



## Office of Health Care Access Certificate of Need Application

**Applicant:** University Standing Open MRI, LLC d/b/a/  
University Standing Open MRI at Stamford, LLC

**Docket Number:** 04-30261-CON

**Project Title:** Establish a Standing Open MRI Service in Stamford

**Statutory Reference:** Sections 19a-638 and 19a-639 of the  
Connecticut General Statutes

**Filing Date:** July 29, 2004

**Hearing Dates:** September 20, 2004, October 6, 2004 &  
October 15, 2004

**Presiding Officer:** Cristine A. Vogel

**Intervenors:** Advanced Radiology Consultants, LLC  
The Stamford Hospital  
Greenwich Hospital

**Decision Date:** November 18, 2004

**Default Date:** November 26, 2004 (with 30 day extension granted)

**Staff Assigned:** Jack A. Huber

**Project Description:** University Standing Open MRI, LLC, d/b/a University Standing Open MRI at Stamford, LLC, proposes to establish a standing open magnetic resonance imaging (“MRI”) center in Stamford, Connecticut, at a proposed total capital cost of \$1,913,000.

**Nature of the Proceedings:** On July 29, 2004, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application of University Standing Open MRI, LLC, d/b/a University Standing Open MRI at Stamford, LLC, (“Applicant”), under Docket Number (“DN”): 04-30261-CON, seeking authorization to establish a standing open magnetic resonance imaging (“MRI”) service in Stamford, Connecticut, at an estimated total capital cost of \$1,913,000. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”)

On August 18, 2004, OHCA issued an Order of Consolidation, pursuant to Sections 19a-638 and 19a-643-21 of the Regulations of Connecticut State Agencies. The Order of Consolidation allows the Certificate of Need (“CON”) applications contained in DN: 04-30277-CON for Advanced Radiology Consultants, LLC (“Advanced Radiology”) and DN: 04-30261-CON for the Applicant to be consolidated for the purposes of conducting a batched public hearing.

On September 9, 2004, OHCA received the Applicant’s request for a thirty (30) day extension of the ninety (90) day review period for its pending CON application. OHCA reviewed the request and granted the Applicant’s time extension request, revising the default date for the CON application from October 27, 2004, to November 26, 2004.

A public hearing regarding the CON application was held on September 20, 2004, October 6, 2004 and October 15, 2004. The Applicant was notified of the date, time, and place of each hearing session and a notice to the public was published in *The Advocate* (Stamford). Commissioner Cristine A. Vogel served as Presiding Officer for this case. 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 Sections 19a-638 and 19a-639, C.G.S.

Advanced Radiology Consultants, LLC, petitioned for party status, or in the alternative intervenor status in the proceeding. The Presiding Officer denied the request for party status and granted the Advanced Radiology’s request for intervenor status with the right to present evidence and argument, as well as the right to cross-examine witnesses for the Applicant on the issues raised in its petition. The Stamford Hospital (“Stamford Hospital”) petitioned for intervenor status in the proceeding and was granted intervenor status with the right to present evidence and argument. Greenwich Hospital petitioned for intervenor status in the proceeding and was granted intervenor status with the right to present evidence and argument.

The Presiding Officer heard testimony from witnesses for the Applicant and witnesses for each of the Intervenors and in rendering this decision, considered the entire record of the proceeding. OHCA’s authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

## Findings of Fact

### Clear Public Need;

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

1. University Standing Open MRI, LLC, d/b/a/ University Standing Open MRI at Stamford, LLC, ("Applicant"), is proposing to establish a diagnostic imaging center that provides magnetic resonance imaging ("MRI") services in Stamford at an estimated total capital cost of \$1,913,000. (*March 1, 2004, Letter of Intent, page 1 and July 29, 2004, CON Application, page 1*)
2. The proposed MRI imaging center will be located at Suite 110, Plaza West, 2001 West Main Street, in Stamford, Connecticut. (*July 29, 2004, CON Application Cover Letter & Schematics to the CON Application and Response to Interrogatories, Exhibits 25 & 26, no designated page number*)
3. The Applicant proposes to acquire a Fonar Indomitable™ Stand-Up™ MRI system, a whole-body, open MRI scanner with a field strength of 0.6 Tesla. (*July 29, 2004, CON Application, Exhibit 13, equipment quotation, page 117*)
4. Scott H. Faro, M.D., is the President and sole owner, of University Standing Open MRI at Stamford, LLC. He is an academic neuroradiologist by training, who is presently the Director of the MRI Center at Drexel University in Philadelphia, Pennsylvania. Dr. Faro has over eight years of management experience and medical imaging expertise in the outpatient MRI field. (*July 29, 2004, CON Application, page 5 & Exhibit 8, Management & Ownership, page 69*)
5. Dr. Faro is also President and Chief Executive Officer of the parent affiliate corporation to the Applicant, University Standing Open MRI, LLC, which is based in Philadelphia, Pennsylvania. The corporation includes five outpatient imaging centers located in Pennsylvania, New Jersey and Connecticut. (*July 29, 2004, CON Application, page 69*)
6. The proposed MRI scanner is a multi-positional system that provides an unrestricted range of motion for flexion and extension studies. It can scan spines and joints in the weight-bearing state or in the conventional recumbent position. (*July 29, 2004, CON Application, pages 2 & 3 and Exhibit 2, pages 20-22*)
7. The Applicant claims the following classes of patients may benefit from use of the proposed MRI scanner:

