

M. JODI RELL
GOVERNOR

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

CRISTINE A. VOGEL
COMMISSIONER

July 9, 2009

IN THE MATTER OF:

An Application for a Certificate
of Need filed pursuant to
Section 19a-639, C.G.S. by:

Capitol Upright MRI, LLC

CERTIFIED MAIL: 7005 0390 0001 3507 0798

Notice of Final Decision
Office of Health Care Access
Docket Number: 08-31255-CON

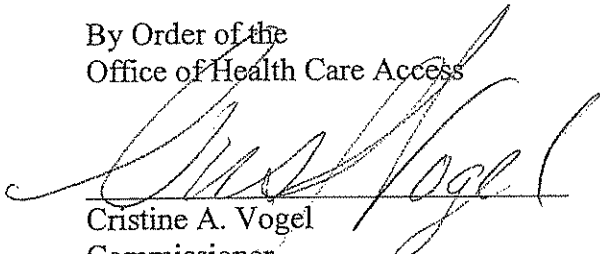
**Acquisition and Operation of a Fonar
Upright Magnetic Resonance Imaging
Scanner in Farmington, Connecticut**

To: Yvette D. Bailey, M.D.
Chief Executive Officer and
Managing Member
Capitol Upright MRI, LLC
58 High Gate Drive
Avon, CT 06001-4111

Dear Dr. Bailey:

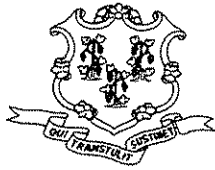
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-639, C.G.S. On July 9, 2009, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the
Office of Health Care Access


Cristine A. Vogel
Commissioner

Enclosure

CAV: swl



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Capitol Upright MRI, LLC

Docket Number: 08-31255-CON

Project Title: Acquisition and Operation of a Fonar Upright Magnetic Resonance Imaging Scanner in Farmington, Connecticut

Statutory Reference: Section 19a-639 of the Connecticut General Statutes

Filing Date: April 13, 2009

Hearing Dates: May 12, 2009 & May 19, 2009

Decision Date: July 9, 2009

Default Date: July 12, 2009

Staff Assigned: Steven W. Lazarus

Project Description: Capitol Upright MRI, LLC ("Applicant") proposes the acquisition and operation of a Fonar Upright Magnetic Resonance Imaging ("Upright MRI") scanner to be located in Farmington, Connecticut, at an estimated total capital expenditure of \$2,000,000.

Nature of Proceedings: On April 13, 2009, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from the Applicant for the acquisition and operation of a 0.6 Tesla Upright MRI scanner to be located at 17 Talcott Notch Road, Farmington, Connecticut, at an estimated total capital expenditure of \$2,000,000.

Pursuant to Section 19a-639, C.G.S., a public hearing regarding the CON application was held on May 12, 2009 and continued on May 19, 2009. On April 23, 2009, the Applicant was

notified of the date, time, and place of the hearing. On April 25, 2009, a notice to the public announcing the hearing was published in *The Hartford Courant*. Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-639, C.G.S.

By petitions dated May 7, 2009, John Dempsey Hospital, Bristol Hospital, Radiologic Associates of Bristol and Farmington; Drs. Jeffrey Blau and Sidney Ulreich d/b/a New Britain Radiologists; and Radiological Society of Connecticut, Inc. all requested Intervenor Status and/or Intervenor Status with Right to Cross Examine regarding the Applicant's CON application. The Presiding Officer designated John Dempsey Hospital, Bristol Hospital, Radiologic Associates of Bristol and Farmington and the New Britain Radiologists as Intervenors with full rights of participation. The Presiding Officer designated Radiological Society of Connecticut, Inc. as an Intervenor with limited rights of participation.

