



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Housatonic Valley Radiological Associates, PC

Docket Number: 04-30331-CON

Project Title: Acquisition of a Replacement, Fixed-based, 1.5 Tesla Strength MRI Unit for the Applicant's Danbury Office

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

Filing Date: October 13, 2004

Hearing Date: December 16, 2004

Presiding Officer: Cristine A. Vogel

Intervenor: Danbury Health Systems, Inc.

Decision Date: January 11, 2005

Default Date: January 11, 2005

Staff Assigned: Jack Huber

Project Description: Housatonic Valley Radiological Associates, PC, proposes to acquire a fixed-based, 1.5 tesla strength Magnetic Resonance Imaging ("MRI") replacement unit for its radiology office located in Danbury, Connecticut, at a total capital cost of \$2,165,977.

Nature of Proceedings: On October 13, 2004, the Office of Health Care Access ("OHCA") received a completed Certificate of Need ("CON") application from Housatonic Valley Radiological Associates, PC, ("Applicant") to acquire a fixed-based, 1.5 tesla strength MRI replacement unit for its Danbury radiology office, at a total capital cost of \$2,165,977.

A public hearing regarding the CON application was held on December 16, 2004. The Applicant was notified of the date, time, and place of the proceeding and a notice to the public was published on November 27, 2004, in *The News-Times* (Danbury). 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 Section 19a-639(c), C.G.S.

Danbury Health Systems, Inc., on behalf of itself and its subsidiaries, Danbury Hospital and Danbury Health Care Affiliates, doing business as Danbury Diagnostic Imaging (“Danbury Health Systems, Inc., et al”) petitioned for intervenor status in the proceeding for Docket Number 04-30331-CON. The Presiding Officer granted Danbury Health Systems, Inc., et al’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 Presiding Officer heard testimony from witnesses for the Applicant and the Intervenor. In rendering this decision, the Presiding Officer considered the entire record of the proceeding. OHCA’s authority to review, approve, modify or deny this proposal is established by Section 19a-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 considered by OHCA in its review.

Findings of Fact

Clear Public Need

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

1. Housatonic Valley Radiological Associates, PC, (“Applicant”) is a private radiology practice providing diagnostic imaging services, with practice locations in the towns of Danbury, New Milford and Southbury. (*July 2, 2004, Letter of Intent (“LOI”) submission, page 6*)
2. The Applicant has been providing magnetic resonance imaging (“MRI”) services since 1989. The Applicant currently operates two mobile MRI scanners. (*July 2, 2004, LOI submission, page 6 and September 8, 2004, CON application, page 5*)
3. On November 22, 1999, under CON Determination Report Number: 99-A3, OHCA determined that the Applicant’s proposal to acquire a 1.0 tesla strength, mobile MRI unit for use at its radiology offices, at a total capital cost of \$364,640, did not require the filing of a CON application. The Applicant acquired this MRI unit in April 2000 (“2000” unit) and the unit initially shared time between the Applicant’s three practice

sites. The “2000” unit currently shares time between the Applicant’s New Milford and Southbury practice sites. *(September 8, 2004, CON application, page 5)*

4. On February 9, 2001, under CON Determination Report Number: 01-N, OHCA determined that the Applicant’s proposal to acquire and install a second mobile MRI unit for use at its radiology offices, at a total capital cost of \$363,580, did not require the filing of a CON application. The Applicant acquired this MRI unit in the spring/summer of 2001 (“2001” unit). The “2001” unit has been used exclusively at the Danbury practice site. *(September 8, 2004, CON application, page 5)*
5. The Applicant proposes to acquire a 1.5 tesla strength MRI replacement unit at a total capital cost of \$2,165,977. The proposed unit is a fixed-based, 1.5 tesla strength Siemen’s Magnetom Avanto-MRI System and it will be installed at the Applicant’s 67 Sandpit Road, Danbury practice site. *(July 2, 2004, LOI submission, page 6 & attached Siemen’s quotation and September 8, 2004, CON application, page 14)*
6. The Applicant intends for the “2001” MRI unit to be removed from its Danbury office and be relocated for use at its Southbury office. The “2000” unit will be stationed at the New Milford office site. *(July 2, 2004 LOI submission, page 6 and September 8, 2004, CON application, page 5)*
7. The Siemens Impact 1.0 tesla strength mobile (“2001”) MRI unit has been used in the Danbury office for basic examinations and can no longer be upgraded to handle increasingly complex diagnostic examinations. *(September 8, 2004, CON application, pages 2 & 3)*
8. The Applicant’s practice location at 67 Sandpit Road, Danbury has provided full service outpatient imaging for the past twenty-five (25) years. The imaging services provided at this practice site include general diagnostic x-ray, digital fluoroscopy, ultrasound, spinal CT scanning, magnetic resonance imaging, vascular studies, diagnostic and screening mammography, minimally invasive biopsies, bone densitometry and echocardiography. *(July 2, 2004, LOI submission, page 6 and October 13, 2004, Completeness Response submission, page 1)*
9. The proposed MRI unit provides a complete range of sequences, protocols and workflow functionality. There are seven dedicated application packages that will be included in the proposed acquisition. The application packages are as follows: neuro-suite, angio-suite, cardiac suite, body suite, onco-suite, ortho-suite and pediatric suite. *(July 2, 2004, LOI submission, attached quotation, page 2)*
10. The population served by the Applicant’s Danbury MRI service includes the primary service area residents from the following Connecticut towns: Danbury, Brookfield, Bethel, Newtown, Ridgefield, Redding and New Fairfield. *(July 2, 2004, LOI submission, page 2 and September 8, 2004, CON application, page 5)*