- Children easily frightened and/or who may require anesthesia, if examined using traditional MRI scanning equipment;
- Patients weighing more than 300 pounds who are not easily accommodated by traditional MRI scanning equipment;
- Patients who may experience claustrophobia when scanned by traditional MRI scanning equipment;
- Patients with difficulties of the spine and joints;
- Patients requiring position-imaging;
- Cardiovascular patients requiring scans undertaken in an upright position; and
- Patients with cerebrovascular insufficiency requiring scans undertaken in an upright position.

*(July 29, 2004, CON Application, pages 2-4 and Exhibit 2, page 20)*

8. The hours of operation of the proposed service will be Monday through Friday, 8:00 a.m. to 5:00 p.m.; Saturday, 8:00 a.m. to 3:00 p.m.; with additional times being considered, as operational demands dictate. *(July 29, 2004, CON Application, page 3)*
9. The Applicant projects its referral base will come from physicians within and outside the proposed service area. *(July 29, 2004, CON Application, pages 2 & 3 and September 20, 2004, Response to Interrogatories, page 10 and Exhibits 6 & 8)*
10. OHCA afforded the Applicant a number of opportunities to correct and/or amend its need analysis relating to this proposal. After presenting its initial need justification in the filing of its CON application, the Applicant modified the proposal's need rationale on three separate occasions. *(September 20, 2004, Response to Interrogatories, pages 2-8, Exhibits 1-6, October 8, 2004, Late File #1, Exhibit 1(a), and October 14, 2004, Revised Late File #1, Revised Exhibit 1(a))*
11. Four different versions of the defined primary and secondary service area ("service area") were offered by the Applicant during the CON review process. Table 1, at the top of the next page, illustrates the four different versions of the proposed service area, itemized by submission date, CON application document and service area towns proposed:

**Table 1: Applicant Versions of the Proposed Service Area**

<b>Submission Date &amp; CON Application Document</b>	<b>Proposed Service Area Towns</b>
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July 29, 2004 CON Application *	Stamford, Greenwich, New Canaan, Darien, Ridgefield, Wilton, Norwalk, Westport
September 20, 2004 Submission: Applicant Response to OHCA Interrogatories **	<b>Towns within a 15 mile radius of Stamford including:</b> Stamford, Greenwich, New Canaan, Darien, Ridgefield, Wilton, Norwalk, Westport  <b>Plus additional NY state towns of Rye, Port Chester, White Plains, Armonk</b>
October 8, 2004 Applicant Late File # 1 Submission***	Original CT towns of Stamford, Greenwich, New Canaan, Darien, Ridgefield, Wilton, Norwalk, Westport  <b>Plus additional CT state towns of Easton, Redding, Weston</b>  <b>Less previous NY state towns of Rye, Port Chester, White Plains, Armonk</b>
October 14, 2004 Applicant Revised Late File # 1 Submission****	Original CT state towns of Stamford, Greenwich, New Canaan, Darien, Ridgefield, Wilton, Norwalk, Westport  <b>Maintains the additional CT towns of Easton, Redding, Weston</b>  <b>Maintains the subtraction of the previous NY state towns of Rye, Port Chester, White Plains, Armonk</b>

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*Notes:* \*The Applicant's initial service area is defined as those towns from the lower Fairfield County. (July 29, 2004, CON Application, pages 2 & 3)

\*\* The revised service area is defined as those towns from Connecticut and New York which are within a fifteen (15) mile radius of Stamford, and is based on the general experience of the Applicant in its other MRI service start-up operations. (September 20, 2004, Response to Interrogatories, page 2 & Exhibit 1)

\*\*\* (October 8, 2004, Late File #1, Exhibit 1(a))

