of the study) and 2006. These are files of insurance claims for all services rendered by physicians and other noninstitutional providers to a random 5 percent of beneficiaries enrolled in fee-for-service Medicare. Among other things, the files contain the date of service, the physician's unique provider identification number and specialty, diagnosis and procedure codes, payment amounts, and information on the patient's characteristics.

ANALYSIS For imaging services¹³ that took place in an office, we identified as self-referred the procedures where claims had the same unique provider identification number in both the referring physician and the performing physician fields. If either identification number was missing, we omitted the claim from the analysis.¹⁴

We grouped imaging services into types based on Berenson-Eggers Type of Service codes.¹³ This classification groups each of the several thousand billing codes in the Current Procedural

Terminology and Healthcare Common Procedure Coding System^{15,16} into one of just over a hundred types of procedures, including twenty-three categories and subcategories of imaging.

For each type of imaging, we computed the percentage of self-referred imaging services that were accompanied by a same-day office visit to the same physician (Exhibit 1). We included only global claims, which charge for the entire imaging service, and technical-component-only claims, which charge for the use of the equipment, space, technicians, and supplies—in other words, for everything except the physician's role in supervising and interpreting the scan. We did not include claims that charge only for the physician's service (professional-component-only claims) because there is an accompanying technical-component-only claim and we did not want to double-count claims.

We examined differences in the rate of same-day imaging based on the specialty of the treating physician. That specialty is recorded on the claim.

In 2007 Medicare was shifting to a different physician identifier system, the national provider identifier. Therefore, to ensure that the 2007 data were not anomalous, we replicated our analyses using Medicare's 2006 Research Identifiable Files. We conducted all data analyses with the statistical analysis software SAS, version 9.1.

EXHIBIT 1

Types Of Self-Referral Imaging And Same-Day Office Visits, 2007

Type of imaging	BETOS codes	Number of self-referred images	Percent of all self-referred images	Number with same-day office visit	Percent with same-day office visit
Most straightforward x-rays	I1A, I1B	621,300	28.2	459,015	73.9
Chest x-rays	I1A	148,076	6.7	117,113	79.1
Musculoskeletal x-rays	I1B	473,224	21.5	341,902	72.2
Other x-rays	I1C, I1D, I1F	37,649	1.7	14,681	39.0
High-tech imaging	I1E, I2	1,079,739	49.0	163,744	15.2
Nuclear medicine	I1E	1,034,426	47.0	153,556	14.8
CT	I2A, I2B	29,241	1.3	7,797	26.7
MRI	I2C, I2D	16,072	0.7	2,391	14.9
Ultrasound	I3	434,159	19.7	149,689	34.5
Abdomen/pelvic	I3B	39,047	1.8	21,836	55.9
Echocardiography	I3C	246,911	11.2	83,878	34.0
Other	I3A-F	148,201	6.7	43,975	29.7
Procedural imaging	I4	29,765	1.4	7,222	24.3
All except most straightforward x-rays	All except I1A, I1B	1,581,312	71.8	335,336	21.2

SOURCE Authors' analysis of Medicare's 2007 Research Identifiable Files. **NOTES** Figures represent only global and technical component-only claims, as explained in the text. BETOS codes are Berenson-Eggers Type of Service codes, used by the Centers for Medicare and Medicaid Services to classify procedures. CT is computed tomography. MRI is magnetic resonance imaging.

Study Results

Provider identifier codes were present on 96.0 percent of 2007 claims and 99.5 percent of 2006 claims.

2007 RESULTS After we omitted claims that lacked provider identifier codes, there remained 2.2 million self-referred imaging services received by the 2.6 million Medicare fee-for-service beneficiaries in the 2007 Research Identifiable Files data set.

Of these images, 28.2 percent were relatively straightforward x-rays—specifically, chest x-rays and musculoskeletal x-rays (Exhibits 1 and 2). Of these, 73.9 percent were accompanied by an office visit on the same day.

In contrast, only 15.2 percent of high-tech images—nuclear medicine, CT scanning, and magnetic resonance imaging (MRI)—had a same-day office visit. Nuclear medicine accounted for 47.0 percent of all self-referred imaging services.

For ultrasound, sometimes thought of as “medium-tech,” 34.5 percent of self-referred services were accompanied by an office visit on the same day. Abdominal and pelvic ultrasound had a same-day rate of 55.9 percent but accounted for just 1.8 percent of all self-referred imaging services.

Overall, 21.2 percent of patients receiving self-referred imaging services other than chest or musculoskeletal x-rays had an office visit on the same day.

Individual specialties vary greatly in the types of self-referred imaging that they predominantly perform. However, for each type of imaging, the percentage of patients with a same-day office visit was quite similar across specialties. It was also similar to the percentages given above for all providers (Exhibit 3).

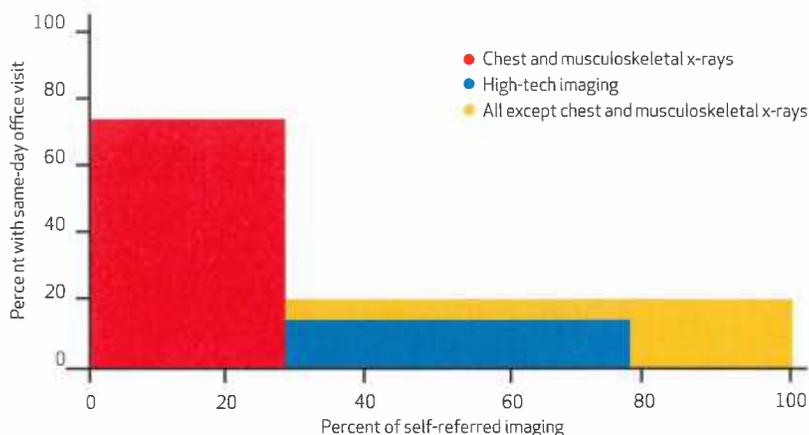
For example, self-referred imaging of orthopedists, not surprisingly, consisted predominantly (95.0 percent) of musculoskeletal x-rays, although those x-rays were only 21.5 percent of all physicians’ self-referred imaging. But the percentage of orthopedists’ patients with a musculoskeletal x-ray and an office visit on the same day was 72.4 percent—virtually identical to the 72.2 percent for patients of all doctors.

2006 RESULTS For 2006 we analyzed 2.1 million self-referred imaging services (Appendix Exhibit A1).¹⁷ For every moderately specific category of imaging, the percentage of self-referred images that had a same-day office visit was very similar in 2006 and 2007. For example, for high-tech self-referred imaging, the same-day office visit rate was 15.6 percent in 2006 and 15.2 percent in 2007.

However, the proportion of total self-referred imaging other than chest and musculoskeletal x-rays that was accompanied by a same-day office

EXHIBIT 2

Percentage Of Self-Referred Imaging With Same-Day Office Visit



SOURCE Authors' analysis of Medicare's 2007 Research Identifiable Files.

visit declined somewhat from 2006 to 2007, from 22.9 percent (Appendix Exhibit A1)¹⁷ to 21.2 percent (Exhibit 1). The decline was due primarily to the growing role of nuclear medicine, whose low same-day office visit rate, approximately 15 percent, did not vary. Nuclear medicine increased from 42.0 percent of all self-referred in-office imaging services in 2006 to 47.0 percent in 2007.

In 2006, as in 2007, the types of specialists who were chiefly responsible for self-referrals differed greatly in the type of self-referred imaging they primarily performed. However, their same-day office visit rate for any given type of imaging was similar to the all-physician average for the same service (Appendix Exhibit A2).¹⁷ For example, in 2006, echocardiography constituted 30.7 percent of cardiologists' self-referred imaging, compared to only 12.1 percent of the self-referred imaging of all physicians. But the same-day office visit rate for echocardiography was 34.8 percent for cardiologists—very similar to the 34.1 percent rate for all physicians (Appendix Exhibit A1).¹⁷

STUDY LIMITATIONS For two reasons, our findings on same-day imaging may seriously overestimate the extent to which self-referral is truly a one-stop process, at least for high-tech imaging. First, Jean Mitchell¹⁸ has shown that much self-referred high-tech imaging that supposedly takes place in the treating physician's office actually occurs at another location under what the Centers for Medicare and Medicaid Services (CMS) terms “abusive” leasing and other arrangements that the Medicare and Medicaid programs are just beginning to curb.^{19–21}

Second, our methodology generally recorded a

EXHIBIT 3

Main Types Of Self-Referral Imaging Services By The Most Common Self-Referring Specialties And All Physicians, 2007

Type of imaging	BETOS codes	Primary care		Cardiology		Orthopedics		All physicians	
		% of imaging self-referred	% with same-day office visit	% of imaging self-referred	% with same-day office visit	% of imaging self-referred	% with same-day office visit	% of imaging self-referred	% with same-day office visit
Most straightforward x-rays	IIA, IIB	37.7	75.4	— ^a	— ^a	95.1	72.4	27.8	73.3
Chest x-rays	IIA	18.0	79.6	— ^a	— ^a	— ^a	— ^a	6.7	77.5
Musculoskeletal x-rays	IIB	19.8	71.7	— ^a	— ^a	95.0	72.4	21.5	72.2
Nuclear medicine	IIE	35.6	17.5	67.0	10.8	— ^a	— ^a	47.2	14.7
Echocardiography	IBC	13.8	31.4	26.9	35.4	— ^a	— ^a	11.0	34.0

SOURCE Authors' analysis of Medicare's 2007 Research Identifiable Files. **NOTE** BETOS codes are Berenson-Eggers Type of Service codes, used by the Centers for Medicare and Medicaid Services to classify procedures. ^aConstitutes only a minimal percentage of the specialty's self-referred imaging.

same-day office visit when self-referral was, in fact, a two-stop process. For example, a patient might visit a treating physician and be scheduled for high-tech imaging several days later. If the patient has an office visit to start treatment on the same day that the imaging took place, we counted that as a same-day visit.²²

Our study included only Medicare beneficiaries. However, as noted below, the limited published data for a younger population are similar to our findings. Moreover, the advantages of one-stop service are probably greater for the elderly, who more often than younger patients have mobility and transportation difficulties.

Our study did not address any advantages claimed for self-referral other than one-stop service.

Discussion

Our analyses of 2007 data and 2006 data produced very similar results. Specifically, same-day imaging was the exception, other than for the most straightforward types of x-rays. Overall, less than one-fourth of imaging other than these types of x-rays was accompanied by a same-day office visit. The fraction for high-tech imaging was even lower—approximately 15 percent.

A likely explanation is that the equipment required for high-tech imaging is expensive, typically costing \$0.5–\$2.0 million per machine, and it is inefficient for such equipment to be idle and available to patients on an essentially walk-in basis. Rather, the norm is to schedule appointments ahead of time, to maximize use of the equipment. It is ironic that a major justification for self-referrers' acquiring this expensive equipment is to provide same-day convenience to their

patients—but, presumably to keep their costs down, the physicians inconvenience the vast majority of their imaging patients by scheduling scans for a later date.

Our results were similar to the very limited data previously published.⁸ These data cover a few combinations of health problems and types of imaging in a population mainly under age sixty-five with health insurance through their employer. The data show very high same-day office visit rates (at least 85 percent) for chest and musculoskeletal x-rays and low rates (averaging 14 percent) for high-tech imaging.

Policy Implications

Medicare generally bans financially self-interested referral but allows it for designated “ancillary services,” including imaging, if the service takes place in a physician’s office.²³

Previous research indicates that self-referral for imaging is associated with high use of imaging. This means that costs and radiation exposure are high. We have shown that self-referral is seldom a one-stop process (with the exception of relatively straightforward x-rays), although its purported benefits are heavily dependent on its being a one-stop process. Thus, relatively straightforward x-rays are the only form of imaging for which one main benefit of self-referral—one-stop service—seems likely to offset its apparent drawbacks.

Two policy implications emerge. First, Medicare should consider limiting its “in-office ancillary services exemption” for imaging to x-rays.²⁴ However, Medicare should first acquire two additional types of empirical evidence.

For one, evidence is needed as to whether the

Same-day imaging was the exception, other than for the most straightforward types of x-rays.

demonstrated relationship between self-referral and high use of imaging is actually causal. Possibly, some physicians who are not radiologists may acquire imaging equipment because their personal pattern of practice makes intensive use of imaging, and their use of imaging might not be affected by their acquisition of equipment.

Also, we need more information on the potential benefits of self-referral beside one-stop service. For example, does self-referral lead to better

coordination and integration of care? Does it shorten episodes of illness? And does it offset the cost of higher use of imaging by providing information that can save money in the long run? We and other researchers are investigating these questions.

The second policy-related implication of our study is that in-office exemptions for ancillary services other than imaging—such as physical therapy, clinical laboratory tests, and durable medical equipment—should be analyzed as well. Are the exemptions associated with high use of these services, and do their purported benefits actually occur? Studies of self-referral for services other than imaging generally find increased use as well as other undesirable effects.^{4,25–30} These undesirable effects include higher markups and “cream skimming”—that is, disproportionately serving patients with relatively mild illnesses or generous insurance, thereby increasing the burden on physicians who care for sicker and less remunerative patients. ■

A version of this paper was presented as a poster at the American Public Health Association Annual Meeting, November 7–11, 2009, in Philadelphia, Pennsylvania.

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 - 21 US Department of Health and Human Services. Centers for Medicare and Medicaid Services, 42 CFR Parts 405, 409, et al.. *Fed Regist* [serial on the Internet]. 2008 Nov 19;73(224):69799–817, 69935–6 [cited 2010 Oct 27]. Available from: <http://edocket.access.gpo.gov/2008/pdf/E8-26213.pdf>
 - 22 When imaging and an office visit take place on the same day, to distinguish this situation from actual one-stop service would require knowing whether the imaging had been scheduled when a previous visit took place. Claims do not include information about when the scheduling of an imaging took place. They provide only the dates of the imaging and office visits.
 - 23 The “in-office ancillary services exemption” is found at 42 USC 1395 nn.
 - 24 X-rays that are not chest or musculoskeletal x-rays are less than 2 percent of all self-referred in-office imaging (Exhibit 1). Thus, the desirability of excluding them from the exemption would probably be offset by the simplicity of an exemption for all x-rays.
 - 25 Scott E, Mitchell JM. Ownership of clinical laboratories by referring physicians: effects on utilization, charges, and profitability. *Med Care*. 1994;32(2):164–74.
 - 26 Swedlow A, Johnson G, Smithline N, Milstein A. Increased costs and rates of use in the California workers' compensation system as a result of self-referral by physicians. *N Engl J Med*. 1992;327(21):1502–6.
 - 27 Mitchell JM, Sunshine JH. Consequences of physicians' ownership of health care facilities—joint ventures in radiation therapy. *N Engl J Med*. 1992;327(21):1497–501.
 - 28 Mitchell JM, Scott E. Physician ownership of physical therapy services: effects on charges, utilization, profits, and service characteristics. *JAMA*. 1992;268(15):2055–9.
 - 29 Strobe SA, Daignault S, Hollingsworth JM, Ye Z, Wei JT, Hollenbeck BK. Physician ownership of ambulatory surgery centers and practice patterns for urological surgery: evidence from the state of Florida. *Med Care*. 2009;47(4):403–10.
 - 30 Mitchell JM. Utilization changes following market entry by physician-owned specialty hospitals. *Med Care Res Rev*. 2007;64(4):395–415.

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION**

.....)
IN RE: CONNECTICUT ORTHOPAEDIC)
SPECIALISTS, P.C. ACQUISTION OF A)
MOBILE 1.5 T MAGENTIC RESONANCE)
IMAGING SCANNER)
.....)
DOCKET NO. 16-32117-CON

.....)
JUNE 27, 2017

NOTICE OF APPEARANCE

In accordance with Section 19a-9-28 of the Regulations of Connecticut State Agencies, please enter the appearance of Updike, Kelly & Spellacy, P.C. (“Firm”) in the above-captioned proceeding on behalf of Advanced Radiology Consultants, LLC (“ARC”). The Firm will appear and represent ARC at the public hearing on this matter, scheduled for July 11, 2017.

Respectfully Submitted,

ADVANCED RADIOLOGY
CONSULTANTS, LLC

By: _____



JENNIFER GROVES FUSCO, ESQ.
Updike, Kelly & Spellacy, P.C.
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CERTIFICATION

This is to certify that a copy of the foregoing was sent via electronic mail this 27th day of June, 2017 to the following parties:

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Updike, Kelly & Spellacy, P.C.

acquisition of a third MRI scanner and this purchase will result in the unnecessary duplication of services in the Orange and Essex service areas. COS has conducted its needs assessment based upon MRI volume within its practice, which is not the applicable standard under the Statewide Healthcare Facilities & Services Plan (“SHP”). Despite COS’s belief that its request to acquire a third MRI unit should be evaluated independent of existing providers, the SHP guidelines make it clear that the proposed acquisition must include a review of all available MRI capacity in the Orange and Essex service areas. There are 29 MRI units currently operating in the Orange and Essex markets. There is ample available capacity on these units, including those operated by ARC within the service area and contiguous towns, to meet the MRI needs of COS patients. In addition, COS’s claims that access, quality and cost-effectiveness of care are improved by co-locating an MRI unit in a private orthopedic office are also overstated and do not, in and of themselves, support the need for a third scanner in the practice.

Operation of the proposed unit in Orange will have an adverse financial impact on ARC, which currently serves hundreds of COS MRI patients from the Orange, Shelton and Stratford service areas. COS concedes that it intends to “recapture” patients that are currently being referred to non-COS providers for MRI services (CON Application, p. 37). This means less scans referred to providers like ARC and the loss of associated revenue.

Moreover, COS has not shown that its acquisition of a third MRI unit will increase access to MRI services for the state’s most vulnerable patients, including Medicaid recipients and indigent persons. The rates at which COS provides MRI services to Medicaid and uninsured patients are nominal at best. The practice is projecting more than 11,000 MRI scans by FY 2020, with only 100

of these being Medicaid recipients and 11 being uninsured (CON Application, p.278). ARC will provide evidence showing that in recent years, the number of MRI scans it performed on COS patients with Medicaid was almost equal to the number of Medicaid scans that COS performed on its own units. Based on the foregoing, ARC questions whether COS is providing meaningful access to MRI services for Medicaid beneficiaries and the indigent.

Questions also exist regarding the quality of both the mobile MRI unit being proposed for purchase by COS and the practice's high-volume MRI service. ARC is in the business of providing imaging services. The practice has owned many MRI machines over the years and is in a unique position to provide testimony on the quality of the proposed unit and of mobile MRI units in general. In addition, ARC will provide testimony regarding the benefits of subspecialized training for radiologists who read MRI scans and having depth of radiologists available to read scans. Again, COS is projecting more than 11,000 MRI scans by FY 2020, and it appears that all of these scans are read by a single general radiologist, with perhaps only the part-time assistance of another as needed.

Lastly, the possibility of overutilization of COS's scanners based on self-referral calls into question the validity of the practice's volume projections and the cost-effectiveness of the proposed MRI unit. ARC will present data regarding the issues around self-referral for major imaging services, a practice that the State of Connecticut may study and potentially limit in the future given implications for the healthcare system and healthcare consumers.

Background

ARC is a private radiology practice with more than 100 years of experience serving patients in Connecticut. The practice has seven offices located in Orange, Shelton, Trumbull, Stratford, Fairfield, Stamford, and Wilton. ARC has been serving the Orange community at its 297 Boston Post Road office for more than 15 years. The practice provides a full range of diagnostic imaging and interventional radiology services, including MRI at each of its office locations. MRI services are provided at the practice's Orange office with a 3.0 Tesla unit. All ARC radiologists are subspecialty trained. The practice provides the highest-quality, accredited MRI services in a cost-effective private physician office setting. ARC receives referrals for MRI services from a broad array of providers including physicians of all specialties, podiatrists and chiropractors, none of whom has a financial interest in any ARC equipment. ARC scans hundreds of COS patients each year, with a majority of COS patients receiving their MRIs at the Orange, Shelton, and Stratford offices. ARC provides services to all patients regardless of their ability to pay. The practice participates in the Medicaid program and serves many Medicaid recipients and indigent patients at each of its practice locations.

ARC's Interests Will Be Adversely Affected by Approval of COS's CON Request

COS is asking OHCA to approve a CON for a third MRI unit to service patients of its orthopedic practice. The unit will split time between COS's offices in Orange and Essex. The COS Orange office at 330 Boston Post Road is located .2 miles or 1,080 feet from ARC's Orange office at 297 Boston Post Road. ARC also has MRI units in Stratford and Shelton, located 10 and 12 miles, respectively, from COS's Orange office. Both of these units operate in the service area identified by COS for its proposed MRI unit.

COS concedes that with a third unit it intends to “recapture” MRI volume that is currently being referred to non-COS providers (CON Application, p. 37). These providers include ARC, which scans approximately 400 COS patient every year. This “recapture” is reflected in the 16% projected increase in MRI volume projected for the first year of operation of the proposed third scanner (CON Application, p. 278).

In FY 2016, ARC performed 398 MRI scans ordered by COS physicians. The value of these services was approximately \$260,000. ARC expects to scan 422 COS patients in FY 2017, with services valued at approximately \$275,000. If COS is authorized to acquire a third MRI unit ARC will certainly lose most of these referrals as COS “recaptures” MRI patients. Although COS downplays any impact of its proposal on existing providers, significant financial losses will result for ARC and therefore the CON proposal will adversely impact an existing provider of MRI services (CON Application, pp. 36-37).

In addition, a majority of the scans referred to ARC by COS were of commercially insured patients. Commercially insured scans generate the highest per-patient revenue for MRI services. The loss of this revenue will further skew ARC’s payer mix towards Medicaid and other governmental payers, which reimburse at much lower rates than commercial insurance. ARC relies on its commercially insured patients to generate the MRI revenues that support the practice’s provision of all imaging services to its patients. The loss of COS-ordered scan volume and commercially insured revenue will undoubtedly have an adverse financial impact on ARC. ARC is entitled to participate in COS’s CON proceeding in order to protect its interests in this regard.

Moreover, because COS provides a limited number of scans to Medicaid recipients and uninsured individuals, providers like ARC and area hospitals are left to accommodate the MRI needs of these patient populations (CON Application, p. 278). Authorizing a third MRI unit for COS does nothing to enhance access for Medicaid program participants, as MRI scans for these patients are expected to grow by a mere 17 scans between FY 2017 and FY 2020 (CON Application, p. 278). Similarly, COS projects that it will provide only 11 scans (.1% of total MRI volume) to uninsured patients annually by FY 2020 (CON Application, p. 278). Compare this with COS's commercially insured MRI volume, which is expected to increase by 1,223 scans during this same time (CON Application, p. 278). COS's third unit, like its other two, will "skim the cream" – namely, commercially insured MRI scans – leaving other providers to care for governmentally insured and uninsured patients. The larger the number of Medicaid and indigent patients ARC cares for, the less financially viable the practice will become. Too significant a shift in payer mix can jeopardize the practice's existence. This in turn jeopardizes access to services at a provider that cares for all patients regardless of their financial means. ARC's interest in ensuring that the practice continues to exist to serve its patients justifies its participation in COS's CON proceeding.

Lastly, COS's status as a self-referral provider can have an adverse impact on healthcare consumers, payers and radiology providers such as ARC. As ARC's witnesses will testify, studies have shown that when providers have a financial interest in advanced imaging equipment they tend to refer patients at higher rates, leading to over utilization, increased cost and, subsequently, decreased cost-effectiveness. Increased healthcare costs due to the performance of unnecessary services impact the healthcare system as a whole and every provider in it.

Summary of Evidence to Be Presented, Manner of Participation and Relief Sought

ARC will ask OHCA to deny COS's request for permission to acquire a third MRI unit. COS has failed to meet several of the statutory criteria for issuance of a CON. Specifically, COS has not established that there is a clear public need for its proposal (Conn. Gen. Stat. §19a-639(3)). ARC will present evidence regarding the applicable SHP guidelines for the acquisition of a third MRI unit by COS and the available capacity of the 29 MRI units already operating in the combined Orange-Essex service area, including three ARC units.

In addition, COS's proposal will result in the unnecessary duplication of existing healthcare services, which will adversely impact existing providers such as ARC (Conn. Gen. Stat. §§19a-639(8) & (9)). This will be demonstrated through the presentation of evidence showing the number and value of scans historically performed by ARC on COS patients, which COS intends to "recapture" with the third MRI unit (CON Application, p. 37). ARC will show that it has accommodated, and will continue to accommodate, COS's overflow scans, making the addition of a third unit unnecessarily duplicative. ARC will further show the adverse financial consequences to the practice of a loss of COS volume, which is primarily commercially insured. This is particularly relevant in light of the fact that ARC serves all patients regardless of ability to pay and any shift in its payer mix could decrease its financial viability.

In addition, COS has failed to establish that its proposal will improve the accessibility of services for Medicaid recipients and indigent persons (Conn. Gen. Stat. §19a-639(5)); rather COS provides limited access to MRI services for Medicaid recipients and indigent persons, without good cause for doing so (Conn. Gen. Stat. §19a-639 (10)). ARC will present evidence regarding COS's

history, or lack thereof, of providing MRI service to these patient populations. This will be compared with ARC's history of providing services to Medicaid program participants and indigent persons, including many referred by COS.

ARC will also testify regarding the quality of the MRI services being proposed by COS. Specifically, ARC will testify regarding the quality of the proposed 2000 mobile MRI unit, and of mobile units generally, and the impact that this can have on scan quality and the care provided to patients. ARC will also testify regarding the benefits of subspecialization and appropriate workload and turnaround time for the interpretation of MRI scans.

Lastly, ARC will present evidence regarding the impact of self-referral on the need for, and cost-effectiveness of, MRI services. ARC will submit studies that show higher rates of referrals for imaging by providers with financial interests in the equipment on which the examinations are performed. ARC will show how this unnecessary utilization may be artificially inflating COS's MRI volume and decreasing the cost-effectiveness of the service they are proposing to augment with the acquisition of a third MRI unit.

If ARC is granted status, it intends to present this and other evidence and legal arguments in support of its positions. The arguments are set forth in detail in the attached testimony of Mr. Yoder and Dr. Karol. ARC respectfully requests that it be allowed to submit written testimony, present evidence and arguments at the July 11, 2017 public hearing on this matter, cross-examine witnesses, and inspect and copy records pertaining to the proceeding. ARC's participation will furnish assistance to OHCA in determining the impact of this proposal on existing providers and access to MRI services for certain patient populations. ARC's participation will also assist OHCA in

evaluating COS's compliance with other statutory CON decision criteria (i.e. need and quality, accessibility and cost-effectiveness of services). ARC's participation is in the interest of justice and will not impair the orderly conduct of these proceedings.

WHEREFORE, for the foregoing reasons, ARC respectfully requests that its Petition to be Designated as an Intervenor With Full Rights be granted.

Respectfully Submitted,

ADVANCED RADIOLOGY CONSULTANTS, LLC

By: 

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CERTIFICATION

This is to certify that a copy of the foregoing was sent via electronic mail this 27th day of June, 2017 to the following parties:

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**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION**

.....)
IN RE: CONNECTICUT ORTHOPAEDIC)
SPECIALISTS, P.C. ACQUISITION OF A)
MOBILE 1.5 T MAGNETIC RESONANCE)
IMAGING SCANNER)
.....)

DOCKET NO. 16-32117-CON

JUNE 27, 2017

**PREFILED TESTIMONY OF CLARK G. YODER, M.B.A.,
CHIEF EXECUTIVE OFFICER OF ADVANCED RADIOLOGY CONSULTANTS, LLC,
IN OPPOSITION TO THE CON REQUEST OF
CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.**

Good morning Hearing Officer Hansted and members of the Office of Health Care Access (“OHCA”) staff. My name is Clark Yoder and I am the Chief Executive Officer (“CEO”) of Advanced Radiology Consultants, LLC (“ARC”). A copy of my Curriculum Vitae is attached for your reference (see Exhibit A). With me today is my colleague, Dr. Ian Karol, ARC’s Chief Medical Officer (“CMO”) and a member of our Radiology Executive Committee. We thank you for this opportunity to testify in opposition to the Certificate of Need (“CON”) Application filed by Connecticut Orthopaedic Specialists, P.C. (“COS”) for acquisition of a third MRI unit.

ARC respectfully requests that COS’s CON Application be denied. COS has not established that there is a clear public need to acquire an unprecedented third MRI scanner for use in its private orthopedic practice.¹ In fact, the markets where COS proposes to operate the unit are already saturated with MRIs, many of which have available capacity. Allowing COS to bring another captive scanner into these markets will adversely impact ARC and other providers

¹ To the best of our knowledge, there is no other orthopedic physician practice in Connecticut that owns three MRI units.

that have capacity and welcome all patients regardless of ability to pay. Moreover, the proposal does not enhance access to MRI services for our state's most vulnerable patients, including Medicaid program participants and indigent persons. Nor does it present the most cost-effective option for meeting the MRI needs of Orange and Essex area residents.

Background on Advanced Radiology Consultants

ARC is a private radiology practice with office locations throughout Fairfield and New Haven Counties, including an office at 297 Boston Post Road in Orange. ARC provides a full range of diagnostic imaging and interventional radiology services. The practice offers MRI at each of its seven locations, including three locations within the proposed service area of COS's Orange MRI unit (Orange, Shelton & Stratford). The Orange office of ARC is located .2 miles or just 1,080 feet from the site of COS's proposed Orange MRI service. ARC's Stratford and Shelton MRI units are located 10 and 12 miles, respectively, from COS's Orange office.² MRI services are provided at ARC's Orange office with a 3.0 Tesla unit and at our Stratford and Shelton offices with 1.5 Tesla units. ARC provides services to all patients regardless of their ability to pay. The practice participates in the Medicaid program and serves many indigent patients in Orange, Stratford, Shelton and elsewhere.

COS Has Not Satisfied the Statutory Decision Criteria for a CON

As discussed in greater detail below COS has failed to meet several of the statutory criteria for issuance of a CON. Specifically, COS has not established that there is a clear public need for the acquisition of an MRI unit based on guidelines contained in the Statewide Healthcare Facilities & Services Plan ("SHP") (Conn. Gen. Stat. §19a-639(3)). In addition,

² ARC also has MRI units in the nearby towns of Trumbull and Fairfield, which have historically served COS patients.

COS's has failed to consider the utilization of existing MRI providers in its assessment of need (Conn. Gen. Stat. §19a-639(8)). As such, this proposal will result in the unnecessary duplication of existing healthcare services, which will adversely impact providers such as ARC (Conn. Gen. Stat. §19a-639(9)). Moreover, COS has failed to establish that its proposal will improve the accessibility of services for Medicaid recipients and indigent persons (Conn. Gen. Stat. §19a-639(5)); rather COS provides limited access to MRI services for Medicaid recipients and indigent persons, without good cause for doing so (Conn. Gen. Stat. §19a-639 (10)).

No Clear Public Need for an Additional MRI Scanner

COS argues clear public need for a third MRI scanner based upon the growth of its practice and the available capacity of COS MRI units located in Hamden and Branford. COS uses a need methodology at page 61 of the SHP that provides a benchmark of 4,000 scans for an MRI scanner and allows for the addition of a scanner if the applicant has an existing scanner in the primary service area operating in excess of 85% capacity (3,400 scans/year) (CON Application, p. 22). COS claims that its Hamden and Branford MRI units are operating at 94% and 110% capacity, respectively, and therefore a third unit is justified per the SHP guidelines (CON Application, p. 23). Note however that the primary service area towns for this proposal are as follows: Orange, New Haven, Woodbridge, Shelton, Derby, West Haven, Milford, Stratford, East Haven, North Haven, Essex, Madison, Guilford, Clinton, Old Saybrook, Westbrook, Old Lyme, Deep River, and Chester (CON Application, pp. 40-41). Neither Hamden nor Branford is listed as a primary service area town for the proposed MRI unit. Accordingly, COS does not have an existing unit in the primary service area of this MRI proposal and it cannot utilize Standards and Guidelines Specific to MRI, Section 3.b. to establish clear public need.

COS argues that because this is a proposal for an in-house MRI unit, the “ordinary capacity calculation” cannot be used (CON Application, p. 24). COS claims that because it controls referrals to its MRI units it does not need to establish a broader service area need for the proposed third unit (CON Application, p. 24). This is not what the SHP guidelines allow for. Because there are other providers in the service area, including ARC, that can and do provide MRI services to COS patients, COS must evaluate the capacity of these existing providers in determining whether there is a need for an additional MRI unit in the Orange and/or Essex service areas. Absent compliance with SHP guidelines in this regard, specialty practices like COS will be able to justify the acquisition of costly imaging equipment without demonstrating public need or assessing impact on existing providers, simply by incrementally growing the number of physicians in their practices through mergers and acquisitions.

The burden is therefore on COS to determine whether the Percent Utilization of Current Capacity in each of the primary service areas to be served by the proposed MRI unit exceeds 85% (SHP, p. 61, Standards and Guidelines Specific to MRI, 3.a.). COS has not undertaken this analysis, but we expect that it would show ample available capacity in the Orange service area, where there are currently 26 MRI units in operation (CON Application, pp. 45-47) (see Exhibit B). Looking at the data provided by COS in Table 9 of the CON Application, 15 of the 26 scanners located in the Orange service area (58%) are operating below 85% capacity (CON Application, pp. 45-47). Assuming each scanner can accommodate 4,000 scans per year, the total capacity of the MRI units in the Orange service area is 104,000 scans (4,000 x 26). In FY 2013, the last year for which utilization data is publically available, these scanners combined to perform 81,022 scans (CON Application, pp. 45-47). This means that in the aggregate the MRI units in the Orange service area are operating at 78% capacity (see Exhibit B). A similar

analysis can be undertaken for Essex, where two of the three scanners in the service area (67%) are operating below 85% capacity. These scanners performed 7,639 scans in FY 2013, out of an available capacity of 12,000 scans, putting them at 64% capacity in the aggregate.

MRI units in the Orange service area that have available capacity include ARC's units in Shelton and Orange. ARC's Shelton unit provided 2,421 scans in FY 2016, which is 61% capacity based upon SHP standards. This unit can accommodate at least 1,000 additional scans before exceeding capacity. The practice's Orange unit performed 4,158 scans in FY 2016, but is on track to perform around 3,900 scans in FY 2017. This is a 3.0 Tesla unit that currently operates Monday through Friday, 7:00 a.m. to 10:00 p.m. ARC has the ability to add weekend hours at this site as needed. In FY 2016, the Orange MRI unit scanned 201 COS patients. This unit can certainly continue to handle these patients, as well as the several hundred additional scans of patients in the Orange service area that COS claims need to be referred to non-COS providers (CON Application, p. 35).

As Dr. Karol will testify, the ARC units are of superior quality to the mobile MRI unit being proposed by COS. Moreover, all MRI scans at ARC are read by subspecialty trained radiologists and turned around as fast, if not faster, than those read by COS's in-house general radiologist. ARC turns its MRI images around to referring physicians in one hour on average during the week, whereas COS's employed radiologist can take up to 24 hours (CON Application, p. 18).

Furthermore, COS suggests that the "access" it provides to its patients is somehow superior to access offered by other MRI service providers (CON Application, pp. 16, 23, 29, 221), creating a need for a third MRI unit within the practice. This "access" takes the form of early morning and late night appointments on weekdays (7:00 a.m. – 9:00 p.m.); ARC's Orange

MRI is open from 7:00 a.m. to 10:00 p.m. on weekdays and its Stratford unit operates from 7:00 a.m. to 11:00 p.m. Like COS, ARC will also open its Orange office on the weekend to accommodate patients and our Stratford MRI operates from 7:00 a.m. to 7:00 p.m. on Saturdays.³ Like COS, ARC holds emergency appointments open daily at each of its offices, including the Orange office. Therefore, COS does not have “improved accessibility over traditional radiology centers” in this regard (CON Application, p. 221).

COS also mentions how traveling can be painful or injurious for an orthopedic patient in need of an MRI and suggests that offering in-house MRI obviates the need to travel to another location for a scan (CON Application, p. 221). Dr. Karol will speak to this in greater detail, but based on ARC’s experience the incidence of “same-day” MRI in the outpatient setting is minimal. This means that most COS patients in need of MRI will have to travel, even if it is just returning to the COS office within a few days for their scans. If the COS Orange office is a convenient location for these patients because it is a short travel distance from their homes, then the ARC Orange MRI unit that sits 1,080 feet away is equally convenient.

Lastly, COS suggests that there is a “time delay” associated with having an MRI performed at a location other than within the orthopedists’ office (CON Application, p. 221). This is misleading. As mentioned above, instances of same-day MRI are rare in ARC’s experience. Assuming a patient is not going to be seen same day, COS likely has the same scheduling considerations as any private radiology office. The practice probably has a backlog of appointments, and the likelihood that a patient will be seen in Orange or Essex immediately is low given that the unit will be in each location only two days per week. Currently, ARC can

³ Presumably, COS’s ability to provide weekend hours at either Orange or Essex will be limited by the location of the mobile unit on any given day. Also, its ability to provide early morning and late evening scans is limited to the 2 days each week that the unit is in each location. In addition, COS is proposing to curtail weekend hours on its Hamden and Branford MRIs to four hours on Saturdays, and no regular weekend hours are proposed for the Orange/Essex unit (CON Application, pp. 34 & 39).

accommodate MRI patients at its Orange and Stratford offices next day and in Shelton within two days.

Unnecessary Duplication of Services & Adverse Impact on Existing Providers

The proposed COS Orange MRI unit and ARC's MRI units in Orange, Shelton and Stratford have overlapping service areas. COS lists its Orange MRI service area towns as Orange, New Haven, Woodbridge, Shelton, Derby, West Haven, Milford, Stratford, East Haven, and North Haven (CON Application, p. 40). In 2016, ARC provided MRI services to COS patients residing in each of the COS Orange MRI service area towns as follows: Orange (27); New Haven (17); Woodbridge (7); Shelton (56); Derby (22); West Haven (38); Milford (36); Stratford (16); East Haven (1); and North Haven (3). The total number of patients scanned by ARC from the COS Orange service area was 223.

The chart below demonstrates the service area overlap between the proposed COS unit and ARC's units in Orange, Shelton and Stratford:

COS Orange	ARC Orange	ARC Shelton	ARC Stratford
Orange	<u>Milford</u>	<u>Shelton</u>	<u>Stratford</u>
New Haven	<u>West Haven</u>	Seymour	<u>Milford</u>
Woodbridge	<u>Stratford</u>	Ansonia	Bridgeport
Shelton	<u>New Haven</u>	Bridgeport	
Derby	Bridgeport	<u>Derby</u>	
West Haven	<u>Orange</u>	<u>Stratford</u>	
Milford	<u>Shelton</u>	Trumbull	
Stratford	Trumbull	Oxford	
East Haven	Ansonia		
North Haven	Hamden		
	<u>Derby</u>		
	Fairfield		
	<u>East Haven</u>		
% of Service Area Towns that Overlap with COS Orange Service Area	62%	38%	67%

In FY 2016, ARC performed 398 scans ordered by COS physicians. ARC's average reimbursement for an MRI scan is \$650. This puts the value of MRI scans for COS patients in FY 2016 at around \$260,000. ARC has scanned 176 COS patients in FY 2017 to date. At this rate ARC expects to receive approximately 422 MRI referrals from COS physicians in FY 2017,

valued at approximately \$275,000. This referral relationship is longstanding, and despite COS's statement that this proposal will not change referral patterns for its own scanner, it will most certainly change referral patterns for providers like ARC who have historically scanned many COS MRI patients each year (CON Application, p. 37). This loss of revenue is significant and will be seriously detrimental to ARC. Since \$275,000 of gross revenue cannot be replaced, and due to the large fixed costs associated with operating an MRI unit, ARC may be forced to enact staffing reductions or other drastic cost savings measures if this application is approved.

By COS's own admission, it is looking to "recapture" scan volume from non-COS providers, which accounts in part for the 16% increase in MRI volume projected for the first year of operation of the new unit (CON Application, pp. 37 & 278). In projecting volume for the proposed Orange MRI unit, COS claims that of the 1,500 to 1,600 scans that will be performed each year (CON Application, p. 43), approximately 1,000 of those represent scans already performed on COS's MRI units in Hamden and Branford (CON Application, p. 35). COS further acknowledges that approximately 450 of the patients that make up the projected MRI volume for COS Orange are currently referred to non-COS providers for their scans (CON Application, p. 35). Thus despite its claim that impact on existing providers will be "minimal," ARC stands to lose 400 or more scans each year valued at over a quarter-of-a-million dollars (CON Application, p. 36).⁴ Similarly, COS projects that it will "recapture" nearly 800 scans from Middlesex Hospital and its affiliates once it establishes MRI services in Essex, which is also not an insignificant impact (CON Application, p. 219).

Providers like ARC are already accommodating COS's overflow scans, and we will continue to do so with the MRI capacity available in our practice. Some of these are patients

⁴ Assuming ARC only lost the COS MRIs performed at its Orange, Shelton and Stratford offices this is still more than 300 scans annually.

who have used ARC for their imaging in the past and for whom we can ensure continuity and coordination of care. Because ARC can and will continue to serve these patients if they so choose, as well as any other patients referred by COS physicians, COS's acquisition of a third unit is an unnecessary duplication of MRI services.

When all is said and done, ARC will be adversely impacted by COS's acquisition of a third MRI unit, if approved by OHCA. In order to meet its volume projections COS physicians will need to refer virtually all of their MRI scans to practice-owned units. This will mean the loss by ARC of a significant number of scans and associated revenue each year. OHCA should not approve a proposal that, by the Applicant's own admission, will adversely impact an existing provider to this extent.

Access for Medicaid Recipients & Indigent Persons

While COS participates in the Medicaid program, its historic and projected MRI scans for Medicaid patients are minimal. In FY 2016, COS appears to have provided only 78 scans to Medicaid patients (9,108 scans total x .86% = 78 Medicaid scans) (CON Application, p. 245). In addition, while COS claims to have recently put a charity care policy in place, its historic provision of MRI services to uninsured patients is less than 10 scans per year or .1% of the practice's annual MRI volume (CON Application, p. 278).

The number of Medicaid scans performed by COS is projected to increase by only 17 scans by FY 2020, after which time the service will be "mature" and Medicaid and other MRI scan volume at COS will remain flat (CON Application, p.278). This means that COS will likely never provide more than 100 MRI scans to Medicaid patients in a year, with Medicaid scans remaining less than 1% of its payer mix. For uninsured patients, that number will in theory never eclipse 11 scans (CON Application, p. 278). At the same time, COS's commercially

insured MRI scan volume is projected to increase by 1,223 scans in just over three years, representing 68% of the practice's MRI payer mix (CON Application, p. 278).

OHCA should inquire as to why COS's Medicaid and uninsured MRI percentages are as low as they are given that the practices has offices between two of the state's largest urban areas, Bridgeport and New Haven. Bridgeport and New Haven are among the cities in Connecticut with the most Medicaid recipients as a percentage of their overall populations, at 45% and 44%, respectively (see Exhibit C). By comparison, ARC also has offices in and around Bridgeport and New Haven and our Medicaid and uninsured scan volumes are a far greater percentage of our overall scans.

Practice-wide, ARC performed 2,190 scans on Medicaid patients in FY 2016 out of 24,697 total exams (9%). This means that while ARC performed just 2.7 times as many MRI scans as COS in FY 2016, it saw 28 times as many Medicaid patients as the orthopedic practice with its captive units. By office, ARC performed 270 Medicaid scans in Orange in FY 2016, which accounted for 6.5% of total scans at that location. In Shelton, ARC performed 155 Medicaid scans accounting for 6.4% of total scan volume. And in Stratford, the 820 Medicaid scans performed by ARC made up 15% of total scan volume. ARC's total Medicaid scans have increased by 469 or 22% since FY 2014.

Moreover, ARC's Orange MRI service provided 158 scans to uninsured and self-pay patients in FY 2016, more than 17 times as many uninsured and self-pay patients as COS scanned in Hamden and Branford combined that same year. ARC also scanned 58 uninsured patients in Shelton and 187 uninsured patients in Stratford in FY 2016. ARC's MRI service as a whole provided 996 scans to uninsured and self-pay patients in FY 2016 or more than 100 times as many uninsured and self-pay scans as COS.

For COS to operate in the same market as ARC and have such dramatically lower Medicaid and uninsured numbers begs the question whether the practice is somehow restricting access for these patients through its outreach, scheduling or other policies. Of note, a fair number of the MRI scans that ARC performs on COS patients are reimbursed by Medicaid. In FY 2016, 51 of the 398 COS patients scanned by ARC were Medicaid recipients (13%). The total number of COS Medicaid patients that ARC scanned in FY 2016 (51) is more than half of the total number of Medicaid scans that COS performed on its own units that year (78) (CON Application, p. 245). Assuming that COS referred Medicaid patients to other non-COS providers as well, it is entirely possible that COS sent out more Medicaid patients for MRI scans than it accommodated in-house.

The CON statutes require that OHCA consider how a CON proposal impacts access to and the quality of care for Medicaid recipients and indigent persons. Section 19a-639(5) of the Connecticut General Statutes requires an applicant to demonstrate how its proposal “will improve the quality, accessibility and cost effectiveness of healthcare delivery in the region, including ... provision of ... and access to services for Medicaid recipients and indigent persons ...” Similarly, Section 19a-639(6) requires OHCA to consider the applicant’s “past and proposed provision of health care services to relevant patient populations and payer mix, including ... access to services by Medicaid recipients and indigent persons.”

COS predicts that it will provide no more than 100 Medicaid scans and 11 uninsured scans in any given year once its MRI service matures (CON Application, p. 278). Of the nearly 750,000 Medicaid beneficiaries in this state, less than 100 are benefitting from COS’s two existing MRI units (see Exhibit C). If a third scanner is approved COS promises to increase its Medicaid volume by 17 scans and its uninsured volume by mere 2 scans. How is this “enhanced

access to care” for these populations? OHCA should not approve a unit that will be nominally beneficial to the state’s most vulnerable patients, particularly when it will have an adverse impact on private radiology practices and hospitals that care for far more Medicaid and indigent patients each year.

Based on the foregoing COS’s proposal does little, if anything, to improve the quality or accessibility of care for Medicaid recipients and indigent persons. In fact, it will adversely impact the area providers who do serve these patients. The fact that COS does not provide MRI services to Medicaid recipients or indigent persons in any appreciable numbers means these patients are being sent to the limited number of providers that do.⁵ Medicaid reimburses far less for MRI services than most commercial insurance plans. Therefore, providers like ARC and area hospitals are losing money on these patients while COS “skims the cream” with a non-governmental payer mix exceeding 80%.

In addition, approximately 57% of the MRI scans that ARC performs on COS patients are covered by commercial insurance. If COS is allowed to acquire a third MRI unit, this business will be lost and the practice’s payer mix will further skew towards governmental payers. As our MRI payer mix shifts, it can threaten the viability of ARC as a whole because the lion’s share of the practice’s profit margin comes from MRI services. This would compromise the practice’s ability to provide a full range of imaging services to all patients, including the Medicaid and indigent patients that COS services in limited numbers. The same is true for the full-service acute-care hospitals in our area, where Medicaid percentages can be even higher.

⁵ Based on data presented in a 2016 Medicaid Access Monitoring Review Plan prepared by the Connecticut Department of Social Services (excerpts attached as Exhibit D), the number of Medicaid-participating physician specialists declined in each county in the state between CY 2014 and CY 2015. This included a loss of 183 specialty providers in Fairfield County (11%) and 253 specialty providers in New Haven County (13%). At the same time, utilization of physician specialists by Medicaid recipients continues to increase. Physician specialist visits grew by approximately 35,000 in Fairfield County, and 34,000 in New Haven County, between CY 2013 and CY 2015.

Conclusion

For the foregoing reasons, COS's request for permission to acquire an unprecedented third MRI unit should be denied. COS has used a flawed need methodology and has not established a clear public need for the acquisition of an MRI unit for use in areas that are already served by 29 existing units. If the third unit is approved, COS will stop referring its patients to ARC for scans, resulting in significant financial harm. Because these patients are already well-served by existing providers such as ARC, the proposed scanner is unnecessarily duplicative. In addition, by COS's own admission, in-house MRI services for Medicaid beneficiaries and indigent persons will be extremely limited. This proposal does not, therefore, meet the policy objectives of increasing access to care for these vulnerable populations.

Thank you again for allowing me to testify. Once Dr. Karol testifies we will be available to answer any question you have.

The foregoing is my sworn testimony.

A handwritten signature in blue ink, appearing to read 'Clark G. Yoder', written over a horizontal line.

Clark G. Yoder, M.B.A.