11. The Applicant is proposing to upgrade the Danbury office unit in order to accomplish the following:

- gain efficiencies in the scanning process and enhance the quality of current MRI applications;
- provide its patients and referring physicians with access to rapidly evolving MRI applications;
- examine individuals who believe they have claustrophobia, as the unit allows for patients to be scanned feet first with their heads remaining outside the unit for most studies;
- examination of obese individuals, as the unit has the capacity to accommodate individuals weighing 440 pounds; and
- improve MRI scheduling, and meet projected increases in MRI demand.
(July 2, 2004, LOI submission, page 6 and September 8, 2004, CON application, pages 2-8)

12. The Danbury office unit (“2001” unit) currently operates 51 hours weekly and approximately 2,652 hours annually on the following weekly schedule:

- Monday, Tuesday & Thursday, 8:30 a.m. to 5:30 p.m.;
- Wednesday, 8:00 a.m. to 7:00 p.m.;
- Friday, 8:00 a.m. to 5:00 p.m.; and
- Saturday, 8:30 a.m. to 12:30 p.m.

The proposed operating schedule for the replacement scanner will remain unchanged from the current service schedule. *(October 13, 2004, Completeness Response submission, page 3 and OHCA staff calculation)*

13. The fiscal year (“FY”) 2001 to FY 2003 actual MRI volumes and the FY 2004 projected/actual MRI volume for the Applicant’s Danbury office are presented in the following table: *(September 8, 2004, CON application, Attachment 1 and October 13, 2004, Completeness Response submission, page 4)*

**Table 1: FY 2001 to FY 2003 Actual MRI Volume and
FY 2004 Projected/Actual MRI Volume**

Practice Site	FY 2001 # Scans	FY 2002 # Scans	FY 2003 # Scans	FY 2004 # Scans
Danbury	931	1,800	1,880	1,812

14. The projected total number of annual MRI scans at the Applicant’s Danbury office for the first three fiscal years of operation, with, without and incremental to the replacement project are as follows: *(September 8, 2004, CON application, Attachment H.2)*

Table 2: Projected Total Number of Annual MRI Scans at the Danbury Practice Site

Description	Year 1	Year 2	Year 3
Projected Total MRI Scans with CON Proposal	3,133	3,446	3,790
Projected Total MRI Scans without CON Proposal	1,880	1,880	1,880
Projected MRI Scans Incremental to CON Proposal	1,253	1,566	1,910

15. Much of the projected MRI volume is anticipated to come from the Applicant's existing patient/referral base. The MRI volume projections are based on the Applicant's current MRI service experience, factors affecting the current delivery of MRI services in the proposed service area and the enhanced imaging capabilities of the proposed MRI replacement unit over the existing MRI unit. The Applicant highlighted the following factors affecting the Year 1 projected total number of MRI scans for its Danbury MRI service: *(September 8, 2004, CON application, pages 8-10)*

	<u>Proj. Scan</u>
• Baseline of 1,880 scans based on 2003 operating experience;	1,880
• Recovery of claustrophobic patients currently seeking MRI exams with existing providers in NY state;	209
• Improved image quality will increase brain, head and neck exams	724
• Improved image quality will increase body exams	132
• Expected annual growth within the industry per ACR projections	<u>188</u>
Total Year One MRI Projected Volume for the Danbury Office	3,133

16. MRI volume projections in Year 2 and 3 of operation are 3,446 and 3,790, respectfully. The Years 2 and 3 projections were calculated by applying a 10 % growth factor, suggested by the American College of Radiology, to each previous year's scan estimate. *(September 8, 2004, CON application, pages 8-10)*

17. The Applicant's assertions concerning the various factors affecting the replacement unit's projected volume, did not contain the source documentation necessary to evaluate the reasonableness of the Applicant's resultant estimate. *(September 8, 2004, CON application and October 13, 2004, Completeness Response Submission)*

18. The other current and prospective (i.e. OHCA authorized, but not yet operational) MRI providers in the Applicant's proposed primary service area are as follows:

Table 3: Other MRI Providers

Provider	Address	MRI Unit	Status
Danbury Hospital (Danbury Health Systems)	24 Hospital Rd. Danbury	1.5 T	Operational
		3.0 T	Prospective*
Danbury Diagnostic Imaging (Danbury Health Systems)	20 Germantown Rd. Danbury	1.5 T	Operational
Northeast Radiology	105 Newtown Rd. Danbury	1.5 T	Prospective