\*\*\*\* The revised service area is modified to include three (3) zip codes within the town of Greenwich that were left out of the Applicant's October 8, 2004, Late File #1, Exhibit 1. (a) analysis. (October 14, 2004, Revised Late File #1, Revised Exhibit 1(a))

12. Sections 19a-634 and 19a-637, C.G.S. specifically mandate that OHCA consider the availability, scope and need for services for the residents of Connecticut. As such, OHCA can not consider out-of-state volume in its evaluation of need for new health services.
13. The Applicant applied a population-based methodology to the three modified versions of the application's proposed service area, ultimately deciding to use the last version of the proposed service area, as delineated in the Applicant's October 14, 2004, Revised Late File #1 submission, to substantiate its need for the proposed service.

**Table 2: Key Measurements and Resulting Statistics used by the Applicant in Defining the Need for the Proposed MRI Service**

Measurement Description	Statistic
1. Projected service area population in 2009*	419,322 individuals
2. MRI use rate: equivalent to the #** annual scans per 1,000 population***	65 scans per 1,000 population
3. Projected # annual scans for the proposed service area (419,322 x .065)	27,256 scans****
4. # Current & prospective***** MRI units in the service area	10 MRI units
5. Projected # annual scans per MRI unit (27,256 scans / 10 units)	2,725 scans per MRI unit*****

Notes: \*Town and regional population projections for each of the modified service areas proposed were provided from information received through Claritas, Inc. The assumptions used in the calculation of the population projections could not be verified due to the proprietary nature of this data. (October 14, 2004, Revised Late File #1, Revised Exhibit 1(a))

\*\* “#” = number of

\*\*\* The source of the use rate ratio used by the Applicant was taken from a March 13, 2004, **New York Times** article entitled “An M.R.I. Machine for Every Doctor?”. The article cites the use rate source as national data obtained from Blue Cross Blue Shield associations, Medicare and IMV National MRI Survey. (September 20, 2004, Response to Interrogatories, page 8 and October 14, 2004, Revised Late File #1, Revised Exhibit 1(a))

\*\*\*\*The Applicant’s mathematical calculation for Lines 3 and 5 above differs slightly from the Table 2 presentation. The Applicant’s projected number of annual scans for the service area equals 27,235 scans and its projected number of annual scans per MRI unit equals 2,723 scans. (OHCA staff calculation)

\*\*\*\*\*The term “prospective MRI units” is defined as those MRI scanners which are proposed and awaiting OHCA CON review or which have been authorized by OHCA after CON review consideration, and in either case have not yet become operational. (Definition established during the course of the formulation of the OHCA Interrogatories conveyed to the Applicant on August 25, 2004)

14. The Applicant’s need evaluation for magnetic resonance imaging services did not contain the following:

- Projection of the future need for magnetic resonance imaging services based on the Applicant’s initially proposed service area applied to a population-based methodology, resulting in a service area need-based calculation; (July 29, 2004, CON Application, pages 2 & 3 and September 20, 2004, Response to Interrogatories, page 2 & Exhibit 1)
- Projection of the prospective number of an annual scans the Applicant expects to perform, by classes of patient (i.e., children, patients weighing more than 300 pounds, claustrophobic patients, patients with difficulties of spine and joint, cardiovascular patients, and patients with cerebrovascular insufficiency), as more specifically identified in the aforementioned finding of fact number 7. of this CON decision; (July 29, 2004, CON Application, pages 2 & 3 and Response to Interrogatories, page 11)
- Source documentation relating to the MRI use rate selected for use in the Applicant’s need analysis; and
- Substantiation that the Applicant’s assertion that the MRI use rate, based on an estimated national average number of annual MRI claims per 1,000 individuals, would be applicable to or representative of the anticipated MRI use rate for the proposed service area; (September 20, 2004, Response to Interrogatories, page 8 and

*testimony by the Applicant based on Intervenor Testimony at the October 6 & 15, 2004 consolidated hearing)*

15. The projected units of service for the first three years of the proposed imaging center are derived from the Applicant's anticipated initial through-put volumes for the scanner, as well as the experience the Applicant has garnered during the development of two earlier MRI service center start-ups. Table 3, below, identifies the elements considered by the Applicant in its calculation of the projected number of annual MRI scans to be accomplished by the proposed MRI scanner in its first three years of the operation:

**Table 3: Projected Number of Annual Scans in Operating Years 1 through 3 for the Proposed MRI Scanner**

Measurement Description	Statistic
<b>Year 1</b>	
Average # MRI scans completed per day per scanner	9 scans
Average # business days per month	22 days
Resulting # <b>MRI scans</b> in year 1 equals (9 x 22 x 12)	2,376 scans
<b>Year 2 - # MRI scans</b>	2,860 scans
<b>Year 3 - # MRI scans</b>	3,120 scans