EXHIBIT A

Clark G. Yoder, MBA, R.T.(R)(MR)(CT)
1370 Fence Row Drive, Fairfield, CT 06824

Professional Experience

Advanced Radiology Consultants, LLC, Shelton, CT	2015- Present
<u>Chief Executive Officer</u>	
Northwell Health and North Shore-LIJ CareConnect Insurance Company Roslyn, NY	2014-2015
<u>Chief Customer Officer and NSLIJ-IPA Vice President</u>	
WESTMED Practice Partners LLC and WESTMED Medical Group, P.C. – Purchase, NY	2000- 2013
<u>Promoted to Chief Operating Officer</u>	
<u>Promoted to Chief Financial Officer</u>	
<u>Promoted to Director of Ancillary Services</u>	
<u>Radiology Manager</u>	
Salick Healthcare, St. Vincents Cancer Center, New York, NY	1999-2000
<u>Radiology Director</u>	
Radiologix/HVRA, New City, NY	1996-1999
<u>Director of Operations</u>	
Greenwich Hospital, Greenwich, CT	1990-1996
<u>Radiology Technologist and Radiologic Technologist Supervisor</u>	

Clark G. Yoder, MBA

Education and Credentials

Master of Business Administration (MBA) – University of Connecticut

Bachelor of Science, Radiology (BS) - Quinnipiac University

Professional and Personal Achievements

Member, Board of Fellows, Health Affairs, Frank Netter, MD School of Medicine, Quinnipiac University

Beta Gamma Sigma Business Society Member

Member American College of Healthcare Executives

Member Radiology Business Management Association

Member Radiological Society of North America

Member Healthcare Leaders of New York

ARRT (MR)(CT)(RT)(R)

President: Ridge Homeowners Association, Inc.

Former Board of Director- Bedford Physicians Risk Retention Group, Inc.

Former Board of Director WPP, LLC

Former Managing Member and Treasurer- Rye Ambulatory Surgery Center, LLC

Former Assistant Treasurer- WESTMED PAC

Former Board of Director- Amerinet Northeast Alliance

EXHIBIT B

Current Local Area Magnets*

ID	Facility (Refer to ID numbers on following map)	Provider Type O = Outpatient H = Hospital	MRI Type	Total Scans (2013) % Capacity	Distance from Connecticut Orthopaedic Specialists 330 Boston Post Road Orange, CT 06477
A	Connecticut Orthopaedic Specialists 330 Boston Post Road Orange, CT 06477	O	1.5T, Mobile, Closed	NA	0
1	Connecticut Orthopaedic Specialists 2416 Whitney Avenue Hamden, CT 06518	O	1.5T, Fixed, Closed	3,773 94.3%	10.0 miles
2	Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT 06405	O	1.5T, Fixed, Closed	3,851 96.3%	9.7 miles
3	Milford Hospital, Inc. 300 Seaside Avenue Milford, CT 06460	H	1.5T, Fixed, Closed	2,005 50.1%	4.4 miles
4	Griffin Hospital 130 Division Street Derby, CT 06418	H	1.5T, Fixed, Closed	1,888 47.2%	6.6 miles
5	Griffin Imaging and Diagnostic Center at Ivy Brook 2 Ivy Brook Road Shelton, CT 06484	H	1.2T, Mobile, Closed	2,341 58.5%	4.9 miles
6	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	4,010 100.2%	4.7 miles
7	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	4,454 111.4%	4.7 miles
8	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	4,020 100.5%	4.7 miles
9	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	2,556 56.4%	4.7 miles
10	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	6,231 155.8%	4.7 miles
11	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	6,130 153.3%	4.7 miles
12	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	6,003 150.1%	4.7 miles

13	Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel Street New Haven, CT 06511	H	1.5T, Fixed, Closed	812 20.3%	4.6 miles
14	Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel Street New Haven, CT 06511	H	3.0T, Fixed, Closed	713 17.8%	4.6 miles
15	Yale-New Haven Hospital, Inc. Temple Radiology New Haven 60 Temple Street New Haven, CT 06510	H	1.5T, Fixed, Closed	2,582 64.6%	4.9 miles
16	Saint Raphael Magnetic Resonance Center 330 Orchard Street New Haven, CT 06511	H	1.5T, Fixed, Closed	1,827 45.7%	4.7 miles
17	Bridgeport Hospital 2595 Main Street Stratford, CT 06615	H	1.5T, Fixed, Closed	1,492 37.3%	8.0 miles
18	Bridgeport Hospital 267 Grant Street Bridgeport, CT 06610	H	1.5T, Fixed, Closed	3,500 87.5%	9.8 miles
19	St. Vincent's Medical Center 2800 Main Street Bridgeport, CT 06606	H	1.5T, Fixed, Closed	4,277 106.9%	11.0 miles
20	Southern Connecticut Imaging Center, LLC (dba Whitney Imaging Center) 2200 Whitney Avenue Hamden, CT 06518	O	1.5T, Mobile, Closed	88 2.2%	9.5 miles
21	Meriden Imaging Center, Inc. (dba Wallingford Diagnostic Imaging Center) 863 North Main Street Wallingford, CT 06492	O	1.5T, Fixed, Open	3,276 81.9%	17.4 miles
22	Diagnostic Imaging Services of CT, LLC (dba Branford Open MRI) 1208 Main Street Branford, CT 06405	O	0.3T, Fixed, Open	924 23.1%	10.3 miles
23	Advanced Radiology Consultants, LLC 297 Boston Post Road Orange, CT 06477	O	3.0T, Fixed, Open	3,114 77.9%	1,080 feet (0.2 miles)
24	Advanced Radiology Consultants, LLC 2876 Main Street Stratford, CT 06477	O	1.5T, Fixed, Closed	5,700 142.5%	7.8 miles
25	Advanced Radiology Consultants, LLC 4 Corporate Drive Shelton, CT 06484	O	1.5T, Fixed, Closed	3,975 99.4%	6.5 miles
26	Advanced Radiology Consultants, LLC 15 Corporate Drive Trumbull, CT 06611	O	1.5T, Fixed, Open	1,480 37.0%	11.7 miles
TOTALS				2013 Scans = 81,022	% Capacity = 77.9%

*Source: Connecticut Orthopaedic Specialists' Main Certificate of Need Application for the acquisition of a 1.5T mobile MRI unit; State of Connecticut Department of Public Health, Office of Health Care Access; Docket No. 16-32117-CON, August 19, 2016.

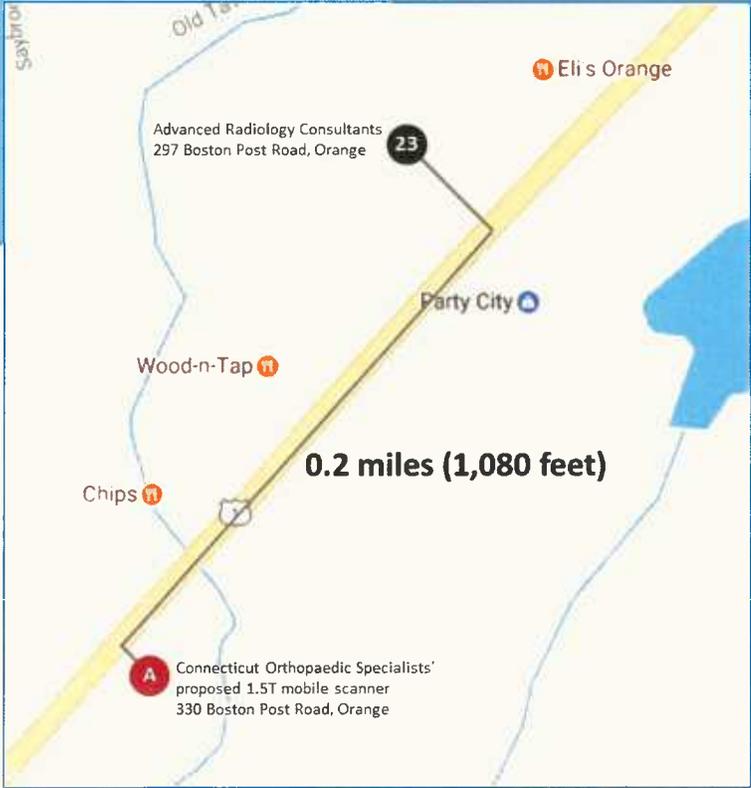
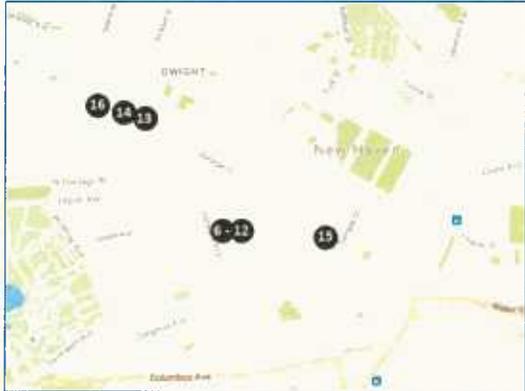


EXHIBIT C

HEALTH CARE

A look at Medicaid enrollment by town

MARCH 21, 2016



Jake Kara
Data Editor

Medicaid enrollment in Connecticut continues to rise (<http://ctmirror.org/2016/01/15/spending-and-enrollment-up-but-medicaid-per-person-cost-is-down/>). The program, which provides health coverage for the poor and disabled, now covers one in five state residents.

There were 748,009 Connecticut residents enrolled in Medicaid on Feb. 16, according to the most recent enrollment report.

The portion of Medicaid which covers parents and their minor children, called HUSKY Health Schedule A in Connecticut, has 458,136 recipients across the state.

The map below shows what percentage of each town's population is enrolled in Medicaid and HUSKY A.

We looked to see whether towns where a large portion of the Medicaid recipients were on HUSKY A also were towns with a younger population. We used census data to determine a town's median age and under-18 population, but we didn't find a strong correlation in either case.

The towns and cities with the most of Medicaid and Husky recipients as a percentage of each town's overall population, include:

1. **Hartford:** 58%, Medicaid; 32%, HUSKY A;
2. **Waterbury:** 51%, 30%;
3. **New Britain:** 47%, 28%;
4. **Bridgeport:** 45%, 27%;
5. **New Haven:** 44%, 24%;

6. **New London:** 43%, 25%;

7. **Windham:** 41%, 23%

8. **Norwich:** 38%, 23%;

9. **East Hartford:** 38%, 23%;

10. **Meriden:** 37%, 22%.

Note that we limited our list to towns with populations over 5,000 because per-capita figures from very small towns can be deceiving. Canaan, with a total population of 1,195 actually had the highest percentage of Medicaid recipients at 64%.

The towns with the smallest percentage of the population receiving Medicaid include:

1. **Weston:** 3.71%, Medicaid; 2.2% HUSKY A;

2. **Darien:** 3.7%, 2.1%;

3. **New Canaan:** 4%, 1.9%;

4. **Westport:** 5.2%, 2.4%;

5. **Redding:** 5.2%, 3.3%;

6. **Ridgefield:** 5.4%, 2.654235%;

7. **Wilton:** 5.9%, 2.3%;

8. **Easton:** 6.3%, 3.4%;

9. **Avon:** 6.6%, 2.8%;

10. **Mansfield:** 6.8%, 3.6%.

Check our work: The GitHub repository containing our work is available here

(https://github.com/trendct/medicaid_enrollment_analysis/blob/master/Husky%20enrollment%20by%20town.ipynb). We encourage you to look over our calculations and expand upon our work.

Correction: This article has been updated to more accurately reflect current enrollment. It was initially reported there were 823,867 people in Connecticut enrolled in Medicaid and 466,087, but that was based on a given year, and recipients can come in and out of the program throughout the year, so that number is higher than the 748,009 recipients counted in the most recent enrollment report.

EXHIBIT D

**STATE OF CONNECTICUT
DEPARTMENT OF SOCIAL SERVICES**

**ACCESS MONITORING
REVIEW PLAN
FOR
CONNECTICUT'S MEDICAID PROGRAM**

**Submitted to the U.S. Centers for Medicare and Medicaid Services (CMS)
pursuant to federal regulations at 42 C.F.R. §§ 447.203(b) and 447.204.**

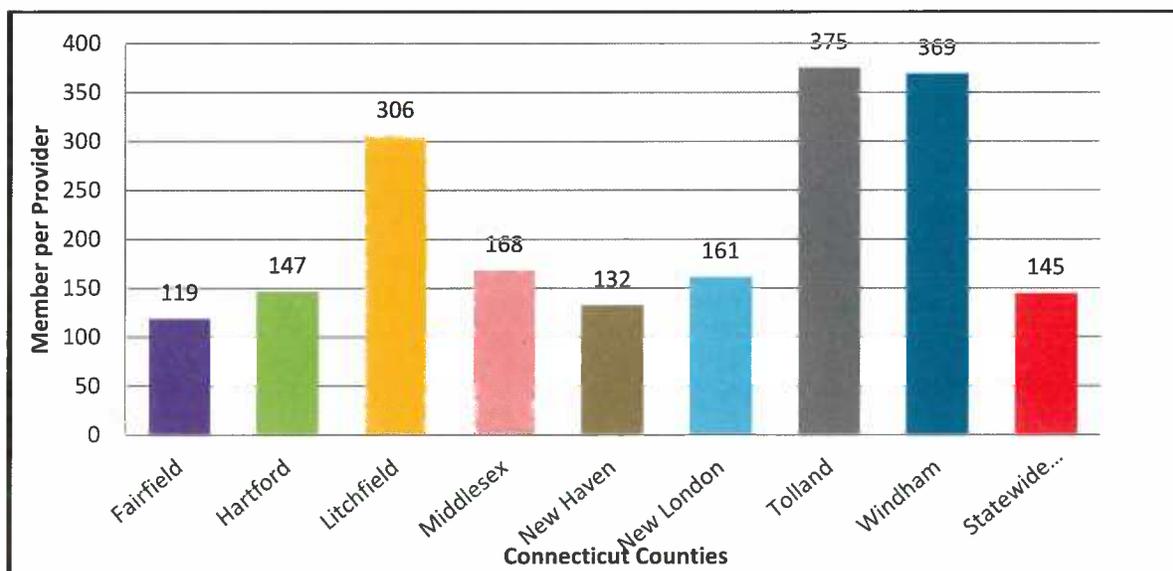
September 30, 2016

Figure 14 above shows the number of members to one provider in each Connecticut County, within the category of Physician, Advanced Practice Registered Nurses and Physician Assistants for primary care. For this particular category of providers, the overall average ratio is 213 members to one provider and ranges from 154 to 340 members per provider. The counties of Fairfield, New Haven and Tolland are close to the statewide average. Meanwhile, New London with the two hundred and seventy members per provider is higher than the statewide average. Meanwhile, Hartford County, with only one hundred and ninety-five (195) members to one provider, though in close proximity, falls slightly below the overall ratio. Similar to Figure 14 above, the counties of Litchfield and Windham have the highest ratio of members to one provider.

Table 14: Counts of CMAP Physician Specialists, Calendar Years 2013 through 2015

Physician Specialists	Statewide Performing Provider Count		
	CY 2013	CY 2014	CY 2015
Provider County			
Fairfield	1,077	1,676	1,493
Hartford	1,421	1,681	1,395
Litchfield	90	121	109
Middlesex	132	169	151
New Haven	1,565	1,877	1,624
New London	368	414	360
Tolland	42	56	51
Windham	75	92	73
Statewide Total Performing Providers	4,770	6,086	5,256

Figure 15: CMAP Health Care Members-to-Provider Statewide Average of CMAP Physician Specialists Calendar Year 2014



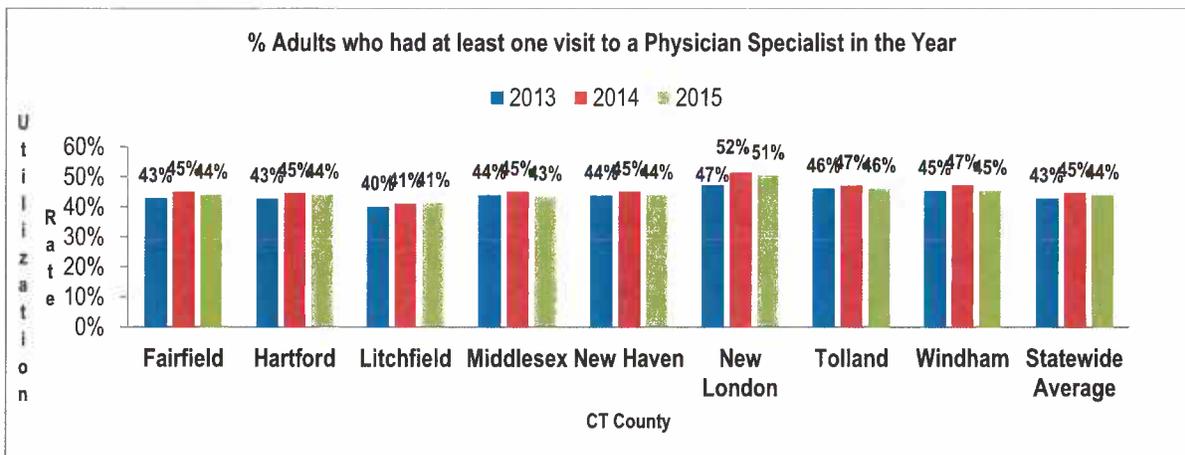
Physician Specialist Services

Table 33: Distribution of Adult Utilization of Physician Specialist Services - CY2013 - CY2015

Member (Adult) County	2013		2014		2015	
	Total Number of Adults	% Who had at least one visit in the CY	Total Number of Adult	% Who had at least one visit in the CY	Total Number of Adults	% Who had at least one visit in the CY
Fairfield	90,976	42.9%	111,508	45.1%	126,411	44.1%
Hartford	129,246	42.8%	147,416	44.6%	162,083	44.2%
Litchfield	18,924	40.2%	22,773	41.2%	25,134	41.4%
Middlesex	15,267	44.0%	18,101	45.1%	20,076	43.5%
New Haven	126,987	43.8%	146,255	45.1%	160,963	44.0%
New London	35,513	47.4%	40,297	51.5%	44,124	50.6%
Tolland	10,393	46.2%	12,579	47.2%	14,195	46.2%
Windham	17,971	45.4%	20,132	47.3%	21,942	45.5%
Statewide	430,919	44.4%	517,214	44.9%	573,682	44.1%

Source:- CT Medicaid Data Warehouse Data from Medicaid Management Information System with data of services from January 1, 2013 through December 31, 2015 of paid claims through May 2016.

Figure 27: Rate of Adult Utilization of Physician Specialist Services – CY 2013-2015



Source:- CT Medicaid Data Warehouse Data from Medicaid Management Information System with data of services from January 1, 2013 through December 31, 2015 of paid claims through May 2016.

Utilization of specialist services was queried based on a provider type and specialty not identified as a primary care, behavioral health, obstetric or home health provider, since these providers are analyzed under their respective category of care as specified in the final rule. The percentage of adult beneficiaries who received service from one of the selected specialist providers at least once during a calendar year remained consistently between 40% and 52% across all eight counties. New London County appears to have had the highest percentages (49% to 52%) of adult beneficiaries who had at least one visit with a specialist in the three year period, Tables 33 and Figure 27 above. Given the wide range of specialist services captured by this analysis, the relatively stable utilization rates, the lack of unresolved access to care

User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, June 27, 2017 11:11 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: 'klg1@aol.com'; jfusco@uks.com
Subject: COS Notice of Appearance & Request To Receive Documents
Attachments: Notice of Appearance.pdf; Request to Receive Documents.pdf

Dear Hearing Officer and OCHA Staff ;

Attached please find a Notice of Appearance and Request to Receive Documents from Connecticut Orthopaedic Specialists, P.C. in OHCA Docket No. 16-32117-CON.

Thank you for your assistance. Please confirm receipt of this transmission.

Best regards,

Glenn Elia, CEO

DEPARTMENT OF PUBLIC HEALTH :
DIVISION OF THE OFFICE OF : DOCKET NO. 16-32117-CON
HEALTH CARE ACCESS :
:
:
:
:
IN RE: CONNECTICUT ORTHOPAEDIC : JUNE 27, 2017
SPECIALISTS, P.C., ACQUISITION OF A :
1.5 T MOBILE MRI :

NOTICE OF APPEARANCE

In accordance with Sec. 19a-9-28 of the Conn. Agencies Reg., please enter the appearance of Patricia A. Gerner of The Law Office of Patricia A. Gerner, LLC on behalf of Connecticut Orthopaedic Specialists, P.C. in the above-captioned matter.

I will attend and participate in the hearing on July 11, 2017 on behalf of Connecticut Orthopaedic Specialists, P.C.

Respectfully Submitted,
THE LAW OFFICE OF PATRICIA A. GERNER, LLC

BY: Patricia A. Gerner

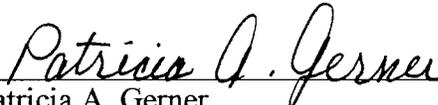
Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Fax: (860) 489-9380
Email: KLG1@aol.com

It's Attorney

Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 27th day of June, 2017 to:

Attorney Jennifer Groves Fusco at:

Updike Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
jfusco@uks.com



Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS**

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C. : **DOCKET NO. 16-032117-CON**

IN RE: ACQUISITION OF A MOBILE 1.5 T MRI : **JUNE 26, 2017**

REQUEST TO RECEIVE DOCUMENTS

A hearing is scheduled in the above-captioned matter to be held on July 11, 2017. The Applicant, Connecticut Orthopaedic Specialists, P.C. ("COS") hereby requests that the Department of Public Health, Division of the Office of Health Care Access, grant COS the right to all information regarding the hearing, sent to the attention of its CEO, Glenn Elia.

Also, as the attorney for COS, I respectfully request to be copied on all documents and correspondence with respect to Docket No, 16-322117-CON.

BY: *Patricia A. Gerner*

Its Attorney: Patricia A. Gerner

The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Fax: (860) 489-8380
Email: KLG1@aol.com

Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 26th day of June, 2017 to:

Attorney Jennifer Groves Fusco at:

Updike Kelly & Spellacy, P.C.
One Century Tower 265 Church Street
New Haven, CT 06510
jfusco@uks.com


Patricia A. Gerner, LLC
The Law Office of Patricia A. Gerner, LLC

Greer, Leslie

Subject: FW: Advanced Radiology Consultants -- Petition for Status & Prefiled Testimony (Docket No. 16-32117-CON)

Attachments: DOCS-#1596401-v1-ARC_COS_OHCA_COVER_LETTER.PDF; DOCS-#1596366-v1-ARC_COS_APPEARANCE_(FINAL).pdf; DOCS-#1596369-v1-ARC_COS_PETITION_FOR_STATUS_(FINAL).pdf; DOCS-#1596370-v1-ARC_COS_YODER_PREFILE_(FINAL).pdf; DOCS-#1596506-v1-ARC_COS_KAROL_PREFILE_(FINAL).pdf

From: Lazarus, Steven

Sent: Wednesday, June 28, 2017 7:27 AM

To: KLG1@aol.com; Glenn F. Elia <gelia@ct-ortho.com>

Cc: User, OHCA <OHCA@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>; Jennifer Groves Fusco (jfusco@uks.com) <jfusco@uks.com>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>

Subject: FW: Advanced Radiology Consultants -- Petition for Status & Prefiled Testimony (Docket No. 16-32117-CON)

Good Morning Attorney Gerner and Dr. Elia,

I'm forwarding you copies of the Request for Status and prefile testimony received by OHCA yesterday from Advanced Radiology Consultants, LLC related to the July 11th hearing. Attorney Fusco contacted me to inform me that she had trouble emailing Dr. Elia the files. Hopefully, you were able to get the files Attorney Fusco had forwarded and if not, hopefully, this email with the 5 attached documents will reach you both.

Thank you and please confirm receipt of this email and documents when you open this email.

Thank you,

Steven

Steven W. Lazarus

Associate Health Care Analyst

Division of Office of Health Care Access

Connecticut Department of Public Health

410 Capitol Avenue

Hartford, CT 06134

Phone: 860-418-7012

Fax: 860-418-7053



From: Jennifer Groves Fusco [<mailto:jfusco@uks.com>]

Sent: Tuesday, June 27, 2017 2:22 PM

To: Lazarus, Steven <Steven.Lazarus@ct.gov>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>; User, OHCA <OHCA@ct.gov>

Cc: Yoder, Clark (clark.yoder@adrad.com) <clark.yoder@adrad.com>; KLG1@aol.com; Glenn F. Elia <gelia@ct-ortho.com>

Subject: Advanced Radiology Consultants -- Petition for Status & Prefiled Testimony (Docket No. 16-32117-CON)

All:

Attached please find the following on behalf of Advanced Radiology Consultants, LLC:

- Cover Letter;
- Notice of Appearance;
- Petition For Status;
- Prefiled Testimony of Clark G. Yoder, M.B.A.; and
- Prefiled Testimony of Ian G. Karol, M.D.

Please let me know if you have any questions.

Thanks,
Jen

Jennifer Groves Fusco, Esq.
Principal
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
Office (203) 786.8316
Cell (203) 927.8122
Fax (203) 772.2037
www.uk.com



LEGAL NOTICE: Unless expressly stated otherwise, this message is confidential and may be privileged. It is intended for the addressee(s) only. If you are not an addressee, any disclosure, copying or use of the information in this e-mail is unauthorized and may be unlawful. If you are not an addressee, please inform the sender immediately and permanently delete and/or destroy the original and any copies or printouts of this message. Thank you. Updike, Kelly & Spellacy, P.C.



Jennifer G. Fusco
(t) 203.786.8316
(f) 203.772.2037
jfusco@uks.com

June 27, 2017

VIA ELECTRONIC MAIL

Yvonne T. Addo, M.B.A.
Deputy Commissioner
Office of Health Care Access Division
Department of Public Health
410 Capitol Avenue
Post Office Box 340308
Hartford, CT 06134-0308

**Re: *Connecticut Orthopaedic Specialists, P.C.*
Acquisition of a Mobile 1.5 Tesla Magnetic Resonance Imaging Scanner
*Docket No. 16-32117-CON***

Dear Deputy Commissioner Addo:

This office represents Advanced Radiology Consultants, LLC (“ARC”). Enclosed are an original and four (4) copies of the following:

- Notice of Appearance of Updike, Kelly & Spellacy, P.C.;
- Petition of Advanced Radiology Consultants, LLC To Be Designated As An Intervenor With Full Rights Including The Right of Cross-Examination;
- Prefiled Testimony of Clark G. Yoder, M.B.A., Chief Executive Officer, Advanced Radiology Consultants; and
- Prefiled Testimony of Ian G. Karol, M.D., Chief Medical Officer, Advanced Radiology Consultants.

These documents are being submitted in connection with the public hearing on the above matter scheduled for July 11, 2017 at 9:00 a.m. Mr. Yoder and Dr. Karol will be present at the hearing to adopt their prefiled testimony under oath and for cross-examination.

Yvonne T. Addo
June 27, 2017
Page 2

Should you require anything further, please feel free to call me at (203) 786-8316.

Very truly yours,



Jennifer Groves Fusco

Enclosures

cc: Clark G. Yoder (w/enc)
Patricia A. Gerner, Esq. (w/enc)

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION**

.....)
IN RE: CONNECTICUT ORTHOPAEDIC)
SPECIALISTS, P.C. ACQUISTION OF A)
MOBILE 1.5 T MAGENTIC RESONANCE)
IMAGING SCANNER)
.....)
DOCKET NO. 16-32117-CON

JUNE 27, 2017

NOTICE OF APPEARANCE

In accordance with Section 19a-9-28 of the Regulations of Connecticut State Agencies, please enter the appearance of Updike, Kelly & Spellacy, P.C. (“Firm”) in the above-captioned proceeding on behalf of Advanced Radiology Consultants, LLC (“ARC”). The Firm will appear and represent ARC at the public hearing on this matter, scheduled for July 11, 2017.

Respectfully Submitted,

ADVANCED RADIOLOGY
CONSULTANTS, LLC

By: _____



JENNIFER GROVES FUSCO, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

This is to certify that a copy of the foregoing was sent via electronic mail this 27th day of June, 2017 to the following parties:

Patricia A. Gerner, Esq.
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057
Klg1@aol.com


JENNIFER GROVES FUSCO, ESQ.
Updike, Kelly & Spellacy, P.C.

acquisition of a third MRI scanner and this purchase will result in the unnecessary duplication of services in the Orange and Essex service areas. COS has conducted its needs assessment based upon MRI volume within its practice, which is not the applicable standard under the Statewide Healthcare Facilities & Services Plan (“SHP”). Despite COS’s belief that its request to acquire a third MRI unit should be evaluated independent of existing providers, the SHP guidelines make it clear that the proposed acquisition must include a review of all available MRI capacity in the Orange and Essex service areas. There are 29 MRI units currently operating in the Orange and Essex markets. There is ample available capacity on these units, including those operated by ARC within the service area and contiguous towns, to meet the MRI needs of COS patients. In addition, COS’s claims that access, quality and cost-effectiveness of care are improved by co-locating an MRI unit in a private orthopedic office are also overstated and do not, in and of themselves, support the need for a third scanner in the practice.

Operation of the proposed unit in Orange will have an adverse financial impact on ARC, which currently serves hundreds of COS MRI patients from the Orange, Shelton and Stratford service areas. COS concedes that it intends to “recapture” patients that are currently being referred to non-COS providers for MRI services (CON Application, p. 37). This means less scans referred to providers like ARC and the loss of associated revenue.

Moreover, COS has not shown that its acquisition of a third MRI unit will increase access to MRI services for the state’s most vulnerable patients, including Medicaid recipients and indigent persons. The rates at which COS provides MRI services to Medicaid and uninsured patients are nominal at best. The practice is projecting more than 11,000 MRI scans by FY 2020, with only 100

of these being Medicaid recipients and 11 being uninsured (CON Application, p.278). ARC will provide evidence showing that in recent years, the number of MRI scans it performed on COS patients with Medicaid was almost equal to the number of Medicaid scans that COS performed on its own units. Based on the foregoing, ARC questions whether COS is providing meaningful access to MRI services for Medicaid beneficiaries and the indigent.

Questions also exist regarding the quality of both the mobile MRI unit being proposed for purchase by COS and the practice's high-volume MRI service. ARC is in the business of providing imaging services. The practice has owned many MRI machines over the years and is in a unique position to provide testimony on the quality of the proposed unit and of mobile MRI units in general. In addition, ARC will provide testimony regarding the benefits of subspecialized training for radiologists who read MRI scans and having depth of radiologists available to read scans. Again, COS is projecting more than 11,000 MRI scans by FY 2020, and it appears that all of these scans are read by a single general radiologist, with perhaps only the part-time assistance of another as needed.

Lastly, the possibility of overutilization of COS's scanners based on self-referral calls into question the validity of the practice's volume projections and the cost-effectiveness of the proposed MRI unit. ARC will present data regarding the issues around self-referral for major imaging services, a practice that the State of Connecticut may study and potentially limit in the future given implications for the healthcare system and healthcare consumers.

Background

ARC is a private radiology practice with more than 100 years of experience serving patients in Connecticut. The practice has seven offices located in Orange, Shelton, Trumbull, Stratford, Fairfield, Stamford, and Wilton. ARC has been serving the Orange community at its 297 Boston Post Road office for more than 15 years. The practice provides a full range of diagnostic imaging and interventional radiology services, including MRI at each of its office locations. MRI services are provided at the practice's Orange office with a 3.0 Tesla unit. All ARC radiologists are subspecialty trained. The practice provides the highest-quality, accredited MRI services in a cost-effective private physician office setting. ARC receives referrals for MRI services from a broad array of providers including physicians of all specialties, podiatrists and chiropractors, none of whom has a financial interest in any ARC equipment. ARC scans hundreds of COS patients each year, with a majority of COS patients receiving their MRIs at the Orange, Shelton, and Stratford offices. ARC provides services to all patients regardless of their ability to pay. The practice participates in the Medicaid program and serves many Medicaid recipients and indigent patients at each of its practice locations.

ARC's Interests Will Be Adversely Affected by Approval of COS's CON Request

COS is asking OHCA to approve a CON for a third MRI unit to service patients of its orthopedic practice. The unit will split time between COS's offices in Orange and Essex. The COS Orange office at 330 Boston Post Road is located .2 miles or 1,080 feet from ARC's Orange office at 297 Boston Post Road. ARC also has MRI units in Stratford and Shelton, located 10 and 12 miles, respectively, from COS's Orange office. Both of these units operate in the service area identified by COS for its proposed MRI unit.

COS concedes that with a third unit it intends to “recapture” MRI volume that is currently being referred to non-COS providers (CON Application, p. 37). These providers include ARC, which scans approximately 400 COS patient every year. This “recapture” is reflected in the 16% projected increase in MRI volume projected for the first year of operation of the proposed third scanner (CON Application, p. 278).

In FY 2016, ARC performed 398 MRI scans ordered by COS physicians. The value of these services was approximately \$260,000. ARC expects to scan 422 COS patients in FY 2017, with services valued at approximately \$275,000. If COS is authorized to acquire a third MRI unit ARC will certainly lose most of these referrals as COS “recaptures” MRI patients. Although COS downplays any impact of its proposal on existing providers, significant financial losses will result for ARC and therefore the CON proposal will adversely impact an existing provider of MRI services (CON Application, pp. 36-37).

In addition, a majority of the scans referred to ARC by COS were of commercially insured patients. Commercially insured scans generate the highest per-patient revenue for MRI services. The loss of this revenue will further skew ARC’s payer mix towards Medicaid and other governmental payers, which reimburse at much lower rates than commercial insurance. ARC relies on its commercially insured patients to generate the MRI revenues that support the practice’s provision of all imaging services to its patients. The loss of COS-ordered scan volume and commercially insured revenue will undoubtedly have an adverse financial impact on ARC. ARC is entitled to participate in COS’s CON proceeding in order to protect its interests in this regard.

Moreover, because COS provides a limited number of scans to Medicaid recipients and uninsured individuals, providers like ARC and area hospitals are left to accommodate the MRI needs of these patient populations (CON Application, p. 278). Authorizing a third MRI unit for COS does nothing to enhance access for Medicaid program participants, as MRI scans for these patients are expected to grow by a mere 17 scans between FY 2017 and FY 2020 (CON Application, p. 278). Similarly, COS projects that it will provide only 11 scans (.1% of total MRI volume) to uninsured patients annually by FY 2020 (CON Application, p. 278). Compare this with COS's commercially insured MRI volume, which is expected to increase by 1,223 scans during this same time (CON Application, p. 278). COS's third unit, like its other two, will "skim the cream" – namely, commercially insured MRI scans – leaving other providers to care for governmentally insured and uninsured patients. The larger the number of Medicaid and indigent patients ARC cares for, the less financially viable the practice will become. Too significant a shift in payer mix can jeopardize the practice's existence. This in turn jeopardizes access to services at a provider that cares for all patients regardless of their financial means. ARC's interest in ensuring that the practice continues to exist to serve its patients justifies its participation in COS's CON proceeding.

Lastly, COS's status as a self-referral provider can have an adverse impact on healthcare consumers, payers and radiology providers such as ARC. As ARC's witnesses will testify, studies have shown that when providers have a financial interest in advanced imaging equipment they tend to refer patients at higher rates, leading to over utilization, increased cost and, subsequently, decreased cost-effectiveness. Increased healthcare costs due to the performance of unnecessary services impact the healthcare system as a whole and every provider in it.

Summary of Evidence to Be Presented, Manner of Participation and Relief Sought

ARC will ask OHCA to deny COS's request for permission to acquire a third MRI unit. COS has failed to meet several of the statutory criteria for issuance of a CON. Specifically, COS has not established that there is a clear public need for its proposal (Conn. Gen. Stat. §19a-639(3)). ARC will present evidence regarding the applicable SHP guidelines for the acquisition of a third MRI unit by COS and the available capacity of the 29 MRI units already operating in the combined Orange-Essex service area, including three ARC units.

In addition, COS's proposal will result in the unnecessary duplication of existing healthcare services, which will adversely impact existing providers such as ARC (Conn. Gen. Stat. §§19a-639(8) & (9)). This will be demonstrated through the presentation of evidence showing the number and value of scans historically performed by ARC on COS patients, which COS intends to "recapture" with the third MRI unit (CON Application, p. 37). ARC will show that it has accommodated, and will continue to accommodate, COS's overflow scans, making the addition of a third unit unnecessarily duplicative. ARC will further show the adverse financial consequences to the practice of a loss of COS volume, which is primarily commercially insured. This is particularly relevant in light of the fact that ARC serves all patients regardless of ability to pay and any shift in its payer mix could decrease its financial viability.

In addition, COS has failed to establish that its proposal will improve the accessibility of services for Medicaid recipients and indigent persons (Conn. Gen. Stat. §19a-639(5)); rather COS provides limited access to MRI services for Medicaid recipients and indigent persons, without good cause for doing so (Conn. Gen. Stat. §19a-639 (10)). ARC will present evidence regarding COS's

history, or lack thereof, of providing MRI service to these patient populations. This will be compared with ARC's history of providing services to Medicaid program participants and indigent persons, including many referred by COS.

ARC will also testify regarding the quality of the MRI services being proposed by COS. Specifically, ARC will testify regarding the quality of the proposed 2000 mobile MRI unit, and of mobile units generally, and the impact that this can have on scan quality and the care provided to patients. ARC will also testify regarding the benefits of subspecialization and appropriate workload and turnaround time for the interpretation of MRI scans.

Lastly, ARC will present evidence regarding the impact of self-referral on the need for, and cost-effectiveness of, MRI services. ARC will submit studies that show higher rates of referrals for imaging by providers with financial interests in the equipment on which the examinations are performed. ARC will show how this unnecessary utilization may be artificially inflating COS's MRI volume and decreasing the cost-effectiveness of the service they are proposing to augment with the acquisition of a third MRI unit.

If ARC is granted status, it intends to present this and other evidence and legal arguments in support of its positions. The arguments are set forth in detail in the attached testimony of Mr. Yoder and Dr. Karol. ARC respectfully requests that it be allowed to submit written testimony, present evidence and arguments at the July 11, 2017 public hearing on this matter, cross-examine witnesses, and inspect and copy records pertaining to the proceeding. ARC's participation will furnish assistance to OHCA in determining the impact of this proposal on existing providers and access to MRI services for certain patient populations. ARC's participation will also assist OHCA in

evaluating COS's compliance with other statutory CON decision criteria (i.e. need and quality, accessibility and cost-effectiveness of services). ARC's participation is in the interest of justice and will not impair the orderly conduct of these proceedings.

WHEREFORE, for the foregoing reasons, ARC respectfully requests that its Petition to be Designated as an Intervenor With Full Rights be granted.

Respectfully Submitted,

ADVANCED RADIOLOGY CONSULTANTS, LLC

By: 

JENNIFER GROVES FUSCO, ESQ.

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CERTIFICATION

This is to certify that a copy of the foregoing was sent via electronic mail this 27th day of June, 2017 to the following parties:

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Updike, Kelly & Spellacy, P.C.

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION**

.....)
IN RE: CONNECTICUT ORTHOPAEDIC)
SPECIALISTS, P.C. ACQUISITION OF A)
MOBILE 1.5 T MAGNETIC RESONANCE)
IMAGING SCANNER)
.....)

DOCKET NO. 16-32117-CON

JUNE 27, 2017

**PREFILED TESTIMONY OF CLARK G. YODER, M.B.A.,
CHIEF EXECUTIVE OFFICER OF ADVANCED RADIOLOGY CONSULTANTS, LLC,
IN OPPOSITION TO THE CON REQUEST OF
CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.**

Good morning Hearing Officer Hansted and members of the Office of Health Care Access (“OHCA”) staff. My name is Clark Yoder and I am the Chief Executive Officer (“CEO”) of Advanced Radiology Consultants, LLC (“ARC”). A copy of my Curriculum Vitae is attached for your reference (see Exhibit A). With me today is my colleague, Dr. Ian Karol, ARC’s Chief Medical Officer (“CMO”) and a member of our Radiology Executive Committee. We thank you for this opportunity to testify in opposition to the Certificate of Need (“CON”) Application filed by Connecticut Orthopaedic Specialists, P.C. (“COS”) for acquisition of a third MRI unit.

ARC respectfully requests that COS’s CON Application be denied. COS has not established that there is a clear public need to acquire an unprecedented third MRI scanner for use in its private orthopedic practice.¹ In fact, the markets where COS proposes to operate the unit are already saturated with MRIs, many of which have available capacity. Allowing COS to bring another captive scanner into these markets will adversely impact ARC and other providers

¹ To the best of our knowledge, there is no other orthopedic physician practice in Connecticut that owns three MRI units.

that have capacity and welcome all patients regardless of ability to pay. Moreover, the proposal does not enhance access to MRI services for our state's most vulnerable patients, including Medicaid program participants and indigent persons. Nor does it present the most cost-effective option for meeting the MRI needs of Orange and Essex area residents.

Background on Advanced Radiology Consultants

ARC is a private radiology practice with office locations throughout Fairfield and New Haven Counties, including an office at 297 Boston Post Road in Orange. ARC provides a full range of diagnostic imaging and interventional radiology services. The practice offers MRI at each of its seven locations, including three locations within the proposed service area of COS's Orange MRI unit (Orange, Shelton & Stratford). The Orange office of ARC is located .2 miles or just 1,080 feet from the site of COS's proposed Orange MRI service. ARC's Stratford and Shelton MRI units are located 10 and 12 miles, respectively, from COS's Orange office.² MRI services are provided at ARC's Orange office with a 3.0 Tesla unit and at our Stratford and Shelton offices with 1.5 Tesla units. ARC provides services to all patients regardless of their ability to pay. The practice participates in the Medicaid program and serves many indigent patients in Orange, Stratford, Shelton and elsewhere.

COS Has Not Satisfied the Statutory Decision Criteria for a CON

As discussed in greater detail below COS has failed to meet several of the statutory criteria for issuance of a CON. Specifically, COS has not established that there is a clear public need for the acquisition of an MRI unit based on guidelines contained in the Statewide Healthcare Facilities & Services Plan ("SHP") (Conn. Gen. Stat. §19a-639(3)). In addition,

² ARC also has MRI units in the nearby towns of Trumbull and Fairfield, which have historically served COS patients.

COS's has failed to consider the utilization of existing MRI providers in its assessment of need (Conn. Gen. Stat. §19a-639(8)). As such, this proposal will result in the unnecessary duplication of existing healthcare services, which will adversely impact providers such as ARC (Conn. Gen. Stat. §19a-639(9)). Moreover, COS has failed to establish that its proposal will improve the accessibility of services for Medicaid recipients and indigent persons (Conn. Gen. Stat. §19a-639(5)); rather COS provides limited access to MRI services for Medicaid recipients and indigent persons, without good cause for doing so (Conn. Gen. Stat. §19a-639 (10)).

No Clear Public Need for an Additional MRI Scanner

COS argues clear public need for a third MRI scanner based upon the growth of its practice and the available capacity of COS MRI units located in Hamden and Branford. COS uses a need methodology at page 61 of the SHP that provides a benchmark of 4,000 scans for an MRI scanner and allows for the addition of a scanner if the applicant has an existing scanner in the primary service area operating in excess of 85% capacity (3,400 scans/year) (CON Application, p. 22). COS claims that its Hamden and Branford MRI units are operating at 94% and 110% capacity, respectively, and therefore a third unit is justified per the SHP guidelines (CON Application, p. 23). Note however that the primary service area towns for this proposal are as follows: Orange, New Haven, Woodbridge, Shelton, Derby, West Haven, Milford, Stratford, East Haven, North Haven, Essex, Madison, Guilford, Clinton, Old Saybrook, Westbrook, Old Lyme, Deep River, and Chester (CON Application, pp. 40-41). Neither Hamden nor Branford is listed as a primary service area town for the proposed MRI unit. Accordingly, COS does not have an existing unit in the primary service area of this MRI proposal and it cannot utilize Standards and Guidelines Specific to MRI, Section 3.b. to establish clear public need.

COS argues that because this is a proposal for an in-house MRI unit, the “ordinary capacity calculation” cannot be used (CON Application, p. 24). COS claims that because it controls referrals to its MRI units it does not need to establish a broader service area need for the proposed third unit (CON Application, p. 24). This is not what the SHP guidelines allow for. Because there are other providers in the service area, including ARC, that can and do provide MRI services to COS patients, COS must evaluate the capacity of these existing providers in determining whether there is a need for an additional MRI unit in the Orange and/or Essex service areas. Absent compliance with SHP guidelines in this regard, specialty practices like COS will be able to justify the acquisition of costly imaging equipment without demonstrating public need or assessing impact on existing providers, simply by incrementally growing the number of physicians in their practices through mergers and acquisitions.

The burden is therefore on COS to determine whether the Percent Utilization of Current Capacity in each of the primary service areas to be served by the proposed MRI unit exceeds 85% (SHP, p. 61, Standards and Guidelines Specific to MRI, 3.a.). COS has not undertaken this analysis, but we expect that it would show ample available capacity in the Orange service area, where there are currently 26 MRI units in operation (CON Application, pp. 45-47) (see Exhibit B). Looking at the data provided by COS in Table 9 of the CON Application, 15 of the 26 scanners located in the Orange service area (58%) are operating below 85% capacity (CON Application, pp. 45-47). Assuming each scanner can accommodate 4,000 scans per year, the total capacity of the MRI units in the Orange service area is 104,000 scans (4,000 x 26). In FY 2013, the last year for which utilization data is publically available, these scanners combined to perform 81,022 scans (CON Application, pp. 45-47). This means that in the aggregate the MRI units in the Orange service area are operating at 78% capacity (see Exhibit B). A similar

analysis can be undertaken for Essex, where two of the three scanners in the service area (67%) are operating below 85% capacity. These scanners performed 7,639 scans in FY 2013, out of an available capacity of 12,000 scans, putting them at 64% capacity in the aggregate.

MRI units in the Orange service area that have available capacity include ARC's units in Shelton and Orange. ARC's Shelton unit provided 2,421 scans in FY 2016, which is 61% capacity based upon SHP standards. This unit can accommodate at least 1,000 additional scans before exceeding capacity. The practice's Orange unit performed 4,158 scans in FY 2016, but is on track to perform around 3,900 scans in FY 2017. This is a 3.0 Tesla unit that currently operates Monday through Friday, 7:00 a.m. to 10:00 p.m. ARC has the ability to add weekend hours at this site as needed. In FY 2016, the Orange MRI unit scanned 201 COS patients. This unit can certainly continue to handle these patients, as well as the several hundred additional scans of patients in the Orange service area that COS claims need to be referred to non-COS providers (CON Application, p. 35).

As Dr. Karol will testify, the ARC units are of superior quality to the mobile MRI unit being proposed by COS. Moreover, all MRI scans at ARC are read by subspecialty trained radiologists and turned around as fast, if not faster, than those read by COS's in-house general radiologist. ARC turns its MRI images around to referring physicians in one hour on average during the week, whereas COS's employed radiologist can take up to 24 hours (CON Application, p. 18).

Furthermore, COS suggests that the "access" it provides to its patients is somehow superior to access offered by other MRI service providers (CON Application, pp. 16, 23, 29, 221), creating a need for a third MRI unit within the practice. This "access" takes the form of early morning and late night appointments on weekdays (7:00 a.m. – 9:00 p.m.); ARC's Orange

MRI is open from 7:00 a.m. to 10:00 p.m. on weekdays and its Stratford unit operates from 7:00 a.m. to 11:00 p.m. Like COS, ARC will also open its Orange office on the weekend to accommodate patients and our Stratford MRI operates from 7:00 a.m. to 7:00 p.m. on Saturdays.³ Like COS, ARC holds emergency appointments open daily at each of its offices, including the Orange office. Therefore, COS does not have “improved accessibility over traditional radiology centers” in this regard (CON Application, p. 221).

COS also mentions how traveling can be painful or injurious for an orthopedic patient in need of an MRI and suggests that offering in-house MRI obviates the need to travel to another location for a scan (CON Application, p. 221). Dr. Karol will speak to this in greater detail, but based on ARC’s experience the incidence of “same-day” MRI in the outpatient setting is minimal. This means that most COS patients in need of MRI will have to travel, even if it is just returning to the COS office within a few days for their scans. If the COS Orange office is a convenient location for these patients because it is a short travel distance from their homes, then the ARC Orange MRI unit that sits 1,080 feet away is equally convenient.

Lastly, COS suggests that there is a “time delay” associated with having an MRI performed at a location other than within the orthopedists’ office (CON Application, p. 221). This is misleading. As mentioned above, instances of same-day MRI are rare in ARC’s experience. Assuming a patient is not going to be seen same day, COS likely has the same scheduling considerations as any private radiology office. The practice probably has a backlog of appointments, and the likelihood that a patient will be seen in Orange or Essex immediately is low given that the unit will be in each location only two days per week. Currently, ARC can

³ Presumably, COS’s ability to provide weekend hours at either Orange or Essex will be limited by the location of the mobile unit on any given day. Also, its ability to provide early morning and late evening scans is limited to the 2 days each week that the unit is in each location. In addition, COS is proposing to curtail weekend hours on its Hamden and Branford MRIs to four hours on Saturdays, and no regular weekend hours are proposed for the Orange/Essex unit (CON Application, pp. 34 & 39).

accommodate MRI patients at its Orange and Stratford offices next day and in Shelton within two days.

Unnecessary Duplication of Services & Adverse Impact on Existing Providers

The proposed COS Orange MRI unit and ARC's MRI units in Orange, Shelton and Stratford have overlapping service areas. COS lists its Orange MRI service area towns as Orange, New Haven, Woodbridge, Shelton, Derby, West Haven, Milford, Stratford, East Haven, and North Haven (CON Application, p. 40). In 2016, ARC provided MRI services to COS patients residing in each of the COS Orange MRI service area towns as follows: Orange (27); New Haven (17); Woodbridge (7); Shelton (56); Derby (22); West Haven (38); Milford (36); Stratford (16); East Haven (1); and North Haven (3). The total number of patients scanned by ARC from the COS Orange service area was 223.