The Presiding Officer heard testimony from the Applicant's witnesses and the Intervenors' witnesses in rendering this decision and considered the entire record of the proceeding.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 9a-639, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Clear Public Need

Impact of the Proposal on the Applicant's Current Utilization Statistics Proposal's Contribution to the Quality of Health Care Delivery in the Region Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. It is found that Capitol Upright MRI, LLC ("Applicant" or "Capitol Upright") is a for-profit limited liability company comprised of four equal members, with a business address of 58 High Gate Drive, Avon, Connecticut. (*March 6, 2009, Initial CON Application Filing, pages 3 and 22*)
2. It is found that the four managing members of the Applicant, each of whom share twenty five percent (25%) ownership, include Yvette D. Bailey, M.D., Chief Executive Officer and Chief Financial Officer, Inam U. Kureshi, M.D., Andrew W. Wakefield, M.D., and Joseph Aferzon, M.D. (*March 6, 2009, Initial CON Application Filing, pages 21 & 22*)
3. The Applicant testified that Dr. Bailey is a member of a 9 radiologist group practice, who jointly own an imaging center in Massachusetts ("MA"). The joint venture owns and operates a 3.0 Tesla Magnetic Resonance Imaging ("MRI") scanner, two 1.5 Tesla MRI scanners and an Open MRI scanner. The Applicant further testified that Dr. Bailey is contracted to read radiological images from a practice located in Connecticut. (*May 19, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member & CEO, Capitol Upright MRI, LLC*)

4. The Applicant testified that Dr. Bailey’s practice in MA does not own or operate an upright MRI scanner. *(May 19, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member & CEO, Capitol Upright MRI, LLC)*
5. According to the Applicant, three of the physician members/owners of Capitol Upright are neurosurgeons with practice offices in the following towns:

Table 1: Office Location of the Three Neurosurgeons Members

Physician Member	Medical Practice	Address	% Ownership
Andrew Wakefield, M.D.	Connecticut Neurosurgery & Spine Associates, LLC	360 Bloomfield Avenue, Windsor, CT 06095	25%
Joseph Aferzon, M.D.	Center for Advanced Neuro and Spine Surgery	114 West Main Street, New Britain, CT 06051	25%
Inam Kureshi, M.D.	Neurosurgeons of Central Connecticut, P.C.	100 Retreat Avenue, Hartford, CT 06106-2565	25%

(April 13, 2009, Responses to OHCA’s Completeness Letter, page 511)

6. The Applicant contends that the proposed upright MRI can be utilized to scan any region of the body, whether the patient is standing, sitting, bending or lying down, in virtually any position of pain or other symptoms. *(March 6, 2009, Initial CON Application Filing, page 16)*
7. The Applicant asserts that the Fonar Upright MRI Scanner is “truly unique” and “sees pathology” that no other scanner can “see.” *(March 6, 2009, Initial CON Application Filing, page 16 and May 7, 2009, Pre-File Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
8. The Applicant further claims that the upright MRI fulfills a need which is not being met and cannot be met by any other MRI in the service area. Specifically, the Applicant claims that “no other MRI scanner in Central and Northern Connecticut” can provide the benefits of the proposed upright MRI scanner. *(March 6, 2009, Initial CON Application Filing, page 17 and May 7, 2009, Pre-File Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
9. The Applicant testified that the article submitted from the “Clinical MRI” demonstrates that proposed upright MRI improves patient outcomes. *(May 19, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D. Managing Member, Capitol Upright MRI, LLC)*
10. It is found that the article submitted by the Applicant that appeared in the Clinical MRI, winter 2006, vol. 15: 3, pp 8-12, briefly reviews four individual studies. The most relevant study being that of 25 patients whereby seated posture scanning aided in the diagnosis that was not apparent in the supine position. Thus, OHCA finds that this article failed to conclusively demonstrate that Upright MRI improves outcomes as compared to conventional MRI.