*(July 29, 2004, CON Application, page 3)*

16. The Applicant, also, based the number of projected annual scans on the anticipated increase in general MRI demand over the next five (5) to ten (10) years. The Applicant's estimates are based on a market analysis attributable to Yale-New Haven Hospital and the Yale University School of Medicine. Conclusions reached in the market analysis are that there will be a 22.1% increase in Connecticut MRI volumes between 2000 and 2005 and an overall increase of 48% from 2000 to 2010. *(July 29, 2004, CON Application, page 68 and September 20, 2004, Response to Interrogatories, pages 14 & 15)*
17. The Applicant's assertion concerning the anticipated increase in general MRI demand did not contain the following:
- Source documentation relating to the Yale-New Haven Hospital and the Yale University School of Medicine ("Yale") market analysis that the Applicant used to assert that an individual could expect an increase in Connecticut MRI volume between 2000 and 2005 and an overall increase in general MRI demand over the next five (5) to ten (10) year period; and *(July 29, 2004, CON Application, page 68 and September 20, 2004, Response to Interrogatories, pages 14 & 15)*
  - Evidence that the results of the Yale market analysis, if verifiable, would be applicable to or representative of the anticipated general MRI demand for the proposed service area. *(July 29, 2004, CON Application, page 68 and September 20, 2004, Response to Interrogatories, pages 14 & 15)*

18. On July 2, 2004, OHCA received a CON application of Advanced Radiology Consultants, LLC, (“Advanced Radiology”) under DN: 04-30277-CON, seeking authorization to replace and relocate its existing low-field strength, open MRI scanner located in Stamford with a high field, 0.6 tesla field strength MRI scanner. *(July 2, 2004, Advanced Radiology Consultant’s CON application and August 18, 2004, OHCA Order of Consolidation for the CON applications filed under DN: 04-30261-CON and DN: 04-30277-CON)*

19. The current and proposed MRI providers in the Applicant’s proposed service area are identified in Table 4 as follows:

**Table 4: Current and Prospective MRI Scanners within the Proposed Service Area**

Existing MRI Scanners	Prospective MRI Scanners
Stamford Hospital (1)- Fixed based, Closed	Advanced Radiology Consultants, Stamford - Upgrade to – Fixed based, Open
Tully Health Center (1)- Fixed based, Closed	University Standing Open MRI, Stamford - Proposed New– Fixed based, Open
Diagnostic Imaging of Darien (1) - Fixed based , Open	Greenwich Hospital -Upgrade of an interim Mobile – Fixed based, Closed
Greenwich Hospital (2) – Fixed based , Closed and Mobile, Closed	Diagnostic Imaging of Darien – Upgrade to - Fixed based , Open
Norwalk Hospital (2) – Two Fixed based , Closed	
Norwalk Radiology (1) - Fixed based , Open	
Advanced Radiology Associates (Stamford) (1) - Fixed based , Open	

*(Response to Interrogatories, page 7 and Prefile testimony of the David Sack, Stamford Hospital, Exhibit F1, page 12)*

20. Advanced Radiology Consultants, LLC, testified to the following: *(Testimony of Henry Soch, Business Development and Marketing Director, presented at the October 15, 2004, consolidated public hearing)*

- The national MRI use rate of 65 scans per 1000 population is overstated in that this data relates to all MRI scanners and that regional use rates can vary greatly from the national rate;
- Information regarding service area is now incomplete and/or inaccurate; and
- The volume statistics in support of the Applicant’s financial projections, which were originally based in part on service area-related demographic data, have changed, thereby making these projections no longer valid.