The chart below demonstrates the service area overlap between the proposed COS unit and ARC's units in Orange, Shelton and Stratford:

COS Orange	ARC Orange	ARC Shelton	ARC Stratford
Orange	<u>Milford</u>	<u>Shelton</u>	<u>Stratford</u>
New Haven	<u>West Haven</u>	Seymour	<u>Milford</u>
Woodbridge	<u>Stratford</u>	Ansonia	Bridgeport
Shelton	<u>New Haven</u>	Bridgeport	
Derby	Bridgeport	<u>Derby</u>	
West Haven	<u>Orange</u>	<u>Stratford</u>	
Milford	<u>Shelton</u>	Trumbull	
Stratford	Trumbull	Oxford	
East Haven	Ansonia		
North Haven	Hamden		
	<u>Derby</u>		
	Fairfield		
	<u>East Haven</u>		
% of Service Area Towns that Overlap with COS Orange Service Area	62%	38%	67%

In FY 2016, ARC performed 398 scans ordered by COS physicians. ARC's average reimbursement for an MRI scan is \$650. This puts the value of MRI scans for COS patients in FY 2016 at around \$260,000. ARC has scanned 176 COS patients in FY 2017 to date. At this rate ARC expects to receive approximately 422 MRI referrals from COS physicians in FY 2017,

valued at approximately \$275,000. This referral relationship is longstanding, and despite COS's statement that this proposal will not change referral patterns for its own scanner, it will most certainly change referral patterns for providers like ARC who have historically scanned many COS MRI patients each year (CON Application, p. 37). This loss of revenue is significant and will be seriously detrimental to ARC. Since \$275,000 of gross revenue cannot be replaced, and due to the large fixed costs associated with operating an MRI unit, ARC may be forced to enact staffing reductions or other drastic cost savings measures if this application is approved.

By COS's own admission, it is looking to "recapture" scan volume from non-COS providers, which accounts in part for the 16% increase in MRI volume projected for the first year of operation of the new unit (CON Application, pp. 37 & 278). In projecting volume for the proposed Orange MRI unit, COS claims that of the 1,500 to 1,600 scans that will be performed each year (CON Application, p. 43), approximately 1,000 of those represent scans already performed on COS's MRI units in Hamden and Branford (CON Application, p. 35). COS further acknowledges that approximately 450 of the patients that make up the projected MRI volume for COS Orange are currently referred to non-COS providers for their scans (CON Application, p. 35). Thus despite its claim that impact on existing providers will be "minimal," ARC stands to lose 400 or more scans each year valued at over a quarter-of-a-million dollars (CON Application, p. 36).⁴ Similarly, COS projects that it will "recapture" nearly 800 scans from Middlesex Hospital and its affiliates once it establishes MRI services in Essex, which is also not an insignificant impact (CON Application, p. 219).

Providers like ARC are already accommodating COS's overflow scans, and we will continue to do so with the MRI capacity available in our practice. Some of these are patients

⁴ Assuming ARC only lost the COS MRIs performed at its Orange, Shelton and Stratford offices this is still more than 300 scans annually.

who have used ARC for their imaging in the past and for whom we can ensure continuity and coordination of care. Because ARC can and will continue to serve these patients if they so choose, as well as any other patients referred by COS physicians, COS's acquisition of a third unit is an unnecessary duplication of MRI services.

When all is said and done, ARC will be adversely impacted by COS's acquisition of a third MRI unit, if approved by OHCA. In order to meet its volume projections COS physicians will need to refer virtually all of their MRI scans to practice-owned units. This will mean the loss by ARC of a significant number of scans and associated revenue each year. OHCA should not approve a proposal that, by the Applicant's own admission, will adversely impact an existing provider to this extent.

Access for Medicaid Recipients & Indigent Persons

While COS participates in the Medicaid program, its historic and projected MRI scans for Medicaid patients are minimal. In FY 2016, COS appears to have provided only 78 scans to Medicaid patients (9,108 scans total x .86% = 78 Medicaid scans) (CON Application, p. 245). In addition, while COS claims to have recently put a charity care policy in place, its historic provision of MRI services to uninsured patients is less than 10 scans per year or .1% of the practice's annual MRI volume (CON Application, p. 278).

The number of Medicaid scans performed by COS is projected to increase by only 17 scans by FY 2020, after which time the service will be "mature" and Medicaid and other MRI scan volume at COS will remain flat (CON Application, p.278). This means that COS will likely never provide more than 100 MRI scans to Medicaid patients in a year, with Medicaid scans remaining less than 1% of its payer mix. For uninsured patients, that number will in theory never eclipse 11 scans (CON Application, p. 278). At the same time, COS's commercially

insured MRI scan volume is projected to increase by 1,223 scans in just over three years, representing 68% of the practice's MRI payer mix (CON Application, p. 278).

OHCA should inquire as to why COS's Medicaid and uninsured MRI percentages are as low as they are given that the practices has offices between two of the state's largest urban areas, Bridgeport and New Haven. Bridgeport and New Haven are among the cities in Connecticut with the most Medicaid recipients as a percentage of their overall populations, at 45% and 44%, respectively (see Exhibit C). By comparison, ARC also has offices in and around Bridgeport and New Haven and our Medicaid and uninsured scan volumes are a far greater percentage of our overall scans.

Practice-wide, ARC performed 2,190 scans on Medicaid patients in FY 2016 out of 24,697 total exams (9%). This means that while ARC performed just 2.7 times as many MRI scans as COS in FY 2016, it saw 28 times as many Medicaid patients as the orthopedic practice with its captive units. By office, ARC performed 270 Medicaid scans in Orange in FY 2016, which accounted for 6.5% of total scans at that location. In Shelton, ARC performed 155 Medicaid scans accounting for 6.4% of total scan volume. And in Stratford, the 820 Medicaid scans performed by ARC made up 15% of total scan volume. ARC's total Medicaid scans have increased by 469 or 22% since FY 2014.

Moreover, ARC's Orange MRI service provided 158 scans to uninsured and self-pay patients in FY 2016, more than 17 times as many uninsured and self-pay patients as COS scanned in Hamden and Branford combined that same year. ARC also scanned 58 uninsured patients in Shelton and 187 uninsured patients in Stratford in FY 2016. ARC's MRI service as a whole provided 996 scans to uninsured and self-pay patients in FY 2016 or more than 100 times as many uninsured and self-pay scans as COS.

For COS to operate in the same market as ARC and have such dramatically lower Medicaid and uninsured numbers begs the question whether the practice is somehow restricting access for these patients through its outreach, scheduling or other policies. Of note, a fair number of the MRI scans that ARC performs on COS patients are reimbursed by Medicaid. In FY 2016, 51 of the 398 COS patients scanned by ARC were Medicaid recipients (13%). The total number of COS Medicaid patients that ARC scanned in FY 2016 (51) is more than half of the total number of Medicaid scans that COS performed on its own units that year (78) (CON Application, p. 245). Assuming that COS referred Medicaid patients to other non-COS providers as well, it is entirely possible that COS sent out more Medicaid patients for MRI scans than it accommodated in-house.

The CON statutes require that OHCA consider how a CON proposal impacts access to and the quality of care for Medicaid recipients and indigent persons. Section 19a-639(5) of the Connecticut General Statutes requires an applicant to demonstrate how its proposal “will improve the quality, accessibility and cost effectiveness of healthcare delivery in the region, including ... provision of ... and access to services for Medicaid recipients and indigent persons ...” Similarly, Section 19a-639(6) requires OHCA to consider the applicant’s “past and proposed provision of health care services to relevant patient populations and payer mix, including ... access to services by Medicaid recipients and indigent persons.”

COS predicts that it will provide no more than 100 Medicaid scans and 11 uninsured scans in any given year once its MRI service matures (CON Application, p. 278). Of the nearly 750,000 Medicaid beneficiaries in this state, less than 100 are benefitting from COS’s two existing MRI units (see Exhibit C). If a third scanner is approved COS promises to increase its Medicaid volume by 17 scans and its uninsured volume by mere 2 scans. How is this “enhanced

access to care” for these populations? OHCA should not approve a unit that will be nominally beneficial to the state’s most vulnerable patients, particularly when it will have an adverse impact on private radiology practices and hospitals that care for far more Medicaid and indigent patients each year.

Based on the foregoing COS’s proposal does little, if anything, to improve the quality or accessibility of care for Medicaid recipients and indigent persons. In fact, it will adversely impact the area providers who do serve these patients. The fact that COS does not provide MRI services to Medicaid recipients or indigent persons in any appreciable numbers means these patients are being sent to the limited number of providers that do.⁵ Medicaid reimburses far less for MRI services than most commercial insurance plans. Therefore, providers like ARC and area hospitals are losing money on these patients while COS “skims the cream” with a non-governmental payer mix exceeding 80%.

In addition, approximately 57% of the MRI scans that ARC performs on COS patients are covered by commercial insurance. If COS is allowed to acquire a third MRI unit, this business will be lost and the practice’s payer mix will further skew towards governmental payers. As our MRI payer mix shifts, it can threaten the viability of ARC as a whole because the lion’s share of the practice’s profit margin comes from MRI services. This would compromise the practice’s ability to provide a full range of imaging services to all patients, including the Medicaid and indigent patients that COS services in limited numbers. The same is true for the full-service acute-care hospitals in our area, where Medicaid percentages can be even higher.

⁵ Based on data presented in a 2016 Medicaid Access Monitoring Review Plan prepared by the Connecticut Department of Social Services (excerpts attached as Exhibit D), the number of Medicaid-participating physician specialists declined in each county in the state between CY 2014 and CY 2015. This included a loss of 183 specialty providers in Fairfield County (11%) and 253 specialty providers in New Haven County (13%). At the same time, utilization of physician specialists by Medicaid recipients continues to increase. Physician specialist visits grew by approximately 35,000 in Fairfield County, and 34,000 in New Haven County, between CY 2013 and CY 2015.

Conclusion

For the foregoing reasons, COS's request for permission to acquire an unprecedented third MRI unit should be denied. COS has used a flawed need methodology and has not established a clear public need for the acquisition of an MRI unit for use in areas that are already served by 29 existing units. If the third unit is approved, COS will stop referring its patients to ARC for scans, resulting in significant financial harm. Because these patients are already well-served by existing providers such as ARC, the proposed scanner is unnecessarily duplicative. In addition, by COS's own admission, in-house MRI services for Medicaid beneficiaries and indigent persons will be extremely limited. This proposal does not, therefore, meet the policy objectives of increasing access to care for these vulnerable populations.

Thank you again for allowing me to testify. Once Dr. Karol testifies we will be available to answer any question you have.

The foregoing is my sworn testimony.

A handwritten signature in blue ink, appearing to read 'Clark G. Yoder', written over a horizontal line.

Clark G. Yoder, M.B.A.

EXHIBIT A

Clark G. Yoder, MBA, R.T.(R)(MR)(CT)
1370 Fence Row Drive, Fairfield, CT 06824

Professional Experience

Advanced Radiology Consultants, LLC, Shelton, CT	2015- Present
<u>Chief Executive Officer</u>	
Northwell Health and North Shore-LIJ CareConnect Insurance Company Roslyn, NY	2014-2015
<u>Chief Customer Officer and NSLIJ-IPA Vice President</u>	
WESTMED Practice Partners LLC and WESTMED Medical Group, P.C. – Purchase, NY	2000- 2013
<u>Promoted to Chief Operating Officer</u>	
<u>Promoted to Chief Financial Officer</u>	
<u>Promoted to Director of Ancillary Services</u>	
<u>Radiology Manager</u>	
Salick Healthcare, St. Vincents Cancer Center, New York, NY	1999-2000
<u>Radiology Director</u>	
Radiologix/HVRA, New City, NY	1996-1999
<u>Director of Operations</u>	
Greenwich Hospital, Greenwich, CT	1990-1996
<u>Radiology Technologist and Radiologic Technologist Supervisor</u>	

Clark G. Yoder, MBA

Education and Credentials

Master of Business Administration (MBA) – University of Connecticut

Bachelor of Science, Radiology (BS) - Quinnipiac University

Professional and Personal Achievements

Member, Board of Fellows, Health Affairs, Frank Netter, MD School of Medicine, Quinnipiac University

Beta Gamma Sigma Business Society Member

Member American College of Healthcare Executives

Member Radiology Business Management Association

Member Radiological Society of North America

Member Healthcare Leaders of New York

ARRT (MR)(CT)(RT)(R)

President: Ridge Homeowners Association, Inc.

Former Board of Director- Bedford Physicians Risk Retention Group, Inc.

Former Board of Director WPP, LLC

Former Managing Member and Treasurer- Rye Ambulatory Surgery Center, LLC

Former Assistant Treasurer- WESTMED PAC

Former Board of Director- Amerinet Northeast Alliance

EXHIBIT B

Current Local Area Magnets*

ID	Facility (Refer to ID numbers on following map)	Provider Type O = Outpatient H = Hospital	MRI Type	Total Scans (2013) % Capacity	Distance from Connecticut Orthopaedic Specialists 330 Boston Post Road Orange, CT 06477
A	Connecticut Orthopaedic Specialists 330 Boston Post Road Orange, CT 06477	O	1.5T, Mobile, Closed	NA	0
1	Connecticut Orthopaedic Specialists 2416 Whitney Avenue Hamden, CT 06518	O	1.5T, Fixed, Closed	3,773 94.3%	10.0 miles
2	Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT 06405	O	1.5T, Fixed, Closed	3,851 96.3%	9.7 miles
3	Milford Hospital, Inc. 300 Seaside Avenue Milford, CT 06460	H	1.5T, Fixed, Closed	2,005 50.1%	4.4 miles
4	Griffin Hospital 130 Division Street Derby, CT 06418	H	1.5T, Fixed, Closed	1,888 47.2%	6.6 miles
5	Griffin Imaging and Diagnostic Center at Ivy Brook 2 Ivy Brook Road Shelton, CT 06484	H	1.2T, Mobile, Closed	2,341 58.5%	4.9 miles
6	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	4,010 100.2%	4.7 miles
7	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	4,454 111.4%	4.7 miles
8	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	4,020 100.5%	4.7 miles
9	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	2,556 56.4%	4.7 miles
10	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	6,231 155.8%	4.7 miles
11	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	1.5T, Fixed, Closed	6,130 153.3%	4.7 miles
12	Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York Street New Haven, CT 06510	H	3.0T, Fixed, Closed	6,003 150.1%	4.7 miles

13	Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel Street New Haven, CT 06511	H	1.5T, Fixed, Closed	812 20.3%	4.6 miles
14	Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel Street New Haven, CT 06511	H	3.0T, Fixed, Closed	713 17.8%	4.6 miles
15	Yale-New Haven Hospital, Inc. Temple Radiology New Haven 60 Temple Street New Haven, CT 06510	H	1.5T, Fixed, Closed	2,582 64.6%	4.9 miles
16	Saint Raphael Magnetic Resonance Center 330 Orchard Street New Haven, CT 06511	H	1.5T, Fixed, Closed	1,827 45.7%	4.7 miles
17	Bridgeport Hospital 2595 Main Street Stratford, CT 06615	H	1.5T, Fixed, Closed	1,492 37.3%	8.0 miles
18	Bridgeport Hospital 267 Grant Street Bridgeport, CT 06610	H	1.5T, Fixed, Closed	3,500 87.5%	9.8 miles
19	St. Vincent's Medical Center 2800 Main Street Bridgeport, CT 06606	H	1.5T, Fixed, Closed	4,277 106.9%	11.0 miles
20	Southern Connecticut Imaging Center, LLC (dba Whitney Imaging Center) 2200 Whitney Avenue Hamden, CT 06518	O	1.5T, Mobile, Closed	88 2.2%	9.5 miles
21	Meriden Imaging Center, Inc. (dba Wallingford Diagnostic Imaging Center) 863 North Main Street Wallingford, CT 06492	O	1.5T, Fixed, Open	3,276 81.9%	17.4 miles
22	Diagnostic Imaging Services of CT, LLC (dba Branford Open MRI) 1208 Main Street Branford, CT 06405	O	0.3T, Fixed, Open	924 23.1%	10.3 miles
23	Advanced Radiology Consultants, LLC 297 Boston Post Road Orange, CT 06477	O	3.0T, Fixed, Open	3,114 77.9%	1,080 feet (0.2 miles)
24	Advanced Radiology Consultants, LLC 2876 Main Street Stratford, CT 06477	O	1.5T, Fixed, Closed	5,700 142.5%	7.8 miles
25	Advanced Radiology Consultants, LLC 4 Corporate Drive Shelton, CT 06484	O	1.5T, Fixed, Closed	3,975 99.4%	6.5 miles
26	Advanced Radiology Consultants, LLC 15 Corporate Drive Trumbull, CT 06611	O	1.5T, Fixed, Open	1,480 37.0%	11.7 miles
TOTALS				2013 Scans = 81,022	% Capacity = 77.9%

*Source: Connecticut Orthopaedic Specialists' Main Certificate of Need Application for the acquisition of a 1.5T mobile MRI unit; State of Connecticut Department of Public Health, Office of Health Care Access; Docket No. 16-32117-CON, August 19, 2016.

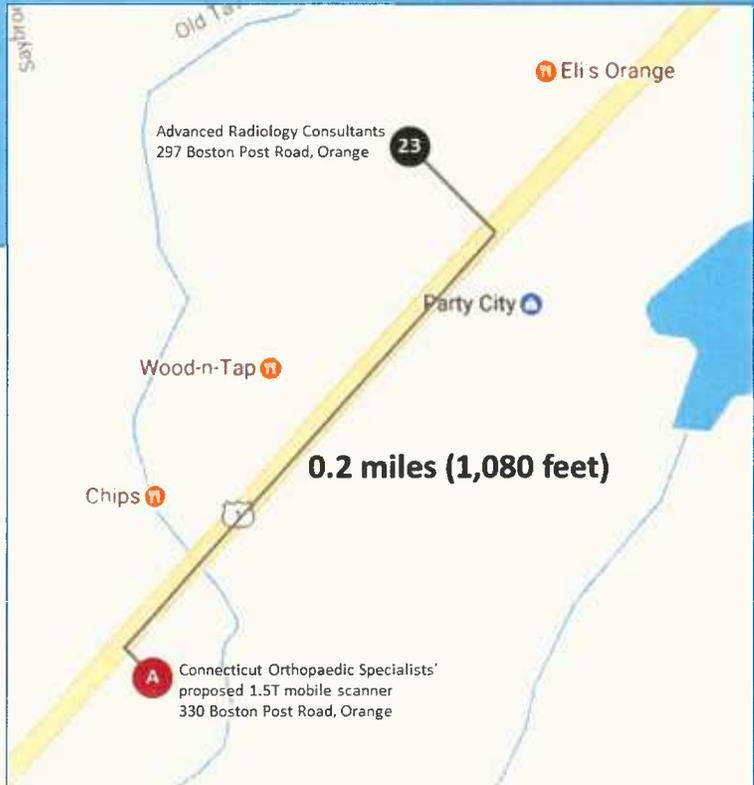


EXHIBIT C

HEALTH CARE

A look at Medicaid enrollment by town

MARCH 21, 2016



Jake Kara
Data Editor

Medicaid enrollment in Connecticut [continues to rise](http://ctmirror.org/2016/01/15/spending-and-enrollment-up-but-medicaid-per-person-cost-is-down/) (<http://ctmirror.org/2016/01/15/spending-and-enrollment-up-but-medicaid-per-person-cost-is-down/>). The program, which provides health coverage for the poor and disabled, now covers one in five state residents.

There were 748,009 Connecticut residents enrolled in Medicaid on Feb. 16, according to the most recent enrollment report.

The portion of Medicaid which covers parents and their minor children, called HUSKY Health Schedule A in Connecticut, has 458,136 recipients across the state.

The map below shows what percentage of each town's population is enrolled in Medicaid and HUSKY A.

We looked to see whether towns where a large portion of the Medicaid recipients were on HUSKY A also were towns with a younger population. We used census data to determine a town's median age and under-18 population, but we didn't find a strong correlation in either case.

The towns and cities with the most of Medicaid and Husky recipients as a percentage of each town's overall population, include:

1. **Hartford:** 58%, Medicaid; 32%, HUSKY A;
2. **Waterbury:** 51%, 30%;
3. **New Britain:** 47%, 28%;
4. **Bridgeport:** 45%, 27%;
5. **New Haven:** 44%, 24%;

6. **New London:** 43%, 25%;

7. **Windham:** 41%, 23%

8. **Norwich:** 38%, 23%;

9. **East Hartford:** 38%, 23%;

10. **Meriden:** 37%, 22%.

Note that we limited our list to towns with populations over 5,000 because per-capita figures from very small towns can be deceiving. Canaan, with a total population of 1,195 actually had the highest percentage of Medicaid recipients at 64%.

The towns with the smallest percentage of the population receiving Medicaid include:

1. **Weston:** 3.71%, Medicaid; 2.2% HUSKY A;

2. **Darien:** 3.7%, 2.1%;

3. **New Canaan:** 4%, 1.9%;

4. **Westport:** 5.2%, 2.4%;

5. **Redding:** 5.2%, 3.3%;

6. **Ridgefield:** 5.4%, 2.654235%;

7. **Wilton:** 5.9%, 2.3%;

8. **Easton:** 6.3%, 3.4%;

9. **Avon:** 6.6%, 2.8%;

10. **Mansfield:** 6.8%, 3.6%.

Check our work: The GitHub repository containing our work is available here

(https://github.com/trendct/medicaid_enrollment_analysis/blob/master/Husky%20enrollment%20by%20town.ipynb). We encourage you to look over our calculations and expand upon our work.

Correction: This article has been updated to more accurately reflect current enrollment. It was initially reported there were 823,867 people in Connecticut enrolled in Medicaid and 466,087, but that was based on a given year, and recipients can come in and out of the program throughout the year, so that number is higher than the 748,009 recipients counted in the most recent enrollment report.

EXHIBIT D

**STATE OF CONNECTICUT
DEPARTMENT OF SOCIAL SERVICES**

**ACCESS MONITORING
REVIEW PLAN
FOR
CONNECTICUT'S MEDICAID PROGRAM**

**Submitted to the U.S. Centers for Medicare and Medicaid Services (CMS)
pursuant to federal regulations at 42 C.F.R. §§ 447.203(b) and 447.204.**

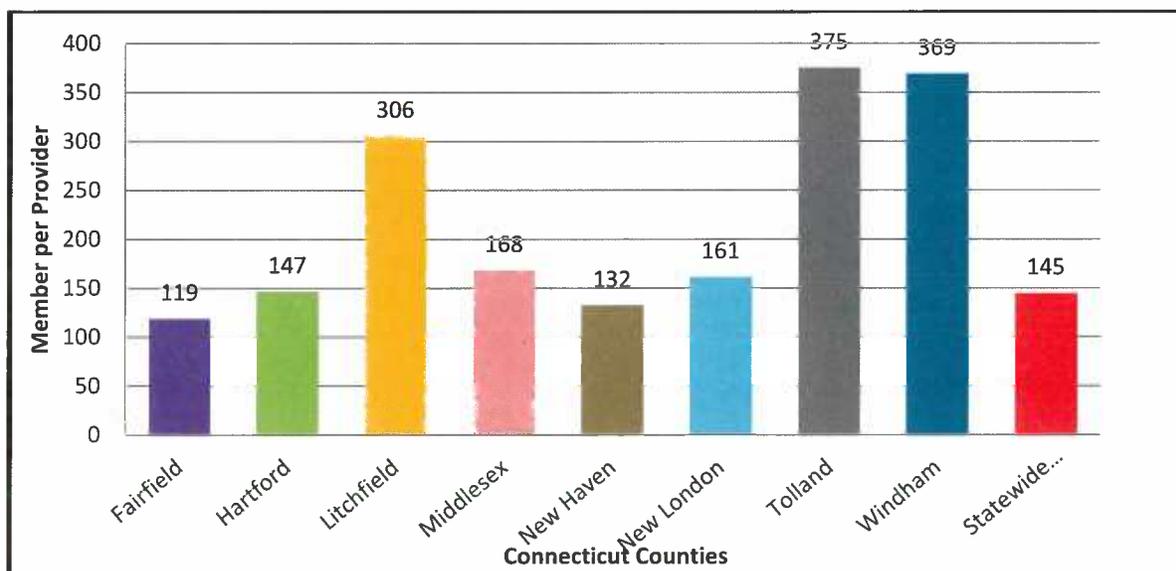
September 30, 2016

Figure 14 above shows the number of members to one provider in each Connecticut County, within the category of Physician, Advanced Practice Registered Nurses and Physician Assistants for primary care. For this particular category of providers, the overall average ratio is 213 members to one provider and ranges from 154 to 340 members per provider. The counties of Fairfield, New Haven and Tolland are close to the statewide average. Meanwhile, New London with the two hundred and seventy members per provider is higher than the statewide average. Meanwhile, Hartford County, with only one hundred and ninety-five (195) members to one provider, though in close proximity, falls slightly below the overall ratio. Similar to Figure 14 above, the counties of Litchfield and Windham have the highest ratio of members to one provider.

Table 14: Counts of CMAP Physician Specialists, Calendar Years 2013 through 2015

Physician Specialists	Statewide Performing Provider Count		
	CY 2013	CY 2014	CY 2015
Provider County			
Fairfield	1,077	1,676	1,493
Hartford	1,421	1,681	1,395
Litchfield	90	121	109
Middlesex	132	169	151
New Haven	1,565	1,877	1,624
New London	368	414	360
Tolland	42	56	51
Windham	75	92	73
Statewide Total Performing Providers	4,770	6,086	5,256

Figure 15: CMAP Health Care Members-to-Provider Statewide Average of CMAP Physician Specialists Calendar Year 2014



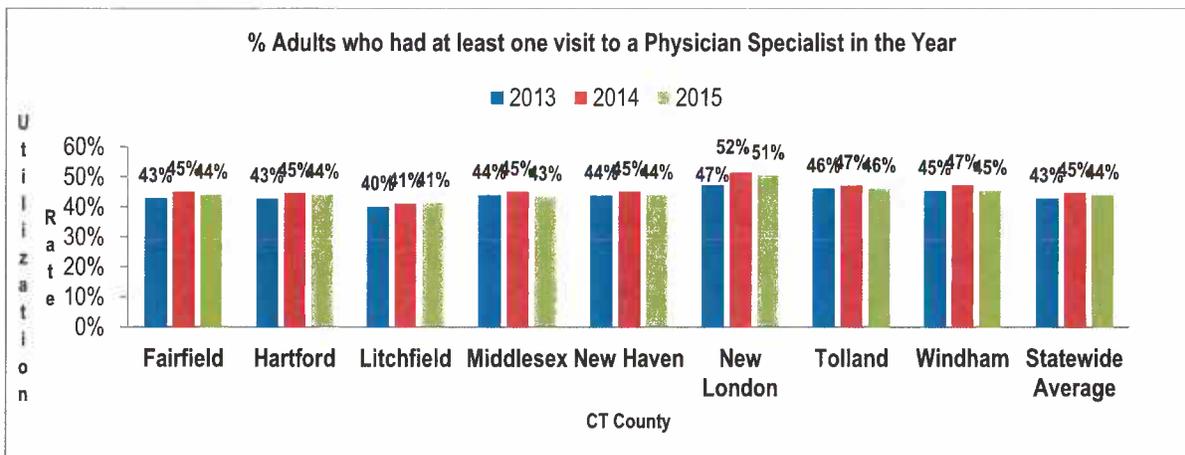
Physician Specialist Services

Table 33: Distribution of Adult Utilization of Physician Specialist Services - CY2013 - CY2015

Member (Adult) County	2013		2014		2015	
	Total Number of Adults	% Who had at least one visit in the CY	Total Number of Adult	% Who had at least one visit in the CY	Total Number of Adults	% Who had at least one visit in the CY
Fairfield	90,976	42.9%	111,508	45.1%	126,411	44.1%
Hartford	129,246	42.8%	147,416	44.6%	162,083	44.2%
Litchfield	18,924	40.2%	22,773	41.2%	25,134	41.4%
Middlesex	15,267	44.0%	18,101	45.1%	20,076	43.5%
New Haven	126,987	43.8%	146,255	45.1%	160,963	44.0%
New London	35,513	47.4%	40,297	51.5%	44,124	50.6%
Tolland	10,393	46.2%	12,579	47.2%	14,195	46.2%
Windham	17,971	45.4%	20,132	47.3%	21,942	45.5%
Statewide	430,919	44.4%	517,214	44.9%	573,682	44.1%

Source:- CT Medicaid Data Warehouse Data from Medicaid Management Information System with data of services from January 1, 2013 through December 31, 2015 of paid claims through May 2016.

Figure 27: Rate of Adult Utilization of Physician Specialist Services – CY 2013-2015



Source:- CT Medicaid Data Warehouse Data from Medicaid Management Information System with data of services from January 1, 2013 through December 31, 2015 of paid claims through May 2016.

Utilization of specialist services was queried based on a provider type and specialty not identified as a primary care, behavioral health, obstetric or home health provider, since these providers are analyzed under their respective category of care as specified in the final rule. The percentage of adult beneficiaries who received service from one of the selected specialist providers at least once during a calendar year remained consistently between 40% and 52% across all eight counties. New London County appears to have had the highest percentages (49% to 52%) of adult beneficiaries who had at least one visit with a specialist in the three year period, Tables 33 and Figure 27 above. Given the wide range of specialist services captured by this analysis, the relatively stable utilization rates, the lack of unresolved access to care

User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Wednesday, July 05, 2017 10:56 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; 'klg1@aol.com'
Subject: OHCA Docket No. 16-32117-COS
Attachments: COS Objection to Request for Status by ARC final version 7.14.17.docx; COS Rebuttal Testimony final version.docx; Petition to Limit Participation ARC.pdf; Rebuttal of Mr. Yoder Testimony.pdf

July 5, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find the Connecticut Orthopaedic Specialists, LLC's Objection to the Request for Status filed by Advanced Radiology Consultants, LLC, and Connecticut Orthopaedic Specialists P.C.'s Rebuttal Testimony. The documents have been filed in both WORD and PDF format.

I would appreciate knowing that OHCA has received this email transmission with its 4 attachments.

Thank you for your assistance.

Best regards,

Glenn F. Elia
Chief Executive Officer
Connecticut Orthopaedic Specialists, P.C.

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS**

**CONNECTICUT ORTHOPAEDIC . : DOCKET NO. 16- 32117-CON
SPECIALISTS, P.C.**

**IN RE: ACQUISITION OF A MOBILE : JULY 5 , 2017
1.5 T MRI**

**PETITION TO LIMIT THE PARTICIPATION BY ADVANCED RADIOLOGY
CONSULTANTS, LLC IN THE ABOVE-CAPTIONED DOCKET**

Pursuant to Conn. Gen. Stat. Sec. 4-177a(d), Connecticut Orthopaedic Specialists, P.C. (“COS”) respectfully requests that if the presiding officer grants the petition filed by Advanced Radiology Consultants, LLC (“ARC”) for intervenor status in the above-captioned case, that the participation be limited to those geographic areas where ARC conducts business. ARC has offices in Orange, Shelton, Trumbull, Stratford, Fairfield, Stamford and Wilton. (Petition of Advanced Radiology Consultants, LLC dated June 17, 2017, ARC Petition for Intervenor Status, p.3). ARC does not provide radiology services in any of the towns included in the Essex service area, which includes Essex, Madison, Clinton, Old Saybrook, Westbrook, Old Lyme, Deep River, Chester or Guilford. The Essex service area was defined by COS in its CON application. (COS CON App., Table 8 B, Record, p. 45). COS requests that ARC be limited to contesting the MRI service COS plans to offer in the Orange area. (COS CON App., Table 8 A, Record, p.44). ARC has offices in Orange, Shelton and Milford which are included in the service area for Orange created by COS. If not so limited, every radiology practice in CT, as well as every institution in CT providing MRI service would have the right to intervene in the COS CON application. COS has not stated any specific legal or personal interest that can be damaged by approval of the COS application for the MRI service in Essex.

COS requests that any right that ARC has to intervene in the COS CON application for a mobile MRI to be used two days a week in Orange and 2 days a week in Essex be limited to testimony and argument about the MRI service two days a week in Orange. COS would also ask that any argument regarding self-referral of ancillary services to Medicare patients be disallowed since self-referral for ancillary services for radiology are specifically an exception to the Stark law, and do not violate any law in Connecticut.

By: _____

Its Attorney: Patricia A. Gerner

The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Fax: (860) 489-8380
Email: KLG1@aol.com

Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 5th day of July, 2017 to:

Attorney Jennifer Groves Fusco at:
Updike Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
jfusco@uks.com

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF THE OFFICE OF	:	DOCKET NO. 16-32117-CON
HEALTH CARE ACCESS	:	
	:	
	:	
IN RE: CONNECTICUT ORTHOPAEDIC	:	JULY 5, 2017
SPECIALISTS, P.C., ACQUISITION OF A	:	
1.5 T MOBILE MRI	:	

REBUTTAL OF MR. YODER’S PREFILE TESTIMONY

Advanced Radiology Consultants, LLC, (“ARC”) has deliberately mischaracterized or misunderstood many of the statements that are in the CON application filed by Connecticut Orthopaedic Specialists, P.C. ARC has chosen to evaluate the COS application as it would an application from any other competing radiology practice. COS is an orthopedic practice using MRI only for its own patients. COS is completely different from a radiology practice, including the fact that radiology practices each offer many more modalities than just MRI scanning. ARC has not taken into account, or has ignored the fact that COS does not offer MRI services to the general public. COS has provided MRI services to its patients (only) for many years. Between FY20013 and FY2015, COS experienced an influx of new patients, not from normal attrition, but all at once, from new COS orthopedic offices which have opened in the Orange and Essex areas.

COS does not charge a facility fee as many of the area providers do. COS is a value-based practice where quality is the top priority, but limiting costs is not far behind. The following list highlights some of the ARC statements that need to be clarified to set the record straight prior to the hearing.

1. Connecticut Orthopaedic Specialists, P.C. (“COS”) is the largest orthopedic practice in Connecticut. It is, therefore, not unusual that with the growth of its practice, the need for additional MRI service would increase also. In FY2016, COS did a total of 9,108 MRI scans in Hamden and Branford, which is a total of 3,872 additional MRI scans over the number of MRI scans performed at those two COS practices in FY2013. (COS CON

App. Record, p. 254.) COS has offered MRI service as part of their integrated practice of orthopedics for many years. Patients select COS due to the quality of the orthopedic care that is provided, not the fact that it is conveniently provided in a certain location. Evidence of this is seen in the number of COS patients living in the Essex service area who have traveled a long distance to go to Hamden or Branford in order to have the MRI scan provided under the supervision of their treating physicians. (COS CON App., p. 27).

2. Contrary to the statements on page 15 of the ARC Prefile Testimony that the COS application will not improve the accessibility of services for Medicaid patients, COS already accepts and treats Medicaid and Medicare patients, as well as indigent persons. Additional MRI service will only increase the number of COS patients who can receive the benefit of MRI scanning as part of their orthopedic treatment, if they so choose. It has only been in the last few years, after the clinics operating at Yale's St. Raphael's Hospital closed their doors, that COS began to see more Medicaid patients showing up in Hamden. They were in need of orthopedic care and were willing to come to Hamden since they no longer had the clinic service in New Haven. The numbers have grown over the last 3 years, and COS expects that as word spreads, there will be more Medicaid patients who seek out COS orthopedic care. The proposed mobile service in Orange may be closer than Hamden or Branford for some individuals who live in the New Haven area and, if the application is approved, will be able to see a COS orthopedic physician. In Essex, the mobile COS MRI scanner will create access to a COS physician practice with MRI scanning capability that has not been available in this part of Connecticut. Also, there are Medicaid patients who are seen in Essex who do not have the means to travel to Hamden or Branford for an MRI scan, but will be able to have the MRI scan in Essex if this application is approved.

3. On p. 15 of ARC's Prefile Testimony, it is stated that COS failed to consider the utilization of existing MRI providers in its assessment of need. This is inaccurate. COS examined the existing radiology practices in both service areas and included that information in its application, (COS CON App., Record, pp. 45 - 48). These are radiology practices, hospitals, and outpatient facilities, not orthopedic specialists. All of

these radiology practices are available to the patients in the Orange and Essex service area, but none of them offer orthopedic physicians for treatment. It is like comparing apples and oranges. Since COS does not advertise its MRI service to the general public, but only to its existing patients (who may choose or decide to go elsewhere for the MRI scan), it was decided to do the need assessment on the basis of the much smaller number of patients who utilize COS orthopedic services in each service area (Orange and Essex), where most of the new COS practices are located, since this is the reality. Since all patients are welcome to utilize COS' orthopedic services, this is not a practice that is selective or discriminatory.

4. In terms of a clear public need, ARC conveniently forgets that COS acquired 4 orthopedic practices between FY2014 and FY 2016 with 20 new orthopedic specialists and 12 new COS offices. (COS Prefile Testimony of Glenn F. Elia, p. 3) It is largely due to the influx of these new patients that the available slots in Hamden and Branford have reached maximum capacity. As Mr. Elia will testify at the hearing, these mergers with other orthopedic physician practices will allow COS to offer orthopedic services at a lower cost.

5. As to the quality of MRI scans, Dr. Gagliardi, who is employed by COS, is not "a general radiologist" as stated by ARC in its petition. (Petition for Status of ARC dated 6/17/17, p. 3). Dr. Gagliardi is a board certified radiologist and an American Board of Radiology Examiner in the musculoskeletal section, who specializes in orthoedic radiology. (See the curriculum vitae of Dr. Gagliardi attached to his Prefile Testimony).

6. ARC states that Hamden and Branford are not in either of the service areas where COS seeks to add additional MRI scanning, and therefore, "it cannot utilize the Standards and Guidelines Specific to MRI, Section 3.b. to establish clear public need." (ARC Prefile, p. 15). COS provides orthopedic services in a broad geographic area which is set forth in the COS CON Application (Record, p. 61 and map attached to this document, Record, p. 60). As you can see from the attached map, the Hamden and Branford COS

orthopedic offices which currently provide all of the COS MRI capability are located in the middle of a larger area where COS orthopedic offices are located.

The influx of new COS patients in FY2014 and FY2015 was created by the addition of the new orthopedic practices that joined COS. This put great stress on the existing COS MRI service in Hamden and Branford, which would like to have expanded their facilities to accommodate the need, but there is no room to expand in either Branford or Hamden. In FY2013, COS did a total of 5,236 MRI scans in its Hamden and Branford offices. (COS CON App., Record, p.42). In 2016, these two MRIs did 9,108 MRI scans. (COS CON App., Record, p. 254). That is an addition of 3,872 scans which came from the entire COS service area, performed in Branford and Hamden. (COS CON App., p. 60). In order to be conservative, and not inflate the number of new patients expected to use the new mobile service, COS went to great lengths to accurately project existing and future need. It deliberately created two new, small service areas which represent exactly where the new mobile scanner is needed. However, these new service areas will not obliterate the Hamden and Branford MRI service, which is located in the heart of the area where COS offices exist. They are definitely part of the service area that COS covers, and they will continue to be so in the future.

A mobile MRI was selected to accommodate the newly acquired need because even though COS will lose one day a week with travel between the two locations, two days a week in each location was considered to be adequate to handle the new patients who have recently begun using the COS orthopedic offices in the Orange and Essex areas. The conclusion was that once MRI service was available in both Essex and Orange, COS patients from those towns and the surrounding towns would not need to travel to Hamden or Branford for an MRI scan. They would have access closer to home for MRI scanning. And this would relieve the stress on the Hamden and Branford MRIs.

COS has demonstrated that its percent utilization of current capacity in Hamden and Branford (which is where all of the COS MRI capacity is currently located) exceeds 85%. The Hamden and Branford COS orthopedic offices and its two MRI units are obviously in the middle of the larger service area covered by COS. COS believes that it has met the requirements of the Statewide Health Care Facilities and Services Plan especially since OHCA can take into account other relevant information. In this case, the need for

additional MRI service did not come about by ordinary attrition at the existing COS MRI scanners, but through a series of mergers which created a large volume of new patients in a short period of time in two distinct areas of the larger COS service area. Branford and Hamden are not seeking to expand their capacity, but are the only COS facilities with all of the current COS MRI volume. That is where need was demonstrated because those two offices experienced all of the rapid growth over the last few years. Other factors that OHCA may consider are the fact that COS has the ability to serve an underserved population and not jeopardize the financial viability of the project, (COS CON App., p. 283), that allowing the two mobile scanners to operate in the distinct areas where COS needs them will avoid delays in timely diagnosis and treatment, and the history of the applicant in running accredited, financially successful facilities.

7. COS does not “control referrals to its MRI units” as claimed on p. 16 of ARC’s prefile. This language does not appear on p. 24 of the COS Application, nor should it appear on any other page in the COS application because it is not true.

8. ARC states on page 17 of its Prefile Testimony that in FY 2016, “ARC scanned 201 COS patients”. On page 19, ARC states that in 2016 “the total number of patients scanned by ARC from the Orange service area was 223”. On page 20 of its Prefile Testimony, ARC states that, “In 2016, ARC performed 398 scans ordered by COS physicians”. COS regularly has patients who present with the need for an MRI scan on a 3.0T scanner, need a contrast study or require an ultra sound exam. COS also sends its patients to ARC whenever they request to use ARC. These patients need to be sent to another radiology service if a 3.0 T scanner is required because COS only utilizes the 1.5T MRI, which is the standard for orthopedic scanning. Patients who appear at any of the COS orthopedic offices are all told that ARC has a 3.0 T MRI unit in the area, and COS has recommended ARC. This type of referral to other providers is not expected to change. There is no intent to stop referring patients to ARC or any other competent radiology practice as needed by the patients. COS cannot perform 3.0 scans and is not asking for permission to begin using a 3.0 T MRI. The fact that 398 patients were referred from COS to ARC is undoubtedly accurate, and only ARC knows how much

reimbursement it received from these patients. Approval of this application will not change the need for the COS patients who require the 3.0T MRI scanner, a contrast study or an ultrasound exam to utilize a provider in the Orange area such as Advanced Radiology Consultants.

9. On page 22 of its Prefile Testimony, ARC states that “In order to meet its volume projections COS physicians will need to refer virtually all of their MRI scans to practice-owned units”. This is not accurate. First, it implies that COS only refers patients to its own MRI service and that all COS patients use the COS MRI service. Many patients have an established relationship with a radiologist (which could be ARC) and will use that practice instead of COS for the MRI scan. Other patients live or work closer to a radiology practice that they can access more easily. Although the COS physicians would prefer that their patients use the COS MRI scanning service because of the close working relationship between the orthopedic physicians and the COS radiologist Dr. Gagliardi, who understands the high quality the COS physicians demand, they respect the patient’s choice to use another provider. COS indicated in its CON Application that COS does not cut the tie with patients who do not use COS for the MRI scan. Patients can go elsewhere for the MRI scan, and still be treated by a COS orthopedic specialist.

Respectfully Submitted,

THE LAW OFFICE OF PATRICIA A. GERNER, LLC

BY: _____

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It's Attorney

Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 5th day of July, 2017 to:

Attorney Jennifer Groves Fusco at:

Updike Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
jfusco@uks.com

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS**

**CONNECTICUT ORTHOPAEDIC . : DOCKET NO. 16- 32117-CON
SPECIALISTS, P.C.**

**IN RE: ACQUISITION OF A MOBILE : JULY 5 , 2017
1.5 T MRI**

**PETITION TO LIMIT THE PARTICIPATION BY ADVANCED RADIOLOGY
CONSULTANTS, LLC IN THE ABOVE-CAPTIONED DOCKET**

Pursuant to Conn. Gen. Stat. Sec. 4-177a(d), Connecticut Orthopaedic Specialists, P.C. ("COS") respectfully requests that if the presiding officer grants the petition filed by Advanced Radiology Consultants, LLC ("ARC") for intervenor status in the above-captioned case, that the participation be limited to those geographic areas where ARC conducts business. ARC has offices in Orange, Shelton, Trumbull, Stratford, Fairfield, Stamford and Wilton. (Petition of Advanced Radiology Consultants, LLC dated June 17, 2017, ARC Petition for Intervenor Status, p.3). ARC does not provide radiology services in any of the towns included in the Essex service area, which includes Essex, Madison, Clinton, Old Saybrook, Westbrook, Old Lyme, Deep River, Chester or Guilford. The Essex service area was defined by COS in its CON application. (COS CON App., Table 8 B, Record, p. 45). COS requests that ARC be limited to contesting the MRI service COS plans to offer in the Orange area. (COS CON App., Table 8 A, Record, p.44). ARC has offices in Orange, Shelton and Milford which are included in the service area for Orange created by COS. If not so limited, every radiology practice in CT, as well as every institution in CT providing MRI service would have the right to intervene in the COS CON application. COS has not stated any specific legal or personal interest that can be damaged by approval of the COS application for the MRI service in Essex.

COS requests that any right that ARC has to intervene in the COS CON application for a mobile MRI to be used two days a week in Orange and 2 days a week in Essex be limited to testimony and argument about the MRI service two days a week in Orange. COS would also ask that any argument regarding self-referral of ancillary services to Medicare patients be disallowed since self-referral for ancillary services for radiology are specifically an exception to the Stark law, and do not violate any law in Connecticut.

By: Patricia A. Gerner

Its Attorney: Patricia A. Gerner

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Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 5th day of July, 2017 to:

Attorney Jennifer Groves Fusco at:
Updike Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
jfusco@uks.com

Patricia A. Gerner
Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

DEPARTMENT OF PUBLIC HEALTH	:	
DIVISION OF THE OFFICE OF	:	DOCKET NO. 16-32117-CON
HEALTH CARE ACCESS	:	
	:	
	:	
IN RE: CONNECTICUT ORTHOPAEDIC	:	JULY 5, 2017
SPECIALISTS, P.C., ACQUISITION OF A	:	
1.5 T MOBILE MRI	:	

REBUTTAL OF MR. YODER’S PREFILE TESTIMONY

Advanced Radiology Consultants, LLC, (“ARC”) has deliberately mischaracterized or misunderstood many of the statements that are in the CON application filed by Connecticut Orthopaedic Specialists, P.C. ARC has chosen to evaluate the COS application as it would an application from any other competing radiology practice. COS is an orthopedic practice using MRI only for its own patients. COS is completely different from a radiology practice, including the fact that radiology practices each offer many more modalities than just MRI scanning. ARC has not taken into account, or has ignored the fact that COS does not offer MRI services to the general public. COS has provided MRI services to its patients (only) for many years. Between FY20013 and FY2015, COS experienced an influx of new patients, not from normal attrition, but all at once, from new COS orthopedic offices which have opened in the Orange and Essex areas.

COS does not charge a facility fee as many of the area providers do. COS is a value-based practice where quality is the top priority, but limiting costs is not far behind. The following list highlights some of the ARC statements that need to be clarified to set the record straight prior to the hearing.

1. Connecticut Orthopaedic Specialists, P.C. (“COS”) is the largest orthopedic practice in Connecticut. It is, therefore, not unusual that with the growth of its practice, the need for additional MRI service would increase also. In FY2016, COS did a total of 9,108 MRI scans in Hamden and Branford, which is a total of 3,872 additional MRI scans over the number of MRI scans performed at those two COS practices in FY2013. (COS CON

App. Record, p. 254.) COS has offered MRI service as part of their integrated practice of orthopedics for many years. Patients select COS due to the quality of the orthopedic care that is provided, not the fact that it is conveniently provided in a certain location. Evidence of this is seen in the number of COS patients living in the Essex service area who have traveled a long distance to go to Hamden or Branford in order to have the MRI scan provided under the supervision of their treating physicians. (COS CON App., p. 27).

2. Contrary to the statements on page 15 of the ARC Prefile Testimony that the COS application will not improve the accessibility of services for Medicaid patients, COS already accepts and treats Medicaid and Medicare patients, as well as indigent persons. Additional MRI service will only increase the number of COS patients who can receive the benefit of MRI scanning as part of their orthopedic treatment, if they so choose. It has only been in the last few years, after the clinics operating at Yale's St. Raphael's Hospital closed their doors, that COS began to see more Medicaid patients showing up in Hamden. They were in need of orthopedic care and were willing to come to Hamden since they no longer had the clinic service in New Haven. The numbers have grown over the last 3 years, and COS expects that as word spreads, there will be more Medicaid patients who seek out COS orthopedic care. The proposed mobile service in Orange may be closer than Hamden or Branford for some individuals who live in the New Haven area and, if the application is approved, will be able to see a COS orthopedic physician. In Essex, the mobile COS MRI scanner will create access to a COS physician practice with MRI scanning capability that has not been available in this part of Connecticut. Also, there are Medicaid patients who are seen in Essex who do not have the means to travel to Hamden or Branford for an MRI scan, but will be able to have the MRI scan in Essex if this application is approved.

3. On p. 15 of ARC's Prefile Testimony, it is stated that COS failed to consider the utilization of existing MRI providers in its assessment of need. This is inaccurate. COS examined the existing radiology practices in both service areas and included that information in its application, (COS CON App., Record, pp. 45 - 48). These are radiology practices, hospitals, and outpatient facilities, not orthopedic specialists. All of

these radiology practices are available to the patients in the Orange and Essex service area, but none of them offer orthopedic physicians for treatment. It is like comparing apples and oranges. Since COS does not advertise its MRI service to the general public, but only to its existing patients (who may choose or decide to go elsewhere for the MRI scan), it was decided to do the need assessment on the basis of the much smaller number of patients who utilize COS orthopedic services in each service area (Orange and Essex), where most of the new COS practices are located, since this is the reality. Since all patients are welcome to utilize COS' orthopedic services, this is not a practice that is selective or discriminatory.