11. Dr. Ulreich testified that although positional, weight-bearing MRI has been cited to allow for improvements in sensitivity and specificity, no studies have adequately addressed the diagnostic accuracy compared to conventional MRI or other diagnostic tests for any of the proposed application. *(May 12, 2009, Public Hearing Testimony of Sydney Ulreich, M.D., New Britain Radiologists and May 7, 2009, Pre-Filed Testimony, page 2)*
12. Dr. Lawson testified that the proposed upright MRI is by no means “state-of-the-art” technology. Its efficacy and utility, as compared with the traditional MRI scanning, has not been validated through peer-reviewed studies and publications. *(May 7, 2009, Pre-Filed Testimony of Andrew J. Lawson, M.D., President of the Radiological Society of Connecticut, Inc., page 9)*
13. Dr. Badiola testified that at this time, the medical literature does not support the use of weight bearing or positional MRI in the routine evaluation of patients with spinal disorders. There is no reliable scientific data showing improved patient outcomes through the use of weight bearing or positional spinal imaging as proposed by the Applicant. *(May 7, 2009, Pre-File Testimony of Carlos Badiola, M.D., MA, Bristol Hospital & University of Connecticut Health Center, page 3)*
14. Dr. Badiola testified that none of the articles or references submitted by the Applicant is a well designed clinical trial demonstrating the superiority of upright open MRI relative to conventional open MRI. *(May 7, 2009, Pre-File Testimony of Carlos Badiola, M.D. MA, Bristol Hospital & University of Connecticut Health Center, page 5)*
15. Dr. Badiola testified that none of the submitted articles provided observational data showing improved health care outcomes through the use of upright or positional MRI. *(May 7, 2009, Pre-File Testimony of Carlos Badiola, M.D., MA, Bristol Hospital & University of Connecticut Health Center, page 5)*
16. OHCA finds that the testimony of the intervenors was credible and that the Applicant failed to demonstrate that upright MRI scanners offer improved patient outcomes when compared to supine MRI scanners.
17. Dr. Lawson testified that there are no specific guidelines pertaining to a stand-up MRI within the American College of Radiology (“ACR”) Practice Guidelines and that many of the guidelines, such as guidelines for functional MRI of the brain and MR spectroscopy, included by the Applicant in the CON application would be inappropriate to perform in any diagnostic or medically meaningful manner on a Fonar system. *(May 7, 2009, Pre-Filed Testimony of Andrew J. Lawson, M.D., President of the Radiological Society of Connecticut, Inc., page 20 and May 12 and 19, 2009, Public Hearing Testimony and the CON pages referenced in Dr. Lawson’s Testimony are in the CON Application pages 212-434)*
18. Dr. Lawson testified that there is no specific ACR accreditation related to an upright MRI scanner. *(May 19, 2009, Public Hearing Testimony of Andrew J. Lawson, M.D., President of the radiological Society of Connecticut, Inc.)*

19. OHCA finds that there is no specific ACR accreditation and/or specific guidelines that exist for an upright MRI scanner, demonstrating that the ACR does not differentiate between supine and upright MRI scanners.
20. The Applicant contends that they developed and administered a questionnaire that included five (5) questions, and received responses from thirty (30) physicians in Central Connecticut. *(March 6, 2009, Initial CON Application Filing, pages 17 & 28-29 and Exhibit A)*
21. The Applicant testified that the questionnaire did not include the names of the practices, physicians, information on the number of patients referred or the number of patients that required an upright MRI. *(May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Representing Capitol Upright MRI, LLC)*
22. Mr. Borda testified that the Applicant did not provide what discussions preceded or accompanied the questions asked; furthermore, the questionnaire does not provide any useful information regarding MRI utilization rates or existing capacity within the service area. *(May 7, 2009, Pre-Filed Testimony of Anthony Borda, Vice President of Operations, John Dempsey Hospital, page 3)*
23. It is found that the findings from the questionnaire presented by the Applicant demonstrate that some physicians were interested in the proposal but failed to demonstrate a need for the proposal.
24. The Applicant offers the following utilization projections for its proposed upright MRI scanner for the current year and the first three years of operation (FYs 2010-2012):

Table 2: Applicant's Projected Upright MRI Utilization

	FY 2009 (Oct.-Dec.)	FY 2010	FY 2011	FY 2012
Number of MRI Scans	585	2,750	3,000	3,250

Note: Fiscal Years ("FY") equal Calendar Years for this proposal.
(March 6, 2009, Initial CON Application Filing, pages 19, 20, 23 & 25)