21. The Stamford Hospital testified to the following: (*Testimony of David J. Sack, Stamford Hospital Radiology Department Director, presented at the October 15, 2004, consolidated public hearing*)
- The accuracy in utilizing a national MRI use rate of 65 scans per 1000 population to reflect the magnetic resonance imaging experience of the proposed revised service area is uncertain and unproven;
  - Utilizing a population-based methodology that calculates current need for MRI services based in part on a service area population projection to 2009 does not make sense when current service need should more appropriately be based on current population figures for the proposed service area; and
  - Allocation of the projected number of annual scans (27,256 scans) within the proposed revised service area among eleven (11) existing area scanners (instead of the ten (10) MRI scanners identified by the Applicant) reduces the projected number of annual scans attributable to each scanning unit by 247 scans from 2,725 to 2,478 scans per MRI unit annually.
22. Greenwich Hospital testified to the following: (*Nancy Levitt Rosenthal, Senior Vice President of Health System Development, presented the October 15, 2004, consolidated public hearing*)
- Calculations are based in part on 2009 population projections and are not based on 2004-2005 population figures. If the 2004-2005 population figures were used in the calculation, these numbers would represent a more reasonable time frame for consideration, since MRI technology is ever evolving and the MRI applications can change considerably between now and 2009;
  - Utilizing the Applicant's need calculation and excluding the three additional towns the Applicant has added to the revised service area, one would expect that the annual projected number of scans per MRI unit in the service area to be 2,312 scans versus the 2,700 scan per MRI unit proposed by the Applicant;
  - Consultants for the Hospital advise that a 1.5 tesla strength MRI unit's annual operating capacity is 4,875 scans. The Hospital operates at an annual scan capacity of 4,400 scans. Using this parameter, the seven (7) service area 1.5 tesla strength MRI units alone can accommodate an annual capacity of 30,800 scans (7 scanners times 4,400 scans per unit per year) for the proposed service area. The 30,800 scan estimate is greater than the projected annual MRI need that the Applicant has estimated for the service area in 2009 of 27,256 scans. This shows that even when one excludes the volume attributable to the four (4) open MRI units, the current number of 1.5 tesla strength MRI units have the capacity to handle current and future (i.e. 2009) MRI scanning needs within the area to be served based on the Applicant's need methodology; and
  - Need as calculated by the Applicant is based on MRI scanning services in general and does not address need specifically for a 0.6 tesla strength MRI unit. Even if there was need for another MRI unit in the service area, the Applicant has not demonstrated that there is a need for a 0.6 tesla strength MRI unit.
23. While the Applicant has stated its expectation of being able to build a solid referral base, it provided no evidence that the creation of a solid referral base will be realized

for the proposed imaging service. *(July 29, 2004, CON Application, pages 2 & 3 and September 20, 2004, Response to Interrogatories, page 10 and Exhibits 6 & 8)*

### **Proposal's Contribution to the Quality of Health Care Delivery in the Region**

24. Dr. Faro is not currently licensed to practice medicine in Connecticut. He is in the process of applying for a Connecticut medical license with the Connecticut Department of Public Health. *(September 20, 2004, Response to Interrogatories, page 14)*
25. Diagnostic Imaging of Milford, P.C., a group of six radiologists, conveyed to the Applicant a letter expressing interest in providing professional services for the proposed imaging center. *(July 29, 2004, CON Application, page 4 & Exhibit 6, pages 65a-65h and September 20, 2004, Response to Interrogatories, pages 13 – 15 and Exhibit 19)*
26. Three of the six radiologists from Diagnostic Imaging of Milford, P.C., are sub-specialists in magnetic resonance imaging. *(September 20, 2004, Response to Interrogatories, pages 14 & 15)*
27. No signed service or proposed service agreement with Diagnostic Imaging of Milford, P.C., was provided. *(September 20, 2004, Response to Interrogatories, page 1 and Exhibit 20)*
28. The imaging center will require the services of two full-time equivalent MRI technicians per shift and four full-time equivalent office associates per shift. Should efforts of the Applicant to recruit qualified Connecticut based MRI technologists prove difficult, the Applicant proposes to contract with an employment services provider. The contractor has committed to provide however many MRI technologists would be required to cover the service needs of the imaging center. *(July 29, 2004, CON Application, Exhibit 12, page 116 and September 20, 2004, Response to Interrogatories, page 5 and Exhibit 11 no page designation)*
29. The proposed imaging center will follow the practice guidelines established by the American College of Radiology (“ACR”) for magnetic resonance imaging. The target date for fulfilling the ACR requirements for accreditation is November 15, 2005. *(July 29, 2004, CON Application, page 5 and September 20, 2004, Response to Interrogatories, page 18)*

### **Financial Feasibility and Cost Effectiveness of the Proposal and The Proposal's Impact on the Applicant's Rates and Financial Condition**

30. The proposal's total capital cost is \$1,913,000 and is itemized by cost component in the following table:

**Table 5: Proposal's Total Capital Cost**

<b>Component Description</b>	<b>Cost</b>
Non-Medical Equipment	\$50,000
Construction/Renovation	270,000
Other: Sales Tax	93,000
<b>Total Capital Expenditure</b>	<b>\$413,000</b>
Imaging Equipment (Lease FMV)	\$1,500,000
<b>Total Capital Cost</b>	<b>\$1,913,000</b>