4. In terms of a clear public need, ARC conveniently forgets that COS acquired 4 orthopedic practices between FY2014 and FY 2016 with 20 new orthopedic specialists and 12 new COS offices. (COS Prefile Testimony of Glenn F. Elia, p. 3) It is largely due to the influx of these new patients that the available slots in Hamden and Branford have reached maximum capacity. As Mr. Elia will testify at the hearing, these mergers with other orthopedic physician practices will allow COS to offer orthopedic services at a lower cost.

5. As to the quality of MRI scans, Dr. Gagliardi, who is employed by COS, is not “a general radiologist” as stated by ARC in its petition. (Petition for Status of ARC dated 6/17/17, p. 3). Dr. Gagliardi is a board certified radiologist and an American Board of Radiology Examiner in the musculoskeletal section, who specializes in orthoedic radiology. (See the curriculum vitae of Dr. Gagliardi attached to his Prefile Testimony).

6. ARC states that Hamden and Branford are not in either of the service areas where COS seeks to add additional MRI scanning, and therefore, “it cannot utilize the Standards and Guidelines Specific to MRI, Section 3.b. to establish clear public need.” (ARC Prefile, p. 15). COS provides orthopedic services in a broad geographic area which is set forth in the COS CON Application (Record, p. 61 and map attached to this document, Record, p. 60). As you can see from the attached map, the Hamden and Branford COS

orthopedic offices which currently provide all of the COS MRI capability are located in the middle of a larger area where COS orthopedic offices are located.

The influx of new COS patients in FY2014 and FY2015 was created by the addition of the new orthopedic practices that joined COS. This put great stress on the existing COS MRI service in Hamden and Branford, which would like to have expanded their facilities to accommodate the need, but there is no room to expand in either Branford or Hamden. In FY2013, COS did a total of 5,236 MRI scans in its Hamden and Branford offices. (COS CON App., Record, p.42). In 2016, these two MRIs did 9,108 MRI scans. (COS CON App., Record, p. 254). That is an addition of 3,872 scans which came from the entire COS service area, performed in Branford and Hamden. (COS CON App., p. 60). In order to be conservative, and not inflate the number of new patients expected to use the new mobile service, COS went to great lengths to accurately project existing and future need. It deliberately created two new, small service areas which represent exactly where the new mobile scanner is needed. However, these new service areas will not obliterate the Hamden and Branford MRI service, which is located in the heart of the area where COS offices exist. They are definitely part of the service area that COS covers, and they will continue to be so in the future.

A mobile MRI was selected to accommodate the newly acquired need because even though COS will lose one day a week with travel between the two locations, two days a week in each location was considered to be adequate to handle the new patients who have recently begun using the COS orthopedic offices in the Orange and Essex areas. The conclusion was that once MRI service was available in both Essex and Orange, COS patients from those towns and the surrounding towns would not need to travel to Hamden or Branford for an MRI scan. They would have access closer to home for MRI scanning. And this would relieve the stress on the Hamden and Branford MRIs.

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Respectfully Submitted,

THE LAW OFFICE OF PATRICIA A. GERNER, LLC

BY: 

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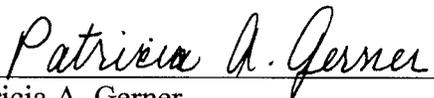
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It's Attorney

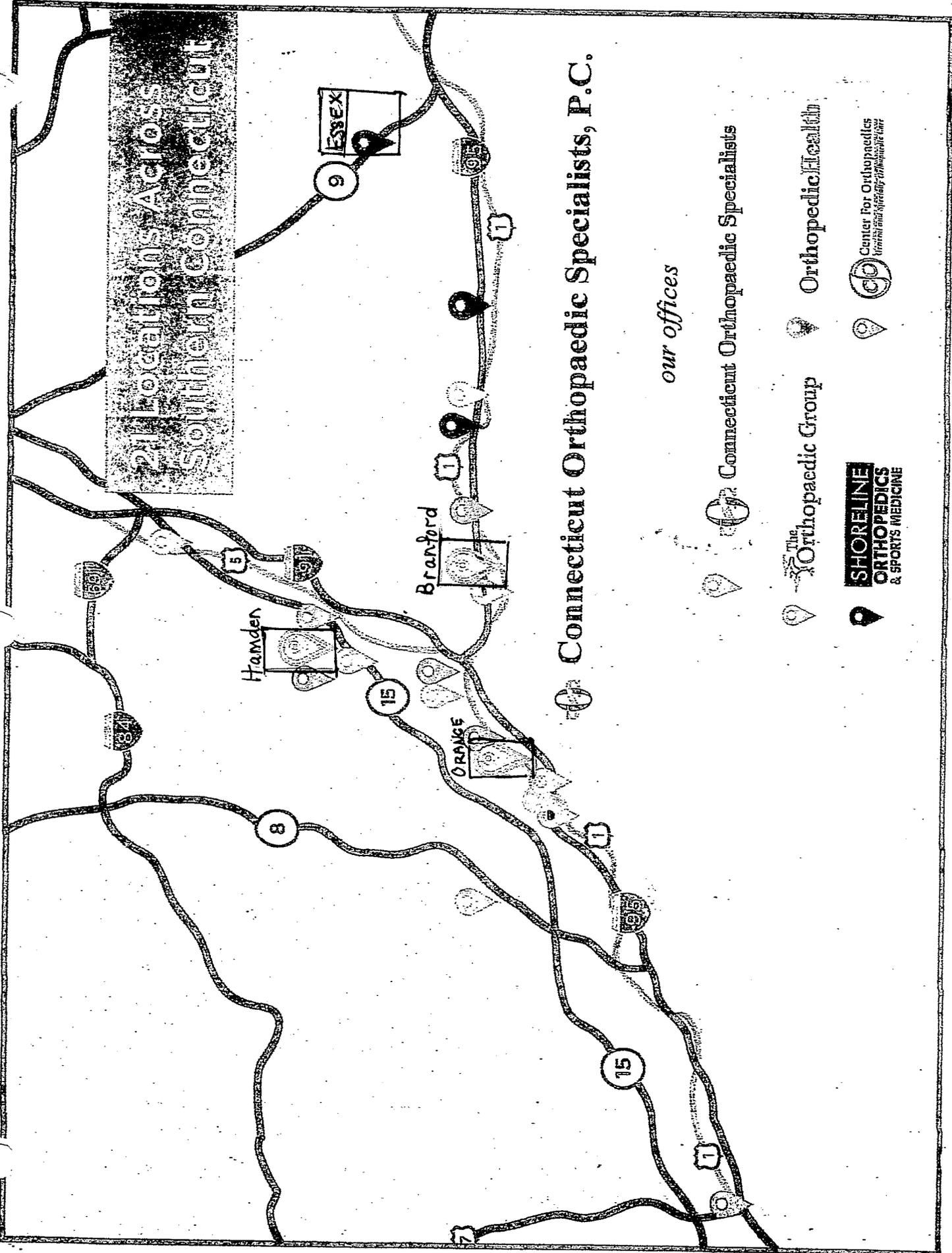
Certification: I hereby certify that a copy of the foregoing has been sent via electronic email this 5th day of July, 2017 to:

Attorney Jennifer Groves Fusco at:

Updike Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
jfusco@uks.com



Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC



Connecticut Orthopaedic Specialists, P.C.

our offices

- Connecticut Orthopaedic Specialists
- The Orthopaedic Group
- Orthopaedic Health
- Shoreline Orthopedics & Sports Medicine
- Center For Orthopedics

User, OHCA

From: Fernandes, David
Sent: Thursday, July 06, 2017 10:26 AM
To: jfusco@uks.com; clark.yoder@adrad.com
Cc: Glenn F. Elia; 'klg1@aol.com'; Riggott, Kaila; Lazarus, Steven; User, OHCA
Subject: Ruling on Intervenor Status
Attachments: 16-32117 Ruling on intervenor status.pdf

Good Morning Ms. Fusco and Mr. Yoder,
Please find attached the ruling on intervenor status for the upcoming hearing on 16-32117-CON.

Thanks,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

IN THE MATTER OF:

A Certificate of Need Application by
Connecticut Orthopaedic Specialists, P.C.
Notice to Petitioner re: Request for Status

Docket Number: 16-32117-CON

RULING ON A PETITION FILED BY ADVANCED RADIOLOGY CONSULTANTS, LLC TO BE DESIGNATED AS AN INTERVENOR

By petition dated June 27, 2017, Advanced Radiology Consultants, LLC ("Petitioner") requested Intervenor status in the public hearing to be held by the Department of Public Health ("DPH") Office of Health Care Access ("OHCA") regarding the Certificate of Need ("CON") application of Connecticut Orthopaedic Specialists, P.C. ("Applicant") filed under Docket Number: 16-32117-CON.

Pursuant to Connecticut General Statutes § 4-177a, the Petitioner is hereby designated as an Intervenor with full rights of cross-examination at the hearing scheduled for July 11, 2017 at 410 Capitol Avenue, Hartford, Connecticut. As an Intervenor with full rights of cross-examination, the Petitioner may participate as indicated below.

The Petitioner is granted the right to inspect and copy records on file with OHCA related to the CON filed under Docket Number 16-32117-CON and shall be copied on all pleadings, correspondence and filings submitted from this point forward by the Applicant until the issuance of a final decision by OHCA. As an Intervenor with full rights of cross-examination, the Petitioner may be cross-examined by the Applicant and the Petitioner has the right to cross-examine the Applicant.

OHCA will make any additional rulings as to the extent of the hearing participation rights of the Petitioner throughout the hearing in the interest of justice and to promote the orderly conduct of the proceedings.

A handwritten signature in blue ink, appearing to read "Kevin T. Hansted".

Digitally signed by Kevin T.
Hansted
Date: 2017.07.06 10:15:32 -04'00'

Kevin T. Hansted
Hearing Officer



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer



User, OHCA

From: Fernandes, David
Sent: Thursday, July 06, 2017 4:04 PM
To: jfusco@uks.com; clark.yoder@adrad.com; Glenn F. Elia; 'klg1@aol.com'
Cc: Riggott, Kaila; Lazarus, Steven; User, OHCA
Subject: Tentative Agenda, Table of the Record and Exhibit One for July 11th Hearing
Attachments: 16-32117 Tentative Agenda.doc; Orange and Essex Area MRI Scanner Tables 1.docx; 32117 table.doc

Good Afternoon ARC and COS,
Attached please find the Tentative Agenda and the Table of the Record. In addition, please find OHCA's Exhibit 1 for the hearing scheduled for July 11th.

Please confirm receipt of this email as well as the three attachments.

Thanks,

David Fernandes
Planning Analyst (CCT)
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Connecticut Department of Public Health
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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

TENTATIVE AGENDA

Docket Number: 16-32117-CON

Connecticut Orthopaedic Specialists, P.C.

Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

July 11, 2017 at 9:00 a.m.

- I. Convening of the Public Hearing**
- II. Applicant's Direct Testimony (10 minutes)**
- III. Intervenor's Direct Testimony (10 minutes)**
- IV. Intervenor's cross-examination of Applicant**
- V. Applicant's cross-examination of Intervenor**
- VI. OHCA's Questions**
- VII. Public Comment**
- VIII. Closing Remarks**
- IX. Public Hearing Adjourned**

An Equal Opportunity Provider

(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)

410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308

Telephone: (860) 418-7001 Fax: (860) 418-7053 Email: OHCA@ct.gov



STATE OF CONNECTICUT
 DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

TABLE OF THE RECORD

APPLICANTS: Connecticut Orthopaedic Specialists, P.C.

DOCKET NUMBER: 16-32117-CON

PUBLIC HEARING: July 11, 2017 at 9:00 am

PLACE: Department of Public Health, Office of Health Care Access
 410 Capitol Avenue, Third Floor Hearing Room
 Hartford, CT 06134

EXHIBIT	DESCRIPTION
A	Letter from Connecticut Orthopaedic Specialists, P.C. (Applicant) dated August 19, 2016 enclosing the Certificate of Need (CON) application for the Acquisition of a Mobile 1.5 T Magnetic Resonance Imaging Scanner under Docket Number 16-32117, received by OHCA on August 22, 2016 (218 Pages)
B	OHCA’s letter to the Applicant dated September 21, 2016, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 16-32117.(3 Pages)
C	Applicant’s responses to OHCA’s letter of September 21, 2016, dated November 8, 2016 in the matter of the CON application under Docket Number 16-32117, received by OHCA on November 8, 2016. (31 Pages)
D	OHCA’s letter to the Applicant dated December 8, 2016, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 16-32117.(3 Pages)
E	Applicant’s responses to OHCA’s letter of December 8, 2016, dated February 2, 2017 in the matter of the CON application under Docket Number 16-32117, received by OHCA on February 2, 2017. (29 Pages)
F	OHCA’s letter to the Applicant dated March 3, 2017, requesting Additional information and/or clarification in the matter of the CON application under Docket Number 16-32117. (4 Pages)

G	Applicant’s responses to OHCA’s letter of March 3, 2017, dated April 18, 2017 in the matter of the CON application under Docket Number 16-32117, received by OHCA on April 18, 2017. (10 Pages)
H	OHCA’s letter to the Applicant dated May 19, 2017 deeming the application complete in the matter of the CON application filed under Docket Number 16-32117. (1 page)
I	Letter from Advanced Radiology to OHCA dated May 31, 2017 requesting a public hearing in the matter of the CON application filed under Docket Number 16-32117. (1 page)
J	Designation of Hearing Officer in the in the matter of the CON application under Docket Number 16-32117, dated June 7, 2017. (1 page)
K	OHCA’s request for legal notification in <i>Hartford Courant</i> and <i>New Haven Register</i> and OHCA’s Notice to the Applicant of the public hearing scheduled for July 11, 2017 and in the matter of the CON application under Docket Number 16-32117, dated June 8, 2017. (6 pages)
L	OHCA’s letter to the Applicant dated June 14, 2017 requesting prefile testimony in the matter of the CON application under Docket Number 16-32117. (2 pages)
M	Applicant’s letter dated June 23, 2017 enclosing Notice of Appearance, and prefile testimonies in the matter of the CON application under Docket Number 16-32117, received by OHCA on June 23, 2017(32 pages)
N	Letter from the from Advanced Radiology Consultants, LLC (“Petitioner”) to OHCA dated June 27, 2017 enclosing notice of appearance, prefile testimony and requesting intervenor status in the in the matter of the CON application under Docket Number 16-32117, received by OHCA on June 27, 2017. (137 pages)
O	Letter from the Applicant dated June 27, 2017 requesting to receive information in the matter of the CON application under Docket Number 16-32117, received by OHCA on June 27, 2017. (5 pages)
P	OHCA’s letter to the Applicant dated June 28, 2017 enclosing request for intervenor status received from Advanced Radiology Consultants, LLC in the in the matter of the CON application under Docket Number 16-32117.(137 pages)
Q	Applicant’s letter to OHCA dated July 5, 2017 enclosing objections to the request for status filed by Advanced Radiology Consultants, LLC in the in the matter of the CON application under Docket Number 16-32117. (20 pages)
R	OHCA’s Ruling on a Petition filed by from Advanced Radiology Consultants, LLC to be designated as an Intervenor with Full Rights in the matter of the CON application under Docket Number 16-32117, dated July 6, 2017. (1 page)

OHCA Exhibit 1: Utilization for the MRI scanners in the proposed service area towns

User, OHCA

From: klg1@aol.com
Sent: Friday, July 07, 2017 12:42 PM
To: User, OHCA; Hansted, Kevin; Riggott.Kaila@ct.gov; Lazarus, Steven; Fernandes, David
Cc: jfusco@uks.com
Subject: Receipt of OHCA Documents dated July 6, 2017

Good afternoon David,

Please allow this email to confirm receipt of OHCA's email yesterday, July 6, 2017, to Glenn Elia and myself, with 1) the Tentative Agenda, 2) The Orange and Essex Area MRI Scanning Volume as OHCA Exhibit 1, and 3) Document 32117: Table of the Record. We received 3 documents rather than 4. If there is a fourth document, please send it both to Glenn Elia and myself. Glenn is out of town today, but has his iPad with him.

Thank you,

The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Fax: (860) 489-9380
Email: klg1@aol.com

User, OHCA

From: Lazarus, Steven
Sent: Friday, July 07, 2017 1:09 PM
To: klg1@aol.com; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com
Subject: RE: Receipt of OHCA Documents dated July 6, 2017

Attorney Gerner,

Just to clarify, David yesterday sent out the email with a total of 3 attachments, which are the ones you acknowledged in your email. Perhaps the confusion is that he asked for confirmation of the receipt of his email plus the 3 attached documents. Hope this helps. There was no 4th document attached.

Steve

Steven W. Lazarus

Associate Health Care Analyst
Division of Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7012
Fax: 860-418-7053



From: klg1@aol.com [mailto:klg1@aol.com]
Sent: Friday, July 7, 2017 12:42 PM
To: User, OHCA <OHCA@ct.gov>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Riggott.Kaila@ct.gov; Lazarus, Steven <Steven.Lazarus@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>
Cc: jfusco@uks.com
Subject: Receipt of OHCA Documents dated July 6, 2017

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The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907

Fax: (860) 489-9380
Email: kg1@aol.com

User, OHCA

From: Fernandes, David
Sent: Friday, July 07, 2017 1:20 PM
To: klg1@aol.com; User, OHCA; Hansted, Kevin; Riggott.Kaila@ct.gov; Lazarus, Steven
Cc: jfusco@uks.com
Subject: RE: Receipt of OHCA Documents dated July 6, 2017

Hello Ms. Gerner,
The email sent out yesterday contained three attachments which you have listed in the below email. There was no fourth attachment.

Thanks,

David Fernandes
Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



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Sent: Friday, July 07, 2017 12:42 PM
To: User, OHCA <OHCA@ct.gov>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Riggott.Kaila@ct.gov; Lazarus, Steven <Steven.Lazarus@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>
Cc: jfusco@uks.com
Subject: Receipt of OHCA Documents dated July 6, 2017

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Thank you,

The Law Office of Patricia A. Gerner, LLC
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P.O. Box 209
New Hartford, CT 06057
Phone: (860) 794-1907
Fax: (860) 489-9380
Email: klg1@aol.com

Docket NO. 16-32117-CON

OHCA Exhibit 1

Orange Area					
Facility	Provider O = Outpatient H = Hospital	MRI Type	Total Scans (2013) % Capacity	Total Scans (2016) % Capacity	Distance from COS 330 Boston Post Rd Orange, CT 0647
COS 330 Boston Post Rd. Orange, CT 06477	O	1.5T, Mobile, Closed	N/A	N/A	0
COS 2416 Whitney Ave. Hamden, CT 06518	O	1.5T, Fixed, Closed	3,773 94.3%	4,339 108.47%	10.0
COS 84 North Main St. Branford, CT 06405	O	1.5T, Fixed, Closed	3,851 96.3%	4,619 115.47%	9.7
Milford Hospital, Inc. 300 Seaside Ave. Milford, CT 06460	H	1.5T, Fixed, Closed	2,005 50.1%	1,193 29.82%	4.4
Griffin Hospital 130 Division St. Derby, CT 06418	H	1.5T, Fixed, Closed	1,888 47.2%	2,663 66.57%	6.6
Diagnostic Imaging of Milford 30 Commerce Park Drive Milford, CT 06460	O	0.7T, Fixed, Open	N/A	1,800 45.0%	4.4
Griffin Imaging and Diagnostic Center at Ivy Brook 2 Ivy Brook Rd. Shelton, CT 06484	H	1.2T, Mobil, Closed	2,341 58.5%	2,421 60.52%	4.9
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	1.5T, Fixed, Closed	4,010 100.2%	3,980 99.5%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	1.5T, Fixed, Closed	4,454 111.4%	4,193 104.82%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	3.0T, Fixed, Closed	4,020 100.5%	4,579 114.47%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St.	H	3.0T, Fixed, Closed	2,556 56.4%	2,371 59.27%	4.7

New Haven, CT 06510					
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	3.0T, Fixed, Closed	6,231 155.8%	7,320 183%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	1.5T, Fixed, Closed	6,130 153.3%	5,741 143.52%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	3.0T, Fixed, Closed	6,003 150.1%	6,098 152.45%	4.7
Yale-New Haven Hospital, Inc. New Haven – Main Campus 20 York St. New Haven, CT 06510	H	3.0T, Fixed, Closed	N/A	2,689 67.22%	4.7
Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel St. New Haven, CT 06511	H	1.5T, Fixed, Closed	812 20.3%	3,175 79.37%	4.6
Yale-New Haven Hospital, Inc. New Haven – Chapel St. Campus 1450 Chapel St. New Haven, CT 06511	H	3.0T, Fixed, Closed	713 17.8%	4,010 100.25%	4.6
Yale-New Haven Hospital, Inc. Temple Radiology New Haven 60 Temple St. New Haven, CT 06510	H	1.5T, Fixed, Closed	2,582 64.6%	2,066 51.65%	4.9
<i>Saint Raphael Magnetic Resonance Center 330 Orchard St. New Haven, CT 06511</i>	<i>H</i>	<i>1.5T, Fixed, Closed</i>	<i>1,827 45.7%</i>	<i>N/A (Closed)</i>	<i>N/A (Closed)</i>
Yale Health d/b/a Yale University 55 Lock St. New Haven, CT 06511	O	1.5T, Fixed, Closed	N/A	2,367 59.17%	8.0
<i>Bridgeport Hospital 2595 Main St. Stratford, CT 06615</i>	<i>H</i>	<i>1.5T, Fixed, Closed</i>	<i>1,492 37.3%</i>	<i>N/A (Closed)</i>	<i>N/A (Closed)</i>
Bridgeport Hospital 5520 Park Ave. Trumbull, CT 06611	H	3.0T, Fixed, Closed	N/A	1,469 36.72%	8.0
Bridgeport Hospital 267 Grant St. Bridgeport, CT 06610	H	1.5T, Fixed, Closed	3,500 87.5%	5,066 126.65%	9.8

St. Vincent's Medical Center 2800 Main St. Bridgeport, CT 06606	H	1.5T, Fixed, Closed	4,277 106.9%	4,277 106.9%	11.0
Southern CT Imaging Center, LLC d/b/a Whitney Imaging Center 2200 Whitney Ave. Hamden, CT 06518	O	1.5T, Mobile, Closed	88 2.2%	5,945 148.62%	9.5
<i>Meriden Imaging Center, Inc. d/b/a Wallingford Diagnostic Imaging Center 863 North Main St. Wallingford, CT 06492</i>	<i>O</i>	<i>1.5T, Fixed, Open</i>	<i>3,276 81.9%</i>	<i>N/A (Closed)</i>	<i>N/A (Closed)</i>
<i>Diagnostic Imaging Services of CT d/b/a Branford Open MRI 1208 Main St. Branford, CT 06405</i>	<i>O</i>	<i>0.3T, Fixed, Open</i>	<i>924 23.1%</i>	<i>N/A (Closed)</i>	<i>N/A (Closed)</i>
ARC 297 Boston Post Rd. Orange, CT 06477	O	3.0T, Fixed, Open	3,114 77.9%	4,274 106.85%	0.2
ARC 2876 Main St. Stratford, CT 06477	O	1.5T, Fixed, Closed	5,700 142.5%	5,636 140.9%	7.8
ARC 4 Corporate Drive Shelton, CT 06484	O	1.5T, Fixed, Closed	3,975 99.4%	2,441 61.02%	6.5
ARC 15 Corporate Drive Trumbull, CT 06611	O	1.5T, Fixed, Open	1,480 37.0%	6,396 159.9%	11.7
Total				2013 Scans = 81,022 % Capacity = 77.9% 2016 Scans = 101,128 % Capacity = 97.23	

Source: 2013 and 2016 Statewide Health Care Facilities and Services Inventory

Essex Area

Facility	Provider O = Outpatient H = Hospital	MRI Type	Total Scans (2013) % Capacity	Total Scans (2016) % Capacity	Distance from COS 12 Bokum Rd. Essex, CT 06426
Guilford Radiology 1591 Boston Post Rd. Guilford, CT 06437	O	1.5T, Fixed, Closed	833 20.82%	1,267 31.67%	18.1
Middlesex Hospital d/b/a Shoreline Medical Center ED 250 Flat Rock Place Westbrook, CT 06498	H	1.5T, Fixed, Closed	2,546 63.65%	3,422 85.55%	4.5
Yale-New Haven Hospital, Inc. Shoreline Medical Center Guilford 111 Goose Lane Guilford, CT 06437	H	1.5T, Fixed, Closed	4,260 106.5%	4,288 107.2%	12.7
Total				2013 Scans = 7,639 % Capacity = 63.65% 2016 Scans = 8,977 % Capacity = 74.80%	

Source: 2013 and 2016 Statewide Health Care Facilities and Services Inventory



Office of Health Care Access

APPLICANT

(Only persons speaking on behalf of Applicants must sign in)

PUBLIC HEARING-SIGN UP SHEET

July 11, 2017

9:00 am

Docket Number: 16-32117-CON

Connecticut Orthopaedic Specialists, P.C.

Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

PRINT NAME	Phone	Email	Title
Patricia A. Gerner	(860) 794-1907	Klg1@aol.com	COS Principal, Law Office of Patricia A. Gerner, LLC
Susan Cole England		<u>wjske@aol.com</u>	Law Office of Patricia A. Gerner, LLC
Susan Bader	(203) 859-0283	<u>sbader@ct-ortho.com</u>	Connecticut Orthopaedic Specialists, P.C.
Billie J. Foraker	(203) 619-2607	<u>bforaker@ct-ortho.com</u>	Connecticut Orthopaedic Specialists, P.C.
Glenn Elia	(203) 407-3576	gelia@ct-ortho.com	CEO, Connecticut Orthopaedic Specialists, P.C.

Docket Number: 16-32117-CON
 Connecticut Orthopaedic Specialists, P.C.
 Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

PRINT NAME	Phone	Email	Title
Mark Lorenze	(860) 964-0569	mlorenze@aol.com	Connecticut Orthopaedic Specialists, P.C., Physician
Brian Hayes	(203) 407-3572	bhayes@ct-orthopaedic.com	Connecticut Orthopaedic Specialists, P.C.
Joseph Gagliardi	(203) 500-5896	Jagmo7@aol.com	Connecticut Orthopaedic Specialists, P.C.
Patrick Ruwe, MD	(203) 407-3574	pruwe@ct-orthopaedic.com	Connecticut Orthopaedic Specialists, P.C.

Applicant Sign up-*Only persons speaking behalf of the Applicant may put their names on this sheet*

Docket Number: 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

Print Name	Phone	Email	Title

Applicant Sign up-*Only persons speaking behalf of the Applicant may put their names on this sheet*



Office of Health Care Access

Intervenors

(Only persons speaking on behalf of Intervenors must sign in)

PUBLIC HEARING-SIGN UP SHEET

July 11, 2017

9:00am

Docket Number: 16-32117-CON

Connecticut Orthopaedic Specialists, P.C.

Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

PRINT NAME	Phone	Email	Representing Organization (Intervenor Name)
Jennifer Groves Fusco	(203) 7806-8516	jfusco@uks.com	Advanced Radiology Consultants
Ian Karol, MD	(203) 258-9343		Advanced Radiology Consultants
Clark Yoder	(203) 567-9004	Clark.yoder@adrad.com	Advanced Radiology Consultants

Docket Number: 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

PRINT NAME	Phone	Email	Representing Organization (Intervenor Name)

Intervenor: Status given through a ruling by OHCA.

Docket Number: 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

PRINT NAME	Phone	Email	Representing Organization (Intervenor Name)

Intervenor: Status given through a ruling by OHCA.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS



CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.

ACQUISITION OF A MOBILE 1.5T
MAGNETIC RESONANCE IMAGING SCANNER

DOCKET NO. 16-32117-CON

JULY 11, 2017

9:06 A.M.

DEPARTMENT OF PUBLIC HEALTH
410 CAPITOL AVENUE
HARTFORD, CONNECTICUT

POST REPORTING SERVICE
HAMDEN, CT (800) 262-4102

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 . . .Verbatim proceedings of a hearing
2 before the State of Connecticut, Department of Public
3 Health, Office of Health Care Access, in the matter of
4 Connecticut Orthopaedic Specialists, P.C., acquisition of
5 a mobile 1.5T Magnetic Resonance Imaging Scanner, held at
6 the Department of Public Health, 410 Capitol Avenue,
7 Hartford, Connecticut, on July 11, 2017 at 9:06 a.m. . .

8 .

9
10
11
12 HEARING OFFICER KEVIN HANSTED: Good
13 morning, everyone. This public hearing before the Office
14 of Health Care Access, identified by Docket No. 16-32117-
15 CON, is being held on July 11, 2017 to consider
16 Connecticut Orthopaedic Specialists, P.C.'s application
17 for the acquisition of a mobile 1.5T Magnetic Resonance
18 Imaging Scanner services.

19 This public hearing is being held pursuant
20 to Connecticut General Statute, Section 19a-639a, and
21 will be conducted as a contested case, in accordance with
22 the provisions of Chapter 54 of the Connecticut General
23 Statutes.

24 My name is Kevin Hansted, and I have been

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 designated by Commissioner Raul Pino of the Department of
2 Public Health to serve as the Hearing Officer for this
3 matter.

4 The staff members assigned to assist me in
5 this case are Kaila Riggott, David Fernandes and Steven
6 Lazarus, and the hearing is being recorded by Post
7 Reporting Services.

8 In making its decision, OHCA will consider
9 and make written findings concerning the principles and
10 guidelines set forth in Section 19a-639 of the
11 Connecticut General Statutes.

12 Specifically, OHCA will consider the
13 following; whether there is a clear public need for the
14 proposed transaction; whether the Applicant has
15 satisfactorily demonstrated how the proposal will impact
16 the financial strength of the healthcare system in the
17 State, or that the proposal is financially-feasible for
18 the Applicant; whether the Applicant has satisfactorily
19 demonstrated how the proposal will improve quality,
20 accessibility and cost effectiveness of healthcare
21 delivery in the region; and whether the Applicant has
22 satisfactorily demonstrated that the proposal will not
23 negatively impact the diversity of healthcare providers
24 and patient choice in the geographic region.

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 Connecticut Orthopaedic Specialists, P.C.
2 has been designated as a party in this proceeding, and
3 Advanced Radiology Consultants, LLC has been designated
4 as an Intervenor with full rights.

5 At this time, I will ask staff to read
6 into the record those documents already appearing in
7 OHCA's Table of the Record in this matter.

8 All documents have been identified in the
9 Table of the Record for reference purposes. Mr. Lazarus?

10 MR. STEVEN LAZARUS: Good morning. Steven
11 Lazarus. For the record, we would like to enter Exhibits
12 A through R on the Table of the Record.

13 We would like to add Exhibit S, a change
14 from what's on there, to OHCA Exhibit 1. That's the
15 utilization for the MRI scanners in the proposed service
16 area, and that what was labeled as Exhibit S will now be
17 T, which is the OHCA's letter to the Applicants and the
18 Intervenors, dated July 6, 2016. That includes the
19 tentative agenda, Table of the Record and OHCA's Exhibit
20 1.

21 HEARING OFFICER HANSTED: Counsel, any
22 objections to anything?

23 MS. PAT GERNER: None on this side.

24 HEARING OFFICER HANSTED: Okay.

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 MS. JENNIFER FUSCO: No objections.

2 HEARING OFFICER HANSTED: Okay, thank you.
3 This morning, the Applicant will be the first to present
4 its Direct testimony, followed by the Intervenor, and,
5 after that, the Applicant may Cross-Examine the
6 Intervenor, and then the Intervenor may Cross-Examine the
7 Applicant. If there's any Redirect required, I'll allow
8 that. That's no problem.

9 After that is completed, then OHCA will
10 ask its questions of the Applicant and, if need be, the
11 Intervenor.

12 I don't think there are any, but if there
13 are any members of the public here that would like to
14 comment on it, we would take the public comment after
15 OHCA's questions are completed.

16 At this point, I would like all the
17 individuals, who are going to testify on behalf of the
18 Intervenor and the Applicant, to please stand, raise your
19 right hand and be sworn in by the court reporter.

20 If you're not sure, just stand up and be
21 sworn in anyway.

22 (Whereupon, the parties were duly sworn
23 in.)

24 HEARING OFFICER HANSTED: And for all

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 those, who were just sworn in, if you could each, one-by-
2 one, come up to a microphone and just identify yourselves
3 for the record? I'd appreciate that. The microphone is
4 right in the center. Whoever wants to start.

5 MR. GLENN ELIA: Glenn Elia, Connecticut
6 Orthopaedic Specialists.

7 DR. MARK LORENZE: Mark Lorenze,
8 Connecticut Orthopaedic Specialists.

9 DR. PATRICK RUWE: Patrick Ruwe,
10 Connecticut Orthopaedic Specialists.

11 MS. BILLIE FORAKER: Billie Foraker,
12 Connecticut Orthopaedic Specialists.

13 MS. SUSAN BADER: Susan Bader, Connecticut
14 Orthopaedic Specialists.

15 DR. JOSEPH GAGLIARDI: Joseph Gagliardi,
16 Connecticut Orthopaedic Specialists.

17 MR. CLARK YODER: Clark Yoder, Advanced
18 Radiology.

19 DR. IAN KAROL: Ian Karol, Advanced
20 Radiology.

21 HEARING OFFICER HANSTED: Did we get
22 everyone? Okay, thank you, everyone. Just one
23 housekeeping matter. The Applicant filed a petition to
24 limit the participation by Advanced Radiology

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 Consultants. It's dated July 5th.

2 Attorney Fusco, I did not receive a
3 written reply to that. Did you want to say anything on
4 the record regarding that petition?

5 MS. FUSCO: I believe the petition was
6 intended to limit our discussion to just Orange versus
7 Essex. I mean I think it's difficult to limit it, given
8 that it's going to be a mobile unit going back and forth,
9 and I think a lot of what we've said has more to do with
10 the unit and the application generally.

11 I can tell you, as far as our
12 presentations go and what we put in our testimony, I
13 don't think we mention too much about the Essex service
14 area, so I don't necessarily think there's a need to
15 limit it.

16 The other thing, if I recall, that was in
17 the petition had to do with limiting discussion of self-
18 referral. If I remember correctly, the basis was that,
19 because the practice is legal, it's not something we
20 should be able to discuss, and our position would be,
21 look, regardless of whether it's legal or not, it's still
22 something that may touch upon the CON decision criteria,
23 including need and cost effectiveness, so I think it's
24 perfectly appropriate to discuss and be questioned on

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 self-referral.

2 HEARING OFFICER HANSTED: Okay. Attorney
3 Gerner, did you have any follow-up?

4 MS. GERNER: Yes, just that I think the
5 objection was intended to limit any remarks on behalf of
6 a provider that's in the Essex area, not to limit the
7 discussion in general, but just not that the Intervenor
8 speak on behalf of anyone in the Essex area, because they
9 have no legal interest, no specific legal, personal, or
10 financial interest in the Essex area.

11 HEARING OFFICER HANSTED: Right. Right.
12 I agree with that. I mean they can't do that. Unless
13 the individual practice is here from that area, they
14 can't speak on their behalf, because they don't represent
15 them.

16 MS. GERNER: Exactly.

17 HEARING OFFICER HANSTED: Attorney Fusco,
18 are you okay with that?

19 MS. FUSCO: We don't have any intentions
20 to speak on behalf of anyone, but ourselves.

21 HEARING OFFICER HANSTED: Okay. Okay, so,
22 understanding that limitation. I actually thought the
23 petition went beyond what you just explained, Attorney
24 Gerner, but, with that explanation, I'll grant the

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 petition. Also, with the understanding that, you know,
2 if any information we receive today we think is
3 irrelevant, we will either not consider it or only give
4 it a specific amount of weight when we consider the
5 application.

6 MS. FUSCO: That's acceptable. When you
7 say granting, you mean granting, as far as us not making
8 any representations on behalf of other providers, but in
9 terms of self-referral, and it's not something we intend
10 to spend a significant amount of time on, but that can
11 remain in the record?

12 HEARING OFFICER HANSTED: Correct. I
13 agree with your argument, that the self-referral could
14 touch on the criteria, the CON criteria. To the extent
15 that it doesn't touch the CON criteria, I would like you
16 to exclude it, because that's not under our jurisdiction,
17 but, with respect to any of our criteria, you could
18 certainly present it.

19 MS. FUSCO: Okay.

20 HEARING OFFICER HANSTED: Okay?

21 MS. FUSCO: Understood.

22 HEARING OFFICER HANSTED: With that,
23 Attorney Gerner, you may proceed.

24 MS. GERNER: Good morning, OHCA. Good

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
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1 morning, Hearing Officer Hansted and OHCA staff. First,
2 I want to thank you for the time that you've put in
3 preparing for the hearing and, also, for the long period
4 of time that you've worked on this file. We appreciate
5 that.

6 This morning, we have a number of people,
7 who will present the testimony on behalf of COS,
8 beginning with Glenn Elia, who is the CEO of Connecticut
9 Orthopaedic Specialists, so I will turn this over to him.

10 MR. ELIA: Good morning, Hearing Officer
11 Hansted and members of the OHCA panel.

12 HEARING OFFICER HANSTED: Good morning.

13 MR. ELIA: Likewise, thank you for the
14 time and energy. This application went in almost a year
15 ago. I know there's been a lot going back and forth, and
16 we appreciate the time and energy.

17 I am hereby adopting my pre-filed
18 testimony. I have with me today Dr. Gagliardi, Dr. Ruwe,
19 Dr. Lorenze to speak on our behalf. We also have Billie
20 Foraker, our Director of Clinic Services, and our Chief
21 Financial Officer, Susan Bader, and Brian Hayes.

22 Connecticut Orthopaedic Specialists is
23 well-known to this Department and to this office. We've
24 been here before. We have two other MRIs that you have

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1 granted us CONs for. We were the first organization in
2 the state to be granted a single specialty surgical
3 center, and we're now working with the Department of
4 Public Health to create the first residential care
5 facility above that surgical center.

6 I bring this to light, because all of
7 those were granted through a partnership with the
8 Department of Public Health and OHCA, as Connecticut
9 Orthopaedic Specialists has developed into an innovative,
10 creative healthcare delivery system in the
11 musculoskeletal bandwidth.

12 This application that we're here before
13 you today is a further extension of the development of
14 that practice.

15 This organization has excellent payer
16 relationships, because we have partnered with payers. We
17 have not acted as adversaries.

18 We have a wonderful reputation, because we
19 have only done the highest quality of care, and we have
20 focused on the patient experience.

21 We have stood up to predatory healthcare
22 delivery system behaviors, and we are an example of what
23 private practice can do to bring high-quality care and
24 reduce the cost of care.

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1 The reason we're here today is because of
2 what we consider to be one of our referral partners has
3 objected to our needs. We refer business to Advanced
4 Radiology, but we're also here today, because, more
5 importantly, we want to strengthen our discussion with
6 you regarding this application.

7 We believe that we have worked very hard
8 to increase efficiency, decrease costs, and increase
9 access for patients, and we believe our application
10 brings all of those points to light.

11 The need has been questioned. The need
12 for orthopedic MRI is undisputable, but the need within
13 Connecticut Orthopaedic Specialists is a result of the
14 fact that, on a national level, the demand on orthopedic
15 care is exploding.

16 We're all part of a population that's
17 rapidly aging, and, as a result, the needs for orthopedic
18 care is nationally and otherwise been noted.

19 We have merged with other groups, in order
20 to maintain our viability in the face of consolidation of
21 healthcare systems, which, as you probably would agree
22 to, has not resulted in the reduction of costs, but has
23 resulted in a more monolithic type of behavior.

24 COS is the solution, and what we are

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1 trying to accomplish here today is a further continuation
2 of that solution.

3 The quality of our care has also been
4 questioned in the objection, and we are proposing a 1.5
5 mobile unit. The quality is no different than the two
6 units that we currently are using, both of which have
7 been accredited by the American Academy of Radiologists,
8 American College of Radiologists.

9 This unit will have no difference in its
10 quality. The only reason we need a mobile unit is
11 because we are trying to increase the accessibility of
12 our patients to the systems in the regions that we've
13 spread to.

14 I can go on and on, because I've been the
15 CEO of this practice for 24 years, and I've watched it
16 grow from a six-man organization to a 48-orthopedic
17 organization, with 600 employees.

18 I'll turn this over in a moment, but let
19 me close by saying that we are not a radiology group.
20 We're not looking to hurt any radiology practices in the
21 area.

22 We are an innovative practice that is
23 working to comply with the Affordable Care Act. We're
24 working to comply with all of the demands that both the

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1 State and Federal regulatory environment have placed upon
2 us.

3 Our creative approach towards bundling
4 care, reduced costs per visit, are all part of the
5 solution here.

6 I'm going to turn this over now to Dr. Joe
7 Gagliardi, who is our radiologist, and can speak to the
8 technical aspects of this application.

9 Thank you, again, for your time.

10 HEARING OFFICER HANSTED: Thank you.

11 DR. GAGLIARDI: Good morning.

12 HEARING OFFICER HANSTED: Good morning.

13 DR. GAGLIARDI: I'd like to briefly cover
14 two issues that have been brought up in the pre-filed
15 testimony. First are my credentials.

16 As you can see from my CV, I've engaged in
17 musculoskeletal imaging research and presented this
18 nationally, as well as internationally.

19 I've published in major peer review
20 journals regarding musculoskeletal topics and engaged in
21 teaching in musculoskeletal imaging since my time in the
22 Army, through private practice and currently at the VA,
23 Yale and area groups that contact me to go give lectures.

24 I'm a Board Examiner in the

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1 Musculoskeletal Section for the American Board of
2 Radiology. That includes putting together the original
3 written and oral exam that the residents would sit
4 through.

5 Currently, this is a one combined exam,
6 and I am a member of that Committee, as well, putting
7 together those questions. The Musculoskeletal Section
8 includes spine imaging, as well.

9 Awards not mentioned in my CV that you
10 should be aware of, for musculoskeletal teaching at the
11 VA from the Yale residents, include Excellence in
12 Teaching 2012, Teacher of the Year at the VA 2013,
13 Teacher of the Year at the VA 2015, Teacher of the Year
14 at the VA 2016.

15 The majority of this teaching are
16 Connecticut Orthopaedic Specialists' imaging studies that
17 I show them to prepare them to become Board Certified
18 radiologists.

19 I think my credentials are adequate to
20 read the studies that Connecticut Orthopaedics generates.

21 The second is the MR unit in question.
22 This is a 1.5 Tesla unit that's the most common type of
23 MR unit out in the community today, and it's similar to
24 the units in Hamden and Branford, both, as you've heard,

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1 are ACR certified.

2 The KCKC Medical Group, LLC has noted the
3 specifications of the mobile are identical to the fixed
4 sites and have confirmed the mobile unit will be
5 serviceable throughout the life of the unit, which I
6 think has also come up in some of the pre-filed
7 testimony.

8 The same process for reading the scans at
9 the fixed sites will be employed to the mobile unit.
10 Mobile units are designed for travel, and it's
11 unreasonable to believe the mobile unit will have imaging
12 issues, because of travel on the highway.

13 I believe, in the early days of OHCA, when
14 MRI came out, mobile units were actually the ones that
15 were used, so that one hospital didn't gain a super
16 saturation of MR imaging, and they were actually shared
17 between hospitals.

18 Currently today, St. Vincent's Medical
19 Center has a mobile mammo, for example. These units do
20 not return to the hospital with the screws loose and the
21 machine falling off the back of the truck.

22 I talked to a colleague in Nebraska, who
23 runs a big medical center, and they have mobile units
24 right now today out there on the road. There's no

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1 problems with imaging, there's no problems with
2 servicing, and they do not come back damaged through
3 vibrations on the highway that's been mentioned.

4 If there's any questions I can help
5 clarify from anyone here in the room, I'm happy to take
6 them now or later for you folks.

7 HEARING OFFICER HANSTED: Okay. Just one
8 thing and for everyone that's going to testify. Would
9 you just please adopt your pre-filed testimony for me?

10 DR. GAGLIARDI: Yes. I adopt my pre-filed
11 testimony.

12 HEARING OFFICER HANSTED: Okay, thank you.
13 This is sort of out of the order, but one quick question
14 for you. You testified that the unit would be
15 serviceable through the life of the unit. What is the
16 life of the unit?

17 DR. GAGLIARDI: As long as Connecticut
18 Orthopaedics wants to own this unit, the images are
19 reasonable, I don't know. It's up to the business when
20 they want to buy a new one or upgrade it.

21 Every once in a while, software upgrades
22 become available, new coils become available, and they
23 can be purchased or not.

24 If the imaging is adequate and there's no

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1 damage or need to be serviced, it depends. Even for
2 fixed units, sometimes something comes out of whack and
3 we need to call a servicing company. They've said you
4 own this, we will service it.

5 HEARING OFFICER HANSTED: Okay, so,
6 there's no set time?

7 DR. GAGLIARDI: I don't think there is,
8 no.

9 HEARING OFFICER HANSTED: Okay. It's just
10 based upon the quality that the unit is producing?

11 DR. GAGLIARDI: Sure.

12 HEARING OFFICER HANSTED: Okay. All
13 right, thank you.

14 DR. GAGLIARDI: Thank you. I'm not sure
15 who is coming up next. It might be Dr. Ruwe, the
16 President of Connecticut Orthopaedics.

17 DR. RUWE: So I adopt my pre-filed.

18 HEARING OFFICER HANSTED: Thank you.

19 DR. RUWE: Good morning, Hearing Officer
20 Hansted and members of the OHCA panel. Thank you for
21 having us here today.

22 My name is Dr. Patrick Ruwe, and I'm the
23 President of Connecticut Orthopaedic Specialists, and I
24 am one of the COS physicians that services our offices in

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1 Orange, Connecticut.

2 I practice sports medicine, and I perform
3 arthroscopic and open surgery on shoulder and knee
4 injuries.

5 I'm here this morning representing the
6 largest group of single orthopedic specialists in
7 Connecticut.

8 As Glenn said, our group has been serving
9 the community for over 50 years. Our orthopedic
10 specialists are experienced and they're highly-respected
11 clinicians, who consider MR scanning, when necessary, to
12 be a critical diagnostic tool and an invaluable part of
13 our patients' treatment.

14 COS physicians value quality and
15 competence. If a patient has a relationship with a
16 radiologist or a radiology group that they trust and they
17 wish to utilize their services, we have no problem with
18 that request.

19 Our patients are free to choose where they
20 have their MRI performed, and we specifically do not
21 require patients to have their scanning done in a COS
22 facility.

23 We also believe strongly in the
24 convenience to patients of the broad range of

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1 musculoskeletal services that we offer, including MRI
2 scannings and in-house readings, and we feel that this is
3 a vital component of what we do to service the healthcare
4 community.

5 To this point, Dr. Gagliardi is an
6 important resource, who provides unequalled access and
7 easy communication, which benefits both patients and
8 providers.

9 It's not unusual for me to speak to him
10 three to four times a day and to actually preview
11 difficult cases.

12 Often, I will review cases with him after
13 having gone to surgery, so as to enhance both of our
14 understandings of relevant anatomy and pathology and to
15 provide direct feedback, so that can positively impact
16 future interpretations and readings.

17 Basically, we get together and we go over
18 cases before and after, and we learn from both
19 experiences.

20 Because of the many new orthopedic
21 specialists who have merged with COS during the past
22 three years, we have reached a point of maximum capacity
23 in our Hamden and Branford units.

24 Our goal in this growth has been to create

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1 a large enough group practice that we can offer programs,
2 such as bundle payments, which help to keep healthcare
3 costs under control.

4 MRI is an important part of that effort.
5 We at COS believe deeply that private practice is a
6 valuable component of the healthcare system that needs to
7 be preserved for the reasons of quality and choice, and
8 we actually feel that we're at the forefront of that
9 fight to preserve private practice.

10 For all the reasons I've set forth, I ask
11 that you approve the COS application. I thank you for
12 the opportunity to speak to you today and for your time
13 in considering our application. Thank you.

14 HEARING OFFICER HANSTED: Thank you,
15 Doctor.

16 DR. LORENZE: Good morning.

17 HEARING OFFICER HANSTED: Good morning.

18 DR. LORENZE: I'm Dr. Mark Lorenze. I
19 will adopt my pre-filed testimony, as well.

20 HEARING OFFICER HANSTED: Thank you.

21 DR. LORENZE: As I said, my name is Dr.
22 Mark Lorenze. I'm a Board Certified orthopedic surgeon.
23 I practice orthopedics working in the offices of COS in
24 Essex, Connecticut.

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1 I'm also the Chief of Surgery at Middlesex
2 Hospital in Middletown, Connecticut. I specialize in
3 hand surgery, worker's compensation injuries and
4 arthroscopic and open surgery.

5 Several years ago, I was part of a small
6 rural practice in Essex, Connecticut, composed of three
7 orthopedic surgeons. Because of increasing difficulties
8 we encountered as a small group in Essex, we were happy
9 to discuss joining COS when we were approached.

10 We believe that joining COS offered a
11 greater efficiency of care, greater economy of scale and
12 quality of care.

13 COS also had a reputation of treating
14 patients in a very caring and efficient manner. We had a
15 very good reputation, and we knew the reputation even as
16 a small group in Essex, Connecticut.