25. The Applicant asserted that the projected number of patients for FY 2010 were based on 1,650 patients referred by the member physicians and 1,100 patients referred from other medical practitioners. *(April 13, 2009, Response to OHCA's Completeness Letter, page 510)*
26. It is found that approximately 60% of all MRI patients referred to the Applicant and also the majority of the commercially insured patients will be referred from the member neurosurgeons.
27. The Applicant claims that approximately 65% or approximately 1,800 of its scans will relate to disorders and conditions of the spine. *(April 13, 2009, Response to OHCA's Completeness Letter, page 507)*

28. The Applicant claims that approximately 35% or 960 of its scans will relate to other types of disorders and conditions, including pediatric patients, patients with claustrophobia, mentally and/or physically disabled patients, patients with pelvic floor dysfunction, large joint disorders (knees and hips), patients with suspected chiari malformations and obese patients. *(April 13, 2009, Response to OHCA's Completeness Letter, page 507)*
29. OHCA finds that the Applicant failed to produce sufficient evidence demonstrating that 35% of its volume would relate to pediatric patients, patients with claustrophobia, mentally and/or physically disabled patients, patients with pelvic floor dysfunction, large joint disorders (knees and hips), patients with suspected chiari malformations and obese patients.
30. The Applicant provided the following information with respect to the number of patients referred for MRI scans from the three member neurosurgeons during 2008:

Table 3: Physician Member's Historical and Future MRI Referrals

Member Neurosurgeon	# of patients referred to MRI (during 2008)	# of patients possibly appropriate for an Upright MRI	# of patients referred to an Upright MRI	# patients who received an Upright MRI
Dr. Aferzon	720	800	100-200	2
Dr. Wakefield	660	700	100-200	2
Dr. Kureshi	700	760	100-200	0
<i>Totals</i>	<i>2,080</i>	<i>2,260</i>	<i>300-600</i>	<i>4</i>

(April 13, 2009, Responses to OHCA's Completeness Letter, pages 514-516 and May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)

31. Based on the data provided by the Applicant (Table 3), OHCA finds that although the Applicant states that "many" patients were referred to an upright MRI service available in New Haven, Connecticut, "only as few as" 4 received the exams.
32. OHCA finds that of the 2,080 patients (Table 3) referred to MRI services from the three member neurosurgeons, 1,650 or 80% of the MRI volume will be referred directly to the proposed upright MRI. It is not clear if the remaining 20% is not being referred because they are covered by a government sponsored program or their condition is not appropriate for an upright MRI scanner.
33. The Applicant projects 55, 60 and 65 MRI scans per week for FYs 2010-2012, respectively. This was based on the growth rate of the member neurosurgeons' individual practices' five year historical utilization. *(May 7, 2009, Pre-File Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
34. It is found that the Applicant did not provide any evidence which illustrates the member neurosurgeons' five year individual practice historical utilization from which

the projections were based; and it is unclear to OHCA how that growth rate relates to the “non-spine” patients.