(July 29, 2004, CON application, page 8)

31. Construction associated with the imaging center is scheduled to commence on March 1, 2005, and is scheduled to be completed on September 1, 2005. The commencement of center operations is slated for October 1, 2005. (September 20, 2004, Response to Interrogatories, page 18)
32. The project will be funded using a capitalized lease with a 66 month term at an anticipated interest rate of 3.01% for the imaging equipment with the remaining costs funded through an equity contribution. The Applicant has received a letter of interest from a lease financing company for the proposed imaging equipment. (July 29, 2004, CON application, pages 9 & 10 and Exhibit 15, pages 126 & 127)
33. University Standing Open MRI at Stamford is a newly formed limited liability company ("LLC"). There are no audited or desk reviewed financial statements to examine. The Applicant provided a five year projected financial summary report for the proposed service. (July 29, 2004, CON Application, page 7 and Exhibit 12, page 116 and September 20, 2004, Response to Interrogatories, page 15)
34. The most recent audited financial statement for University Standing Open MRI, LLC, the parent affiliate to University Standing Open MRI at Stamford, LLC, was sought by OHCA, but was not provided by the Applicant. (September 12, 2004, Response to Interrogatories, page 15)

35. The Applicant projects the following revenue from operations, operating expenses, and earnings from operations associated with the proposal:

**Table 6: Projected Financials for Operating Years 1 through 3**

<b>Description</b>	<b>Projected Year 1</b>	<b>Projected Year 2</b>	<b>Projected Year 3</b>
Revenue from Operations	\$1,683,636	\$2,057,777	\$2,244,848
Operating Expenses	1,390,066	1,903,564	1,998,184
<b>Earnings from Operations</b>	<b>\$293,570</b>	<b>\$154,213</b>	<b>\$246,664</b>

*(July 29, 2004, CON application, page 7 and Exhibit 12, page 116)*

36. The Applicant's anticipated payer mix percentages projected for operating years one through three of the proposal are as follows:

**Table 7: Projected Payer Mix Percentages for Operating Years 1 through 3**

<b>Payer Source</b>	<b>Projected % Yr. 1</b>	<b>Projected % Yr. 2</b>	<b>Projected % Yr. 3</b>
Medicare	10	10	15
Medicaid	5	5	5
<b>Total Govt. Payers</b>	<b>15</b>	<b>15</b>	<b>20</b>
Commercial Insurers	50	45	35
Self-Pay	0	0	0
Workers Compensation	35	40	45
<b>Total Non-Govt. Payers</b>	<b>85</b>	<b>85</b>	<b>80</b>
Uncompensated Care	0	0	0
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

*(July 29, 2004, CON Application, page 10)*

37. There will be a sliding fee schedule used by the proposed imaging center for uninsured or underinsured patients receiving MRI examination. *(September 10, 2004, Response to Interrogatories, page 17 and Exhibit 23, no page designated)*

### **Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

The following findings are made pursuant to the principles and guidelines set forth in Section 19a-637, C.G.S.:

38. There is no State Health Plan in existence at this time. *(July 29, 2004, CON Application, page 2)*
39. The Applicant's proposal is consistent with its long-range plan. *(July 29, 2004, CON Application, page 2)*
40. The proposed imaging center will not result in new teaching or research responsibilities for the Applicant. *(July 29, 2004, CON Application, page 6)*
41. The proposed imaging center will not possess any unique characteristics relating to the center's anticipated patient/physician mix. *(July 29, 2004, CON Application, page 7)*
42. The Applicant did not demonstrate that the proposal will improve productivity or contain costs within the area to be served. *(September 23, 2002, CON Application, pages 2 & 3, Response to Interrogatories, pages 1-6 and Exhibits 1-6, 9 & 10, Late File #1 and Revised Late File #1)*

43. The Applicant possesses sufficient technical and managerial competence to provide efficient and adequate magnetic resonance imaging services to the public. (*July 29, 2004, CON Application, pages 4-6 and Exhibit 8, page 69*)

## Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for proposed services on a case by case basis. Certificate of Need (“CON”) applications for magnetic resonance imaging (“MRI”) services do not lend themselves to general applicability due to a variety and complexity 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 proposed services.

The proposal of University Standing Open MRI, LLC, d/b/a University Standing Open MRI at Stamford, LLC, (“Applicant”), is to establish a standing open magnetic resonance imaging center at an estimated total capital cost of \$1,913,000. The imaging center will be located at 2001 West Main Street, in Stamford, Connecticut. The center will be equipped with a whole-body, open Fonar Indomitable™ Stand-up™ MRI system operating at a field strength of 0.6 Tesla.