17 Therefore, when we joined, we expected, by
18 joining COS, that our patients should be offered that
19 same quality of care and efficiency.

20 Currently, most of our patients, because
21 of geographic locations, choose Middlesex Hospital MRI
22 scan, because of its location and convenience on the
23 Route 9 corridor.

24 Over the years, there have been several

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1 difficulties we have encountered with Middlesex MRI scans
2 and reading of MRI scans. MRI scan is read by a variety
3 of radiologists at the hospital, some of whom are not
4 highly trained in musculoskeletal MRIs, and that creates
5 a problem, because, if it's a radiologist that we don't
6 necessarily use, who reads the MRI scan, we have to track
7 that radiologist down and often have to call another
8 radiologist to read our MRI scans, especially if it's a
9 difficult case or an MRI scan that's difficult to read.

10 So I often have to make additional phone
11 calls to speak with a certain radiologist that I trust,
12 and that could be difficult in the setting of a busy
13 office day or a time when I'm very busy and the patients
14 are waiting, so it becomes very inconvenient for the
15 patient, who often has to wait in the office until I
16 contact the radiologist. It becomes time consuming and
17 effects efficiency.

18 I would prefer to have an MRI scan that is
19 done within the COS system, because I can easily contact
20 Dr. Gagliardi, as Dr. Ruwe mentioned.

21 It also, by speaking with Dr. Gagliardi
22 and reviewing the MRI scan with him, helps me stay
23 involved with the process and improves efficiency and it
24 improves patient care.

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1 And for the patient, who obviously is the
2 most important part of this process, it means a
3 convenient geographic location, no admission to another
4 facility, no additional paperwork and no facility fee for
5 the MRI scan.

6 The most important thing for me and my
7 patients is that I would be more closely connected to
8 their care.

9 I also want to just briefly mention
10 Exhibit 1, which is some information about the MRI usage
11 in what is classified as the Essex area.

12 I have to say that we almost never use --
13 my patients never choose to use Guilford Radiology. It's
14 18 miles from Essex, so I don't think -- we're in
15 Middlesex County. We're not in New Haven County.
16 Guilford is New Haven County.

17 I think to say that Guilford Radiology is
18 in our sort of geographic location is not really
19 accurate. It's 18 miles away, and patients don't want to
20 go that far for their MRI scans, so I just wanted to
21 mention that as part of Exhibit 1.

22 Thank you for your time, and thank you for
23 reviewing our application.

24 HEARING OFFICER HANSTED: Thank you,

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1 Doctor.

2 MS. GERNER: I think that completes the
3 presentation by Connecticut Orthopaedic Specialists.

4 HEARING OFFICER HANSTED: Okay. Attorney
5 Fusco, if you'd like to present your argument at this
6 time?

7 MS. FUSCO: Absolutely. With me here
8 today is Clark Yoder, who is the CEO of Advanced
9 Radiology Consultants, and Ian Karol, who is the Chief
10 Medical Officer. They'll be giving our presentation.

11 MR. YODER: Good morning. My name is
12 Clark Yoder.

13 HEARING OFFICER HANSTED: Good morning.

14 MR. YODER: I'm the CEO of Advanced
15 Radiology Consultants.

16 I'd first like to thank Hearing Officer
17 Hansted and OHCA staff for allowing us to participate in
18 this hearing. We appreciate all the hard work that you
19 have done and have afforded us this opportunity to speak
20 in front of you today.

21 I would like to adopt my pre-filed
22 testimony to start with.

23 As Attorney Fusco mentioned, I'm here with
24 Dr. Ian Karol, who is our Chief Medical Officer of

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1 Advanced Radiology and a longstanding partner of the
2 practice.

3 Advanced Radiology has been around for
4 over 110 years in the state, and we're a full-service
5 imaging provider, and really what that means, out of all
6 of our locations, we provide CT, MR, mammograms,
7 ultrasounds, x-rays, bone densitometry, PET scans. You
8 name it, we do it.

9 We have offices located from Stamford,
10 Fairfield, Wilton, Stamford, Trumbull, Shelton and
11 Orange, and all these locations we provide these advanced
12 services, and MRIs are at each location, including the
13 Orange office we're talking about today.

14 The diagnostic imaging industry in
15 Connecticut is really at a tipping point. Independent
16 radiology practices, such as ARC, provide this full-
17 service imaging to all patients, regardless of their
18 ability to pay, and we provide these services thankfully
19 because we have MRI units in the practice.

20 MRI generates 85 percent of our profit in
21 our organization. We use that profit to reinvest into
22 our organization every single year.

23 Just recently, we invested in brand new
24 digital mammography units for all of our sites at the

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1 cost of \$3 million, and we were able to really fund that,
2 based on MRI.

3 When we provide a mammogram, it costs us,
4 at the end of the day, we lose \$75 for each mammogram
5 that we provide. For each x-ray we provide, we lose \$10.

6 Those are consistent year-after-year
7 money-losing operations, however, we support the
8 community, and we support our patients, and we provide
9 those services, regardless of everyone's ability to pay.

10 By contrast, when we look at how COS can
11 generate profits versus us, we just had the avenue of
12 MRI. They have the fortunate ability to have ambulatory
13 surgery centers, physical therapy. They provide high-
14 cost drugs, which are highly reimbursed, and they also
15 provide appliances, DME appliances for orthopedics, and
16 those are avenues for income for them. To get into MRI
17 is just another avenue to generate profit in the
18 organization.

19 By approving this CON, ARC will have a
20 disproportionate financial impact to our practice, which
21 is clearly unfair and goes directly against one of the
22 main principles of the CON laws.

23 Recently in the state, we have seen a
24 number of orthopedic practices join and merge together,

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1 and COS, in this business model that they are providing,
2 is an aggregation of practices, which then they're saying
3 generates a need, and that's not really the case.

4 These patients that they have an
5 orthopedist in the community that joined COS are active
6 patients, who had imaging prior to that. That need is
7 not a need. It's just that shift of volume of care from
8 independent radiology practices, like ARC, and moving
9 those imaging into COS and being self-contained.

10 So, therefore, this is not a new, it's not
11 new increased volume that COS claims that it is. It's
12 actually just a shift of scans from existing providers
13 like ARC.

14 As has been well-published, the population
15 of Connecticut is contracting, and the growth of
16 patients, who require scans, is becoming stagnant.

17 By redistributing the scans through self-
18 referral, we are approaching a precipice of a crisis for
19 independent radiology practices of the state.

20 COS's business model and this CON request
21 is a case in point. COS is before OHCA today asking that
22 you manufacture a clear standard for clear public need,
23 based upon their captive patient volume and without
24 regard to the fact that other providers in the service

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1 area, specifically ARC, have the capacity to meet and are
2 already are meeting the MRI needs of COS patients.

3 COS has also conveniently ignored the
4 adverse financial impact that its proposal to acquire a
5 third unit and, in their words, to recapture MRI volume
6 that will certainly have on ARC.

7 We are asking OHCA please do not ignore
8 this fact. If OHCA approves the CON, it will set a
9 dangerous precedent, and, before long, every other major
10 orthopedic practice in the state will have multiple MRIs
11 in-house, leading to the demise of the independent
12 radiology practice, like ARC, who has been around for
13 over 110 years.

14 COS claims that this acquisition is
15 motivated by desire to provide its patients with the most
16 accessible, highest quality MRI services, which is
17 incorrect.

18 By the end of the day, it's not about
19 quality. It's not about access. It's about COS making
20 profits and harming ARC at the same time.

21 COS clearly understands that MRI services
22 are profitable. MRI is the highest profit margin
23 diagnostic imaging service, and you can see it, based
24 upon the fact that the proposed third COS unit will

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1 generate \$632,000 in incremental net income at a 53
2 percent margin by fiscal year 2020.

3 COS is capitalizing by purchasing an
4 antiquated scanner at the lowest possible cost, in order
5 to generate the highest profit margin. This will, then,
6 lead to higher physician income.

7 This margin is achieved by a payer mix
8 that is nearly 80 percent non-governmental, with just one
9 percent of the MRI scans, which come from Medicaid and
10 uninsured patients.

11 COS is projecting its Medicaid MRI volume
12 to grow by a mere 17 scans by fiscal year 2020, topping
13 out at 101 scans as the service matures.

14 We talk about bundled payments. There is
15 some question in the application does COS participate
16 with bundled payments? I don't know that answer. I can
17 represent that ARC does participate with bundled
18 payments, and we have experience doing so.

19 One hundred and one Medicaid MRIs on three
20 scanners equates to approximately 34 scans per unit each
21 year. This means that only three Medicaid patients are
22 being scanned on each unit on any given month, and the
23 numbers for the uninsured scans are worse, with the
24 practice scanning less than one uninsured patient per

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1 month.

2 Despite anything COS says to the contrary,
3 they are not providing meaningful access to MRI services
4 for Medicaid and uninsured patients, and this proposal
5 will do nothing to enhance access to these vulnerable
6 patients. The numbers speak for themselves.

7 And the history has shown us, as with
8 other orthopedic groups in our area, the lack of care for
9 Medicaid MRI patients by these same providers is the
10 norm.

11 There is no system of checks and balances
12 to ensure meaningful access for these patients, and
13 there's no reason to believe, based upon what has been
14 presented in COS's application, that they will be
15 providing anything, other than limited service.

16 We strongly recommend that OHCA establish
17 and annually enforce Medicaid and charity care minimum
18 thresholds for providers holding CONs as a means to hold
19 them accountable and prevent providers from selectively
20 choosing which patients to self-refer, based upon their
21 insurance status, or they should face consequences and
22 jeopardize their CON privilege.

23 This program should be similar to New York
24 State's Public Health Council, Medicaid and charity care

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1 requirements for ambulatory surgery centers.

2 With respect to the Orange market, ARC has
3 available capacity in its Orange unit, which is located
4 just over 1,000 feet away from the proposed mobile unit
5 for Orange, and we also have capacity at our Shelton
6 unit.

7 ARC historically has scanned about 400 COS
8 patients annually, and we can continue to accommodate
9 these patients, as well as any other COS patients that
10 cannot be accommodated by the practice's two existing MRI
11 units.

12 COS acknowledges in their own CON
13 submission that it tends to, I quote, "recapture" MRI
14 volume that is currently referred to non-COS providers.
15 COS estimates the number of these scans in the Orange
16 service area to be approximately 450.

17 In total, this loss of revenue by this
18 recapture will be excess of \$1 million over the next four
19 years to ARC, and it would greatly impact our ability to
20 upgrade our services, as necessary, to care for all of
21 our patients, including thousands of Medicaid
22 beneficiaries and indigent persons, each year, and, far
23 worse, ARC may be forced to cut back services, which it
24 currently provides.

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1 In fact, we believe COS is in discussions
2 with other orthopedic providers in Fairfield County about
3 merging. We expect the result will be COS looking for
4 additional MRI units, coming back to OHCA, and to embed
5 even deeper into ARC's core service area, which would
6 devastate our practice.

7 In conclusion, I cannot express in strong
8 enough words ARC's positions have about setting precedent
9 in approving COS's CON request.

10 Allowing specialty practices to acquire
11 their own MRI units, based upon intentionally generating
12 need, is a slippery slope for OHCA to consider and poses
13 a real danger to independent radiology practices like
14 ARC. Unlike COS, we only have that one way to generate
15 profits.

16 For all these reasons we have discussed
17 here today and in our submission, we urge OHCA to deny
18 COS's request for an unnecessary third MRI unit.

19 In the event that OHCA decides to approve
20 the CON, we ask that you place clear conditions on any
21 final decision that prohibits COS from operating the
22 mobile unit anywhere other than Orange and Essex for the
23 two days per week proposed at the location, and ARC is
24 prepared to consider all available options if it is

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1 approved.

2 I want to thank you again for allowing me
3 to present. I would like to introduce Dr. Ian Karol, Our
4 Chief Medical Officer.

5 HEARING OFFICER HANSTED: Thank you.

6 DR. KAROL: Hi.

7 HEARING OFFICER HANSTED: Good morning.

8 DR. KAROL: Thank you for your time, like
9 everyone else has said, and I'm the last speaker. You've
10 heard a lot of talk so far, so I hope not to put any of
11 you guys to sleep and just to give you some succinct
12 details about my presentation and talking points.

13 So I'd like to adopt my pre-filed
14 testimony.

15 HEARING OFFICER HANSTED: Thank you.

16 DR. KAROL: Like everybody else. My name
17 is Ian Karol. I am the Chief Medical Officer of Advanced
18 Radiology. I've been there since 1999, so I've been in
19 the group for 18 years.

20 I completed my radiology residency at
21 Montefiore Medical Center in the Bronx. I was a Chief
22 Resident the final two years. Montefiore had 52
23 residents. The Milton Elfin Award(phonetic) for the
24 Resident of the Year, I was honored to get that award.

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1 After completing my residency at
2 Montefiore in radiology and my chief residency, I then
3 went to Yale for a one-year fellowship, which was a
4 target specialty fellowship in body imaging with MSK
5 training, targeted MSK training, so I am a fellowship-
6 trained MSK radiologist.

7 So, in general, Advanced Radiology -- you
8 might have heard before from some testimony that some
9 hospitals have general readers. That is not how Advanced
10 Radiology works. How we've been in practice for 110
11 years, we dedicate ourselves to have sub-specialty reads.

12 We have 31 radiologists. Out of the 31
13 radiologists in our group, only four read MSK MRIs. Of
14 the 31 radiologists in our group, only five read neuro
15 MRIs, so we are highly targeted and highly specific in
16 our reads. That gives you better quality. That gives
17 you less over calls. That gives the patient less anxiety
18 and less stress by misreads.

19 I will tell you that, since I'm the Chief
20 Medical Officer, I get complaints whenever there's an
21 issue, whether it be either at Bridgeport Hospital, or at
22 St. Vincent's, or any referring office.

23 In my career, I have not heard of one
24 single complaint from COS about our readings, so, to me,

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1 the fact of not hearing a complaint would mean to me that
2 our readings must be pretty good, so I think that's an
3 important thing to understand.

4 So let me now go about the MRI unit, which
5 COS is proposing to acquire. The unit is 17 years old.
6 We have never purchased a unit actively that is 17 years
7 old.

8 It is basically an end of the life unit,
9 which technology is old. Let me say that we just bought
10 a unit for our Wilton office, and that unit was, you
11 know, in the million dollar range, and the reason you pay
12 more money and because we actively want to be cutting
13 edge and provide the patients the best care, you have new
14 technology.

15 There's metal suppression, so if someone
16 has an orthopedic replacement, let's say a hip
17 replacement or shoulder replacement, instead of doing it
18 on a regular old unit, where the images will have
19 artifact and be non-diagnostic, we have special sequences
20 that can help reduce that artifact, and we pay for that,
21 and we want the patients to have that better care, and I
22 will give you an example.

23 Would you buy a 17-year-old car that
24 didn't have airbags or seatbelts? You'd want to provide

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1 your patient, your family, with the best quality you
2 could, and I don't think that's with a 17-year-old unit.
3 That's with buying active new units with new technology,
4 and that's what we do at Advanced Radiology.

5 So the other points about this 17-year-old
6 unit is what about the parts? Eventually, the parts will
7 stop being made.

8 We've had urology groups in our area ask
9 us to help them with their x-ray machines, because they
10 can't find parts anymore. They can't find people to
11 service them anymore, because their floor equipment is so
12 old.

13 I would have concerns about a 17-year-old
14 unit, about those parts, about the maintenance, about the
15 overall quality, and I just think it's not in the
16 patient's best interest. I don't think it's in the
17 citizens of Connecticut's best interest.

18 My other question I would also have is are
19 the patients notified of this? Is this a transparency?
20 Are the patients notified that you have a choice between
21 going to a unit that's 17 years old or going to a brand
22 new unit of two years across the street, that you can
23 walk in less than a minute? Are patients openly given
24 that choice? Because, if I was, I know what I would

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1 choose.

2 The CON also suggests that patients will
3 benefit by having the MRI scanned by an in-house
4 radiologist compared to some private practice.

5 I just went through the fact that, in our
6 group, we have four of 31 that read MSK MRIs, and I don't
7 get many complaints, so I don't think that will be any
8 case or really any better service from having an in-house
9 radiologist.

10 Dr. Gagliardi, I know him. He's a super
11 nice person, great character. I can't say anything
12 better about him. He's a wonderful person.

13 At the end of the day, he's not fellowship
14 trained. He did not have training in MSK radiology. You
15 can say you're a Board Examiner, you can say you teach
16 here and give all the stuff that you like, but you didn't
17 have that formal training, and there's a reason you spent
18 a year of your life doing that extra training. It's not
19 easy, but you do it for patient care.

20 So the other thing I would like to point
21 out is orthopedics. You might order MSK MRIs of knees
22 and shoulders, and, like they said, you'll order spine
23 MRs. Well guess what? You come to Advanced Radiology, I
24 don't read your spine MR. I read your shoulders, I read

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1 your knees, I read your hips, read your ankles, read your
2 feet. I do not read your spines. Your spine is read by
3 a neuro-radiologist, someone who is specialized in spine
4 MRI. That is the person you want to review your case.

5 You come to Advanced Radiology, every
6 spine MRI at Advanced Radiology is read by five people,
7 who all have fellowship training in neuro-radiology, so
8 there is a distinct quality difference here.

9 Dr. Gagliardi, as far as I'm aware,
10 currently is the major, if only reader of MRI scans at
11 COS. Well guess what? This deprives the patient of
12 second or third opinions.

13 In Advanced Radiology, every day we have
14 two or three people reading these MRIs. We have, like
15 you have on your phone to instant message people, we have
16 PACT software, where I can instant message co-
17 radiologists of mine, who also have 20 years or more of
18 experience, and I am look at this case. What do you
19 think? And we will have an academic talk, because, just
20 like real life, medicine is not always black and white.

21 There's gray zones, and some you need a
22 second opinion, and that is a benefit from Advanced
23 Radiology, that you not only get one, but two or three
24 sub-specialist radiologists to review your case. There's

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1 a quality difference there.

2 Thirdly, I'd like to talk about peer
3 review. Advanced Radiology uses American College of
4 Radiology Peer Review System, and we actively review
5 people's cases, so, if someone is going through a
6 stressful part of their life and something is happening
7 and maybe the reads aren't as good as they used to, that
8 could be picked up earlier, and it's a quality issue for
9 patients, and it's something that is encouraged by the
10 American College of Radiology.

11 I'm not aware of COS having any peer
12 review process in place. Dr. Gagliardi was the main
13 radiologist, the only one reading for them. I'm not
14 really sure how that would be accomplished, but, at
15 Advanced Radiology, we pride ourselves in that.

16 We also have the benefit of having 31
17 radiologists and 220 employees and we have a Standards
18 Committee, and, in our Standards Committee, everything
19 goes before them, including the rad peer results, and
20 then the physicians are counseled in cases they may have
21 missed or readings they've had, so I think it's just a
22 higher level of care.

23 So let me just touch real quickly on a
24 common myth, you know, when you hear these things that

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1 you watch on TV, the Fleecing of America. Well there's
2 this orthopedic myth of convenience, that it's patient
3 convenience to have an MRI in the orthopedic office.

4 If that's not a myth, I don't know what
5 is, because over 98 percent of MRIs are not done the same
6 day. They are scheduled, because there's pre-
7 authorization involved, there's other patients that are
8 already scheduled in the MRI, and the exam takes at least
9 30 minutes, if not, 45 sometimes, so you can't just say,
10 oh, get off now. I'm putting another patient on.

11 Over 98 percent of MRs are not same day,
12 so there's really not convenience factor, especially when
13 the proposal is the MRI literally across the street from
14 our MRI in Orange. There's no convenience. It takes me
15 longer to walk across the street to Subway to get my
16 lunch for a sandwich than it would to walk to their
17 office, so I don't see how that really parlays at all the
18 convenience, but that is liked to be thrown out that
19 there. You'll read a lot of times it's patient
20 convenience. It's not true.

21 The other thing I would like to talk
22 about, as far as that, would be that we do accommodate
23 stat cases when they do come up, and the fact that
24 Advanced Radiology has seven or eight other offices all

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1 with MRIs we have the ability to move patients around and
2 scan stat patients whenever those one or two percentages
3 patients I said that come up. We can handle that,
4 because of our size and our flexibility.

5 We typically accommodate all stat cases
6 when they have to happen within an hour. Our cell phones
7 are given to all the hospital operators, as well as all
8 the operators at Advanced Radiology.

9 I commonly will have at least 10 to 15
10 texts a day, asking about various cases in the practice,
11 which I can give active reads and active interpretations
12 to, so our radiologists are available.

13 And we also have software that we have
14 that can go on someone's Tablet, can go on your iPad, or
15 on your phone, which our referring doctors can see the
16 cases anywhere in the world there's internet and can
17 access us anywhere in the world there's internet, so it's
18 a totally different, higher level of technology and good
19 for the patients and good for the referring physicians,
20 as well.

21 Finally, I'd like to touch base briefly on
22 self-referral. As the information included in my written
23 testimony shows, self-referral for MRI services results
24 in increased utilization and costs for patients and

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1 payers. Just because the practice is legal doesn't mean
2 it shouldn't be considered by OHCA relative to a CON
3 decision criteria regarding need and cost, in particular.

4 Also, we understand the legislature, maybe
5 commissions, to study self-referral in the coming year
6 and its impact on healthcare and costs, so one might
7 think we can wait to see what the outcome of that is
8 before making a decision that would then have to
9 retroactively addressed.

10 If the issue of self-referral is important
11 enough for the Health Care Cabinet to study, OHCA can
12 consider not approving additional self-referral units
13 until the recommendations are made with need to this
14 practice.

15 So, in my summary, I believe there's
16 several aspects to the Certificate of Need. We do not
17 see a need, particularly in the Orange area, for a 17-
18 year-old mobile unit, which is at the end of life, to be
19 placed across the road from us in Orange when, overall,
20 cases are not urgent.

21 A reasonable person should hope and
22 appreciate not only is this in the financial interest of
23 an orthopedic group, but clearly will do professional
24 harm to Advanced Radiology and the few remaining

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1 independent radiology groups in the state.

2 The victims of this will be the local
3 citizens of Connecticut. As Mr. Yoder pointed out, the
4 great majority of our profits are in MRI, and we don't
5 have many avenues if that's our only avenue left to make
6 a profit and to offset other things.

7 And if we can't provide mammography to
8 women and we can't provide examinations to pediatric
9 children in Connecticut, I think their access will be
10 limited, and they'll be forced to go to hospitals than
11 rather our accessible outpatient centers, so there will
12 be financial harm to Advanced Radiology.

13 So, for all these reasons, we urge you to
14 deny COS's request for a third MRI unit. I'd like to
15 thank you for allowing me, as well as Mr. Yoder, the time
16 for this presentation, and we are available to answer any
17 questions that you guys might have.

18 HEARING OFFICER HANSTED: Okay, thank you,
19 Doctor.

20 MS. GERNER: Excuse me, Hearing Officer
21 Hansted.

22 HEARING OFFICER HANSTED: Yes?

23 MS. GERNER: I had asked the people from
24 Connecticut Orthopaedic Specialists to limit their

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1 remarks to three to four minutes each, and I think you've
2 taken a little more time than that to get all of your
3 comments out on the record, so, if we could Redirect at
4 some point, so that people, who did not have a chance to
5 get out some of the information they wanted to say, but
6 were told they were limited, we'd like to be able to do
7 that.

8 HEARING OFFICER HANSTED: As I said in the
9 beginning, I have no problem with Redirect.

10 MS. GERNER: Okay.

11 HEARING OFFICER HANSTED: I would ask
12 that, if there is any more Direct testimony, that it be
13 limited to anything that is not before us already in the
14 pre-filed testimony.

15 MS. GERNER: Okay.

16 HEARING OFFICER HANSTED: Because we have
17 the pre-filed, so we do review that. I just don't want
18 to be repetitive in these proceedings.

19 MS. GERNER: I understand.

20 HEARING OFFICER HANSTED: Okay?

21 MS. GERNER: Thank you.

22 HEARING OFFICER HANSTED: You're welcome.

23 And I think what we'll do, before we get to the Cross-
24 Examination, we'll take a five-minute break, if that's

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1 okay with everybody. Okay? We're off the record.

2 (Off the record)

3 HEARING OFFICER HANSTED: Okay, we're back
4 on the record. At this point, we'll start the Cross-
5 Examination. Attorney Fusco, if you want to begin, and
6 then we'll go to the Applicant Cross?

7 MS. FUSCO: Absolutely. Could I just ask?
8 I'm unclear, Attorney Gerner, whether you're going to be
9 providing rebuttal testimony. When you asked before for
10 a chance to provide rebuttal, should that rebuttal come
11 before I ask questions?

12 MS. GERNER: It can come at the very end,
13 if you want.

14 HEARING OFFICER HANSTED: Well I think she
15 would like it first, just so she can Cross.

16 MS. GERNER: Oh, okay.

17 MS. FUSCO: On everything, and it may
18 clarify some of the things I want to ask questions on.

19 MS. GERNER: Well I have to ask the
20 questions first on Cross-Examination, but I think I'm
21 going to need to have Redirect.

22 HEARING OFFICER HANSTED: Do you want to
23 Cross first? Would that help?

24 MS. FUSCO: I mean if you're just talking

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1 about asking questions, that's fine. I thought you were
2 going to have your witnesses come up and provide
3 additional narrative, oral testimony.

4 HEARING OFFICER HANSTED: Let's go off the
5 record.

6 (Off the record)

7 HEARING OFFICER HANSTED: All right, we're
8 back on the record. Okay, Attorney Fusco. If you'd like
9 to start?

10 MS. FUSCO: Yeah, sure. I don't have too,
11 too many questions, and they're going to be primarily for
12 Mr. Elia and Dr. Gagliardi. Dr. Gagliardi, if you want
13 to come up? And, certainly, feel free to answer it. If
14 I direct it to the wrong person, anyone can answer.

15 HEARING OFFICER HANSTED: Just a reminder,
16 you're still all under oath.

17 MS. FUSCO: Dr. Gagliardi, I'll start with
18 you. Can you tell me a little about what your
19 responsibilities are at the West Haven VA? I know you
20 mentioned in your Direct testimony the teaching that you
21 do, the teaching awards you've received. What do you do?

22 DR. GAGLIARDI: I'm a full-time staff
23 employee at the VA in West Haven, Connecticut, and we
24 train the Yale residents, who rotate there on various

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1 services five days a week.

2 MS. FUSCO: Okay, five days a week. It's
3 entirely teaching, or it's patient care, as well, or
4 both?

5 DR. GAGLIARDI: Both.

6 MS. FUSCO: Okay, so, it's five days a
7 week. How many hours a day?

8 DR. GAGLIARDI: 8:30 to 5:00.

9 MS. FUSCO: Okay.

10 DR. GAGLIARDI: I usually get in the
11 office at 6:30.

12 MS. FUSCO: Okay, so, that's where you are
13 Monday through Friday, 8:30 to 5:00?

14 DR. GAGLIARDI: Yes.

15 MS. FUSCO: You're providing full-time
16 teaching and patient care responsibilities at the VA?

17 DR. GAGLIARDI: Yes.

18 MS. FUSCO: Okay, so, during that time,
19 are you available to read Connecticut Orthopaedic scans?

20 DR. GAGLIARDI: Yes.

21 MS. FUSCO: How do you do that? If you're
22 a full-time employee at the VA during those hours --

23 DR. GAGLIARDI: We review the scans all
24 day long. That's one of the things that's made the

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1 teaching so coveted by the residents.

2 MS. FUSCO: Okay, so, you review
3 Connecticut Orthopaedic's scans of non-VA patients while
4 you're at the VA?

5 DR. GAGLIARDI: Absolutely. My supervisor
6 is aware, absolutely. It enhances their education.
7 We've turned a rotation that students didn't want to come
8 to. Now they request to do an entire month with me.

9 If Dr. Ruwe calls me on the phone, I put
10 them on speaker phone, so they get to hear that question
11 and hear how we go back and forth to enhance their
12 education. They don't get that at the VA. Most of the
13 people at the VA are octogenarians, older people with
14 arthritic needs.

15 They have surgeons that are pediatrics,
16 and we're seeing younger athletes. Pro athletes come in
17 out-of-state, and it's great for the education, so we go
18 back and forth.

19 So the question comes to me. It could
20 come to them in their career. I want them to hear the
21 question. I want them to hear the back and forth, so it
22 enhances the whole educational process.

23 MS. FUSCO: Okay. I mean you have some
24 responsibilities there that require you either to be with

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1 a patient, to be giving a lecture.

2 DR. GAGLIARDI: I do that, too.

3 MS. FUSCO: But I assume you don't have
4 absolute flexibility to stop what you're doing any time
5 of the day and read a Connecticut Orthopaedic scan.

6 DR. GAGLIARDI: Well, like any practice,
7 you might be tied up doing something else, sure, of
8 course.

9 MS. FUSCO: Okay and, so, you're not -- it
10 follows that you're not on premises at the Connecticut
11 Orthopaedic offices, either in Branford or Hamden, where
12 the MRIs are located during the week or on weekends while
13 scans are being --

14 DR. GAGLIARDI: No. It's like you have
15 the websites, where people go now a days. Everything is
16 remote. You can go to look at your images remotely at
17 different sites. We do the same thing.

18 MS. FUSCO: Understood.

19 DR. GAGLIARDI: That's standard today.

20 MS. FUSCO: So you don't interact with
21 patients while they're getting the scans at Connecticut
22 Orthopaedics?

23 DR. GAGLIARDI: I very rarely interact
24 with the patients at the VA that are being scanned.

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1 MS. FUSCO: Okay, but I'm saying, with the
2 Connecticut Orthopaedic patients, you don't?

3 DR. GAGLIARDI: No.

4 MS. FUSCO: And you don't convey the MRI
5 results to them, do you?

6 DR. GAGLIARDI: I don't convey the MRI
7 results to the patients at the VA either. That's up to
8 the clinician, who ordered the study, to talk to their
9 patient.

10 MS. FUSCO: Understood. And because one
11 of the things that's been said in support of having an
12 MRI unit within an orthopedic practice, particularly one
13 that has one radiologist reading all the scans, is that
14 it's good for patients to be familiar with the
15 radiologist that's reading the scan, so would it be fair
16 to say that none of the Connecticut Orthopaedics or very
17 few are familiar with you?

18 DR. GAGLIARDI: I think that's a
19 mischaracterization. I think it's familiar for the
20 orthopedic surgeons to be familiar with the radiologist.

21 I do not believe patients are coming in
22 and shaking Alan Kaye's hand to say, Dr. Kaye, how are
23 you, nice to meet you. I just don't think that's
24 happening. It didn't happen in St. Vincent's where I

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1 was. Most private practice places don't do that.

2 MS. FUSCO: Okay.

3 DR. GAGLIARDI: And, by the way, Alan Kaye
4 is a hero of mine, so I'm using him as an example, but,
5 nonetheless, that doesn't happen in radiology.

6 Have you been to a radiology office, where
7 you get a hand x-ray and they come in and say hello?
8 That just doesn't happen. It doesn't happen at the VA I
9 can you, and that's not out of the norm that I'm reading
10 cases remotely. I'm not there to meet the patient and
11 greet them.

12 MS. FUSCO: Understood. I just want to
13 clarify, because I know, and perhaps the testimony
14 mischaracterizes it, but I know it says in here, and I
15 was confused, as well, it says, on I think it's page 10
16 of Mr. Elia's testimony, that it's always the better
17 alternative medically, because of, you know, the speed
18 with which the MRI can be done, the fact that the patient
19 doesn't have to make another appointment and register and
20 receive results from a radiologist, who is not a part of
21 the same practice and is not familiar with the patient,
22 so that suggests to me that Connecticut Orthopaedics is
23 saying it's beneficial, because you or I am receiving my
24 MRI results from -- I mean that's what it says. It says

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1 receive from a radiologist, who is not part of the same
2 practice and is not familiar with the patient.

3 DR. GAGLIARDI: So let me help clarify it.
4 I get calls on Sunday. I got calls last night, 9:00 at
5 night. If they want to know a stat result, I tell them,
6 and then that doctor tells the patient.

7 Likewise, if I look at a chest x-ray for
8 lung cancer, I tell the doctor your patient has a mass
9 and needs a CAT scan. I don't call that Veteran to say
10 you have this problem. I call the referring doctor, and
11 the referring doctor deals with that.

12 MS. FUSCO: That's right, but that's what
13 I assumed. So the patient doesn't have to have
14 familiarity with you, because you don't interact with the
15 patient, and, so, you know, if Dr. Karol were to have
16 done the scan, does it matter that the patient isn't
17 familiar with Dr. Karol, as long as the Connecticut
18 Orthopaedic physicians are familiar and can get in touch
19 with Dr. Karol and ask him questions? It's not a matter
20 of the patient --

21 DR. GAGLIARDI: It's a matter of the
22 doctors, who want to operate and cut that patient open,
23 to have a familiarity with the doctor and their results
24 over time.

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1 MS. FUSCO: Correct. And we've heard
2 testimony today, that they do have that familiarity with
3 Advanced Radiology and presumably other referrers, who do
4 hundreds of COS scans every year, correct --

5 DR. GAGLIARDI: -- at ARC, I'm unaware.

6 MS. GERNER: Attorney Fusco, before you go
7 on to something else, what page were you referring to?

8 MS. FUSCO: It was page 10 of Dr. Elia's
9 testimony, that last full paragraph.

10 MS. GERNER: Okay, thank you.

11 MS. FUSCO: Dr. Gagliardi, do you get paid
12 a fixed salary by Connecticut Orthopaedics, or do you get
13 paid by the read?

14 DR. GAGLIARDI: Fixed salary.

15 MS. FUSCO: Okay and do you share in the
16 profits from the MRI unit?

17 DR. GAGLIARDI: No.

18 MS. FUSCO: Okay. Who does peer reviews
19 of your scans, if anyone, and how often are they peer
20 reviewed?

21 DR. GAGLIARDI: The orthopedic surgeons do
22 that.

23 MS. FUSCO: Do you have radiologists that
24 peer review your scans?

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1 DR. GAGLIARDI: We have Ramon Gonzalez
2 there, who does look at some of the scans, but to say
3 that's done all the time would be a bit of a reach.

4 It's the orthopedic surgeons, who will
5 call me or go to surgery and call me with a result that
6 may be discrepant, which is unusual.

7 MS. FUSCO: Okay, but you don't have sort
8 of a system in place? You heard Dr. Karol testify about
9 the ACR recommendations for sort of random peer review or
10 someone, where another radiologist is going to go in and
11 review one of your reads for quality assurance?

12 DR. GAGLIARDI: We don't have another
13 radiologist. We have an orthopedic surgeon, who is
14 actually operating on the patient.

15 MS. FUSCO: And you brought up -- I'm
16 sorry. Forgive me. Is it Ramon?

17 DR. GAGLIARDI: Dr. Ramon Gonzalez. He's
18 on site to do all the arthrograms. He's a radiologist.
19 Board Certified, I believe.

20 MS. FUSCO: Okay. Are you currently
21 reading all 9,000-plus MRI scans every year?

22 DR. GAGLIARDI: Yes.

23 MS. FUSCO: And is it your intention to
24 read all 11,100 and --

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1 DR. GAGLIARDI: Yes.

2 MS. FUSCO: I don't know the exact number.

3 DR. GAGLIARDI: Yes.

4 MS. FUSCO: Okay, so, there's no one
5 helping you do that?

6 DR. GAGLIARDI: No.

7 MS. FUSCO: And, so, you'll read 11,000-
8 plus scans and provide reports and have regular contact
9 with COS doctors, in addition to having a full-time
10 teaching and patient care position at the VA?

11 DR. GAGLIARDI: Sure.

12 MS. FUSCO: Okay. Give me one second.
13 Okay.

14 DR. GAGLIARDI: Am I excused?

15 MS. FUSCO: Yeah, I think so.

16 DR. GAGLIARDI: Okay.

17 MS. FUSCO: If I need you, I'll call you
18 back.

19 DR. GAGLIARDI: Thank you.

20 MS. FUSCO: Mr. Elia, I just have a few
21 questions for you.

22 MR. ELIA: Sure.

23 MS. FUSCO: Can you tell us, in 2016,
24 which was the last full year of data we had, how many COS

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1 Medicaid patients received their MRI scans at non-COS
2 providers?

3 MR. ELIA: I cannot.

4 MS. FUSCO: Okay.

5 MR. ELIA: They don't track it.

6 MS. FUSCO: So you don't?

7 MR. ELIA: Most of our Medicaid business
8 is done through the hospital, through the hospital
9 clinics, and, so, whether they're seen in the Yale or St.
10 Raphael's clinics, then those patients are, then,
11 referred back to the Yale or St. Raphael's radiology
12 departments for their studies.

13 MS. FUSCO: Okay, so, in looking at the
14 information you submitted with the CON, it looks like,
15 and I'm sorry if I misquote the number, but I think it
16 was like 78 or 86 Medicaid. Seventy-eight I think
17 Medicaid scans that you guys did in-house in 2016.

18 Advanced Radiology has record of having
19 done 51 Medicaid scans, okay? Do you use a centralized
20 scheduling system for MRI? How are your patients' MRI
21 scans scheduled? You see a patient in the office, a
22 physician sees a patient, they need an MRI, how is that
23 MRI scheduled?

24 MR. ELIA: It's done at the time of

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1 service, and then, if the patient requests or we think
2 it's in the best interest of a patient's convenience to
3 send them to the outside sources, it's then setup, but
4 there's no central scheduling. There's no logging of it.

5 MS. FUSCO: Okay, so, I assume the patient
6 just goes to the front desk after their appointment?

7 MR. ELIA: It's done by the medical
8 assistant right there, right outside the exam room.

9 MS. FUSCO: Okay and how does the
10 conversation go, in terms of where they can have their
11 scan and when they can have it?

12 MR. ELIA: I think Dr. Ruwe, who does that
13 work, himself, would probably be the best person to
14 answer that question.

15 DR. RUWE: Right, so, I see a patient.

16 HEARING OFFICER HANSTED: Are you picking
17 that up okay? Hold on one second.

18 DR. RUWE: I'm sorry. Okay, so, a patient
19 comes to see me, and I determine that it's appropriate to
20 get an MRI scan, and I'll tell my MA, who is sitting
21 there with me, that we need to get an MRI scan, and then
22 my remote secretary or the -- I think there is a
23 scheduling. There is a central scheduling place. The
24 MRI people will find an MRI that's convenient for the

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1 patient, so I don't directly get involved with that. MRI
2 actually ends up doing.

3 MS. FUSCO: Okay, so, it's your schedulers
4 that determine whether the patient -- what I'm trying to
5 get at --

6 DR. RUWE: They ask the patient questions
7 of convenience and timing.

8 MS. FUSCO: Convenience and timing, okay.
9 So, you know, would there be a reason why, you know,
10 almost -- from what we can see, and you say you don't
11 track the data and we don't want to speak on behalf of
12 any other providers, but what we can see from the data we
13 have is that, you know, Advanced Radiology does almost as
14 many COS Medicaid MRI scans in a year as COS does, and
15 what I'm trying to get at is how those patients are
16 getting referred out, why such a significant percentage
17 of your Medicaid MRI scans are going elsewhere, and it
18 could be even more. We only have our own data.

19 MR. ELIA: I understand. You're speaking
20 to the \$270,000 worth of work that we've sent to Advanced
21 Radiology?

22 MS. FUSCO: No. I'm speaking just to --
23 let's look at last year, so we compare apples and apples.
24 In 2016, 51 of the 400 COS scans that ARC did were

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1 Medicaid patients.

2 In 2016, COS only scanned 78 Medicaid
3 patients, so we did almost as many of your Medicaid MRI
4 scans as you did, and I'm trying to figure out how those
5 patients are getting referred out in such large numbers,
6 because I only have our data. Presumably, other
7 providers in the area scan your Medicaid patients, as
8 well.

9 MR. ELIA: If the implication is that
10 we're selectively sending Medicaid patients to you,
11 that's not factual. That's not what happens.

12 As Dr. Ruwe has just said, it's done not
13 by the provider, but by the medical assistant and the
14 people who do the prior authorization, and, so, there's a
15 random distribution, so, as you can see, we're sending
16 400-some-odd patients to you.

17 We send those patients to you payer blind.
18 We don't selectively choose which patients go to what
19 locations, and, as what's been implied by your testimony,
20 that we are doing it for the benefit of enhancing our
21 profits, it's categorically wrong.

22 MS. FUSCO: But you would agree that
23 proportionately ARC is doing a disproportionate amount of
24 Medicaid scans compared to the Medicaid scans that you do

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1 versus commercial?

2 The amount of commercial scans you send
3 them versus commercial scans you keep, that ratio is a
4 lot lower than Medicaid scans they receive, Medicaid
5 scans you keep.

6 MR. ELIA: The numbers speak for
7 themselves in that respect.

8 MS. FUSCO: Yeah, they do.

9 MR. ELIA: But what does not speak to
10 those numbers is the high volume of Medicaid patients
11 that we see and treat, without any remuneration at the
12 hospitals.

13 MS. FUSCO: Those are you're providing MRI
14 services to those patients without remuneration?

15 MR. ELIA: Yeah. We're providing all
16 services and referring them to the hospital, so I think
17 the vast majority of the Medicaid patients are being done
18 by the hospital-based system.

19 MS. FUSCO: Understood, but, in terms of
20 MRI, which, again, we've talked about MRI being a
21 significant percentage of a practice's profit margin,
22 you're not providing free care, free MRI services to
23 Medicaid patients, are you?

24 MR. ELIA: No, we're not.

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1 MS. FUSCO: Okay. On the CON application,
2 there's a copy of your charity care policy that it says
3 you've recently adopted. Can you tell me how recently
4 you adopted that?

5 MR. ELIA: We formally adopted it I would
6 say in the last two years, however, the policy was an
7 informal process.

8 Again, we are payer blind. We provide the
9 services as they're needed. We write off a tremendous
10 amount of services, both from radiology through physical
11 therapy, or, you know, ambulatory, surgical. We deal
12 with each patient on a need basis.

13 MS. FUSCO: But, again, in terms of MRI
14 services, you know, the charity care policy would really
15 only apply to -- would it only apply to self-pay
16 patients, or patients, who are going to have to pay out-
17 of-pocket?

18 MR. ELIA: No. We take all things into
19 consideration, depending on patient balances. Our
20 billing and collections departments works with patients.

21 MS. FUSCO: So co-pays?

22 MR. ELIA: Everything from co-pays to
23 large deductibles. As we've seen now, with patients'
24 deductibles getting higher and higher, we try to relieve

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1 some of the burden.

2 MS. FUSCO: In terms of self-pay patients,
3 you don't, for MRI services, you don't see a lot of
4 those, correct?

5 MR. ELIA: There's not a lot of self-pay
6 patients out there.

7 MS. FUSCO: In terms of sort of the cost
8 effectiveness of your proposal, you know, throughout your
9 initial CON submissions at least and in your testimony
10 and here today, you've talked about kind of the
11 groundbreaking developments at COS with respect to bundle
12 payments. I think it was a bundle payment program for
13 outpatient total joint procedures, correct?

14 MR. ELIA: Correct.

15 MS. FUSCO: But you have clarified for
16 OHCA that the cost of an MRI is not, an initial MRI is
17 not included in that bundle, correct?

18 MR. ELIA: That is correct. Not the
19 initial. Any complications that occur post-surgically
20 that will require MRI scans are included in the bundle.

21 MS. FUSCO: But the initial, the
22 diagnostic MRI is not?

23 MR. ELIA: The diagnostic is not.

24 MS. FUSCO: Okay. Does the amount that an

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1 insurer reimburses you for an MRI scan is it going to
2 depend upon which scanner you use? Is an insurance
3 company going to pay less for a scan you perform on this
4 17-year-old unit?

5 MR. ELIA: The payers do not pay
6 selectively, based on the units.

7 MS. FUSCO: Okay and they don't pay you
8 less, because you've got two units or three units?

9 MR. ELIA: No, they don't. Do they pay
10 you less?

11 MS. FUSCO: I don't get anything. Do they
12 pay less for a mobile versus a fixed?

13 MR. ELIA: No, they do not.

14 MS. FUSCO: All right, so, basically, in
15 terms of cost effectiveness, I mean the patients, who are
16 scanned on this unit, their insurers and their co-pays
17 are going to be the same whether they, you know, whether
18 they were scanned on your Branford unit, your Hamden
19 unit, or this unit, so buying this unit, buying this low-
20 cost unit doesn't save patients or insurers any money.
21 It saves you guys money, correct?

22 MR. ELIA: I would clarify that we're not
23 buying that unit. That unit was put into the application
24 for the purposes of demonstrating. That unit is not

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1 available right now. No one has held that unit for one
2 year during the application process.

3 At the time, assuming that a Certificate
4 of Need is granted, we will go into the marketplace and
5 acquire a unit, but the units that are shown in that
6 application are not sitting in a closet, waiting for us
7 to buy.

8 MS. FUSCO: No, but I mean you've
9 represented to OHCA that you intend to buy a low-cost --

10 MR. ELIA: A Gold Seal, a Gold Seal, GE
11 Gold Seal unit that will have completely updated
12 software, so the analogy of driving a 17-year-old car is,
13 quite frankly, irrelevant.

14 If you have upgraded that 17-year-old car
15 with new brakes, transmissions and air bags and new
16 tires, it works pretty well.

17 MS. FUSCO: Do you know where that unit
18 has been?

19 MR. ELIA: I haven't acquired it yet.

20 MS. FUSCO: Okay, so, if you were going to
21 acquire that particular unit, you don't know where it's
22 been for the last 17 years?

23 MR. ELIA: I would know where it's been
24 for the last period of time before I buy it, because it

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1 would go back to the factory, it would have a complete
2 overhaul and would receive a Gold Seal standard from GE.

3 MS. FUSCO: And that would make it, in
4 your opinion, comparable to a brand new fixed 1.5 Tesla
5 unit? You're saying that a unit, let's assume it's going
6 to be a 17-year-old unit, can be made to be comparable
7 from a clinical perspective to a brand new unit?

8 MR. ELIA: The standard by which you're
9 asking me to judge it is somewhat irrelevant. The
10 standard by which a unit is determined to be relevant is
11 the ACR certification.

12 Once those images go, to which Dr. Kaye is
13 the President, and that unit is deemed to provide images
14 that allow that unit to be, then, certified, it means
15 that that unit, then, provides images that meet that
16 standard.

17 We live and die by that accreditation.
18 The payers live and die by that accreditation.

19 MS. FUSCO: Sure, but I mean --

20 MR. ELIA: So if we acquire a unit that
21 achieves the quality standards to receive that
22 certification, the age of the unit is irrelevant.

23 MS. FUSCO: But would you agree that, you
24 know, and it's relevant to anything, to a unit, to a

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1 facility, you can meet accreditation standards, but you
2 can also exceed accreditation standards, and that was
3 what I was asking, is, I mean, there are, you know, if
4 you're talking about buying a 17-year-old unit, there are
5 units, probably manufactured in 2015, '16, '17, that
6 will, you know, have better capabilities, be superior
7 technologically, even though they all meet standards?

8 MR. ELIA: I disagree, respectfully.

9 MS. FUSCO: Okay.

10 MR. ELIA: The standard by which the
11 American College has established is the standard, and one
12 can exceed that standard, but that's not necessary.

13 MS. FUSCO: Okay.

14 MR. ELIA: You could --

15 MS. FUSCO: But you can --

16 MR. ELIA: -- have driven a Porsche here,
17 or you could drive a Ford here.

18 MS. FUSCO: Well that's good, back to the
19 car analogy.

20 MR. ELIA: But we both got here.

21 MS. FUSCO: You can exceed a standard.

22 Fair enough. That was my only question. I only have
23 like one or two more questions.

24 Just one last question. You had mentioned

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1 somewhere in your testimony that the need -- it was a bit
2 of a theme. You had mentioned, historically, before you
3 merged with practices, that you needed to merge with
4 those practices, in order for your practice to survive,
5 and I think you mention in your testimony, and I quoted
6 it at page eight, that, you know, this proposal to
7 acquire a third MRI unit is necessary to keep COS alive.
8 Those were the words that were used.

9 Are you claiming that, without the
10 acquisition of this unit, the practice is in some
11 financial jeopardy?

12 MR. ELIA: Thankfully, the practice is not
13 in financial jeopardy. It is part of the ongoing
14 progressive nature of COS, and alive is a relative term,
15 in the same way that clearly ARC is in a self-
16 preservation mode and looking to continue to have a
17 referral relationship with us, ironically.

18 The use of this third unit would continue
19 to allow us our growth and to continue to meet the needs
20 of our patients.

21 MS. FUSCO: But, in 2015, Connecticut
22 Orthopaedics, from the income statement you put in, had
23 \$9.3 million in net income, so assuming -- and that's
24 without a third MRI, so, you know, would you expect that

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1 to be -- you certainly don't need a third MRI unit to
2 maintain that level, or do you?

3 MR. ELIA: I'm not sure the profitability
4 of COS and how we run our organization is really
5 relevant.

6 MS. FUSCO: Well it's relevant, because
7 you're suggesting to this agency in testimony that this
8 is necessary to keep COS alive, and I don't want to leave
9 them with the mistaken impression that, if they don't
10 approve this CON, COS is going to go out of business.