35. Applicant claims that approximately 1,100 of the 2,750 referrals (Table 2) during the first full year of operation will be from other medical practitioners. This number is derived from the physicians who wrote letters of support. *(April 13, 2009, Responses to OHCA’s Completeness Letter, page 510)*
36. The physicians who wrote letters of support did not testify nor did they provide historical utilization with respect to how many patients they refer for MRI scans.
37. OHCA finds that there is insufficient evidence to substantiate the Applicant’s claim that there will be an additional 1,100 scans during the first full year of operation from the physicians who submitted letters of support.
38. The Applicant asserted that there are currently approximately 30 MRI scanners in the service area. *(April 13, 2009, Response to OHCA’s Completeness Letter, page 509)*
39. Mr. Edelman testified that there are currently 26 MRI providers in the service area. *(May 7, 2009, Pre-File Testimony of Mr. Marc Edelman, Vice President of Operations, Bristol Hospital, page 5)*
40. Mr. Borda testified that there are currently 26 MRI scanners in operation within the proposed service area, including 16 high-field (1.0 Tesla or higher) and 10 low-field scanners. *(May 7, 2009, Pre-Filed Testimony of Anthony Borda, Vice President of Operations, John Dempsey Hospital, pages 2-3)*
41. Dr. Ulreich testified that there are currently two MRIs operating in Farmington, both of which operate below capacity. *(May 12, 2009, Public Hearing Testimony of Sydney Ulreich, M.D. on behalf of the New Britain Radiologists)*
42. Dr. Blau testified that his practice recently began operating a new 1.5 Tesla MRI scanner in West Harford and will have available capacity for an indefinite period. Further, many of the available MRI centers within 10 miles of the proposed MRI scanners are operating under capacity. *(May 7, 2009, Pre-File Testimony and May 12, 2009, Public Hearing Testimony of Jeffery Blau, M.D., on behalf of New Britain Radiologists)*
43. Mr. Borda testified that there are also currently 2 open MRI scanners in Farmington, a 0.6 Tesla located on the John Dempsey Hospital (“JDH”) campus and a 0.23 Tesla operated by the Farmington Imaging Center, both of which have excess capacity. *(May 7, 2009, Pre-Filed Testimony of Anthony Borda, Vice President of Operations, John Dempsey Hospital, pages 2-3)*
44. Dr. Badiola testified that at this time, there is excess open MRI capacity in the immediate service area, including the University of Connecticut, the Farmington Imaging Center and the Bristol Radiology Center; therefore, the Applicant’s proposal will duplicate existing MRI services. *(May 7, 2009, Pre-File Testimony of Carlos Badiola, M.D. MA, Bristol Hospital & University of Connecticut Health Center, page 6)*

45. OHCA finds that there are 26 MRI scanners currently providing services to residents in the service area and there is available capacity on the scanners operated by existing providers.

**Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicant's Rates and Financial Condition;
Impact of the Proposal on the Interests of Consumers of Health Care Services and the Payers for Such Services and
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

46. The project's total capital expenditure of \$2,000,000 is comprised of \$1,600,000 for the proposed Fonar Upright MRI scanner. *(March 6, 2009, Initial CON Application Filing, page 25)*
47. Each of the four (4) members made an initial investment of \$60,000, for a total of \$240,000 (used as deposit). Each of the 4 members has contributed an additional \$10,000 (total of \$40,000) as additional working capital. The remainder of the amount will be financed through Bank of America Leasing & Capital, LLC ("Bank"). *(March 6, 2009, Initial CON Application Filing, page 23)*
48. The Bank has offered to lend Capitol Upright up to \$2,000,000, amortized over a term of five years. *(March 6, 2009, Initial CON Application Filing, page 23)*
49. The Applicant claimed that since it plans to accept referrals from Community Health Services, Inc., in its entirety, without conditions, as well as HUSKY and Charter Oak patients, it will alleviate a portion of the existing burden on the University of Connecticut Medical Center, John Dempsey Hospital ("JDH"). *(March 6, 2009, Initial CON Application Filing, page 21)*
50. OHCA finds the Applicant failed to demonstrate that the patients within this payer category at JDH are patients that would benefit from receiving an Upright MRI scan.
51. The Applicant contends that there is no difference between reimbursement rates of a traditional MRI scanner versus the proposed Fonar Upright MRI scanner. *(May 6, 2009, Responses to OHCA's Interrogatories, page 550)*
52. The Aetna reimbursement policy with regard to Open Air, Low Field Strength and Positional MRI Units provides in relevant part as follows: "Magnetic resonance imaging (MRI) is considered medically necessary for appropriate indications without regard to the field strength or configuration of the MRI unit." *(Last Review, April 22, 2009, Aetna Clinical Policy Bulletin: Open Air, Low Field Strength, and Positional MRI Units)*
53. The Anthem Medical Policy with respect to "positional MRI" concluded that "there is currently insufficient evidence to demonstrate that positional MRI offers any advantages over conventional MRI methods." It further provides that there is no

specific CPT code to indicate a positional MRI scan. (*Anthem Medical Policy, Positional MRI, RAD.00052, Current Effective Date: July 9, 2008*)