With respect to the clear public need for the proposal, OHCA afforded the Applicant a number of opportunities to correct and/or amend its need analysis relating to this CON request. After presenting its initial need justification in its CON application filing, the Applicant modified the proposal’s need rationale on three separate occasions. The Applicant modifications to the proposal’s need rationale created a number of serious questions and/or concerns for OHCA with regard to the various data elements that were being modified to substantiate need. Consequently, OHCA has a number of substantial concerns with respect to the Applicant’s assessment of a clear public need for this Certificate of Need application.

The Applicant provided four different definitions of its primary and secondary service areas. The Applicant initially submitted a service area consisting of 8 lower Fairfield County towns as follows: Stamford, Greenwich, New Canaan, Darien, Ridgefield, Wilton, Norwalk and Westport. Important factors such as the characteristics of the population to be served, the current utilization of MRI services in the region, and a quantification of unused capacity in the region were not provided by the Applicant in its need analysis for this initial service area. The Applicant then expanded the service area to include all Connecticut and New York state towns within a 15 mile radius of Stamford, which includes the 8 original Connecticut service area towns, plus 4 additional New York State towns. The Applicant’s rationale for selecting this service area radius is based on its general experience in handling other MRI service start-ups. Sections 19a-634 and 19a-637 of the Connecticut General Statutes (“C.G.S.”) specifically mandate, however, that OHCA

consider the availability, scope and need for services for the residents of Connecticut only. Consequently, OHCA does not consider out-of-state volume in its evaluation of need for new health services.

The Applicant's third and fourth submissions to define the proposed service area included the following modifications: the inclusion of the eight original Connecticut service area towns, plus the addition of 3 Connecticut state towns consisting of Easton, Redding and Weston. It should be noted that the final service area definition included the addition of 3 zip codes assigned to the town of Greenwich that were inadvertently left out of the third service area modification. For each definition of the service area the Applicant did not provide quantifiable data relating to the selection of the towns and the population projections related to the service area. Therefore, OHCA is unable to reach a conclusion regarding the reasonableness of the service area definitions. Furthermore, OHCA does not endorse any prescribed distance or travel time in the consideration of a reasonable or appropriate service area definition.

The Applicant chose to utilize a population-based need methodology applied to the fourth service area delineation to determine need for the proposed MRI imaging center. The Applicant applied a national MRI use rate of 65 scans per 1,000 individuals to the 11 town service area population projected to calendar year ("CY") 2009 (419,322 individuals), yielding a projected 27,256 MRI scans within the prescribed service area for CY 2009. The proposed number of annual MRI scans in the service area was then divided by the 10 known MRI scanners in the service area, as identified by the Applicant, which results in a projected 2,725 scans per MRI scanner per year.

OHCA has a number of concerns with elements that the Applicant has employed in its use of the population-based methodology to substantiate the need for the proposed service. The first concern relates to the use of the selected MRI use rate prescribed by the Applicant. The use rate of 65 MRI scans per 1000 individuals is derived from an estimate of the average number of MRI claims per 1,000 individuals in the country. This value was cited in a March 13, 2004, *New York Times* article, entitled "*An M.R.I. Machine for Every Doctor?*". The article cites data obtained from Blue Cross, Blue Shield associations, Medicare and IMV National MRI Survey as its source for the use rate estimate. OHCA is concerned that the source of the use rate estimate is a newspaper article, not a peer-reviewed, nationally recognized professional journal. In addition, OHCA believes that a national use rate does not adequately reflect the historical use rate that exists in the proposed service area; regional use rates may vary greatly from the national use rate. Inasmuch as a national use rate value relates more readily to all MRI scanners in general and not to the specialized type of imaging equipment (i.e. stand-up open MRI unit) being proposed by the Applicant, the value of using a national use rate is diminished. Utilization of an area specific use rate would provide a more accurate estimation of the regional need requirements for additional MRI services. MRI use rates that are equal to or, at the very least, approximate the historical use rate within the proposed region to be served, would provide a more accurate picture of the future MRI need requirements of this defined region.

Secondly, OHCA does not accept the Applicant's projections of future MRI need using calendar year 2009 as the base year. The source data relative to the projected population figures supplied by Claritas, Inc., cannot be examined or verified, as the information is considered proprietary. Furthermore, OHCA considers that population figures from 2004-2005 more appropriately represent the time reference which should be under consideration when evaluating current MRI need in the region. Projections that extend this far into the future tend to become less reliable with time. There is a decreasing reliability in the projected numbers as the length of time between the latest U.S. census data collection and the established project baseline increases. As the timeline increases, more variables, such as changes in the field of magnetic resonance imaging technology have an opportunity to come into play, thereby causing greater variation in the projected need within a defined geographic region.