11 MR. ELIA: Yeah, I think they probably are
12 self-assured that we're not going to go out of business.

13 MS. FUSCO: Okay. We're all set. No
14 other questions. Thank you.

15 MR. ELIA: Thank you.

16 MS. GERNER: I just have a few questions,
17 and they're primarily for Mr. Yoder.

18 The first one is on page -- let's see.
19 This would be page 21 of the ARC pre-file. I think it's
20 about page nine of your -- page nine of your pre-filed
21 testimony.

22 MS. FUSCO: But page 21 of the total
23 submission, the one that starts with "valued at" at the
24 top?

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1 MS. GERNER: Yes.

2 MS. FUSCO: Okay.

3 MS. GERNER: Yes. "Valued at approximately
4 \$275,000." Okay. You're claiming that there's been --
5 that the referrals from COS in fiscal year 2017 were
6 valued at \$275,000. Is that accurate?

7 MS. FUSCO: Sorry. Say the year again?

8 MS. GERNER: The year is 2017, 2017.

9 MS. FUSCO: Yeah. That's an anticipated.
10 If you go back a page.

11 MS. GERNER: Right. Peel back to the
12 bottom of page 20 of your testimony.

13 MS. FUSCO: Um-hum.

14 MS. GERNER: Okay and I have another
15 question on that page, right above where you are, under
16 the table. It says that ARC's average reimbursement for
17 an MRI scan is \$650, and I wondered if you could clarify
18 whether that is just for the MRI, itself, or whether that
19 includes any other services that surround it? Are there
20 additional services that go along with that?

21 MR. YODER: Just the MRI.

22 MS. GERNER: Just the MRI?

23 MR. YODER: Just the MRI.

24 MS. GERNER: And that includes the read?

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1 MR. YODER: Yes.

2 MS. GERNER: Okay, now, I'd like to go to
3 page 53 of the CON, of the original CON application,
4 where we put out some overall assumptions. You have
5 talked about ARC, you know -- let me get my question
6 straight before I ask it here.

7 You've talked about the fact that a need
8 has come about, and hold onto that page if you would,
9 because I want to ask one question before that. I assume
10 you've read this whole application and you know, you
11 know, what's in here, and I notice that, in your
12 presentation, you've never spoken about the new patients,
13 who have come in, because COS expanded between 2014 and
14 '16, and that these patients are being taken away from
15 other radiology practices, where, in fact, if you look at
16 page 254, it's Table 5, the Utilization of Service by COS
17 --

18 MS. FUSCO: I'm sorry. What page? 253?

19 MS. GERNER: 254. Do you see what COS was
20 doing at the top in Table 5? Do you see what they're
21 doing in fiscal year 2012 and the small gain in 2013?

22 And then, if you notice, 2014 you begin to
23 see a more dramatic increase, which is even bigger in
24 2015 and then in 2016.

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1 I find it hard to believe that you believe
2 that COS is just manufacturing or taking patients from
3 other people, rather than having developed that there was
4 a need to service these new practices that came in, you
5 know, that they merged with, so I wondered if you could
6 explain why you've made no reference to any new patients
7 in this application.

8 MR. YODER: Clearly, in my opinion, that
9 this is directed, just as you merge practices in together
10 under one larger umbrella and become more efficient, and
11 you're incentivized to maintain those referrals in-house,
12 so it's clear to me, in my experience with medical groups
13 and how this works, is that, as you grow larger as a
14 practice, going from 30, 40, 50, 60, 70, all you're doing
15 is having that same breadth of patient population,
16 because a physician's panel is usually, as an orthopedist
17 gets to a fixed size, the only way you can grow it is by
18 adding more physicians under that umbrella.

19 So those scope of MRIs, then, are just
20 done under COS, and it's incentivized not to be out.

21 MS. GERNER: So, Mr. Yoder, those aren't
22 patients that have crossed your path, particularly,
23 except for the ones that COS has referred out to you?

24 MR. YODER: So these are clearly

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1 physicians that have been one or two small practices that
2 have been in the community that have been referring out
3 to multiple independent providers in the community.

4 As they merge and join under a COS tax ID
5 and umbrella, those referrals are, then, kept in-house.
6 All of those outside referrals have dried up, so those
7 referrals disappear overnight, and that's how you drive
8 up your volume.

9 MS. GERNER: Mr. Yoder, have you any way
10 of knowing and measuring the drops from the other
11 orthopedic groups? Obviously, orthopedic, there's a need
12 for orthopedic. MRI scans have been growing. It does
13 not, unless you have evidence to put forth, it doesn't
14 necessarily mean that those people would have come to ARC
15 or somewhere else.

16 If the market is expanding, which it
17 clearly is, there are new patients, they go to whatever
18 practice they prefer, and I object to the constant
19 referral of saying that, you know, COS self-refers,
20 because every patient is given a choice of where they
21 want to go for their scan.

22 Sometimes, it's a matter, as you know and
23 I think you would agree, of where they work, where they
24 live. Would you not agree that there is that choice?

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1 And because the patients are coming first not to a
2 radiologist in this group, they're coming for orthopedic
3 care, so they're not choosing a radiology practice.
4 They're choosing --

5 MR. YODER: There's definitely a choice,
6 because Medicaid, or Medicare, I'm sorry, requires that a
7 provider, who is ordering a study, gives the patient a
8 choice of the providers that are in that market area.

9 That's by law, so, as an orthopedist, as
10 an internist, as a neurologist, they order an MRI of the
11 brain, a CAT scan of the brain, you have to give the
12 patient a piece of paper, saying these are the choices
13 where you can go in your service area, so it is a choice,
14 and it is a requirement to have happen, however, there's
15 ways to, as we talked about the centralized scheduling
16 component that COS does have, you can manage those
17 referrals much more easily to contain them.

18 MS. GERNER: But do you have evidence that
19 COS does that?

20 MR. YODER: I have no evidence that COS
21 does it.

22 MS. GERNER: Just because they have a
23 person, who helps the patient figure out where they're
24 going to go?

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1 MR. YODER: I have no evidence that COS
2 provides it. I have experience with multiple different
3 practices and multiple different organizations where this
4 has happened and we see that.

5 HEARING OFFICER HANSTED: But not
6 specifically COS?

7 MR. YODER: No.

8 MS. GERNER: Okay. All right, I have one
9 more question that I'd like to ask, and this requires us
10 to look at page 53, where COS set out its overall
11 assumptions for this project.

12 The third bullet down in overall
13 assumptions on page 53 indicates that, as part of this
14 CON application, COS will reduce the hours in Hamden and
15 Branford and operate fewer hours, which makes room for
16 additional scans to be done.

17 They need to reduce the number in the
18 first place, because they're far over maximum capacity,
19 so, for safety reasons and for cost efficiency, just
20 efficiency of using those two MRIs, they would like to be
21 at a slightly, at about an 85 percent level, rather than
22 over 100 percent.

23 And if you look at -- put this together
24 with page 55 and page 56, there's a listing in Table D1

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1 of all the people in the Orange area, who live in Orange,
2 the utilization currently of these people going to one of
3 the two scanners, Hamden or Branford.

4 The people, who live in Orange, it lists
5 which one they went to, whether it was the Hamden COS MRI
6 or the Branford COS, and Table 2 does the same thing for
7 Essex, so there is a large number of patients right now,
8 who are COS patients, who have been going to Hamden and
9 Branford, because that was their choice.

10 Now they may have had to drive a long
11 distance, especially the people from Essex, to get there,
12 and, so, my question for you is, when we talked and you
13 mentioned in your Direct testimony about recapturing
14 patients, I think I don't like that word anymore, because
15 you really can't recapture.

16 A patient makes up their own mind. You
17 can't go out and recapture them, but the recapture that
18 was intended is these are already patients, who have a
19 COS orthopedic physician, who have gone to Hamden and
20 Branford.

21 There's a large number, enough, when you
22 put those numbers together, that would fill up the space
23 on one whole MRI unit, because it's only going to be used
24 two days a week in Hamden and two days a week in Essex,

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1 and it's going to do about 1,440 scans per year.

2 Those people, that are already with a COS
3 orthopedic specialist, if they go in the town, and we
4 don't know, we have no way of knowing what they're going
5 to do, but we assume that some of them, especially the
6 ones who live in Essex, would be able to stay. If that
7 scanner is out there, they'd be able to stay in that area
8 and use that scanner.

9 So I don't know if you want to clarify
10 your remarks from before, but it seemed to me that you
11 were indicating that COS was going to try to, with this
12 new machine, go out and capture all those people that
13 other radiology practices have and that was not the
14 intention.

15 MR. YODER: Attorney, as I read the
16 answers that COS provided to OHCA on the original
17 application, I think it's on page 37.

18 MS. GERNER: Okay.

19 MR. YODER: The first paragraph on top.
20 "For COS patients, who have had to use other providers in
21 the past, COS will be recapturing its own patients, so
22 that their treatment can be delivered under the direction
23 of one orthopedic specialist.

24 MS. GERNER: Right.

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1 MR. YODER: So --

2 MS. FUSCO: That is for patients, who have
3 used other providers in the past, and I can point you to
4 there are examples, as well.

5 MS. GERNER: Yeah. I see what you're
6 saying here, and that's why I said I think, you know,
7 recapturing was not, this part, was not meant to -- I
8 mean, if they have used other providers in the past,
9 there's evidence in the record of those patients, who are
10 using COS in Hamden and Branford now, that live in these
11 two service areas.

12 MS. FUSCO: Well, understood, but, I mean,
13 and you've spoken a lot and have asked my client to
14 clarify. I mean this is throughout the CON.

15 In Mr. Elia's testimony on page seven, it
16 speaks to those 447 COS patients in the Orange service
17 area, who were referred to non-COS provider MRIs.

18 "We anticipate that a majority of these
19 patients will use the mobile MRI unit in Orange once it's
20 approved." That's the recapturing we're talking about.

21 MS. GERNER: All right.

22 MS. FUSCO: Mr. Yoder's testimony is
23 accurate in that regard, and it's throughout here. I
24 mean we can find the word recapture 10 times in here.

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1 MS. GERNER: Right. The 437 does belong
2 with recapture. I agree with that.

3 MS. FUSCO: And that's what we've said.

4 MS. GERNER: Right.

5 MS. FUSCO: That the intent to recapture I
6 believe we used 450. We rounded 447 up.

7 MS. GERNER: Right.

8 MS. FUSCO: So I think that's accurate
9 testimony.

10 MS. GERNER: If that's when you're
11 referring just to those patients that are not already
12 with, and this says had used other providers in the past,
13 they'll have an opportunity, if they want to use the
14 mobile scanner, they'll have an opportunity to use it,
15 but existing patients that have been using, and this is,
16 of course, you know, filed at the time we were sitting
17 down, but it's we're still in the same situation, where
18 that many patients are using Hamden and Branford that are
19 seeing the COS orthopedic physician, and those people
20 alone, those numbers, pale in comparison with 437.

21 How many COS referrals did you say you
22 receive a year?

23 MR. YODER: Okay, so, in 2016, just over
24 400.

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1 MS. GERNER: Okay and that could be some
2 of the same people that you're talking about that are out
3 there that have been referred by COS to you.

4 Do you have certain services that COS does
5 not provide on the MRI that you're capable of doing and
6 that they have referred to you?

7 MR. YODER: I really don't know the
8 capabilities of the two magnets that COS has in Hamden
9 and Branford.

10 MS. GERNER: Okay, fair enough. Okay, I
11 think that's it.

12 HEARING OFFICER HANSTED: Okay.

13 MS. GERNER: Okay.

14 HEARING OFFICER HANSTED: Okay. Attorney
15 Fusco, do you have any Redirect?

16 MS. FUSCO: No, thank you.

17 HEARING OFFICER HANSTED: Any Redirect on
18 your end?

19 MS. GERNER: Yes.

20 HEARING OFFICER HANSTED: Okay.

21 MS. GERNER: I'd like to ask Mr. Elia what
22 the reimbursement is to COS for an MRI, including the
23 read.

24 MR. ELIA: In 2016, it was \$540 per scan.

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1 MS. GERNER: Okay and --

2 MR. ELIA: That's a blended average,
3 including the contrast studies and the non-contrast
4 studies.

5 MS. GERNER: Okay. That's it. Oh, I had
6 one question for Dr. Gagliardi. Let me see if I can find
7 it. Oh, and I have two questions for Dr. Gagliardi.
8 They're short.

9 HEARING OFFICER HANSTED: Okay. Can I
10 just interrupt?

11 MS. GERNER: Yes.

12 HEARING OFFICER HANSTED: You mentioned
13 contrast studies. What is contrast used for, in what
14 type of read or scan?

15 DR. GAGLIARDI: Can I answer that?

16 HEARING OFFICER HANSTED: Okay. I guess
17 we can still switch chairs.

18 DR. GAGLIARDI: Okay, so --

19 HEARING OFFICER HANSTED: As long as
20 you're going to be questioned, you might as well switch
21 chairs.

22 DR. GAGLIARDI: Okay. There's different
23 types of contrast studies. Some patients need contrast
24 directly injected into their joints. That's where Dr.

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1 Ramon Gonzalez comes in. He's on site as our staff
2 radiologist.

3 That extends the joint and allows you to
4 look for pathology and disease that you would not see,
5 because the muscles sort of clamp everything down.

6 There's other contrast studies, such as
7 intravenous contrast, which I would think, and I'll look
8 at the data sent to Advanced Radiology, because they can
9 provide those services for intravenous, injecting into
10 your veins to look for inflammation, infection, abscess,
11 those types of studies, so that should answer your
12 question about contrast.

13 Interarticular, in the joint; intravenous,
14 in your vein in your system.

15 HEARING OFFICER HANSTED: Okay. Okay,
16 thank you.

17 MS. GERNER: Dr. Gagliardi, you were asked
18 a lot of questions by Attorney Fusco about the time you
19 spend and where you spend it and how you get all this
20 work done.

21 Could you tell OHCA how long does it take
22 for you to read a scan and send it off to the particular
23 orthopedic physician?

24 DR. GAGLIARDI: It takes five to 10

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1 minutes to read a scan, on the most part. Some are more
2 complicated than others. Sometimes, I need to do
3 research in the literature and pull research articles,
4 but like I tell my daughter, we've actually done this
5 with the residents. I put my phone down. Let's see how
6 long it takes to take the trash out, for you to take the
7 trash outside. We put the button, we go in the kitchen,
8 we go to the trashcan, two minutes. Take the trash out.
9 When daddy comes home from work, I want the trash taken
10 out.

11 With the residents, we look at this. How
12 long does it take us to look at this knee MR accurately,
13 and you put a stopwatch, it's about five, 10 minutes.

14 In other words, it's surprising. You
15 would think it would take longer. It doesn't take that
16 long, so to think that there's this overwhelming burden
17 of volume coming in it's really not, if you know what
18 you're looking at.

19 I'm not an attorney, I can't go through
20 these documents as well as these folks can, but, when we
21 do what we do, we get specialized. We have
22 specialization in radiology. It's quick. For the most
23 part, it is quick.

24 HEARING OFFICER HANSTED: Is it unusual

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1 for a radiologist to read 9,000 to 11,000 scans per year?

2 DR. GAGLIARDI: No. No. And, to be
3 honest with you, I have other Board Examiners, a friend
4 in Florida, Hawaii and Texas. I've sent them images all
5 the time on my phone. What do you think of this case?
6 This is what I think. What do you think? So I have
7 people I can refer cases to all the time. We do it, and
8 it's a lot of fun. It's never a burden.

9 They send me cases. I send them cases.
10 We do this back and forth. I get cases from ex-residents
11 all over New York, Ohio. They're sending me cases all
12 the time and it's fun.

13 I show the residents sitting with me what
14 do you think of this? Here's what I think. Let's see
15 what they thought, and that makes the day actually
16 interesting when the phone rings or we're getting these
17 consults, so it makes the day go by pretty good.

18 HEARING OFFICER HANSTED: You can
19 continue.

20 MS. GERNER: Thank you.

21 HEARING OFFICER HANSTED: Sorry. I had to
22 jump in there.

23 MS. GERNER: That's great. That's fine.

24 Dr. Gagliardi, how much have you -- have you figured out

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1 how much added time it's going to take for you to do the
2 new scans if this application is approved?

3 DR. GAGLIARDI: So 15 a unit, 10 minutes,
4 150, 60 minutes to an hour, an hour or two a day extra,
5 two hours a day, I would think, roughly. There's
6 downtime already during our day to look at them. It's
7 not overwhelming.

8 Again, this is what makes the day
9 interesting on my end, is seeing these things and not
10 looking at a, you know, paratrooper's foot from Korea,
11 who is all destroyed. This is the fun part, is the MRIs.

12 MS. GERNER: Thank you.

13 HEARING OFFICER HANSTED: All set?

14 MS. GERNER: I think I'm all set.

15 HEARING OFFICER HANSTED: Okay. Attorney
16 Fusco?

17 MS. FUSCO: Can I ask just one brief
18 Redirect question?

19 HEARING OFFICER HANSTED: Sure.

20 MS. FUSCO: Actually, two, but they'll be
21 so short. I promise.

22 HEARING OFFICER HANSTED: Now you're
23 pushing it. All right. Two and that's it.

24 MS. FUSCO: I just want to clarify.

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1 You're working at the VA. It's a paid job, right?

2 DR. GAGLIARDI: Yes.

3 MS. FUSCO: So the United States
4 government pays you to work at the VA from 8:00 to 5:30,
5 Monday through Friday, and, during that time, when the
6 United States government is paying you to work for them,
7 you read scans for Connecticut Orthopaedic, and they pay
8 you, too?

9 DR. GAGLIARDI: No. I'm reviewing those
10 scans. I'm not reading them until the evening. I'm
11 reviewing those scans and going over the findings as a
12 teaching tool for the residents.

13 MS. FUSCO: Okay, so, you're going to read
14 all 11,000 scans the practice does each year after hours?

15 DR. GAGLIARDI: It's not a lot.

16 MS. FUSCO: Okay.

17 DR. GAGLIARDI: It's quick. It's quicker
18 than you think. They've already been reviewed. They've
19 already been looked at.

20 MS. FUSCO: But you're the radiologist.
21 You review the scans and prepare the reports, correct?

22 DR. GAGLIARDI: Sure.

23 MS. FUSCO: Okay and you'll do all of that
24 after hours?

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1 DR. GAGLIARDI: It's on the phone. We
2 dictate into the phone and it's typed up freehand. It's
3 not the voice recognition system that makes it harder on
4 radiologists. It slows them down.

5 MS. FUSCO: And I just want to clarify one
6 other thing, and I didn't have a chance to look at it. I
7 apologize, Pat, before you had asked the question, but
8 you had asked about the average reimbursement for a COS
9 scan.

10 Looking at the financials on page 215 of
11 the CON, if I divide the net service revenue by the
12 number of scans in any given year, I come up with an
13 average per scan cost of \$600, and you had said it was
14 substantially lower than that, so I just wanted to
15 clarify.

16 I mean I know ours is a little higher,
17 because we do more contrast studies, but I think you had
18 said yours was as low as 540, and that's not what the
19 numbers suggest, unless I'm reading them wrong.

20 MS. GERNER: Okay, so, you're on page 215?

21 MS. FUSCO: 215. So if you pick a year,
22 like if you look at -- well they don't have years on the
23 top. Column seven. If I divide the debt patient
24 revenue, which is at line four and a half --

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1 MS. GERNER: Before you go any further,
2 could we look at page 283, which is the most recent?
3 Remember, this application has spread over a long period
4 of time.

5 MS. FUSCO: Did you resubmit the pro
6 forma?

7 MS. GERNER: Yes. Should we have her come
8 up, Susan Bader, who is the CFO?

9 HEARING OFFICER HANSTED: That might be
10 easier, yes.

11 MS. GERNER: Okay, thank you. I do have a
12 number, but I think the CFO might be the better one to
13 provide it to you.

14 MS. BADER: So, for 2016, we've got total
15 operating revenue of 5,297,697, and we had 9,108 scans,
16 so that comes out to 581 per scan.

17 MS. GERNER: That's what I have, too.

18 MS. FUSCO: As you project going forward,
19 like if you look at 2020, I think that's where we're
20 getting the higher number.

21 MS. BADER: It goes up to 591 in 2020,
22 and, again, that's based on an assumption of payer mix,
23 which we have no idea what it's really going to be in
24 2020.

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1 MS. FUSCO: And do you do, and you might
2 not be the right person, but do you do a significant
3 number of contrast scans?

4 MS. BADER: Yes.

5 MS. FUSCO: That tend to get reimbursed at
6 a higher rate? You do?

7 MS. BADER: Well it's a mix. I mean
8 that's in the average.

9 MS. FUSCO: I think it's suggested in the
10 CON that those get referred out.

11 MS. FORAKER: Six, four days a week.

12 COURT REPORTER: I'm sorry. Who said
13 that?

14 HEARING OFFICER HANSTED: You want to come
15 up to the microphone? Is that six scans with contrast,
16 four days per week?

17 MS. FORAKER: Yes, four days per week, six
18 scans. Six to seven scans per day.

19 HEARING OFFICER HANSTED: Okay.

20 MS. FORAKER: And that's with the
21 contrast.

22 MS. GERNER: And would you give your name?

23 MS. FORAKER: My name is Billie Foraker.
24 I'm the head of Radiology at Connecticut Orthopaedic

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1 Specialists.

2 HEARING OFFICER HANSTED: Thank you.

3 MS. FUSCO: That's it. Thank you very
4 much. We're all set.

5 HEARING OFFICER HANSTED: You have someone
6 behind you raising their hand.

7 MS. FUSCO: Oh, I'm sorry.

8 DR. KAROL: Just as an education point for
9 everybody. The contrast studies, there's two types.
10 There's direct and indirect.

11 HEARING OFFICER HANSTED: Right.

12 DR. KAROL: Into the joint and there's
13 intravenous, so, usually, as you go with the term
14 contrast, I'm not -- that doesn't always really connote
15 really with the study.

16 HEARING OFFICER HANSTED: Okay.

17 DR. KAROL: It's MR of the brain with IV
18 contrast and not contrast.

19 HEARING OFFICER HANSTED: Okay. All
20 right, thank you. All right, at this point, we're going
21 to take a -- we'll take a 15-minute break, and then we'll
22 come back, and OHCA has some questions. Thank you.

23 (Off the record)

24 HEARING OFFICER HANSTED: Okay, we're back

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1 on the record. At this point, OHCA has some questions
2 for both the Intervenor and the Applicant.

3 MR. LAZARUS: Good morning. I'm Steven
4 Lazarus. I'm going to ask a couple of questions about
5 quality, and I'll start off with COS, the Applicant.

6 Throughout the pre-filed application and,
7 also, some issues that were brought up today, they
8 discussed quality relating to the machine, as well as to
9 the radiologist, as far as reading kind of stuff.

10 Just discussing the machine, itself, and
11 we understand it could be a different kind of machine,
12 because you haven't purchased one yet, but it's going to
13 be a Gold Star machine, so like a certified machine, and
14 is it going to be up-to-date with all the software and
15 the coils that would be required for the type of scanning
16 that your practice does or requires?

17 MR. ELIA: Absolutely. Both the units
18 that we have now have updated software and updated coils,
19 and the unit that we will purchase will have the same
20 level, if not, higher. We'll buy the best quality unit
21 we can find.

22 Again, our standard is to establish a
23 certification.

24 MR. LAZARUS: Okay and you are proposing

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1 to get that machine certified, accredited through ACR
2 within 18 months?

3 MR. ELIA: Absolutely. Our payer
4 contracts mandate such.

5 MR. LAZARUS: Okay. Regarding the
6 radiologist, we've heard testimony today that Dr.
7 Gagliardi is going to be reading the all 9,000 scans.

8 Actually, even in the application it
9 states the same thing. And something was brought up
10 today that I think, Dr. Gagliardi, you had testified that
11 you read versus review.

12 Could you sort of help clarify that for
13 me, the difference between you reading and reviewing a
14 scan?

15 DR. GAGLIARDI: Sure. Yes, sir. So I
16 review the cases during the day with the residents. I go
17 home at night, I've already seen the case once, look at
18 it again, and a report is generated.

19 MR. LAZARUS: Okay, so, basically, the
20 reading part is just finishing out?

21 DR. GAGLIARDI: Yes, sir.

22 MR. LAZARUS: Okay.

23 DR. GAGLIARDI: Sometimes, that's done in
24 the morning. I get to work at 6:30. We're not required

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1 by federal law to start working until 8:30, so I have a
2 two-hour window in the morning and I have evening, so
3 there is time on each end of the scale to generate the
4 final report, but it's not a problem.

5 The review part is more of the teaching
6 aspect for the residents and provides the orthopedic
7 surgeon with a timely review. God forbid there's a
8 critical finding. It needs to be called immediately.

9 MR. LAZARUS: If there is a -- if COS does
10 require something to be read immediately or it's an
11 urgent matter, how do you address that during the day?

12 DR. GAGLIARDI: I call them right up. I
13 look at it, review it and give them a phone call and say
14 this person has bone cancer, or a fracture, something is
15 unstable. It needs to be addressed. That does happen.
16 It doesn't happen a lot, but it does happen, yes.

17 MR. LAZARUS: Okay. As far as the
18 practice, itself, you had mentioned, the application
19 mentioned there are two radiologists on staff, yourself
20 and --

21 DR. GAGLIARDI: Yes, sir. Dr. Gonzalez.

22 MR. LAZARUS: Okay. Are you both Board
23 Certified?

24 DR. GAGLIARDI: I believe Ramon is. I

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1 have not seen his CV.

2 MR. LAZARUS: Okay and how many scans a
3 year does he read?

4 DR. GAGLIARDI: He doesn't read the scans.
5 He does the arthrograms. He's there on site to put the
6 needle in the joint as the radiologist to ensure the
7 contrast is where it's supposed to be.

8 MR. LAZARUS: Okay. Do you have like a
9 backup plan in place? Say you're on vacation, say things
10 like that. How are those scans read during the day?

11 DR. GAGLIARDI: I don't get sick.

12 HEARING OFFICER HANSTED: Do you take
13 vacation?

14 DR. GAGLIARDI: I read on vacation.

15 HEARING OFFICER HANSTED: You read on
16 vacation?

17 DR. GAGLIARDI: I read on vacation in a
18 hotel in Maui with a six-hour time zone. I get up and
19 read them, go to my meeting, come back and read them.
20 Sure, absolutely. I've been doing that for eight, nine
21 years now. It's never been a problem.

22 MR. LAZARUS: Okay. Is there a
23 radiologist present during the scan at each site at the
24 practice?

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1 MR. ELIA: I can answer that question.

2 MR. LAZARUS: Sure.

3 MR. ELIA: Often times, Dr. Gonzalez is on
4 site in Hamden, but, Branford, we do run scans without a
5 radiologist on site, but there's always a physician on
6 site.

7 MR. LAZARUS: There's a physician on site,
8 okay. For the two proposed sites, would there be a
9 radiologist present there during the operation of the
10 scanner?

11 MR. ELIA: No. Will there be a physician
12 on site?

13 MR. LAZARUS: Yes.

14 MR. ELIA: Or did you say a radiologist?

15 MR. LAZARUS: A radiologist, but a
16 physician will be on site?

17 MR. ELIA: A physician will be on site. A
18 radiologist will not.

19 Mr. Lazarus, just a point of reference to
20 your prior question to Dr. Gagliardi, Dr. Gonzalez is
21 available. If Dr. Gagliardi was not available, Dr.
22 Gonzalez is Board Certified, teaches at Quinnipiac
23 University, and is certainly capable of picking up any
24 slack or reading in Dr. Gagliardi's absence.

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1 He hasn't been called upon to do so, but
2 he is available to do so.

3 MR. LAZARUS: Okay.

4 MS. GERNER: Would you like a late file
5 with his credentials?

6 HEARING OFFICER HANSTED: Yes, let's get
7 that from you, his credentials. That will be Late File
8 No. 1.

9 MS. KAILA RIGGOTT: And could I just ask a
10 question about the contrast studies? Are both types of
11 contrast studies done just the intra-joint and the IV are
12 referred out? Thank you.

13 DR. GAGLIARDI: Yes, ma'am.

14 HEARING OFFICER HANSTED: I have one more
15 question, as far as reading the scans. Are any scans
16 sent out to a third party for reading?

17 MR. ELIA: No, sir.

18 HEARING OFFICER HANSTED: Okay.

19 MR. DAVID FERNANDES: Good morning. David
20 Fernandes. So the next few questions will involve the
21 recently merged group practices and its payer mix, so
22 we're going to request a second late file. Would you
23 please provide patient volume for the most recently
24 completed fiscal year for the Shoreline Orthopedics and

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1 Sports Medicine, Center for Orthopaedics, The Orthopedic
2 Group and Orthopedic Health?

3 So that's just the patient volume for the
4 most completed fiscal year for the four recently-merged
5 physician offices.

6 HEARING OFFICER HANSTED: That will be
7 Late File No. 2.

8 MR. ELIA: So, Mr. Fernandes, just for
9 clarification, those groups that have come into COS --

10 MR. FERNANDES: Within the past.

11 MR. ELIA: In the past year, so we're
12 talking 2016, and, so, would you like those physicians
13 broken out, as if they were still in their own
14 independent practice, because they're fully integrated
15 into a single group practice?

16 We don't segregate them. Once they've
17 merged into the practice, we continue to use the name for
18 historical purposes for their patients to continue to
19 find them, but once those physicians are in the group,
20 they are, then, disbursed throughout the entire COS
21 system, so they're not necessarily confined to the
22 regions where their practices formally were run.

23 MR. FERNANDES: Would it be possible to
24 generate patient volume, based on origin, where a patient

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1 originated? Like, say, a patient first came in to COS
2 through Center for Orthopaedics. Would you be able to
3 create a patient volume, based on how they entered COS?

4 MR. ELIA: Once they come into COS
5 following a merger or an -- in the case of Center for
6 Orthopaedics, there wasn't a merger. They became
7 employees of COS, but all those patients are then
8 registered, so we don't bring the files from the previous
9 groups in, so once those patients come in, we don't have
10 a prior track of where they came from or what facilities
11 they used. They basically are starting fresh with us.

12 MR. FERNANDES: Okay, well, one of reasons
13 we decided to pose that question is because, the way
14 that's submitted information regarding Shoreline
15 Orthopedics, you were able to calculate Medicaid
16 percentage and Medicare percentage.

17 MR. ELIA: Yes. So they were unique.
18 When Shoreline came on board, they were using Allscripts
19 as their EMR system. The rest of the practice is on
20 Greenway.

21 We allowed them to stay on using
22 Allscripts for a one-year period of time during the
23 initial transition.

24 When we did the application, because they

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1 were on a standalone platform, we were able to go back
2 and manually go back and extract the data, which is why
3 the data had a little bit more pinpoint accuracy with
4 regards to Shoreline, and we were able to give you more
5 details, as to where we sent those patients outside the
6 system, but it was because it was on a standalone
7 platform and it was done manually.

8 That being said, we would obviously want
9 to comply with what you're trying to achieve. I just
10 need a little more clarification, as to what you want to
11 see.

12 MR. LAZARUS: How would you be able to
13 provide it for the patient volume?

14 MR. ELIA: Well we certainly can give you
15 payer mix.

16 MR. LAZARUS: Okay.

17 MR. ELIA: And we can give you payer mix
18 by town. We can give you payer mix by provider, but if
19 you're looking for payer mix from the group formally
20 known as Orthopedic Health, that really is not
21 necessarily capable or relevant, because those providers
22 are no longer in just Milford, for example.

23 MR. FERNANDES: Okay.

24 HEARING OFFICER HANSTED: All right, we'll

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1 strike Late File No. 2.

2 MR. FERNANDES: Based on Mr. Elia's pre-
3 filed testimony, it stated that Medicaid payer mix has
4 been increased in the last couple of years.

5 Since you had just mentioned that you can
6 provide the payer mix, based on -- excuse me for a
7 second.

8 MR. ELIA: Sure.

9 MR. FERNANDES: Okay, so, since you had
10 mentioned you can provide the payer mix, based on town,
11 would you be able to provide that, based on town for the
12 towns where the recently merged physician practices are
13 located?

14 MR. ELIA: Sure. We can do that. We can
15 give you Milford, Orange. You have all that data
16 already, because it's contained in the application, and
17 we can give you Shoreline. Shoreline now is on one
18 unified platform, so we have brought them onto Greenway.

19 We certainly can give you a payer mix by
20 each town, but I think you have that.

21 MR. LAZARUS: But not for those three
22 practices?

23 MR. ELIA: Those practices. Yeah, the
24 only practice that you probably don't have is Center for

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1 Orthopaedics' providers, but CFO remains CFO. As I
2 mentioned, some of their providers left their
3 organization and went elsewhere. One went to Yale. One
4 went to UConn. Some became employees of COS, so they
5 didn't remain an intact unit.

6 MR. FERNANDES: So the next question is in
7 regards to alternative proposals.

8 MR. ELIA: Just do you want --

9 HEARING OFFICER HANSTED: No, there will
10 be no late file.

11 MR. ELIA: Okay. Happy to comply, but.

12 MR. FERNANDES: The next question is more
13 of a discussion question. We'd like to get an idea, as
14 far as what proposal COS discussed internally in regards
15 to whether the factors that went towards purchasing a
16 mobile MRI over a fixed MRI at one site or at both sites.

17 MR. ELIA: Well the practical answer is
18 that it's challenging enough to get one CON, not two, and
19 we had a dispersion of patients, both in two different
20 geographical regions, and, so, the most practical way to
21 achieve that was to take a unit that could be in both
22 places.

23 And, so, that's why we proposed two days
24 in Essex and two days in Orange. We felt that it would

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1 not only meet the geographical spread of patients that we
2 have, but it would also meet the demands.

3 A single unit in one location, we wouldn't
4 have had enough demand in either one of those two
5 locations to meet a full-time demand, and, yet, the
6 demand for two days is adequate, just based on taking the
7 existing patient volumes, without the suggestion of
8 reducing patient flows to other practices.

9 We have adequate patients in Hamden,
10 because we're running Saturday and Sunday nights even. If
11 you take that patient volume alone and knowing that they
12 came from Orange and put them into that mobile unit two
13 days a week, the unit is being adequately used, and we
14 don't have to staff it or bring our patients out in the
15 evening at 9:00 on a Sunday night.

16 The suggestion, that we're going to
17 cannibalize patients from Advanced Radiology, is flawed,
18 because we have adequate patients to staff both units
19 without any change of referral relationships.

20 MR. FERNANDES: Is there one region that
21 you'd say has more potential volume than the other?

22 MR. ELIA: No, I don't think so. I mean,
23 clearly, the shoreline is growing, and we have increased
24 our presence out there, but the Orange, the population

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1 density of Orange, Milford, Woodbridge, West Haven,
2 Shelton is there.

3 As I said before, our patient volumes are
4 growing almost exponentially for a lot of reasons, and
5 our offices are exploding with patients, and, so, I don't
6 believe one region represents a greater demand than the
7 other.

8 MR. FERNANDES: Would you say the patient
9 volume that's grown is coming from one specific physician
10 practice?

11 MR. ELIA: Oh, absolutely not. It's
12 coming from the general population. Obviously,
13 orthopedics is a growing demand, as evidenced by the fact
14 that Hartford Hospital and Yale have tried to establish
15 orthopedic institutes.

16 The population, if you look at the
17 studies, for example, just total joints alone, they're
18 expecting the number of total joints to increase
19 something like six fold over the next 10 years, and, so,
20 we're not relying on patient or medical practices to
21 refer to us.

22 Quite frankly, in our region, there are no
23 more medical practices to refer to us. Yale has
24 cannibalized them.

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1 Advanced Radiology doesn't send patients
2 to us. We send patients to them. Patients come to us,
3 because they find us. They find us on the web. They
4 find us through word of mouth. They find us, because we
5 opened up OrthoNOW, which is an orthopedic only walk-in
6 center, so that they don't have to go to the ERs.
7 Another innovation to keep costs down.

8 That's how patients find us, and that's
9 why our volumes are expanding, not because of patients
10 being referred to us or by us really taking on anything
11 new. They're coming to us.

12 MR. FERNANDES: In terms of size of the
13 four recently-merged physician practices, you mentioned
14 Shoreline has expanded. Relatively, how -- well is there
15 another physician practice within COS as large as
16 Shoreline Orthopedics and Sports Medicine, or are they
17 considered the largest?

18 MR. ELIA: Shoreline was a three-man
19 practice. Center for Orthopaedics was an eight-man
20 practice. The Orthopaedic Group was an eight or nine-man
21 practice.

22 My phone rings every week from groups
23 around the entire state looking to join COS, because of
24 what we've created, the quality that we're doing, the

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1 opportunity to participate in unique payer contracts.

2 There's no one single type of group that
3 is attracted to us. What we're attracted to is quality.
4 If we determine the quality of the providers are adequate
5 to join our organization, then we consider it.

6 MR. FERNANDES: Thank you.

7 MS. RIGGOTT: I actually have a follow-up
8 question to something that -- it was mentioned, I
9 believe, in Cross, and I think my question is for ARC.

10 It was mentioned, in 2015, that there were
11 78 Medicaid scans that COS did and that there were 51
12 Medicaid scans, I believe, referred to ARC.

13 I'm trying to determine whether or not you
14 have information on those patients. Not specific
15 information, but were they referred, because they needed
16 a 3T? Is there any information that you can provide on
17 those patients that would give us a better understanding
18 of those Medicaid patients?

19 MR. YODER: I think the only way to
20 adequately research -- I don't have that with me.

21 MS. RIGGOTT: Okay.

22 MR. YODER: To investigate would be to
23 pull the prescriptions or the orders for all those
24 patients to really try to identify if there was some

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1 clinical indication or if there was an orthopedic request
2 that these patients needed to be done on a 3T.

3 It's something that we typically just
4 don't monitor or try to assess whether they go to 3T or
5 not or what's available with that.

6 MS. FUSCO: I mean and I can tell you
7 that, of the 51, only 19 were done on 3T. It's only 19
8 of the 51 were done on 3Ts. The other ones were on 1.5.

9 MR. YODER: And that does not necessarily
10 mean that the patients needed a 3T. We just had
11 appointment slots open, and they were the first available
12 slot, and we put them in there, or they were close to
13 their home, whatever it may be.

14 MR. ELIA: If I might? There was a
15 question asked earlier about unique services and why COS
16 may refer to practices like Advanced Radiology.

17 Mr. Yoder answered the question by saying
18 he doesn't know what we do, but the fact of the matter is
19 that they have an open MRI.

20 In many of the patients that we do refer
21 to Advanced is because they have an open MRI. They have
22 services that we do not provide, and that's why those
23 patients get sent over there.

24 So whether or not that population of

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1 Medicaid patients represents the need for an open MRI,
2 but the fact of the matter is that an open MRI is a
3 certain type of patient need that will always be there,
4 regardless of whether or not the Certificate of Need is
5 granted to us or not. Likewise, the intravenous
6 contrasting.

7 So the breakdown of the studies of the
8 patients we send there and the assumption that that
9 number will decrease is really the devil is in the
10 details of the type of patients that are being referred
11 there.

12 MR. YODER: Just to clarify, we don't have
13 an open MRI, and we haven't had one for dozens of years.
14 I know that Milford Diagnostic or Diagnostic Imaging of
15 Milford, a small radiology practice of three or four
16 providers, they do have an open MRI unit.

17 MR. ELIA: I stand corrected.

18 DR. RUWE: Do you have a unit with a
19 larger aperture?

20 HEARING OFFICER HANSTED: Well, no.
21 You're not allowed to question them.

22 DR. RUWE: Okay. They're saying something
23 that's --

24 HEARING OFFICER HANSTED: And we're beyond

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1 that point. We're not going to get into those specifics.

2 COURT REPORTER: What is your name?

3 DR. RUWE: I'm Dr. Ruwe.

4 MS. FUSCO: Yeah, I'm just trying to get a
5 better understanding, in general, what those patients
6 received, in terms of services there.

7 MR. ELIA: So, for point of clarification,
8 I was in error. It's not an open MRI, but we refer
9 patients to other radiology practices that have services
10 that we can't comply with, and it may be the size of the
11 bore may be different and things along those lines.

12 MS. FUSCO: Thank you. If it's something
13 that you want us to look into and see what we can find?
14 I mean I certainly don't want you guys to be left with
15 the impression that I think they've given in the CON,
16 that, you know, all 400 patients they send to us are sent
17 to us, because they need IV contrast, because they need a
18 3T.

19 I mean it's a generalization that, without
20 data to back it up, I don't think they can make that. I
21 think they've made it pretty clear in the CON that
22 they're looking to recapture scans that are referred out
23 of COS.

24 So, I mean, we can look and see what we

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1 have. That might help clarify specific to the 51
2 Medicaid patients. I don't know what we can find.

3 HEARING OFFICER HANSTED: I think that
4 would be helpful. Specifically, to the 51.

5 MS. FUSCO: To the 51?

6 HEARING OFFICER HANSTED: Right, and that
7 will be Late File No. 2.

8 MR. LAZARUS: I have one additional
9 question, just for clarification, for ARC. The machines
10 you have in Trumbull and Orange, are those open MRIs or
11 not?

12 MR. YODER: No.

13 MR. LAZARUS: They're not open MRIs?

14 MR. YODER: No.

15 MR. LAZARUS: Okay, because we were
16 looking at our inventory.

17 MR. FERNANDES: In our recently-submitted
18 inventory, it was labeled as open for Orange and open in
19 Trumbull.

20 DR. KAROL: The Orange magnet is a 3T.
21 It's not open. The one in Trumbull is an Espree. It's
22 1.5.

23 MR. FERNANDES: It might have been
24 reported wrong.

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1 MR. LAZARUS: So what you're saying is
2 it's reported wrong on the most recently-completed
3 inventory?

4 DR. KAROL: I don't know what terminology
5 they used. I'm just saying, in my experience, people
6 don't send them to those sites, saying, oh, we're looking
7 for an open MRI. That's not an accurate statement.

8 MR. LAZARUS: Okay.

9 DR. KAROL: Open MRIs or the one you'll
10 see in Milford is of very low-field strength, and they
11 have, because they're open, they're very wide, the field
12 strength is very low, so the quality is usually lower and
13 the scans take longer to achieve.

14 We do not have any scanners like that
15 anymore.

16 HEARING OFFICER HANSTED: Anything else?
17 Okay, we're going to take a 10-minute break. We're off
18 the record.

19 (Off the record)

20 HEARING OFFICER HANSTED: Okay, we're back
21 on the record.

22 MR. ELIA: Excuse me. Hearing Officer
23 Hansted?

24 HEARING OFFICER HANSTED: Sure.

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1 MR. ELIA: Can we clarify this point that
2 was discussed before the recess with regards to the open
3 MRI? I said I stood corrected.

4 HEARING OFFICER HANSTED: Yes.

5 MR. ELIA: We, during the recess, looked
6 at Advanced Radiology's website, where they advertise
7 that they have open MRI. We also called Advanced
8 Radiology during the recess and said we were
9 claustrophobic. Do you have open MRI? And they said,
10 yes, we have open MRI in Orange, Trumbull and Fairfield
11 and Shelton.

12 I think the semantical term, open MRI,
13 needs to be clarified here.

14 HEARING OFFICER HANSTED: Well I don't
15 know that it's necessary for our purposes for this
16 application. I mean, essentially, what we were trying to
17 get at with our question was why would you refer to ARC
18 instead of doing a scan yourself, and it's obviously
19 because they have a capability that you don't, and that's
20 the point we're trying to make.

21 MR. ELIA: That's fine.

22 HEARING OFFICER HANSTED: I don't want to
23 hash out semantics with respect to the MRI.

24 MR. ELIA: Understood. As long as that

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1 point is clarified.

2 HEARING OFFICER HANSTED: Okay.

3 MR. ELIA: Thank you.

4 HEARING OFFICER HANSTED: Thank you.

5 Okay, did you have more questions? You're all set?

6 Okay. All right, OHCA doesn't have any more questions.

7 Looking around the room, I don't see
8 anybody from the public here, but is there anybody from
9 the public that would like to make a statement?

10 Okay. Hearing and seeing no one, I will
11 allow counsel to make closing remarks. I'll start with
12 Attorney Fusco.

13 MS. FUSCO: I won't take too much time. I
14 know we've been here a long time, and thank you for all
15 the work you've done on this CON and for, you know, for
16 holding a hearing at ARC's request, so that you could
17 discuss these issues that really are of critical
18 importance to Advanced Radiology and to the future of,
19 you know, independent radiology practices and other full
20 service imaging providers in our state.

21 We hope that the information that we've
22 given you in our submissions and during our discussions
23 here today has helped you, you know, better understand
24 the issues that we're facing.

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1 This isn't just a CON about, you know,
2 Advanced Radiology trying to stifle competition. In my
3 many years of doing this, I've sat in many radiologist
4 versus radiologist CON proceedings, where it was all
5 about territory and who is going to get this patient and
6 who is going to get that patient.

7 It's really about sort of the change in
8 the business model and how non-radiology practices are
9 trying to establish need for this incredibly profitable
10 service that practices like Advanced Radiology use to
11 subsidize their businesses.

12 I mean we're taking a step to try to
13 ensure that a practice, like ARC, that invests millions
14 of dollars in state-of-the-art technology, that hires,
15 you know, the highest quality professional staff, and we
16 talk a lot about subspecialists. It's not inexpensive to
17 staff the practice with all fellowship-trained
18 radiologists, but they do, because they know how
19 important it is to the quality of care that they provide.

20 You've also got a practice, and it's
21 probably the most important point, that takes all
22 patients, regardless of their ability to pay.

23 And, you know, we've been down this road
24 before. You've got a radiology practice that's seeing

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1 thousands and thousands of Medicaid and uninsured
2 patients every year, you know, attempting to compete, and
3 that's exactly what it is for MRI services with these,
4 you know, captive self-referred practices that are able
5 to, you know, adjust their payer mixes, so they're not
6 seeing as many of the costs losing patients.

7 In terms of need, I mean the CON statute
8 still, for now, requires us to look at clear public need,
9 and, you know, I think it's a simple equation, and the
10 questions were being asked, and I think Mr. Yoder tried
11 to explain this is not new need.

12 COS keeps saying to us you don't
13 understand. Like we're getting new patients. Our
14 patient volume is increasing. It's growth in patients.
15 It's growth in MRI. I think that mischaracterizes it.

16 This is a practice that is merging with
17 other practices, and, if they pick up a two or three-
18 physician practice, those orthopedists become members of
19 COS, and those orthopedists previously wouldn't have
20 referred to a COS MRI, because they couldn't, so they
21 would have referred to Advanced Radiology, or Yale-New
22 Haven Hospital, or Middlesex.

23 Well now they're under the COS umbrella,
24 and they're going to send their scans internally, and

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1 what they see is an increase in patient visits, an
2 increase in need for MRI, but it's not. It's a shift.
3 It's a shell game.

4 You know, the patients are just moving,
5 and, so, the end result of that is you have providers,
6 like ARC, that are just going to start to lose the
7 business.

8 They can say what they want, you know,
9 about patients that need to go to Advanced Radiology. We
10 don't dispute that there are orthopedic patients that
11 need to be on a 3T or that might need an IV contrast
12 study, but, you know, they've stated clearly, and we'll
13 focus on the Orange service area, that there are 447
14 patients they project in that area that go to non-COS
15 providers for MRI, because they can't accommodate them
16 in-house, okay?

17 We do 400. I'm sure some other providers
18 do some. Maybe they're not going to take everything from
19 us, but, you know, we're not talking about an impact of a
20 few thousand dollars here. We're talking about, you
21 know, potentially a quarter of a million dollars or more
22 in impact.

23 And when MRI services are the lion's share
24 of your profit and you need them to subsidize mammography

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1 that loses money, an x-ray that loses money, losing a
2 quarter of a million dollars in revenue is huge.

3 It means you might have to lay off staff.
4 It means you might not be able to staff late night hours,
5 or weekend hours, because you don't have the revenue to
6 do it, and I think they clearly understand the adverse
7 impact. They're just trying to sort of shift the focus
8 away from that, so it appears that this is just a
9 straightforward case.

10 We have a lot of patients. Our units are
11 full. Give us another one. And they think a lot of what
12 we talked about in our written submissions had to do with
13 sort of what the standards should be and what you guys
14 should look at, in terms of need.

15 Just to reiterate, you know, Advanced
16 Radiology has three units in their defined Orange service
17 area; Orange, which has capacity and it has the ability
18 to extend evening hours and weekend hours right now if
19 they need to, you know, a unit that's right across the
20 street from COS, that, you know, has stat appointments
21 open.

22 You've got docs that will read a scan
23 within an hour versus waiting until they go home after
24 their other full-time job is done.

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1 You've got, you know, patients that, or
2 physicians that have never given COS physicians a
3 problem, in terms of speaking with them.

4 I mean Advanced Radiology is doing it for
5 them now. They're doing a good job. They can continue
6 to handle what they're handling, and they can handle
7 overflow if there's a need.

8 They've got a Shelton unit that I think is
9 doing less than 3,000 scans, so there's available
10 capacity and there's quality available capacity in the
11 area.

12 Just touching briefly on some of the
13 issues we've spoken about related to Medicaid, and this
14 is all in our written submissions, but, you know,
15 Medicaid access has to be meaningful, or it's nothing.