54. The Applicant testified that there is no special coding (i.e. CPT code) for the proposed Upright MRI scanner and all insurance companies in Connecticut reimburse for the proposed Upright MRI scanner. (*May 19, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Member/CEO Capitol Upright MRI, LLC*)
55. It is found by OHCA that insurance companies reimburse for MRI services and do not differentiate by type of MRI; no unique CPT codes exists for the Upright MRI; and no specific guidelines or accreditation process exists by the ACR; and therefore it appears that the insurance and radiological industries do not acknowledge any difference between the upright and the traditional supine MRI scanning technology.
56. The Applicant asserted that its three year projected payer mix for the proposed service (based on Gross Patient Revenue) is as follows:

Table 4: Applicant's 3-Year Projected Payer Mix

Description	Year 1	Year 2	Year 3
Medicare*	6%	6%	6%
Medicaid*	6%	6%	6%
CHAMPUS and TriCare	0%	0%	0%
Total Government	12%	12%	12%
Commercial Insurers*	72%	72%	72%
Self Pay	3%	3%	3%
Workers Compensation	13%	13%	13%
Total Non-Government	88%	88%	88%
Total Payer Mix	100%	100%	100%

* Includes managed care activity.

(*March 6, 2009, Initial CON Application Filing, page 14 and April 13, 2009, Responses to OHCA's Completeness Letter, pages 519-520 and Exhibit S*)

57. The Applicant claimed that it is in compliance with the Federal Stark Laws. It will neither be billing nor accepting payment from any of the member neurosurgeons' Medicare or Medicaid patients, and such volume has been factored into the Applicant's anticipated Charity Care. (*April 3, 2009, Responses to OHCA's Completeness Letter, pages 519-520*)
58. Dr. Bailey testified that if three neurosurgeon member practices' have a patient that had Husky or Charter Oak that required an upright MRI, the patient would receive that upright MRI and there would be no bill sent to the Husky, Charter Oak, Medicare, Medicaid or the patient. (*May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC*)
59. The Applicant confirmed during testimony that it would "neither be billing nor accepting payment from any of the member neurosurgeons' Medicare and Medicaid patients and that such volume has been factored into the Applicant's anticipated

Charity Care.” *(May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*

60. The Applicant also testified that it would provide free care to the member neurosurgeons’ Medicare and Medicaid patients. *(May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
61. Additionally, the Applicant testified that providing free care to the member neurosurgeons’ Medicare and Medicaid patients would not be considered preferential treatment, as it would be the patient’s choice to obtain an upright MRI from Capitol Upright. *(May 12, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
62. The Applicant testified that its volume projections did not include the member neurosurgeons’ Medicare and Medicaid patients. *(May 19, 2009, Public Hearing Testimony of Yvette D. Bailey, M.D., Managing Member and CEO, Capitol Upright MRI, LLC)*
63. OHCA remains unclear with respect to how the Medicare and Medicaid patients of the member neurosurgeons have been accounted for as the Applicant’s testimony regarding the member neurosurgeons’ Medicare and Medicaid patients is conflicting and the proposed Charity Care line item shows 84 patients in the uninsured category but does not provide a basis for this projection.
64. The Applicant claims to project a gain in Net Income incremental to the proposal, based on achieving the projected volumes, for each of the first three FYs of the proposal of \$150,968, \$840,944, \$933,962 and \$1,011,927, during FYs 2009 (partial year) and full FYs 2010-2012, respectively.

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for Certificate of Need (“CON”) proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Capitol Upright MRI, LLC (“Applicant”) is a for-profit limited liability company comprised of four equal members, with a business address of 58 High Gate Drive, Avon, Connecticut. The Applicant proposes to acquire and operate a 0.6 Tesla Upright MRI scanner to be located at 17 Talcott Notch Road, Farmington, Connecticut.