Another OHCA concern with the Applicant's methodology relates to the addition of Easton, Redding and Weston to the proposed service area without considering the existing MRI scanners that serve these towns. When the number of MRI scanners is applied to the projected number of service area scans for 2009, it produces the anticipated number of scans to be performed by each MRI scanner in that year. By the Applicant's count there are ten MRI scanners in the proposed service area. Based on this count the resulting MRI scans per MRI unit is projected to be 2,725 scans in 2009. The Applicant's calculation, however, fails to take into account the fact that there are other additional MRI scanners operating in cities such as Danbury and Fairfield that provide MRI services to individuals residing in the three additional service area towns. The Applicant should not be adding the population of the three additional service area towns to increase its need assessment without considering the capacity of these other existing area MRI providers. When the additional MRI units are considered in the mix, a reduction occurs in the Applicant's 2,725 calculated scans to be performed by each MRI scanner for 2009. In addition, it should be noted that at the present time there are seven 1.5 tesla strength MRI scanners in the proposed service area. Historically, Greenwich Hospital has operated its 1.5 tesla MRI scanners at an annual scan capacity of 4,400 scans. Using the Greenwich Hospital operating parameter of 4,400 scans per unit per year, the seven service area 1.5 tesla strength MRI units alone should accommodate an annual capacity of 30,800 scans (7 MRI scanners x 4,400 scans per unit per year) for the proposed service area. This estimate of 30,800 annual scans is 13% higher than the 27,256 projected annual scans calculated by the Applicant for the service area in 2009. This illustrates that current MRI scanning capacity is more than adequate to meet the present and future needs of the proposed service area.

Based on the aforementioned factors, OHCA has major concerns with respect to the Applicant's evaluation of the need for the proposed service and whether the Applicant will be able to achieve its projected service volumes. The Applicant's need assessment lacked documentation and initially did not contain demographic data regarding the population in the proposed service area, a description of a methodological approach, the calculation used to project service area volume and an assessment of the current demand for MRI services

in the proposed service area. Secondly, when the Applicant chose to pursue a population-based need methodology, the need assessment again lacked documentation to verify the accuracy of specific elements used in the Applicant's need calculation. The need assessment also contained information that required correction, thereby, producing a result which appears to indicate that the expectant demand on existing MRI units in the service area will be sufficient to accommodate current and future demand. Therefore, OHCA concludes that inasmuch as the agency has made a sincere effort to understand the numerous scenarios brought forth by the Applicant in its attempt to justify the need for the proposed imaging center and that as each scenario in the Applicant's need analyses possesses flaws or a number of inherent shortcomings, OHCA concludes that the Applicant has not substantiated a need for the proposed service in the designated area to be served.

Finally, OHCA is concerned with the financial viability of this proposal. The Applicant has projected a CON total capital cost of \$1,913,000 to be financed through a combination of capitalized lease and equity contribution. The financial feasibility of the proposal rests with the ability of the Applicant to achieve its utilization projections. The utilization projections are questionable given the uncertainty of the methods employed by the Applicant to substantiate the need for additional MRI services in the area to be served, as well as theoretical magnetic resonance imaging capacity, which exists in this region of the state. Further, as an audited financial statement regarding the operations of University Standing Open MRI, LLC, the parent affiliate of the Applicant, could not be examined; OHCA is not in a position to evaluate the financial condition of the Applicant. Consequently, OHCA cannot reach a conclusion regarding financial viability of the proposed imaging service. More significantly, however, as the Applicant's financial forecasts of the proposal are based on volume projections that appear to be overstated, OHCA believes that the projected volume will not be realized and the Applicant will experience financial losses. OHCA, therefore, concludes that the CON proposal is neither financially feasible nor cost-effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of University Standing Open MRI, LLC, d/b/a University Standing Open MRI at Stamford, LLC, to establish a standing open magnetic resonance imaging center, to be located in Stamford, Connecticut, at a total capital cost of \$1,913, 000, is hereby DENIED.

### **Order**

The proposal of University Standing Open MRI, LLC, d/b/a University Standing Open MRI at Stamford, LLC, to establish an open magnetic resonance imaging center to be located in Stamford, Connecticut, at a total capital cost of \$1,913, 000, is hereby denied.

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



By Order of the  
Office of Health Care Access

November 18, 2004

Signed by Cristine A. Vogel  
Commissioner

CAV: jah  
Decision DN: 04-30261