16 You've got scanners here, where they're
17 providing, you know, they're projecting 11,187 scans and
18 100 of those are going to be Medicaid patients out of
19 the, you know, close to a million Medicaid patients we
20 have in this state.

21 That's not meaningful. They're buying a
22 whole other unit to add 17 scans a year. It's not. And
23 I don't know why more of their patients are coming out
24 versus staying in, whether it's their scheduling, but

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1 they're not providing that meaningful access, and they're
2 not sitting before you proposing to add technology to the
3 market that's going to make things better for Medicaid
4 patients. They're just not.

5 And, again, you know, you've got practices
6 in the area that do that and that do it on a regular
7 basis and that, if you approve this CON, I mean it's
8 going to hurt them, and it's going to impede their
9 ability to do that, and that's what they have to do, and
10 that's what they've committed to do, despite the fact
11 that they're not particularly profitable patients.

12 And then, you know, another thing we've
13 mentioned is that, and you guys know this, because we've
14 done many of these before, like it's difficult. It's
15 difficult, if you approve something like this, to keep
16 check on whether they are meeting any standards with
17 respect to Medicaid patients, whether they're going to
18 serve as many as they say, or whether they're going to
19 serve more, so, you know, now is the time to fix that.

20 In terms of quality, I think we've kind of
21 beaten quality to death here today, but, you know, it's
22 concerning to us that they would choose to purchase a 17-
23 year-old unit, even if they're going to upgrade the
24 software.

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1 I mean why not purchase a newer unit? I
2 mean it's about cost. A new unit is going to cost them
3 1.5 million, and this one costs \$500,000.

4 Dr. Gagliardi is a great guy, you know?
5 But he's reading over 11,000 scans, and he's doing it
6 after hours, having had a full-time job. Whether, you
7 know, whether and to what extent he's accessible we don't
8 know, but we do know that, again, we're serving COS
9 patients, and we are offering them a higher level of
10 radiological services than that.

11 We've got units that exceed the ACR Gold
12 Standards of specialized radiologists, you know, the
13 second opinions, peer review. We're there for them.
14 We're doing it now, and we can help them, but there's
15 this need to sort of pull everything in-house, and I
16 think it's a myth.

17 It's, like Dr. Karol mentioned, it's not
18 necessarily better done in-house, you know? There's no
19 same-day MRI. They're not getting better access.
20 Everything that they say they can do we can do, so I
21 don't think that what they're saying, the benefits of
22 coordinated care, in and of themselves, justify another
23 unit.

24 Mr. Yoder had said it in his presentation.

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1 I mean we would hope that you would deny the CON, based
2 upon the fact that there is no need, that it's just a
3 shifting of volume, that it's not going to increase the
4 quality of care for MRI patients in the area, and that
5 it's certainly not going to increase, you know, access to
6 care for Medicaid recipients, and, at the same time, it's
7 going to be, you know, financially injurious to
8 practices, like ARC and hospitals and others, but, you
9 know, to the extent that OHCA does approve it, which we
10 sincerely hope will not be the case, I think, you know,
11 we would ask that you be mindful of sort of the expansion
12 plans of that practice.

13 I mean, over the course of the last few
14 years, they've merged with, or acquired numerous
15 practices. You heard Mr. Elia say that he gets calls
16 every single day, and we're aware of conversations that
17 they're having with practices in Fairfield County, and
18 our biggest concern is you approve this mobile unit for
19 Orange and Essex and, the next thing you know, they're
20 upgrading it to a fixed unit, and they're moving it
21 somewhere in Fairfield County, because that's their plan.

22 So, you know, I think, if you decide that
23 they've shown a need for this unit, a mobile unit to
24 operate two days a week in Essex and two days a week in

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1 Orange, then there should be conditions on the decision
2 that limit it to two days a week in each place.

3 With that, again, thank you, and we
4 appreciate your time.

5 HEARING OFFICER HANSTED: Okay. Thank
6 you, counsel. Attorney Gerner?

7 MS. GERNER: First, I would like to thank
8 you again for all of your efforts and especially sitting
9 through the hearing this morning.

10 I don't think that this is a charade of
11 any sort or, you know, hiding the ball and pretending
12 that these are patients that are not new and that have
13 not come into the system and that there's no need.

14 There's a very real physical need with the
15 number of patients that are required to have an MRI with
16 all of the volume that has grown up in the last few
17 years.

18 The assumption, that everything is self-
19 referred and, you know, they're trying to keep everything
20 in-house, couldn't be further from the truth.

21 They have so many patients now that, if
22 patients -- clearly, there are many reasons why patients
23 go to another radiology practice, I mean go to a
24 radiology practice, other than coming to COS and having

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1 their scan done in-house, and that is, you know, they may
2 have a connection with a radiology practice.

3 They may have gone there, and even those
4 patients over the last couple of years, who may have used
5 Advanced Radiology, who weren't there to use a special
6 service, but just needed to go somewhere, they now have
7 had a relationship with them, and, you know, clearly,
8 they'll ask to go back if they were pleased with the
9 service, it was accessible to them. They'll ask to go
10 back to that service. They're not going to, you know,
11 come over to MRI.

12 So while we hope that some patients will,
13 there's no guarantee, and there's no way that that can be
14 forced.

15 The need for the number of people, which
16 has come in, is very well-documented, and, again, we're
17 not -- this is not a radiology practice. We are not
18 competing head-to-head with Advanced Radiology or any
19 other radiology practice.

20 This is an orthopedic specialist group,
21 who believes strongly that the MRI scan is such an
22 important part of the process.

23 That diagnostic test, if it's needed, it's
24 the first step in what guides the entire course of

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1 treatment.

2 They have been very successful using the
3 people that they have, and I'd like to say that quality
4 does not just depend upon spending a lot of money on
5 brand new equipment. It depends upon the end result,
6 which, in the case of Orthopaedic Specialists, is the
7 care that the physicians provide, and the patient knows
8 who is going to be looking at that scan.

9 If they need to be operated on, if they
10 need to be treated, they trust that individual physician,
11 and this goes back to the old private practice of
12 medicine, which are being brought up more and more by
13 larger institutions, so Orthopaedic Specialists wants to
14 stay in business doing what they do best, which is caring
15 for orthopedic patients.

16 And the MRI service, which they like to
17 have, so it's accessible to the patient and it's
18 available to the patient, does not mean that it's
19 required of the patient. They're not bound.

20 As I think I said in one of the documents,
21 you know, they are not just bodies that need a scan.
22 They're human beings, who like working with COS.

23 And if COS hasn't done such a good job in
24 quality, I don't think people would be asking to come in

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1 and join with them.

2 One of the things that was not discussed
3 at great length, but it's in the application, I think, is
4 the cost savings that will be achieved when you have a
5 larger group.

6 One of the goals is to have a large enough
7 platform, and this was something that was strived for in
8 the Patient Protection and Affordable Care Act, was to
9 have a large enough platform, and it's one of the reasons
10 that the Stark Law Exception has not been taken out of
11 the law, is that, if you have a larger platform and you
12 can contain costs better, then that helps everyone.

13 It helps the patients, the State, the
14 federal government that pays for a lot of healthcare, as
15 well.

16 So just expanding for the sake of
17 expansion is not what these people are about. They are
18 expanding, because they have a vision that they can offer
19 quality care at a lower price.

20 If they thought that their MRI was going
21 to be insufficient, if they thought Dr. Gagliardi was not
22 extremely capable at what he does and if he didn't do a
23 good job, they would be able to hire other people.

24 They would be able to, if they wanted, buy

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1 another machine, you know, with a lot of extra things on
2 it, but that's not the standard for orthopedic care, and
3 that's all they do.

4 Advanced Radiology treats a broad range of
5 -- scans that are coming in from different kinds of
6 doctors. And I know they have subspecialists that read
7 them, so that's not an issue, but COS does just
8 orthopedic, and the 1.5 Tesla MRI is considered the
9 standard.

10 For those people, who are outside of that,
11 we have sent, COS has sent the scans over to Advanced
12 Radiology, because they have the 3.0 Tesla MRI.

13 For other reasons, as well, for the
14 intravenous type of scan, for open scans, many of which,
15 you know, patients in this Medicaid population, we don't
16 know why this number was sent over there, but if there
17 were any of those issues involved, they would have been
18 referred over to Advanced Radiology, because of its
19 accessibility and the closeness to where COS is located.

20 Medicaid patients only just started
21 finding, and this goes back several years, when this was
22 not as important as it is today.

23 I think, you know, there's been such an
24 awareness of getting services out to Medicaid patients,

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1 and, years ago, if they came in, you know, they were
2 hurt, but unseen, but it's only been in the last couple
3 of years that COS has been actively aware and has been
4 trying to raise the number of Medicaid patients that it
5 has.

6 It hasn't looked the other way, or tried
7 to say, you know, we really don't want these people.
8 We're going to shove them off somewhere else, because we
9 don't want to keep them.

10 By adding an additional scanner, they will
11 have more space for everybody, including Medicaid
12 patients, which they will try to raise the level and the
13 number.

14 When Yale and when St. Raphael's closed in
15 New Haven about two years ago, that's where a lot of
16 Medicaid patients in the New Haven area went, and, when
17 they closed those clinics, that's when the Hamden COS
18 office began seeing many more than they had even before
19 that in prior years, because they had to come out to the
20 Hamden area, because they weren't getting that service
21 with St. Raphael's and Yale closing down those clinics.

22 Doing their fair share of what's out there
23 is entirely understandable to COS, and we've had many
24 discussions about that, about how to go about doing that

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

1 and incorporating more Medicaid patients.

2 Some of it is happening on its own,
3 because word of mouth spreads, and, as Mr. Elia stated,
4 having OrthoNOW, where people can just come right in off
5 the street, has been a huge help, as well.

6 They accept Medicaid. They accept
7 Medicare. They accept many different kinds of financial
8 arrangements and do have a charity care plan for those
9 people, who have no insurance and don't even have
10 Medicaid.

11 This is not going to change anything, by
12 adding the scanner. It's not going to change the way COS
13 will try to incorporate all of that, but what it will do
14 is take the pressure off of Hamden and Branford, which
15 are way over 100 percent at this point.

16 By taking and -- by scaling back their
17 hours and allowing some of that volume to go to these two
18 new units will bring each unit almost up to like half of
19 -- at least half of what they need for a full year of
20 scanning, and there are people going back to their home
21 area.

22 Table 8, 7 and 8 in our application, show
23 how many people from towns have been going to Hamden and
24 Branford, because that's what they wanted. They wanted

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1 to keep all of their care within an orthopedic practice.

2 And I think I've said enough, and we'll
3 conclude at this point, unless you have any other
4 questions. Thank you very much.

5 HEARING OFFICER HANSTED: Thank you. Just
6 one point of housekeeping. The late files will be due
7 July 26th. Does that give you both enough time?

8 MR. YODER: Yes.

9 HEARING OFFICER HANSTED: Okay and, with
10 that, I thank everyone, and this hearing is adjourned.

11 (Whereupon, the hearing adjourned at 12:26
12 p.m.)

CONNECTICUT ORTHOPAEDIC SPECIALISTS, P.C.
JULY 11, 2017

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User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Wednesday, July 19, 2017 9:06 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; 'klg1@aol.com'
Subject: OCHA Docket No. 16-32117-CON
Attachments: COS CV for Ramon Gonzalez M.D. 7.18.17.pdf; COS CV for Ramon Gonzalez M.D. 7.18.17.docx

July 19, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find Late File #1 in OHCA Docket No. 16-32117-CON, the curriculum vitae (C.V.) for Dr. Ramon Gonzalez, the second radiologist who works for Connecticut Orthopaedic Specialists, P.C..

I would appreciate knowing that OHCA has received this email transmission with its 1 attachment.

Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Curriculum Vitae

Ramon Gonzalez M.D.

EDUCATION

July 1968-June 1972	Colegio Helvetia, Bogota, Colombia.	B.S.
July 1972-June 1977	Colegio Mayor de Nuestra Senora del Rosario School of Medicine, M.D. Bogota, Colombia	
July 1977- June 1978	Internship Military Hospital Bogota, Colombia	
July 1978- June 1981	Post Doctoral Fellowship Diagnostic Radiology, Sections of Ultrasound and Computed Tomography Yale University School of Medicine New Haven, CT	
July 1983-June 1985	Diagnostic Imaging Residency Yale New Haven Hospital New Haven, CT	

CAREER

November 2011 to present	Radiologist Connecticut Orthopaedic Specialists Hamden ,CT	
January 2009-present	Attending Physician, Diagnostic Imaging Yale New Haven Hospital, New Haven, CT	
August 2007 - 2016	Radiologist Reliant Medical Group formerly Fallon Clinic, Worcester, MA Precision Medical Imaging	
August 2007-2009	Radiologist Radiology Imaging Inc, Springfield, MA	
July 1987- August 2008	Senior Attending Radiologist Middlesex Hospital, Middletown, CT	
	Honorary Senior Attending Since August 2008	

July 1987-July 2007	Radiologist Radiological Associates ,Middletown, CT
July 1996 –June 2005	Attending Physician, Diagnostic Radiology Yale New Haven Hospital, New Haven, CT
July 1996 – June 1999	Attending Radiologist Veterans Administration Hospital, Rocky Hill, CT
July 1986 -June 1987	Radiologist Naugatuck and Watertown Radiology Philip M. Roth Feld M.D. P.C.
July 1985-June 1986	Attending Radiologist Diagnostic Imaging Yale New Haven Hospital New Haven , CT
July 1981-June 1983	Chief, Section of Ultrasound Radiology Department, Marley Clinic Bogota, Colombia
July 1981-June 1983	Chief, Section of Ultrasound Diagnostic Imaging Medical Center of los Andes Bogota, Colombia
TEACHING	
July 2014-present	Medical Director Radiologist and Physician Assistant Programs Quinnipiac University, Hamden, CT.
October 2013 – present	Director Community Access Imaging Quinnipiac University, Hamden, CT.
July 2012- present	Assistant Professor of Medical Sciences, Frank H. Netter School of Medicine Quinnipiac University, Hamden, CT.
January 2009-present	Clinical Assistant Professor, Diagnostic Radiology Yale University School of Medicine, New Haven, CT
April 2008- 2016	Director Radiology Assistant Program School of Health Sciences, Quinnipiac University, Hamden, CT

July 1996 –June 2005	Clinical Assistant Professor Diagnostic Imaging Yale University School of Medicine New Haven, CT
July 1985-June 1986	Instructor Diagnostic Radiology Yale University School of Medicine, New Haven , CT
July 1981- June 1983	Instructor, Radiology Department La Samaritana University Hospital Bogota, Colombia

COMMITTEES

2017-present	Member Inclusion and Diversity Council FH Netter MD School of Medicine, Quinnipiac University, Hamden, CT.
2017-present	Board of Directors Project Access New Haven
2013-present	Board of Directors Connecticut Foundation for Better Health
2010 - present	Voluntary Faculty Committee Diagnostic Imaging Department Yale University School of Medicine.
2009- present	American Registry of Radiologic Technologists Registered Radiologist Assistant Essay Evaluation Committee
2008- present	Radiologist Assistant Educational Council
2010-2014	Board of Governors New Haven County Medical Association
2011-2012	Foundations of Medicine Course Committee Frank Netter MD School of Medicine, Quinnipiac University
2011-2012	Search Committee Basic Science faculty School of Medicine, Quinnipiac University
2010 -2011	Search Committee Dean Medical School Quinnipiac University

PROFESSIONAL MEMBERSHIPS

American College of Radiology
 Radiologic Society of North America
 American Institute of Ultrasound In Medicine
 American Roentgen Ray Society
 Connecticut Radiology Society
 New England Roentgen Ray Society
 Connecticut State Medical Society

LICENSURE

Connecticut License #26003, 1984
Massachusetts License #53293, 1984
New York License #241869-1, 2006
New Jersey License # 25MA08218400, 2007
Pennsylvania License #MD431234, 2007
Virginia License # 0101242775, 2007
D.E.A. # AG 2958758
E.C.M.F.G. #359-759-8,1983
F.L.E.X. #550802028,1984

BOARD CERTIFICATION

Diplomate American Board of Radiology, 1987

AWARDS

“Health Care Visionary” Greater New Haven Chamber
June 13, 2017

PUBLICATIONS

Viscomi GN, **Gonzalez R**, Taylor KJW, Crade Ultrasonic evaluation of hepatic and splenic trauma. Arch Surg 115:320-321, 1980.

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Viscomi, GN, **Gonzalez R**, Mannes E, Taylor KJW: Histopathological correlation of ultrasound appearances of liver metastases. 3 Clin Gastroenterol 3:395-400,1981.

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Gonzalez R, Rosenfield AT: Traumatic Urinoma (Case Study). (In) Taylor KJW, Viscomi GN: "Emergency Room Ultrasound", Clinics of Diagnostic Ultrasound, April 1981.

Gonzalez R, Rosenfield AT: Iatrogenic Hepatic Hematoma (Case Study) (In) Taylor KJW, Viscomi GN: "Emergency Room Ultrasound", Clinics of Diagnostic Ultrasound, April 1981.

Bia MJ, Baggish D, Katz L, **Gonzalez R**, Kliger AS, Rosenfield AT: Computed tomography in the diagnosis of pelvic abscesses in renal transplant patients. JAMA 246:1435-1437, September 1981.

Pawar S, Kay CJ, **Gonzalez R**, Taylor KJW, Rosenfield AT: Sonography of splenic abscess. AJR 138:259-262, February 1982.

Gonzalez R, Richman AH, Taylor KJW, Rosenfield AT: Urinary tract ultrasonography. Finberg H, Edit. Clinics of Diagnostic Ultrasound, 9:29-30, Churchill Livingstone, New York, 1981.

Sommer FG, **Gonzalez R**, Taylor KJW: Computed tomography and ultrasound findings of a gas-containing splenic abscess. Yale J. Biol.Med.. 53:161-163, 1980.

Sommer FG, **Gonzalez R**, Taylor KJW: Prenatal ultrasonographic diagnosis of fetal cystic hygroma. Journal of the Interamerican College of Radiology, July 1980.

CHAPTERS

Gonzalez R, Siskind BN, Burrell MI: The radiographic evaluation of intestinal obstruction. Fielding P. And Welch J, editors. Intestinal obstruction, Clinical Surgery –1987 International, Churchill Livingstone.

Conlogue G, Viner M, Beckett R, Bekvalac J, **Gonzalez R**, Sharkey M, Kramer K, Koverman B.A Post-Mortem Evaluation of the Degree of Mobility in an Individual with Severe Kyphoscoliosis Using Direct Digital Radiography (DR) and Multi-Detector Computed Tomography (MDCT).Chapter in New Developments in the Bioarchaeology of Care. Further Case Studies and Expanded Theory Editors: Tilley, Lorna, Schrenk, Alecia A. Springer 2017

PRESENTATIONS

Viscomi GN, **Gonzalez R**, Taylor KJW: Ultrasound detection of uterine abnormalities after DES exposure. Proceedings, The Radiological Society of North America Annual Meeting, #94, 1979.

Woodward, J, C Gaither,**R Gonzalez**, R Beckett, G Conlogue, C Cool, S Groshong. Re-thinking Anthracosis: A Critical Re-examination of a DiagnosticTrend.7th World Congress on Mummy Studies San Diego, California. June 2011

T. Cassese, A. Bernard, M. Testa, **R. Gonzalez**, R. Palma: ApplyingVascular and Cardiac Sonography to Improve Medical Student Performance of Cardiac Auscultation and Assessment of Jugular Venous Pulsations.

NEGEA Annual Retreat The Warren Alpert Medical School of Brown University Providence, Rhode Island. April 8-9, 2016.

POSTER PRESENTATIONS

Conlogue, G, T Blyth, B Mele, J Posh, **R Gonzalez**, J Jones, J Li, N Pelletier. Tracking Bullet Trajectories: A Comparison of Multi-Detector Computed Tomography (MDCT) and Magnetic Resonance (MR) Proceedings of the 63rd Annual Scientific Meeting American Academy of Forensic ,Chicago ,Illinois.2011

Conlogue, G, T Blyth, J Li, R Beckett, A Dhody, **R Gonzalez**, Cerrone, M Schlenk, D Lindicsh. Revealing Her Secrets One Modality at a Time. 37th Annual North American Paleopathology Association Meeting Albuquerque, New Mexico. 2010

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Jordan Keller MHS RRA, Scott Blanchette MHS RRA, Michael Rolan MD, **Ramon Gonzalez MD**, Diego Nunez MD, Syed Bokhari MD. The Radiologist Assistant (RRA) Role in Emergency Radiology. American Society of Emergency Radiology, August 2014.

Effects of Training on ACL Volume in Female Intercollegiate Soccer Athletes : Gene Kim, Bernadette Mele, Karen Myrick, Richard Feinn, **Ramon Gonzalez**, Juan C. Garbalosa. Poster presentations at the American College of Sports Medicine Annual Conference in Boston, Mass., May 31 – June 4, 2016.

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Newman G, Rosenberg I, **Gonzalez R**, Tommasini S, Macica C. Pulmonary Function in adults with XLH who display Kyphoscoliosis. Accepted American Society for Bone and Mineral Research, 2017 Annual meeting, Denver Colorado.

PERSONAL

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203.453.1338

Born Bogota, Colombia

Citizenship U.S.

User, OHCA

From: Lazarus, Steven
Sent: Wednesday, July 19, 2017 9:23 AM
To: Glenn F. Elia; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; 'klg1@aol.com'
Subject: RE: OCHA Docket No. 16-32117-CON

Thank you Mr. Elia. OHCA will include this email in the original record and review the submitted material prior to closing the hearing. Please use this email as confirmation of receipt by OHCA of your email and the one attachment.

Sincerely,

Steven

Steven W. Lazarus

Associate Health Care Analyst
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7012
Fax: 860-418-7053
Email: steven.lazarus@ct.gov



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Cc: 'klg1@aol.com'
Subject: RE: OCHA Docket No. 16-32117-CON

Thank you for the notification, and again thank you for your time and consideration of this matter.

Best regards,
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Riggott, Kaila <Kaila.Riggott@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>

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Sent: Tuesday, July 25, 2017 11:19 AM
To: User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David; Lazarus, Steven
Cc: Yoder, Clark (clark.yoder@adrad.com); Glenn F. Elia; KLG1@aol.com
Subject: Docket No. 16-32117-CON -- Advanced Radiology Consultants Late File
Attachments: DOCS-#1619351-v1-ARC_COS_LATE_FILE.PDF

All:

Attached is Advanced Radiology Consultant's response to OHCA's Late File request.

Thanks and please let me know if you require anything further.

Jen

Jennifer Groves Fusco, Esq.
Principal
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
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Advanced Radiology Consultants, LLC

**COS's Request of Third MRI Unit for Orange & Essex
Docket No. 16-32117-CON**

July 25, 2017

Advanced Radiology Late File #1

In FY 2016, Connecticut Orthopaedic Specialists, P.C. ("COS") referred 51 Medicaid MRI scans to Advanced Radiology Consultants, LLC's ("ARC") offices located in Orange, Shelton, Stratford, Trumbull, and Fairfield. COS performed just 78 Medicaid scans in FY 2016, meaning COS referred nearly as many Medicaid MRI patients to ARC as it scanned in-house that year. COS suggested in its pre-hearing submissions and hearing testimony that many patients are referred to ARC because they require a type of MRI unit, or level of care, that COS cannot provide. OHCA has asked ARC to research the 51 COS Medicaid MRI referrals for FY 2016, and indicate the reasons for each referral.

In response to OHCA's request, ARC reviewed screening forms, requisitions and reports for the 51 Medicaid MRI scans referred by COS in FY 2016. In order to ascertain whether referral of a particular Medicaid patient was clinically indicated, ARC looked at factors including whether the scan was an arthrogram with intra-articular contrast; whether intravenous contrast was administered; and whether the COS physician ordering the scan made a specific request for 3.0 Tesla technology.

The results of ARC's review are set forth in the chart attached as Exhibit A. Please note the following:

- The number of COS-referred Medicaid MRI scans that required intravenous contrast was zero. Accordingly, COS is not referring Medicaid patients to ARC because they require intravenous contrast, which COS does not perform.
- The number of COS-referred Medicaid MRI scans that involved a COS physician's request for 3.0 Tesla technology was zero. In fact, only 19 of the 51 Medicaid MRI scans referred by COS were actually performed on 3.0 Tesla units. Accordingly, COS is not referring Medicaid patients to ARC because they require 3.0 Tesla MRI.
- Of the 51 COS-referred Medicaid MRI scans, 15 were MR arthrograms (MRI performed after the administration of intra-articular contrast). These are scans that could have been performed by COS, based on their testimony at the public hearing. But instead they were referred to ARC. Note that the amount Medicaid reimburses for MR arthrograms is

minimal. Accordingly, these scans result in an even greater loss of money to ARC than other Medicaid MRI scans. COS would experience these same losses if they performed MR arthrograms on their own Medicaid patients.

- All of the COS-referred Medicaid MRI scans were non-urgent requests. Based on the information reviewed by ARC, there were no clinical reasons why these patients could not have been scanned on the existing COS MRI units.

As ARC indicated at the public hearing, and as its record review confirmed, COS's direction of Medicaid patients to ARC has nothing to do with clinical need. More likely, it has to do with the lower rate of reimbursement for Medicaid MRI scans, particularly MR arthrograms. It is unclear exactly how COS decides which patients it will scan and which it will refer out. But the fact is Medicaid scans accounted for only .86% of COS's total MRI volume in FY 2016, or just 78 out of 9,108 scans. Compare this with COS's referral of 398 scans to ARC in FY 2016, 51 or 13% of which were Medicaid patients. ARC's ratio of Medicaid to non-Medicaid MRI scans for COS patients was 15 times greater than COS's ratio of Medicaid to non-Medicaid MRI scans for its own patients. Consider also that the practice referred almost as many Medicaid scans to ARC as it kept in-house last year (51 vs. 78), and it suggests that these patients are deliberately referred elsewhere.

In addition, COS was unable to provide specific information on other MRI providers who scan the practice's Medicaid patients. COS performed only 27 more Medicaid scans on its own patients in FY 2016 than ARC performed on COS patients. Assuming at least 28 COS Medicaid patients were referred to other non-COS providers for MRI scans, then COS scanned less of its own Medicaid patients than it referred out. This ratio is not likely to improve with the acquisition of a third MRI unit, given that COS is projecting only 17 additional Medicaid MRI scans between FY 2017 and FY 2020 when the service matures.

The foregoing shows a pattern of limited access to MRI services for COS's Medicaid patients. The acquisition of a third MRI unit and the nominal incremental increase in Medicaid scans will not enhance access to care for these individuals, as the CON statutes require. OHCA should not approve a CON for the acquisition of an MRI unit by a provider that limits access to Medicaid patients, particularly when it will have an adverse financial impact on a provider like ARC that provides MRI services to all patients regardless of payer source.

EXHIBIT A

Pt Identifier	ARC Location	Exam	Arthrogram/ Intraarticular contrast	Intravenous Contrast	COS Physician Request for 3.0 Tesla MRI	Non- Urgent Request
44895	FAIRFIELD	Cervical Spine	N	N	N	Y
2540	FAIRFIELD	Hip	N	N	N	Y
45954	FAIRFIELD	Hip	N	N	N	Y
91633	FAIRFIELD	Hip Arthrogram	Y	N	N	Y
61029	FAIRFIELD	Knee	N	N	N	Y
86508	FAIRFIELD	Shoulder Arthrogram	Y	N	N	Y
7600	ORANGE	Elbow	N	N	N	Y
89724	ORANGE	Elbow Arthrogram	Y	N	N	Y
36723	ORANGE	Hip	N	N	N	Y
89598	ORANGE	Hip Arthrogram	Y	N	N	Y
43232	ORANGE	Knee	N	N	N	Y
67261	ORANGE	Knee	N	N	N	Y
82181	ORANGE	Knee	N	N	N	Y
12276	ORANGE	Knee	N	N	N	Y
34648	ORANGE	Knee	N	N	N	Y
80275	ORANGE	Lumbar Spine	N	N	N	Y
2646	ORANGE	Shoulder Arthrogram	Y	N	N	Y
33174	ORANGE	Shoulder Arthrogram	Y	N	N	Y
80979	ORANGE	Wrist Arthrogram	Y	N	N	Y
24689	SHELTON	Ankle	N	N	N	Y
71257	SHELTON	Knee	N	N	N	Y
38953	SHELTON	Knee	N	N	N	Y
55353	SHELTON	Knee	N	N	N	Y
99524	SHELTON	Knee	N	N	N	Y
34511	SHELTON	Knee	N	N	N	Y
75191	SHELTON	Knee	N	N	N	Y
92469	SHELTON	Knee	N	N	N	Y
18860	SHELTON	Knee	N	N	N	Y
44437	SHELTON	Knee	N	N	N	Y
86705	SHELTON	Knee	N	N	N	Y
22209	STRATFORD	Ankle Arthrogram	Y	N	N	Y
14840	STRATFORD	Knee	N	N	N	Y
26563	STRATFORD	Knee	N	N	N	Y

32678	STRATFORD	Knee		N			N	N	N	Y
99641	STRATFORD	Knee		N			N	N	N	Y
20948	STRATFORD	Lumbar Spine		N			N	N	N	Y
78853	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
83101	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
95397	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
59655	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
37290	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
48641	STRATFORD	Shoulder Arthrogram		Y			N	N	N	Y
10970	STRATFORD	Wrist Arthrogram		Y			N	N	N	Y
78727	TRUMBULL	Knee		N			N	N	N	Y
24808	TRUMBULL	Knee		N			N	N	N	Y
90380	TRUMBULL	Knee		N			N	N	N	Y
39552	TRUMBULL	Knee		N			N	N	N	Y
63417	TRUMBULL	Knee		N			N	N	N	Y
75028	TRUMBULL	Knee		N			N	N	N	Y
2554	TRUMBULL	Shoulder		N			N	N	N	Y
75032	TRUMBULL	Thoracic Spine		N			N	N	N	Y

User, OHCA

From: Lazarus, Steven
Sent: Tuesday, July 25, 2017 1:53 PM
To: Jennifer Groves Fusco; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David
Cc: Yoder, Clark (clark.yoder@adrad.com); Glenn F. Elia; KLG1@aol.com
Subject: RE: Docket No. 16-32117-CON -- Advanced Radiology Consultants Late File

Thank you Jen. We'll have them added to the original record.

Steve

Steven W. Lazarus

Associate Health Care Analyst
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Fax: 860-418-7053
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From: Jennifer Groves Fusco [mailto:jfusco@uks.com]
Sent: Tuesday, July 25, 2017 11:19 AM
To: User, OHCA <OHCA@ct.gov>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>; Lazarus, Steven <Steven.Lazarus@ct.gov>
Cc: Yoder, Clark (clark.yoder@adrad.com) <clark.yoder@adrad.com>; Glenn F. Elia <gelia@ct-ortho.com>; KLG1@aol.com
Subject: Docket No. 16-32117-CON -- Advanced Radiology Consultants Late File

All:

Attached is Advanced Radiology Consultant's response to OHCA's Late File request.

Thanks and please let me know if you require anything further.

Jen

Jennifer Groves Fusco, Esq.
Principal
Updike, Kelly & Spellacy, P.C.
One Century Tower

265 Church Street
New Haven, CT 06510
Office (203) 786.8316
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User, OHCA

From: klg1@aol.com
Sent: Thursday, July 27, 2017 3:30 PM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; gelia@ct-ortho.com
Subject: Response to ARC's Late File #1
Attachments: COS Response to ARC Late File 7.27.17.docx; COS ATTACHMENT #1 Mobile MRI.docx; Medicaid 2016 by Revenue Category Units-8.docx; COS Response to ARC Late File 7.27.17.pdf; COS ATTACHMENT #1 Mobile MRI.pdf; Medicaid 2016 by Revenue Category Units.pdf

July 27, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find a document from Connecticut Orthopaedic Specialists, P.C. responding to Advanced Radiology Consultants' Late File #1 in OHCA Docket No. 16-32117-CON.

I would appreciate knowing that OHCA has received this email transmission with its 2 attachments and cover sheet, all documents in both Word and "pdf" format. If there are any problems in the transmission of these documents, please do not hesitate to call and let me know.

Thank you for your assistance.

Best regards,

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

Connecticut Orthopaedic Specialists, P.C.

**COS CON Application for Mobile MRI : Docket No. 16-32117-CON
July 27, 2017**

This document is in response to the Late File submitted by Advanced Radiology Consultants on July 25,2017.

The following points need a response:

- Advanced Radiology Consultants (ARC) submitted information to OHCA in the Statewide Health Services and Facilities Inventory that ARC had one open MRI in Orange and one in Trumbull. (See OHCA Exhibit 1, p.3). Then at the hearing on July 11, 2017, Mr. Yoder testified that ARC did not have any open MRI scanners. During a break in the hearing, COS called the ARC office in Orange, and was told that an appointment could be made for an MRI scan on their open scanner. On the Internet, at www.adrad.com, ARC advertises that it has open MRIs scanners at 5 additional locations: Orange, Fairfield, Stamford, Trumbull and Wilton. This does not include the new Stamford MRI recently approved by OHCA, giving ARC a total of eight (8) MRIs.

Patients, both Medicaid and non-Medicaid patients, are often in need of an open MRI either for claustrophobic reasons, or because of the size limitation of a standard MRI. In Late File #1, ARC created a list, at the request of OHCA, of the 51 COS Medicaid patients who were referred to ARC in FY2016 and created columns for the reasons the procedures were performed. There is no column for Medicaid patients who needed an Open MRI.

- Because ARC has so many more MRI locations than Connecticut Orthopaedic Specialists, P.C. ("COS"), Medicaid patients may find the ARC MRI locations more accessible for the MRI scan because they are closer to where the patients live and work. Assuming that the towns listed in the ARC table are the towns where the MRI scanning is performed, it is reasonable to assume that if you live in Fairfield and are being treated by a COS physician in the Orange service area, it would be advantageous for the patient to have the MRI performed closer to home and then return to the COS orthopedic physician in the Orange service area for treatment.
- But even the other towns that are listed, which are within the Orange service area are not locations where COS has an MRI scanner. COS patients currently go to Branford or Hamden for an MRI scan. And in FY2016, those two COS MRI units reached maximum capacity, making it difficult to schedule any new COS patients at those locations. So it is not inconceivable that many of the COS Medicaid patients chose to use an ARC office with an MRI scanner closer

to where they live or work, to save time out of work and the cost of transportation. This same rationale has undoubtedly been used by non-Medicaid patients as well since 2016.

- COS does not treat Medicaid patients any differently than any other patients. If COS does not have the MRI scanner required to obtain the image the orthopedic specialist needs for appropriate treatment, the Medicaid patient would be advised to go to a provider with the appropriate MRI unit for clinical reasons, not because COS does not want to perform the MRI scan because the reimbursement is lower.

COS would not tell any patient (Medicaid or non-Medicaid) to see another MRI provider if there were not a medical reason for doing so. ARC “suggests” that Medicaid patients were “deliberately referred elsewhere”, suggesting that, “it has to do with the lower rate of reimbursement for Medicaid MRI scans” ARC Late File #1, p.2.

- According to ARC’s own calculations, 398 COS patients were scanned at ARC in FY2016, of which 51 were Medicaid patients. ARC Late File #1, p.2. The other 347 were non-Medicaid patients, and therefore ARC did not receive the lower Medicaid rate for these patients. The 347 additional COS patients who came in to ARC for MRI scanning brought in far more revenue than was lost on the 51 scans done for Medicaid patients. The reimbursement issue appears to be important to ARC.
- COS has been a Medicaid provider since 1977. To say that COS deliberately refers Medicaid patients to other providers because of the lower rate of reimbursement is categorically incorrect. In FY2016, there were 6,442 Medicaid patient visits with COS physicians in their orthopedic practices, (and obviously were reimbursed at the lower Medicaid rate.) (See Attachment #1).

The volume of COS patients needing MRI scans is different than the volume of patients who are being treated by COS physicians. COS treats Medicaid, Medicare and charity patients. The CON application for a mobile MRI has focused only on the volumes involved in the scanning process. The number of COS Medicaid MRI patients has been increasing only in the last few years as other providers and clinics have closed their doors. The Medicaid patient numbers are growing, and so are the numbers for MRI scanning of the Medicaid population. This is expected to continue in the future. The COS projections for future Medicaid MRI volume in the application are very conservative. However, it is anticipated that with a mobile MRI unit available two days a week in the Orange area, more Medicaid patients who live in the Orange area will be able to get to the mobile MRI for an MRI scan rather than travel to Hamden, which is currently the closest COS MRI west of

New Haven. This will alleviate the number of COS Medicaid MRI patients going to other providers.

This CON application is specific to the acquisition of a mobile MRI. It has not focused on the orthopedic care that is being provided in each of the offices that make up COS. The fact that COS physicians had a total of 6,442 Medicaid patient visits in their practices in FY2016, should be sufficient evidence of the COS commitment to treating Medicaid patients. COS has never backed away from its responsibility to treat Medicaid patients, nor will it back away from that responsibility in the future.

ATTACHMENT #1

Medicaid Units 2016 for Connecticut Orthopaedic Specialists - TIN 06-0855842

Procedure: Revenue Category	Charge: Net Units	Insurance: Charge Primary Ins. Class
ARTHROGRAM	19	Medicaid
CASTING	381	Medicaid
CONSULTS	176	Medicaid
DME	491	Medicaid
FRACTURE CARE	219	Medicaid
HOSPITAL	36	Medicaid
IME	3	Medicaid
JOI TENDON INJECTIONS	552	Medicaid
LAB	94	Medicaid
MEDIA	2321	Medicaid
MRI	75	Medicaid
NERVE CONDUCTION	21	Medicaid
OV EST	3380	Medicaid
OV NEW	744	Medicaid
PAIN MANAGEMENT	76	Medicaid
POST OP	333	Medicaid
PT/OT	3310	Medicaid
RADIOLOGY	2337	Medicaid
SURGERY	723	Medicaid

User, OHCA

From: Lazarus, Steven
Sent: Thursday, July 27, 2017 3:31 PM
To: klg1@aol.com; User, OHCA; Hansted, Kevin; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; gelia@ct-ortho.com
Subject: RE: Response to ARC's Late File #1

Thank you Attorney Gerner.

Steven W. Lazarus

Associate Health Care Analyst
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7012
Fax: 860-418-7053
Email: steven.lazarus@ct.gov



From: klg1@aol.com [mailto:klg1@aol.com]
Sent: Thursday, July 27, 2017 3:30 PM
To: User, OHCA <OHCA@ct.gov>; Hansted, Kevin <Kevin.Hansted@ct.gov>; Lazarus, Steven <Steven.Lazarus@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>; Fernandes, David <David.Fernandes@ct.gov>
Cc: jfusco@uks.com; gelia@ct-ortho.com
Subject: Response to ARC's Late File #1

July 27, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find a document from Connecticut Orthopaedic Specialists, P.C. responding to Advanced Radiology Consultants' Late File #1 in OHCA Docket No. 16-32117-CON.

I would appreciate knowing that OHCA has received this email transmission with its 2 attachments and cover sheet, all documents in both Word and "pdf" format. If there are any problems in the transmission of these documents, please do not hesitate to call and let me know.

Thank you for your assistance.

Best regards,

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

User, OHCA

From: Jennifer Groves Fusco <jfusco@uks.com>
Sent: Saturday, July 29, 2017 7:58 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: 'klg1@aol.com'; Glenn F. Elia; Yoder, Clark
Subject: FW: Response to ARC's Late File #1
Attachments: DOCS-#1624800-v1-ARC_COS_REBUTTAL_(FINAL).pdf

Please see attached in response to COS's request for the number of Medicaid patients referred to ARC in need of "open" MRI services.

Thanks,
Jen

From: klg1@aol.com [mailto:klg1@aol.com]
Sent: Thursday, July 27, 2017 3:30 PM
To: OHCA@ct.gov; Kevin.Hansted@ct.gov; steven.lazarus@ct.gov; kaila.riggott@ct.gov; david.fernandes@ct.gov
Cc: Jennifer Groves Fusco; gelia@ct-ortho.com
Subject: Response to ARC's Late File #1

July 27, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find a document from Connecticut Orthopaedic Specialists, P.C. responding to Advanced Radiology Consultants' Late File #1 in OHCA Docket No. 16-32117-CON.

I would appreciate knowing that OHCA has received this email transmission with its 2 attachments and cover sheet, all documents in both Word and "pdf" format. If there are any problems in the transmission of these documents, please do not hesitate to call and let me know.

Thank you for your assistance.

Best regards,

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

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Advanced Radiology Consultants, LLC

**COS's Request of Third MRI Unit for Orange & Essex
Docket No. 16-32117-CON**

July 28, 2017

Response to COS

In its July 27, 2017 response to Advanced Radiology Consultants, LLC's ("ARC") Late File submission, Connecticut Orthopaedic Specialists, P.C. ("COS") states that ARC has neglected to include patients in need for open MRI as a category of referrals for Medicaid scans. Putting aside whether ARC's units are truly "open" units such as those needed to accommodate severely claustrophobic or obese patients versus simply larger-bore units, ARC has undertaken the review suggested by COS. Each requisition form for the 51 Medicaid scans referred by COS in FY 2016 has a box for the referring physician to check if the patient is claustrophobic. The box was unchecked on each of the 51 COS-referred Medicaid MRI scan requisitions.

In addition, COS still has not provided the total number of Medicaid MRI scans required by its patients so that these could be compared to the 78 Medicaid scans performed in-house in FY 2016. COS had a total of 6,442 Medicaid patient visits in FY 2016. By its own calculation, 15.6% of COS patients need MRI scans (CON Application, p. 26). If these Medicaid visits are unduplicated patients, that means approximately 1,005 Medicaid MRI scans were ordered. Even if there was some duplication of patient visits, the total number of Medicaid MRI scans ordered by COS physicians likely far exceeds the 78 scans performed in-house by the practice in FY 2016, or the 101 Medicaid scans that the practice will top out at by FY 2020.

User, OHCA

From: klg1@aol.com
Sent: Monday, July 31, 2017 8:51 AM
To: User, OHCA; Hansted, Kevin; Lazarus, Steven; Riggott, Kaila; Fernandes, David
Cc: jfusco@uks.com; gelia@ct-ortho.com
Subject: COS CON Application Docket No. 16-32117-CON
Attachments: COS Response to ARC #3 7.30.17.docx; COS Response to ARC #3-1 7.30.17.pdf

July 31, 2017

Hearing Officer Hansted and OHCA Staff,

Attached please find a document from Connecticut Orthopaedic Specialists, P.C. responding to Advanced Radiology Consultants' Response to COS dated July 28, 2017 in OHCA Docket No. 16-32117-CON.

I would appreciate knowing that OHCA has received this email transmission with its 1 attachment in both Word and "pdf" format. If there are any problems in the transmission of these documents, please do not hesitate to call and let me know.

Thank you for your assistance.

Best regards,

Patricia A. Gerner
The Law Office of Patricia A. Gerner, LLC

klg1@aol.com

Response to ARC's Document dated July 28, 2016

ARC has taken a number used by COS (6,442) Medicaid patient visits in FY2016, and has tried to turn that number into the total number of Medicaid patients treated by COS in 2016. The document COS submitted to support the number of Medicaid visits is titled "Medicaid Units", not Medicaid patients. If this were a listing of Medicaid patients, the listing would have zip codes to identify each patient's residence. The chart that is attached to the COS 2nd Late File lists procedures.

The COS Medicaid population has always been a very small percentage of its total population when compared to all other types of payers combined. COS submitted that information regarding the number of Medicaid visits to the orthopedic physicians so that OHCA would understand that COS does treat Medicaid patients in its orthopedic practice.

Conn. Gen. Stat. Sec. 19a-639(a) requires that an applicant demonstrate that it has not failed to provide Medicaid services. COS has demonstrated that it treats Medicaid patients within its orthopedic practice, as well as its MRI service. In FY2016 when it could not accommodate all of the Medicaid patients who required scanning, 51 of them were referred to ARC along with 347 non-Medicaid patients. Approximately 85% of all of the patients sent to ARC in 2016 from COS were non-Medicaid patients, with only 15% being Medicaid patients. This should demonstrate that COS could not accommodate any more of its patients on its own MRIs, and needed to refer many of them out of the COS practice. COS did not selectively send Medicaid only patients to ARC.

COS is not cost-shifting its patients who have a lower reimbursement amount out to other facilities as ARC seems to be suggesting. If that were the case, COS would not have sent 347 non-Medicaid patients to ARC in 2016 along with 51 Medicaid patients. This was done because COS had no room in Branford or Hamden to accommodate all of its MRI patients. While COS is comfortable with its Medicaid participation at this point, along with its efforts to try to expand the volume of Medicaid patients it sees, if OHCA has any reservations or concerns, COS is willing to meet any specific volume of Medicaid patients that OHCA believes is appropriate.

As a condition of approval, COS is willing to accept a set percentage of Medicaid patients for MRI scanning on an annual basis. A threshold can be established so that COS is accepting what OHCA considers a fair percentage of Medicaid MRI scanning in the two service areas where it seeks to use a mobile MRI scanner.

User, OHCA

From: Fernandes, David
Sent: Wednesday, August 09, 2017 10:05 AM
To: User, OHCA; jfusco@uks.com; klg1@aol.com; gelia@ct-ortho.com; Yoder, Clark
Cc: Lazarus, Steven; Riggott, Kaila; Hansted, Kevin
Subject: 16-32117 Close of Public Hearing
Attachments: 16-32117 closure of hearing.pdf

Good Morning,

Please see the attached letter, closing the hearing held on July 11, 2017, in the matter referenced above. Any questions, please feel free to contact me directly.

Sincerely,

David Fernandes

Planning Analyst (CCT)

Office of Health Care Access

Connecticut Department of Public Health

410 Capitol Avenue, Hartford, Connecticut 06134

P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Healthcare Access

August 9, 2017

VIA EMAIL ONLY

Patricia A. Gerner, Esq.
The Law Office of Patricia A. Gerner, LLC.
240 Ramstein Road
P.O. Box 209
New Hartford, CT 06057

RE: Docket Number 16-32117-CON
Aquisition of a mobile 1.5T magnetic resonance imaging scanner.

Dear Attorney Gerner:

Please be advised, by way of this letter, the public hearing held on July 11, 2017, in the above referenced docket is hereby closed as of August 9, 2017. The Office of Health Care Access will receive no additional public comments or filings.

If you have any questions regarding this matter, please feel free to contact Kaila Riggott at (860) 418-7037.

Sincerely,

Kevin T. Hansted
Hearing Officer

C: Jennifer Groves Fusco, Esq.



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Hartford, Connecticut 06134-0308
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Affirmative Action/Equal Opportunity Employer



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Certificate of Need Agreed Settlement

Applicant: Connecticut Orthopaedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518

Docket Number: 16-32117-CON

Project Title: Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

Project Description: Connecticut Orthopaedic Specialists, P.C. ("COS" or "Applicant") is proposing to acquire and operate a mobile 1.5 Tesla magnetic resonance imaging ("MRI") scanner to be located at 330 Boston Post Road, Orange, Connecticut and 12 Bokum Road, Essex, Connecticut at an associated capital cost of \$730,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in the *Hartford Courant* (Hartford) on June 27, 28 and 29, 2016, the *New Haven Register* (New Haven) on June 27, 28 and 29, 2016, the *Middletown Press* (Middletown) on June 27, 28 and 29, 2016, and the *Connecticut Post* (Bridgeport) on July 7, 8 and 9, 2016. On August 22, 2016, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on May 19, 2017.

On May 31, 2017 OHCA received a written request for a public hearing from Advance Radiology Consultants, LLC ("ARC"), in accordance with Connecticut General Statute sec. 19a-639a(e). On June 8, 2017, the Applicant was notified of the date, time, and place of the public hearing. On that same date, a notice to the public announcing the hearing was published in the *New Haven Register* and the *Hartford Courant*. On June 27, 2017, ARC filed a petition requesting intervenor status. ARC was granted intervenor status with full rights. Pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(f)(2), a public hearing regarding the CON application was held on July 11, 2017.



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Affirmative Action/Equal Opportunity Employer



Commissioner Pino designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform-Administrative Procedure Act (Chapter 54 of Conn. Gen. Stat.). The public hearing record was closed on August 9, 2017. Deputy Commissioner Addo considered the entire record in this matter.

Findings of Fact and Conclusions of Law

1. Connecticut Orthopaedic Specialists, P.C. (“COS” or “Applicant”) is a private orthopedic physician practice in the south-central Connecticut region. COS provides care for children and adults with musculo-skeletal injuries and diseases. Ex. A, p. 15.
2. COS has physician offices in Hamden, Branford, Orange, Essex, Madison, New Haven, Milford, Shelton and Wallingford with two fixed 1.5 Tesla (“T”) magnetic resonance imaging scanners (“MRI”) in the Hamden and Branford offices. Ex. A, pp. 15, 51; Ex. E, p. 256.
3. COS only performs MRI scans on COS patients and does not accept scan referrals from other providers. Ex. A, p. 27.
4. Between fiscal year (“FY”) 2014 and 2015, COS merged with four private practice orthopedic physician groups, increasing the total number of COS offices from 8 to 21. Ex. A, p. 16; Ex. E, p. 256.
5. As a result of the merging of the physician practices, the number of COS patients requiring scans increased. Even with extended hours of operation, increasing from 64 to 75 hours per week in both Hamden and Branford in 2016, COS was not able to accommodate the number of necessary scans. Ex. A, pp. 17, 23, 25-26.
6. As shown in the table below, the Applicant experienced a 45% increase in the number of scans performed from FY2014 to FY2016 due to the increased volume resulting from its recent mergers.