The Applicant’s proposal was based upon the assertion that the upright MRI is “truly unique” and offered benefits that could not be provided by the traditional supine MRI scanners. (FINDING OF FACT 7-8). Thus, the application was not based on whether the area required additional MRI services capacity but rather upon the claimed unique benefits of the upright MRI. (FINDING OF FACT 7-8). Although the application included many presentation materials and articles, OHCA finds that the one article that the Applicants testified supported their claim of improved patient outcomes was a small study of 25 patients and failed to conclusively demonstrate that upright MRI improved patient outcomes. (FINDING OF FACT 10). The Intervenors provided credible testimony with respect to the lack of well designed clinical trials demonstrating the superiority of the upright versus the supine position. (FINDING OF FACT 11-16).

Evidence provided with respect to the radiological and insurance industries view points on the upright versus supine positioning demonstrated that there are no specific American College of Radiology (“ACR”) guidelines or accreditation processes that are different from the accreditation processes and guidelines for a traditional MRI. (FINDING OF FACT 17-19). Additionally, insurance companies do not have any specific reimbursement category for the upright MRI and reimburse according to their MRI policies. (FINDING OF FACT 51-53). Also, OHCA finds that no unique CPT codes exist for upright MRI scans and that the traditional MRI CPT codes are used for coding and reimbursement purposes. (FINDING OF FACT 54-55).

Based upon the foregoing evidence and testimony, including a lack of evidence demonstrating improved patient outcomes, the lack of a unique coding and reimbursement process for upright MRI; and the lack of a specific ACR accreditation process and practice guidelines; OHCA concludes that the upright MRI cannot be sufficiently differentiated from the traditional supine MRI. Accordingly, OHCA concludes that the Applicant’s claim that the Fonar Upright MRI is “truly unique” and provides benefits that no other scanner in the service area can provide is without merit.

The Applicant asserts that a clear public need exists for this allegedly “unique” type of MRI scanner since no upright MRI scanner is located in the service area; however, the area is served by 26 MRI scanners and testimony from Intervenors stated that existing providers of

MRI services have adequate available capacity. (FINDING OF FACT 39-45) OHCA finds that the volume projections provided are not supported by credible evidence that referrals to the upright MRI will materialize beyond the self referrals made by the three member neurosurgeons. (FINDING OF FACT 35-37). This volume alone, which is approximately 1,650 patients, does not demonstrate that an unmet need exists in the area. The Applicant asserts that approximately 35% of the volume (not referred by the member neurosurgeons) would relate to other types of disorders and conditions including claustrophobic patients, pediatrics patients, mentally/physically disabled patients, etc.; however, the evidence provided to support this claim was not sufficient (FINDING OF FACT 28). Based upon the foregoing, OHCA concludes that the Applicant did not demonstrate a clear public need exists for the proposal.

OHCA also finds that the financial projections are not reliable and, therefore, is concerned that this proposal is not financially feasible. The Applicant strongly relies on direct self referral volume by the member neurosurgeons and OHCA remains unclear how the Medicaid and Medicare patients of the three member neurosurgeons will be seen and billed. The Applicant provided conflicting testimony around this critical aspect of the proposal. (FINDING OF FACT 57-62).

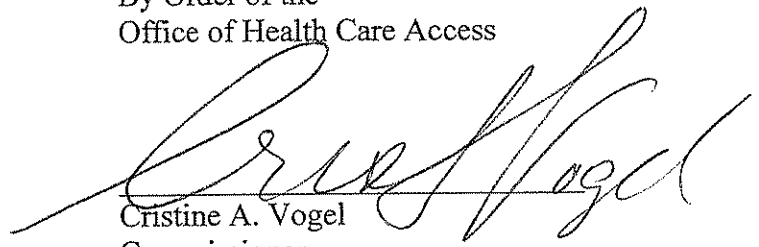
Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of Capitol Upright MRI, LLC, for the acquisition and operation of a 0.6 Tesla Upright MRI scanner to be located at 17 Talcott Notch Road, Farmington, Connecticut, at an estimated total capital expenditure of \$2,000,000, is hereby DENIED.

All the forgoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

7-9-09
Date


Cristine A. Vogel
Commissioner

CAV:swl