TABLE 1
COS’ HISTORICAL NUMBER OF SCANS PERFORMED BY FISCAL YEAR

Equipment	Fiscal Year*			
	2014	2015	2016	2017
Branford MRI	2,577	3,851	4,698	4,839
Hamden MRI	3,725	3,773	4,410	4,542
Grand Total	6,302	7,624	9,108	9,381

*Applicant’s fiscal year is January 1 to December 31.
Ex. A, pp. 33, 52; Ex. E, pp. 253-254, 256; Ex. G, pp. 278-279.

7. COS is proposing the acquisition of a GE 1.5T mobile MRI to be shared between its Orange and Essex locations, operating at each site two days per week. Ex. A, pp. 15, 20, 23, 34, 51.
8. The Applicant selected to operate the mobile MRI at its Orange office due to the office’s geographic proximity to six existing COS offices, none of which currently have on-site MRI capabilities. Ex. A, pp. 17-18, 25, 27.
9. The Applicant selected to operate the mobile MRI at its Essex location due to the lack of an MRI machine at that or its Madison office, as well as the lack of any non-hospital based MRI machines nearby. The majority of patients originating from these offices currently receive scans from Middlesex Hospital’s Shoreline site MRI. Ex. A, pp. 17-18, 25, 27.

10. The Applicant divided its service area into two regions based on its two proposed locations for the mobile MRI: the “Orange Region” and the “Essex Region.” Each consists of:
 - a. The town in which the MRI was to be located (i.e., either Orange or Essex),
 - b. Towns contiguous to either Essex or Orange from which COS drew patients in FY2015, and
 - c. Towns adjacent to the contiguous towns. Ex. A, p. 24.
11. Based upon the Applicant’s stated defined service areas, the service areas are as follows:

**TABLE 2
SERVICE AREA TOWNS**

Mobile MRI Location	Town
Orange	Ansonia, Bethany, Derby, East Haven, Hamden, Milford, Monroe, New Haven, North Haven, Orange, Seymour, Shelton, Stratford, Trumbull, West Haven, Woodbridge
Essex	Chester, Clinton, Deep River, East Haddam, East Lyme, Essex, Killingworth, Old Lyme, Old Saybrook, Salem, Westbrook

Ex. A, pp. 24, 27, 40-41.

12. The Hamden and Branford scanners were unavailable for 82 hours during FY2016 for scanner and building maintenance and American College of Radiology (“ACR”) testing. The mobile MRI will provide back up for periods when the existing MRIs are inoperable. Ex. E, pp. 256, 273-274.
13. Of COS patients originating from the Orange Region in 2015, 2,430 scans were performed by COS at its Hamden location and 1,686 scans were performed at its Branford location. Ex. A, pp. 179-181.
14. Of COS patients originating from the Essex Region in 2015, 33 received scans at COS’ Hamden location and 309 at its Branford location. Ex. A, pp. 179-181.

15. As shown below, there are 24 existing scanners in the Orange Region, which has a population of 577,680.¹

**TABLE 3
EXISTING SCANNERS IN THE ORANGE REGION IN 2016**

Location type	Facility Name	City	Tesla Strength	Number of Scans 2016
Hospital-Based	Griffin Hospital	Derby	1.5	2,663
	Milford Hospital, Inc.	Milford	1.5	1,193
	Yale New Haven Hospital, Inc.	New Haven	1.5	5,741
	Yale New Haven Hospital, Inc.	New Haven	1.5	3,980
	Yale New Haven Hospital, Inc.	New Haven	3	4,579
	Yale New Haven Hospital, Inc.	New Haven	3	6,098
	Yale New Haven Hospital, Inc.	New Haven	3	2,371
	Yale New Haven Hospital, Inc.	New Haven	3	7,320
	Yale New Haven Hospital, Inc.	New Haven	1.5	4,193
	Yale New Haven Hospital, Inc.	New Haven	3	2,689
Hospital Satellite Location	Bridgeport Hospital	Trumbull	3	1,469
	Griffin Imaging and Diagnostics Center at Ivy Brook	Shelton	1.2	2,421
	Yale-New Haven Hospital, Inc. (North Haven Radiology)	North Haven	3	3,820
	Yale-New Haven Hospital, Inc. (Temple Radiology New Haven)	New Haven	1.5	2,066
	Yale-New Haven Hospital, Inc. at Chapel Street Campus	New Haven	1.5	3,175
	Yale-New Haven Hospital, Inc. at Chapel Street Campus	New Haven	3	4,010
Non-Hospital Based	Advanced Radiology Consultants, LLC	Orange	3	4,274
	Advanced Radiology Consultants, LLC	Shelton	1.5	2,441
	Advanced Radiology Consultants, LLC	Stratford	1.5	5,636
	Advanced Radiology Consultants, LLC	Trumbull	1.5	6,396
	Connecticut Orthopaedic Specialists, P.C.	Hamden	1.5	4,339
	Diagnostic Imaging of Milford	Milford	0.7	1,800
	Fairfield County Imaging, LLC	Trumbull	1	NOTE: new 2017
	Southern Connecticut Imaging Center LLC d/b/a Whitney Imaging Center	Hamden	1.5	5,945

¹ US Census Bureau, *State Population Totals Tables 2010-2016*, available at <https://www.census.gov/data/tables/2016/demo/popest/state-total.html>.

Statewide Health Care Facilities and Services Inventory-2016, accessed on 10/26/17.
<http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>

16. Twelve of the machines located in the Orange Region were operating at or above their estimated scan capacities in 2016.
17. Of the 12 machines with available scan capacity in the Orange Region, seven were non-hospital or hospital satellite based.
18. Only three non-hospital based machines with available capacity in the Orange Region were of a comparable strength--1.5T or greater—to that proposed by the Applicant.
19. In 2016, 88,619 scans were performed on scanners in the Orange region placing overall utilization at 92.31%. This is an increase of 21,725 scans from 2014. Statewide Health Care Facilities and Services Inventory-2014, 2016, accessed on 10/26/17.
<http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>
20. There is only one MRI scanner located within the Essex Region, located at Middlesex Hospital's Shoreline Medical Center campus in Westbrook. In 2016, it performed 3,422 scans, an increase of 876 scans from 2014. Statewide Health Care Facilities and Services Inventory-2014, 2016, accessed on 10/26/17. <http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>
21. COS projects a 15.7% increase in volume in FY2018 based on its retention of scan patients, rather than directing them to another provider.

TABLE 4
COS'S PROJECTED NUMBER OF SCANS

	FISCAL YEAR*		
	2018	2019	2020
Number of Scans by Scanner:			
Branford MRI	3,870	3,986	3,986
Hamden MRI	3,870	3,986	3,986
Orange MRI	1,545	1,591	1,591
Essex MRI	1,577	1,624	1,624
Total	10,862	11,187	11,187

* Applicant's fiscal year is January 1 to December 31.

The decreased volume of Hamden and Branford is attributable to those facilities' reduction in hours of operation to pre-merger levels.

Ex. A, pp. 33-34, 52-53, 55; Ex. G, pp. 278-279.

22. Patients who previously received MRI scans from other providers will continue to have the option to seek services from hospitals, outpatient clinics and non-COS imaging centers. Ex. A, pp. 36-38.
23. COS will continue to refer patients to outside providers in the event it does not have the capability to perform a particular scan required by the patient. Ex. V, Transcript, Mr. Elia, p. 108.
24. COS projects the payer mix will remain unchanged as a result of the proposal.

**TABLE 5
COS'S CURRENT & PROJECTED PAYER MIX**

Payer	CFY2017		Projected by Fiscal Year					
			2018		2019		2020	
	Scans	%	Scans	%	Scans	%	Scans	%
Medicare*	1,998	21.3%	2,314	21.3%	2,383	21.3%	2,383	21.3%
Medicaid*	84	.9%	98	.9%	101	.9%	101	.9%
CHAMPUS & TriCare	0	0%	0	0%	0	0%	0	0%
Total Government	2,083	22.2%	2,411	22.2%	2,484	22.2%	2,484	22.2%
Commercial Insurers	6,351	67.7%	7,354	67.7%	7,574	67.7%	7,574	67.7%
Uninsured	9	.1%	11	.1%	11	.1%	11	.1%
Workers Compensation	938	10%	1,086	10%	1,119	10%	1,119	10%
Total Non-Government	7,298	77.8%	8,451	77.8%	8,703	77.8%	8,703	77.8%
Total Payer Mix	9,381	100%	10,862	100%	11,187	100%	11,187	100%

*Includes managed care activity.

Ex. A, p. 44; Ex. C, p. 222; Ex. E, pp. 254, 260; Ex. G, p. 278.

25. The Applicant has adopted a Charity Care Policy based on a patient's insurance coverage status and income level relative to federal poverty guidelines. Ex. A, pp. 24, 28, 176.

26. COS does not charge a facility fee at any of its current or proposed MRI scanning offices. Ex. A, pp. 18, 24, 31; Ex. M, p. 2.

27. The proposal's total capital expenditure is shown below:

**TABLE 6
COS'S TOTAL PROPOSED CAPITAL EXPENDITURE**

Item	Cost
Equipment (Medical, Non-Medical, Imaging)	\$575,000
Construction/Renovation	\$155,000
Total Capital Expenditure	\$730,000

Ex. C, p. 223.

28. First Niagara has approved COS for a loan in an amount sufficient to finance the purchase of the scanner and anticipated construction costs. Ex. A, p. 205.

29. The Applicant projects no incremental losses from operations.

**TABLE 7
COS'S PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY2018*	FY2019*	FY2020*
Revenue from Operations	\$875,271	\$1,067,346	\$1,067,346
Total Operating Expenses	\$543,694	\$568,420	\$572,939
Gain/Loss from Operations	\$331,577	\$498,926	\$494,407

*COS's fiscal year is Jan. 1-Dec. 31.

Ex. A, pp. 32, 42; Ex. G, p. 279.

30. A physician will be present during the operation of the mobile MRI. Ex. V, Transcript, Mr. Elia, p. 95.

31. The mobile MRI will be accredited by the ACR. Ex. A, p. 22; Ex. V, Transcript, Mr. Elia, pp. 66, 92.

32. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)) (Ex. A, p. 22).
33. This proposal is consistent with the overall goals of the Statewide Health Care Facilities and Service Plan. (Conn. Gen. Stat. § 19a-639(a)(2)) (Ex. A, pp. 22-24; Ex. C, p. 221).
34. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)) (Ex. A, pp. 24-28).
35. The Applicant has demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)) (Ex. A, pp. 31-33, 41-42, 200-218; Ex. G, pp. 279-283).
36. The Applicant has satisfactorily demonstrated that the proposal will improve the accessibility and cost effectiveness of health care delivery in the region while also maintaining quality. (Conn. Gen. Stat. § 19a-639(a)(5)) (Ex. A, pp. 28-30; Ex. C, pp. 221-222, 224).
37. The Applicant has shown that there would be no adverse change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)) (Ex. A, pp. 33-35, 42-43; Ex. E, p. 260; Ex. G, pp. 278-279).
38. The Applicant has satisfactorily identified the population to be affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)) (Ex. A, pp. 35-36, 44-45).
39. The Applicant's historical provision of services in the area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)) (Ex. A, pp. 36-37, 45-48).
40. The Applicant has satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)) (Ex. A, pp. 37-38; Ex. C, pp. 219-221; Ex. E, p. 249-252).
41. The Applicant has demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)) (Ex. A, p. 31; Ex. C, p. 222).
42. The Applicant has demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)) (Ex. A, p. 38).
43. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or access to care. (Conn. Gen. Stat. § 19a-639(a)(12)) (Ex. A, p. 31).

DISCUSSION

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

The Applicant, Connecticut Orthopaedic Specialists, is a private orthopedic physician practice. Office locations are primarily in southern Connecticut with two 1.5T MRI units located in Hamden and Branford offices. COS began expanding in 2014 and increased its offices from eight to 21. As a result of the expansion, the number of COS patients requiring an MRI scan has increased, causing the current scanners to operate at or above their capacity. To address the growth in volume, COS has extended its MRIs' hours of operations. Even with the extension of hours, the demand for MRI services exceeds the available openings. As a result, COS proposes to obtain a mobile MRI to be shared between its Orange and Essex locations. *FF 1-7*.

The Applicant has demonstrated a clear public need for an MRI in the Orange and Essex regions.

There has been a demonstrated increase in the demand for MRI scans in the area served by COS. From 2014 to 2016, the number of scans COS performed increased by 45%. Likewise, the reported number of scans performed by all providers in the Orange and Essex Regions cumulatively increased by 33% from 2014 to 2016. *FF 6, 15-16*.

The sole MRI machine currently located in the Essex Region performed 3,422 scans in 2016, or 85% of its estimated operating capacity of 4,000 scans per year. Notably, there are currently no machines that are not hospital-based to serve the population of approximately 91,227² in the region. Of the 24 MRI machines in the Orange Region, which has a population of 577,680,³ 12 were operating at or above their estimated operating capacities. Of the 12 machines with available scan capacity, only three were non-hospital based and of a 1.5T strength or greater. *FF 14, 16*.

The influx of patients from COS's merger with four other physician practices has resulted in COS's scanners operating above their maximum capacities--with the Branford-based MRI performing 4,698 scans and the Hamden MRI performing 4,410 in 2016. Consequently, COS has had little scheduling flexibility and patients experienced delays when scanners were inoperable, as was the case in FY 2016 when the scanners were down for unscheduled maintenance for a total of 82 hours. *FF 6, 11*.

Not only will the addition of the machine provide increased access to the COS patients in the Essex and Orange Region, it will also alleviate demand on COS's existing machines and open appointments for patients presenting at COS's Branford and Hamden offices. With the introduction

² US Census Bureau, *State Population Totals Tables 2010-2016*, available at <https://www.census.gov/data/tables/2016/demo/popest/state-total.html>

³ *Id.*

of the mobile scanner in those offices, as many as 1,995 fewer scans would be performed in Branford and 2,463 fewer in Hamden. *FF 12-13.*

The Applicant has shown the proposal will improve diversity of health care providers and cost effectiveness of health care delivery in the region.

Patients seeking MRI services in the proposed area are expected to benefit from having a non-hospital option in an area dominated by hospital-based providers. Due to variances in insurance reimbursement and coverage, non-hospital based MRIs may be significantly more cost efficient for patients. Furthermore, COS does not charge a facility fee at any of its offices. These factors coupled with the Applicant's recent adoption of a Charity Care Policy will enable the uninsured and underinsured an additional provider to receive MRI services. *FF 21-22.*

Additionally, COS has secured a loan sufficient to cover the purchase price of an MRI machine as well as projected renovation costs and the Applicant projects incremental gains from FY2018 through FY2020. As such, the proposal is financially feasible for the Applicant. *FF 24-25.*

The Applicant has satisfactorily demonstrated how the proposal will impact Medicaid payers.

COS has indicated it has and continues to accept Medicaid recipients practice-wide. In 2017, Medicaid patients represented only 0.9% of COS's patients receiving scans. To ensure an appropriate level of Medicaid recipients are served in the area, COS has agreed to accept a set percentage of Medicaid patients for MRI scanning on an annual basis and develop an outreach plan for Medicaid patients.⁴ The Applicant shall take the actions as stated in the order attached hereto. *FF 20*

An additional MRI will alleviate the capacity constraints experienced at COS's existing MRI facilities, increasing accessibility for COS patients who will now be able to be accommodated within the practice.

⁴ Ex. AA.

ORDER

Based upon the foregoing Findings of Fact and Discussion, the Applicant's request to acquire and operate a 1.5 Tesla mobile MRI scanner to be located at 330 Boston Post Road, Orange, Connecticut and 12 Bokum Road, Essex, Connecticut, is hereby **Approved** under Conn. Gen. Stat. § 19a-639(a) subject to the enumerated conditions (the "Conditions") set forth below.

All references to days in these Conditions shall mean calendar days, and OHCA shall mean the Office of Health Care Access or its successor.

1. Connecticut Orthopaedic Specialists ("COS") shall not operate the mobile MRI that is the subject of this application prior to its receiving accreditation from the American College of Radiology ("ACR").
2. COS shall submit to OHCA documentation confirming ACR accreditation not more than 30 days within its receipt of notification of accreditation.
3. The "operational year" is a reporting period commencing on the date upon which COS begins performing scans on patients. There shall be, for the purposes of this Order, one operational start date for both the Orange and Essex locations.
4. COS shall, within two weeks of commencing operation, notify OHCA in writing of its start date.
5. COS shall take all practical steps to achieve a payer mix, based on cumulative patient volume at the Orange and Essex offices, which includes 5% Connecticut Medicaid patients for its orthopedic services within the first year of operation of the MRI. Within sixty (60) days of the execution of this Agreement, COS shall provide a plan detailing the steps to be taken to achieve the targeted payer mix. COS shall report such payer mix to OHCA at the end of its first year of operation of the mobile MRI services and if this threshold is not met, COS shall submit such documentation as OHCA determines appropriate to demonstrate COS's efforts to re-evaluate its outreach initiatives and develop strategies to increase utilization by Connecticut Medicaid patients.
6. COS shall not divert any Medicaid patients to other non-COS providers for MRI scans for any reasons other than those based on medical necessity or patient preference.

7. COS shall submit annual reports to OHCA for three years for the information outlined in the example tables below. The annual periods shall be based upon COS's operational year. The report is due no later than two (2) months after the end of each annual period.

a. The number of *unduplicated patients treated at the Orange and Essex locations* for all orthopedic/specialty services by payer category.

Connecticut Orthopaedic Specialists Orange* & Essex Location								
	Total	Medicare	Medicaid	CHAMPUS/ Tricare	Commercially Insured	Uninsured	Self-Pay	Workers' Comp
COS Patients								
Percent (%)								

* excludes OrthoNOW patients at the Orange office

b. The number of unduplicated patients at the Orange and Essex locations *receiving MRIs* on the mobile machine by payer category

Connecticut Orthopaedic Specialists Essex & Orange Location*								
	Total	Medicare	Medicaid	CHAMPUS / Tricare	Commercially Insured	Uninsured	Self-Pay	Workers' Comp
MRI Patients								
Percent (%)								

* excludes OrthoNOW patients at the Orange office

c. The number of COS orthopedic patients (presenting at the Orange or Essex offices only) covered by Medicaid who required MRI scan(s) but received such scan(s) at a non-COS provider; list the reasons said patients could not be accommodated and the aggregate number who could not be for each reason. Omit patient identifiable information. The table below is for demonstrative purposes only and may be modified to reflect additional/other reasons.

Reason Received Non-COS Scan	Number of Medicaid Patients
Patient choice	
Medical necessity (i.e., Tesla limitation, bore size, etc.)	
Lack of scheduling availability	
Other (indicate)	
Total	

8. COS shall operate the mobile MRI machine that is the subject of this authorization exclusively in the towns of Orange and Essex and shall not perform or authorize the performance of any scans on the approved mobile unit outside of these towns.

9. The proposed mobile MRI shall operate for no more than two days at COS's Essex office and two days at its Orange office.
10. COS shall not replace or upgrade the mobile MRI without prior authorization from OHCA.
11. OHCA and COS agree that this settlement represents a final agreement between OHCA and the Applicant with respect to OHCA Docket No. 16-32117-CON. The execution of this settlement resolves all objections, claims and disputes, which may or could have been raised by COS with regard to OHCA Docket Number 16-32117-CON.
12. OHCA may enforce this settlement under the provisions of Conn. Gen. Stat. §§ 19a-642; 19a-653 and all other remedies available at law, with all fees and costs of such enforcement to be paid by the Applicant.
13. This settlement shall be binding upon the Applicant and its successors and assigns.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

Date

Yvonne T. Addo, MBA
Deputy Commissioner

Date

Duly Authorized Agent for Connecticut
Orthopaedic Specialists, P.C.

Signed by _____

(Print name)

(Title)

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Certificate of Need Agreed Settlement

Applicant: Connecticut Orthopaedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518

Docket Number: 16-32117-CON

Project Title: Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner

Project Description: Connecticut Orthopaedic Specialists, P.C. ("COS" or "Applicant") is proposing to acquire and operate a mobile 1.5 Tesla magnetic resonance imaging ("MRI") scanner to be located at 330 Boston Post Road, Orange, Connecticut and 12 Bokum Road, Essex, Connecticut at an associated capital cost of \$730,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in the *Hartford Courant* (Hartford) on June 27, 28 and 29, 2016, the *New Haven Register* (New Haven) on June 27, 28 and 29, 2016, the *Middletown Press* (Middletown) on June 27, 28 and 29, 2016, and the *Connecticut Post* (Bridgeport) on July 7, 8 and 9, 2016. On August 22, 2016, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on May 19, 2017.

On May 31, 2017 OHCA received a written request for a public hearing from Advance Radiology Consultants, LLC ("ARC"), in accordance with Connecticut General Statute sec. 19a-639a(e). On June 8, 2017, the Applicant was notified of the date, time, and place of the public hearing. On that same date, a notice to the public announcing the hearing was published in the *New Haven Register* and the *Hartford Courant*. On June 27, 2017, ARC filed a petition requesting intervenor status. ARC was granted intervenor status with full rights. Pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(f)(2), a public hearing regarding the CON application was held on July 11, 2017.



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Affirmative Action/Equal Opportunity Employer



Commissioner Pino designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform-Administrative Procedure Act (Chapter 54 of Conn. Gen. Stat.). The public hearing record was closed on August 9, 2017. Deputy Commissioner Addo considered the entire record in this matter.

Findings of Fact and Conclusions of Law

1. Connecticut Orthopaedic Specialists, P.C. (“COS” or “Applicant”) is a private orthopedic physician practice in the south-central Connecticut region. COS provides care for children and adults with musculo-skeletal injuries and diseases. Ex. A, p. 15.
2. COS has physician offices in Hamden, Branford, Orange, Essex, Madison, New Haven, Milford, Shelton and Wallingford with two fixed 1.5 Tesla (“T”) magnetic resonance imaging scanners (“MRI”) in the Hamden and Branford offices. Ex. A, pp. 15, 51; Ex. E, p. 256.
3. COS only performs MRI scans on COS patients and does not accept scan referrals from other providers. Ex. A, p. 27.
4. Between fiscal year (“FY”) 2014 and 2015, COS merged with four private practice orthopedic physician groups, increasing the total number of COS offices from 8 to 21. Ex. A, p. 16; Ex. E, p. 256.
5. As a result of the merging of the physician practices, the number of COS patients requiring scans increased. Even with extended hours of operation, increasing from 64 to 75 hours per week in both Hamden and Branford in 2016, COS was not able to accommodate the number of necessary scans. Ex. A, pp. 17, 23, 25-26.
6. As shown in the table below, the Applicant experienced a 45% increase in the number of scans performed from FY2014 to FY2016 due to the increased volume resulting from its recent mergers.

TABLE 1
COS’ HISTORICAL NUMBER OF SCANS PERFORMED BY FISCAL YEAR

Equipment	Fiscal Year*			
	2014	2015	2016	2017
Branford MRI	2,577	3,851	4,698	4,839
Hamden MRI	3,725	3,773	4,410	4,542
Grand Total	6,302	7,624	9,108	9,381

*Applicant’s fiscal year is January 1 to December 31.

Ex. A, pp. 33, 52; Ex. E, pp. 253-254, 256; Ex. G, pp. 278-279.

7. COS is proposing the acquisition of a GE 1.5T mobile MRI to be shared between its Orange and Essex locations, operating at each site two days per week. Ex. A, pp. 15, 20, 23, 34, 51.
8. The Applicant selected to operate the mobile MRI at its Orange office due to the office’s geographic proximity to six existing COS offices, none of which currently have on-site MRI capabilities. Ex. A, pp. 17-18, 25, 27.
9. The Applicant selected to operate the mobile MRI at its Essex location due to the lack of an MRI machine at that or its Madison office, as well as the lack of any non-hospital based MRI machines nearby. The majority of patients originating from these offices currently receive scans from Middlesex Hospital’s Shoreline site MRI. Ex. A, pp. 17-18, 25, 27.

10. The Applicant divided its service area into two regions based on its two proposed locations for the mobile MRI: the “Orange Region” and the “Essex Region.” Each consists of:
 - a. The town in which the MRI was to be located (i.e., either Orange or Essex),
 - b. Towns contiguous to either Essex or Orange from which COS drew patients in FY2015, and
 - c. Towns adjacent to the contiguous towns. Ex. A, p. 24.
11. Based upon the Applicant’s stated defined service areas, the service areas are as follows:

**TABLE 2
SERVICE AREA TOWNS**

Mobile MRI Location	Town
Orange	Ansonia, Bethany, Derby, East Haven, Hamden, Milford, Monroe, New Haven, North Haven, Orange, Seymour, Shelton, Stratford, Trumbull, West Haven, Woodbridge
Essex	Chester, Clinton, Deep River, East Haddam, East Lyme, Essex, Killingworth, Old Lyme, Old Saybrook, Salem, Westbrook

Ex. A, pp. 24, 27, 40-41.

12. The Hamden and Branford scanners were unavailable for 82 hours during FY2016 for scanner and building maintenance and American College of Radiology (“ACR”) testing. The mobile MRI will provide back up for periods when the existing MRIs are inoperable. Ex. E, pp. 256, 273-274.
13. Of COS patients originating from the Orange Region in 2015, 2,430 scans were performed by COS at its Hamden location and 1,686 scans were performed at its Branford location. Ex. A, pp. 179-181.
14. Of COS patients originating from the Essex Region in 2015, 33 received scans at COS’ Hamden location and 309 at its Branford location. Ex. A, pp. 179-181.

15. As shown below, there are 24 existing scanners in the Orange Region, which has a population of 577,680.¹

**TABLE 3
EXISTING SCANNERS IN THE ORANGE REGION IN 2016**

Location type	Facility Name	City	Tesla Strength	Number of Scans 2016
Hospital-Based	Griffin Hospital	Derby	1.5	2,663
	Milford Hospital, Inc.	Milford	1.5	1,193
	Yale New Haven Hospital, Inc.	New Haven	1.5	5,741
	Yale New Haven Hospital, Inc.	New Haven	1.5	3,980
	Yale New Haven Hospital, Inc.	New Haven	3	4,579
	Yale New Haven Hospital, Inc.	New Haven	3	6,098
	Yale New Haven Hospital, Inc.	New Haven	3	2,371
	Yale New Haven Hospital, Inc.	New Haven	3	7,320
	Yale New Haven Hospital, Inc.	New Haven	1.5	4,193
	Yale New Haven Hospital, Inc.	New Haven	3	2,689
Hospital Satellite Location	Bridgeport Hospital	Trumbull	3	1,469
	Griffin Imaging and Diagnostics Center at Ivy Brook	Shelton	1.2	2,421
	Yale-New Haven Hospital, Inc. (North Haven Radiology)	North Haven	3	3,820
	Yale-New Haven Hospital, Inc. (Temple Radiology New Haven)	New Haven	1.5	2,066
	Yale-New Haven Hospital, Inc. at Chapel Street Campus	New Haven	1.5	3,175
	Yale-New Haven Hospital, Inc. at Chapel Street Campus	New Haven	3	4,010
Non-Hospital Based	Advanced Radiology Consultants, LLC	Orange	3	4,274
	Advanced Radiology Consultants, LLC	Shelton	1.5	2,441
	Advanced Radiology Consultants, LLC	Stratford	1.5	5,636
	Advanced Radiology Consultants, LLC	Trumbull	1.5	6,396
	Connecticut Orthopaedic Specialists, P.C.	Hamden	1.5	4,339
	Diagnostic Imaging of Milford	Milford	0.7	1,800
	Fairfield County Imaging, LLC	Trumbull	1	NOTE: new 2017
	Southern Connecticut Imaging Center LLC d/b/a Whitney Imaging Center	Hamden	1.5	5,945

¹ US Census Bureau, *State Population Totals Tables 2010-2016*, available at <https://www.census.gov/data/tables/2016/demo/pepest/state-total.html>.

Statewide Health Care Facilities and Services Inventory-2016, accessed on 10/26/17.
<http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>

16. Twelve of the machines located in the Orange Region were operating at or above their estimated scan capacities in 2016.
17. Of the 12 machines with available scan capacity in the Orange Region, seven were non-hospital or hospital satellite based.
18. Only three non-hospital based machines with available capacity in the Orange Region were of a comparable strength--1.5T or greater—to that proposed by the Applicant.
19. In 2016, 88,619 scans were performed on scanners in the Orange region placing overall utilization at 92.31%. This is an increase of 21,725 scans from 2014. Statewide Health Care Facilities and Services Inventory-2014, 2016, accessed on 10/26/17.
<http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>.
20. There is only one MRI scanner located within the Essex Region, located at Middlesex Hospital's Shoreline Medical Center campus in Westbrook. In 2016, it performed 3,422 scans, an increase of 876 scans from 2014. Statewide Health Care Facilities and Services Inventory-2014, 2016, accessed on 10/26/17. <http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557560&dphNav=|>
21. COS projects a 15.7% increase in volume in FY2018 based on its retention of scan patients, rather than directing them to another provider.

TABLE 4
COS'S PROJECTED NUMBER OF SCANS

	FISCAL YEAR*		
	2018	2019	2020
Number of Scans by Scanner:			
Branford MRI	3,870	3,986	3,986
Hamden MRI	3,870	3,986	3,986
Orange MRI	1,545	1,591	1,591
Essex MRI	1,577	1,624	1,624
Total	10,862	11,187	11,187

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The decreased volume of Hamden and Branford is attributable to those facilities' reduction in hours of operation to pre-merger levels.

Ex. A, pp. 33-34, 52-53, 55; Ex. G, pp. 278-279.

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Total Government	2,083	22.2%	2,411	22.2%	2,484	22.2%	2,484	22.2%
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Total Payer Mix	9,381	100%	10,862	100%	11,187	100%	11,187	100%

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25. The Applicant has adopted a Charity Care Policy based on a patient's insurance coverage status and income level relative to federal poverty guidelines. Ex. A, pp. 24, 28, 176.

26. COS does not charge a facility fee at any of its current or proposed MRI scanning offices. Ex. A, pp. 18, 24, 31; Ex. M, p. 2.

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28. First Niagara has approved COS for a loan in an amount sufficient to finance the purchase of the scanner and anticipated construction costs. Ex. A, p. 205.

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Ex. A, pp. 32, 42; Ex. G, p. 279.

30. A physician will be present during the operation of the mobile MRI. Ex. V, Transcript, Mr. Elia, p. 95.

31. The mobile MRI will be accredited by the ACR. Ex. A, p. 22; Ex. V, Transcript, Mr. Elia, pp. 66, 92.

32. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)) (Ex. A, p. 22).
33. This proposal is consistent with the overall goals of the Statewide Health Care Facilities and Service Plan. (Conn. Gen. Stat. § 19a-639(a)(2)) (Ex. A, pp. 22-24; Ex. C, p. 221).
34. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)) (Ex. A, pp. 24-28).
35. The Applicant has demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)) (Ex. A, pp. 31-33, 41-42, 200-218; Ex. G, pp. 279-283).
36. The Applicant has satisfactorily demonstrated that the proposal will improve the accessibility and cost effectiveness of health care delivery in the region while also maintaining quality. (Conn. Gen. Stat. § 19a-639(a)(5)) (Ex. A, pp. 28-30; Ex. C, pp. 221-222, 224).
37. The Applicant has shown that there would be no adverse change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)) (Ex. A, pp. 33-35, 42-43; Ex. E, p. 260; Ex. G, pp. 278-279).
38. The Applicant has satisfactorily identified the population to be affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)) (Ex. A, pp. 35-36, 44-45).
39. The Applicant's historical provision of services in the area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)) (Ex. A, pp. 36-37, 45-48).
40. The Applicant has satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)) (Ex. A, pp. 37-38; Ex. C, pp. 219-221; Ex. E, p. 249-252).
41. The Applicant has demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)) (Ex. A, p. 31; Ex. C, p. 222).
42. The Applicant has demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)) (Ex. A, p. 38).
43. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or access to care. (Conn. Gen. Stat. § 19a-639(a)(12)) (Ex. A, p. 31).

DISCUSSION

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

The Applicant, Connecticut Orthopaedic Specialists, is a private orthopedic physician practice. Office locations are primarily in southern Connecticut with two 1.5T MRI units located in Hamden and Branford offices. COS began expanding in 2014 and increased its offices from eight to 21. As a result of the expansion, the number of COS patients requiring an MRI scan has increased, causing the current scanners to operate at or above their capacity. To address the growth in volume, COS has extended its MRIs' hours of operations. Even with the extension of hours, the demand for MRI services exceeds the available openings. As a result, COS proposes to obtain a mobile MRI to be shared between its Orange and Essex locations. *FF 1-7*.

The Applicant has demonstrated a clear public need for an MRI in the Orange and Essex regions.

There has been a demonstrated increase in the demand for MRI scans in the area served by COS. From 2014 to 2016, the number of scans COS performed increased by 45%. Likewise, the reported number of scans performed by all providers in the Orange and Essex Regions cumulatively increased by 33% from 2014 to 2016. *FF 6, 15-16*.

The sole MRI machine currently located in the Essex Region performed 3,422 scans in 2016, or 85% of its estimated operating capacity of 4,000 scans per year. Notably, there are currently no machines that are not hospital-based to serve the population of approximately 91,227² in the region. Of the 24 MRI machines in the Orange Region, which has a population of 577,680,³ 12 were operating at or above their estimated operating capacities. Of the 12 machines with available scan capacity, only three were non-hospital based and of a 1.5T strength or greater. *FF 14, 16*.

The influx of patients from COS's merger with four other physician practices has resulted in COS's scanners operating above their maximum capacities--with the Branford-based MRI performing 4,698 scans and the Hamden MRI performing 4,410 in 2016. Consequently, COS has had little scheduling flexibility and patients experienced delays when scanners were inoperable, as was the case in FY 2016 when the scanners were down for unscheduled maintenance for a total of 82 hours. *FF 6, 11*.

Not only will the addition of the machine provide increased access to the COS patients in the Essex and Orange Region, it will also alleviate demand on COS's existing machines and open appointments for patients presenting at COS's Branford and Hamden offices. With the introduction

² US Census Bureau, *State Population Totals Tables 2010-2016*, available at <https://www.census.gov/data/tables/2016/demo/popest/state-total.html>

³ *Id.*

of the mobile scanner in those offices, as many as 1,995 fewer scans would be performed in Branford and 2,463 fewer in Hamden. *FF 12-13.*

The Applicant has shown the proposal will improve diversity of health care providers and cost effectiveness of health care delivery in the region.

Patients seeking MRI services in the proposed area are expected to benefit from having a non-hospital option in an area dominated by hospital-based providers. Due to variances in insurance reimbursement and coverage, non-hospital based MRIs may be significantly more cost efficient for patients. Furthermore, COS does not charge a facility fee at any of its offices. These factors coupled with the Applicant's recent adoption of a Charity Care Policy will enable the uninsured and underinsured an additional provider to receive MRI services. *FF 21-22.*

Additionally, COS has secured a loan sufficient to cover the purchase price of an MRI machine as well as projected renovation costs and the Applicant projects incremental gains from FY2018 through FY2020. As such, the proposal is financially feasible for the Applicant. *FF 24-25.*

The Applicant has satisfactorily demonstrated how the proposal will impact Medicaid payers.

COS has indicated it has and continues to accept Medicaid recipients practice-wide. In 2017, Medicaid patients represented only 0.9% of COS's patients receiving scans. To ensure an appropriate level of Medicaid recipients are served in the area, COS has agreed to accept a set percentage of Medicaid patients for MRI scanning on an annual basis and develop an outreach plan for Medicaid patients.⁴ The Applicant shall take the actions as stated in the order attached hereto. *FF 20*

An additional MRI will alleviate the capacity constraints experienced at COS's existing MRI facilities, increasing accessibility for COS patients who will now be able to be accommodated within the practice.

⁴ Ex. AA.

ORDER

Based upon the foregoing Findings of Fact and Discussion, the Applicant's request to acquire and operate a 1.5 Tesla mobile MRI scanner to be located at 330 Boston Post Road, Orange, Connecticut and 12 Bokum Road, Essex, Connecticut, is hereby **Approved** under Conn. Gen. Stat. § 19a-639(a) subject to the enumerated conditions (the "Conditions") set forth below.

All references to days in these Conditions shall mean calendar days, and OHCA shall mean the Office of Health Care Access or its successor.

1. Connecticut Orthopaedic Specialists ("COS") shall not operate the mobile MRI that is the subject of this application prior to its receiving accreditation from the American College of Radiology ("ACR").
2. COS shall submit to OHCA documentation confirming ACR accreditation not more than 30 days within its receipt of notification of accreditation.
3. The "operational year" is a reporting period commencing on the date upon which COS begins performing scans on patients. There shall be, for the purposes of this Order, one operational start date for both the Orange and Essex locations.
4. COS shall, within two weeks of commencing operation, notify OHCA in writing of its start date.
5. COS shall take all practical steps to achieve a payer mix, based on cumulative patient volume at the Orange and Essex offices, which includes 5% Connecticut Medicaid patients for its orthopedic services within the first year of operation of the MRI. Within sixty (60) days of the execution of this Agreement, COS shall provide a plan detailing the steps to be taken to achieve the targeted payer mix. COS shall report such payer mix to OHCA at the end of its first year of operation of the mobile MRI services and if this threshold is not met, COS shall submit such documentation as OHCA determines appropriate to demonstrate COS's efforts to re-evaluate its outreach initiatives and develop strategies to increase utilization by Connecticut Medicaid patients.
6. COS shall not divert any Medicaid patients to other non-COS providers for MRI scans for any reasons other than those based on medical necessity or patient preference.

7. COS shall submit annual reports to OHCA for three years for the information outlined in the example tables below. The annual periods shall be based upon COS's operational year. The report is due no later than two (2) months after the end of each annual period.

a. The number of *unduplicated patients treated at the Orange and Essex* locations for all orthopedic/specialty services by payer category.

Connecticut Orthopaedic Specialists Orange* & Essex Location								
	Total	Medicare	Medicaid	CHAMPUS/ Tricare	Commercially Insured	Uninsured	Self-Pay	Workers' Comp
COS Patients								
Percent (%)								

* excludes OrthoNOW patients at the Orange office

b. The number of unduplicated patients at the Orange and Essex locations *receiving MRIs* on the mobile machine by payer category

Connecticut Orthopaedic Specialists Essex & Orange Location*								
	Total	Medicare	Medicaid	CHAMPUS / Tricare	Commercially Insured	Uninsured	Self-Pay	Workers' Comp
MRI Patients								
Percent (%)								

* excludes OrthoNOW patients at the Orange office

c. The number of COS orthopedic patients (presenting at the Orange or Essex offices only) covered by Medicaid who required MRI scan(s) but received such scan(s) at a non-COS provider; list the reasons said patients could not be accommodated and the aggregate number who could not be for each reason. Omit patient identifiable information. The table below is for demonstrative purposes only and may be modified to reflect additional/other reasons.

Reason Received Non-COS Scan	Number of Medicaid Patients
Patient choice	
Medical necessity (i.e., Tesla limitation, bore size, etc.)	
Lack of scheduling availability	
Other (indicate)	
Total	

8. COS shall operate the mobile MRI machine that is the subject of this authorization exclusively in the towns of Orange and Essex and shall not perform or authorize the performance of any scans on the approved mobile unit outside of these towns.

9. The proposed mobile MRI shall operate for no more than two days at COS's Essex office and two days at its Orange office.
10. COS shall not replace or upgrade the mobile MRI without prior authorization from OHCA.
11. OHCA and COS agree that this settlement represents a final agreement between OHCA and the Applicant with respect to OHCA Docket No. 16-32117-CON. The execution of this settlement resolves all objections, claims and disputes, which may or could have been raised by COS with regard to OHCA Docket Number 16-32117-CON.
12. OHCA may enforce this settlement under the provisions of Conn. Gen. Stat. §§ 19a-642; 19a-653 and all other remedies available at law, with all fees and costs of such enforcement to be paid by the Applicant.
13. This settlement shall be binding upon the Applicant and its successors and assigns.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access



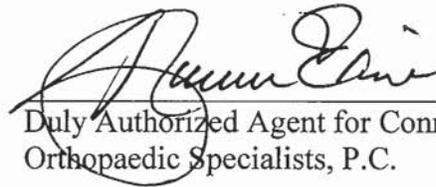
Yvonne T. Addo, MBA
Deputy Commissioner

11/28/2017

Date

11/28/17

Date



Duly Authorized Agent for Connecticut
Orthopaedic Specialists, P.C.

Signed by

GLENN FINA
(Print name)

CEO

(Title)

Olejarz, Barbara

From: Microsoft Outlook
To: klg1@aol.com; Glenn Elia; 'jfusco@uks.com'
Sent: Tuesday, November 28, 2017 3:08 PM
Subject: Relayed: Agreed Settlement

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

klg1@aol.com (klg1@aol.com)

[Glenn Elia \(gelia@ct-ortho.com\)](mailto:Glenn.Elia@ct-ortho.com)

'jfusco@uks.com' ([jfusco@uks.com](mailto:'jfusco@uks.com'))

Subject: Agreed Settlement

Olejarz, Barbara

From: Olejarz, Barbara
Sent: Tuesday, November 28, 2017 3:08 PM
To: Glenn Elia; 'klg1@aol.com'; 'jfusco@uks.com'
Subject: Agreed Settlement
Attachments: 16-32117-CON Agreed Settlement.pdf

Tracking:	Recipient	Delivery	Read
	Glenn Elia 'klg1@aol.com' 'jfusco@uks.com'		
	OHCA-DL All OHCA Users McLellan, Rose Foreman, Rebecca 'daniels@chime.org'		
	Bruno, Anthony M. Johnson, Colleen M	Delivered: 11/28/2017 3:08 PM	
	Shauna.Walker@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Rose.C.McLellan@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Ronald.Ciesones@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Yvonne.Addo@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Kaila.Riggott@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Srinivasa.Chalikonda@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Kimberly.Martone@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Carmen.Cotto@ct.gov	Delivered: 11/28/2017 3:08 PM	
	David.Fernandes@ct.gov	Delivered: 11/28/2017 3:08 PM	
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	Anthony.M.Bruno@ct.gov	Delivered: 11/28/2017 3:08 PM	
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	Olga.Armah@ct.gov	Delivered: 11/28/2017 3:08 PM	
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	Steven.Lazarus@ct.gov	Delivered: 11/28/2017 3:08 PM	
	Barbara.Olejarz@ct.gov	Delivered: 11/28/2017 3:08 PM	

Recipient	Delivery	Read
Jessica.Schaeffer-Helmecki@ct.gov	Delivered: 11/28/2017 3:08 PM	
Ciesones, Ron		Read: 11/28/2017 3:09 PM
Carney, Brian		Read: 11/28/2017 3:09 PM
Chalikonda, Srinivasa		Read: 11/28/2017 3:09 PM
Roberts, Karen		Read: 11/28/2017 3:10 PM

11/28/17

Please see attached Agreed Settlement for Docket Number: 16-32117-CON for Connecticut Orthopaedic Specialist, P.C. for the acquisition of a mobile MRI.

Thank you

Barbara K. Olejarz
 Administrative Assistant to Kimberly Martone
 Office of Health Care Access
 Department of Public Health
 Phone: (860) 418-7005
 Email: Barbara.Olejarz@ct.gov



User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Monday, February 05, 2018 10:49 AM
To: Clarke, Ormand
Cc: Roberts, Karen; User, OHCA; klg1@aol.com; Billie Foraker; Susan Bader; patrick ruwe
Subject: RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.
Attachments: COS- Plan for Medicaid patients to use Mobile MRI 2.1.18.docx

Dear Mr. Clarke:

Attached you will find the COS plan of Action for achieving a minimum of 5% Medicaid patients as outlined in our Agreed Settlement for Docket Number 16-32117-CON. COS is in the process of showing for a mobile MRI unit while we make appropriate modifications to the physical plants in Orange and Essex to accommodate a mobile unit. We will notify OHCA as to our projected start date for seeing patients.

Please confirm receipt of the email and the attachment of the Plan of Action.

Any questions, please feel free to contact me directly. My cell is (203) 415-4830.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

From: Clarke, Ormand [mailto:Ormand.Clarke@ct.gov]
Sent: Tuesday, January 30, 2018 1:46 PM
To: Glenn F. Elia <gelia@ct-ortho.com>
Cc: Roberts, Karen <Karen.Roberts@ct.gov>; User, OHCA <OHCA@ct.gov>
Subject: RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialist, P.C.
2408 Whitney Avenue
Hamden, CT 06518 gelia@ct-ortho.com

RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.

Dear Mr. Elia:

On November 28, 2017, the Office of Health Care Access ("OHCA") entered an Agreed Settlement for Docket Number: 16-32117-CON for Connecticut Orthopaedic Specialist ("COS"), P.C. for the acquisition of a mobile MRI.

Core requirements of the Agreement included:

Condition # 5: "COS shall take all practical steps to achieve a payer mix, based on cumulative patient volume at the Orange and Essex offices, which includes 5% Connecticut Medicaid patients for its orthopedic services within the first year of operation of the MRI. Within sixty (60) days of the execution of this Agreement, COS shall provide a plan detailing the steps to be taken to achieve the targeted payer mix. COS shall report such payer mix to OHCA at the end of its first year of operation of the mobile MRI services and if this threshold is not met, COS shall submit such documentation as OHCA determines appropriate to demonstrate COS's efforts to re-evaluate its outreach initiatives and develop strategies to increase utilization by Connecticut Medicaid patients."

To the current date, OHCA has not received documentation to support compliance with Condition # 5, above. Please file a response to the above by February 6, 2018. It is requested that any response submitted to OHCA should continue to be delivered to the general inbox at OHCA@ct.gov, as in prior instances.

Please do not hesitate to contact me if there are any questions.

Respectfully,

Ormand Clarke
Health Care Analyst
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308
P: (860) 418-7047 / F: (860) 418-7053 / E: ormand.clarke@ct.gov



As required by the terms of OHCA Agreed Settlement in Docket No. 16-32117-CON, Connecticut Orthopaedic Specialists plans to treat Medicaid patients on the mobile MRI at a minimum volume of 5% percent of its payer mix. The plan will be closely watched over the first 3 months to make sure that Medicaid volume is increasing, and can be adjusted if it is not working.

The plan is as follows:

1. Make sure that all of the COS physicians who will be using the mobile MRI in Essex and Orange are aware that it is their responsibility to accept and encourage Medicaid patients as part of their individual practices.
2. Reach out to primary care physicians in Essex and Orange and the additional towns in the two service areas used in the CON application indicating that COS accepts Medicaid patients for orthopedic treatment and MRI scanning if needed.
3. Reach out to the federally qualified health centers (“FQHCs”) in both service areas so that they are aware that COS accepts Medicaid patients.
4. Advertise that the “COS-Now” clinics, which allow walk-in patients to be treated without an appointment, accept Medicaid patients.
5. Contact town social workers to be sure that they are aware that COS will treat Medicaid patients.

COS does not expect to have a problem increasing the Medicaid population as that population already started to increase over the last year when many residents in the New Haven area began using the Hamden “Ortho Now” office when word spread that Medicaid is accepted. These were patients who were accustomed to using St. Raphael’s before it closed.

Essex already has a significant Medicaid population, and when the mobile COS MRI is located there, it is anticipated that they will use it rather than having to travel to another facility due to their difficult transportation issues.

COS will utilize the plan outlined above, using as many of the listed possible ways to increase the Medicaid population as necessary, and also looking for other means of achieving the same results; that all Medicaid patients will make up at least 5% of the MRI scanning performed on the mobile MRI in the two approved locations. New ideas may develop once the mobile MRI begins operation.

User, OHCA

From: Clarke, Ormand
Sent: Monday, February 05, 2018 11:26 AM
To: Glenn F. Elia
Cc: User, OHCA
Subject: RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.

Thanks for your prompt response, Mr. Elia. This email acknowledges receipt of your submitted Plan of Action for achieving a minimum of 5% Medicaid patients as outlined in the Agreed Settlement for Docket Number 16-32117-CON.

Sincerely,
Ormand.

From: Glenn F. Elia [mailto:gelia@ct-ortho.com]
Sent: Monday, February 5, 2018 10:49 AM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Cc: Roberts, Karen <Karen.Roberts@ct.gov>; User, OHCA <OHCA@ct.gov>; klg1@aol.com; Billie Foraker <BForaker@ct-ortho.com>; Susan Bader <SBader@ct-ortho.com>; patrick ruwe <patrickruwemd@gmail.com>
Subject: RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.

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Sent: Tuesday, January 30, 2018 1:46 PM
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Subject: RE: Certificate of Need Application, Docket Number 16-32117-CON Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner.

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialist, P.C.

2408 Whitney Avenue
Hamden, CT 06518 gelia@ct-ortho.com

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Please do not hesitate to contact me if there are any questions.

Respectfully,

Ormand Clarke
Health Care Analyst
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308
P: (860) 418-7047 / F: (860) 418-7053 / E: ormand.clarke@ct.gov