* Note: Hospital received authorization to operate an interim 1.5 T unit pending installation of the OHCA authorized 3.0 T scanner.
(September 8, 2004, CON application, page 7; CON authorization and CON Determination Request action rendered by OHCA)

19. The Applicant indicates that its proposal will have minimal impact on existing providers of MRI services in the proposed service area. While the Applicant has operated a MRI service for 15 years, the historical MRI volume DHS has experienced during this time has continually increased. Similarly, the Applicant has not experienced significant reductions in MRI volume with improvements in MRI services instituted by DHS. *(September 8, 2004, CON application, page 7)*
20. The Applicant states that scan times will be faster with the proposed 1.5 tesla strength replacement unit. This will allow the Applicant to increase patient throughput. The estimated annual MRI capacity for the proposed replacement unit will be 5,304 scans, based on the anticipated throughput of 30 minutes per scan and the anticipated 2,652 hours of scheduled operation for the proposed scanner annually. *(October 13, 2004, Completeness Response submission, page 3 and Applicant testimony provided at the public hearing)*
21. Gerard D. Robilotti, Executive Vice President for Danbury Health Systems et al, testified that there is currently a need for an additional 1.5 tesla strength MRI scanning unit in the greater Danbury area. *(Intervenor response to Applicant inquiry during cross examination by the Applicant at the public proceeding)*
22. The Applicant maintains a Quality Assurance Plan. *(September 8, 2004, CON application, page 12)*
23. The Applicant's magnetic resonance imaging services, as well as its other imaging services are accredited by the American College of Radiology ("ACR"). The Applicant intends to pursue ARC accreditation for the proposed replacement scanner. *(July 2, 2004, LOI submission, page 6 and September 8, 2004, CON application, pages 11 & 12)*
24. The Applicant's MRI examinations will continue to be performed by Housatonic Valley Radiological Associate staff and read/interpreted by doctors Jeffrey Stein, M.D. and Conrad Ehrlich, M.D. *(July 2, 2004 LOI submission, page 6 and September 8, 2004, CON application, page 11)*

**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**

25. The Applicant's total capital cost of \$2,165,977 includes \$1,713,186 for the fair market value of the proposed Siemen's MRI unit, \$350,000 for facility renovations and \$102,791 for sales tax. *(July 2, 2004, LOI submission, page 3 and September 8, 2004, CON application, page 14)*
26. The Applicant's total capital cost will be financed through an equity contribution of \$452,791 from the Applicant's operating funds and through an operating lease for the \$1,713,186 associated with the scanner acquisition. *(July 2, 2004, LOI submission, pages 3 & 4 and September 8, 2004, CON application, page 14 & 17)*

27. The Applicant projects incremental revenue from operations, total operating expense and revenue over expense associated with the CON proposal as follows:

Table 4: Incremental Financial Projections for Operating Years 1 through 3

Description	Year 1	Year 2	Year 3
Incremental Revenue from Operations	\$858,305	\$1,072,710	\$1,308,350
Incremental Total Operating Expense	\$809,485	\$925,485	\$1,010,834
Incremental Revenue Over Expense	\$48,820	\$147,225	\$297,516

(September 8, 2004, CON application, Exhibit H.1.)

28. The projected incremental revenue over expense in each of the first three operating years is due to the projected number of incremental MRI scans associated with the operation of the proposed replacement unit. (September 8, 2004, CON application, Exhibit H.1.)

29. The Applicant's current payer mix and projected payer mix during the first three years of operation of the proposed replacement unit is as follows:

(September 8, 2004, CON application, page 18)

Table 5: Applicant's Current and Three-Year Projected Payer Mix

Description	Current Mix	Year 1	Year 2	Year 3
Medicare	20.00%	27.70%	27.70%	27.70%
Medicaid	1.00%	5.92%	5.92%	5.92%
TriCare (CHAMPUS)	0.00%	0.00%	0.00%	0.00%
Total Government	21.00%	33.62%	33.62%	33.62%
Commercial Insurers	72.00%	63.78%	63.78%	63.78%
Self-Pay	1.00%	2.60%	2.60%	2.60%
Workers Compensation	6.00%	0.00%	0.00%	0.00%
Total Non-Government	79.00%	66.38%	66.38%	66.38%
Uncompensated Care	0.00%	0.00%	0.00%	0.00%
Total Payer Mix	100.00%	100.00%	100.00%	100.00%

30. The proposed MRI unit will be installed in a separate physical space within the Danbury practice site, which will allow the existing MRI unit to remain in operation until the replacement unit has been installed and is fully operational.

(September 8, 2004, CON application, page 10)

31. The Applicant proposes the following project schedule for the renovations necessary to accommodate the proposed replacement unit in its Danbury office:

(September 8, 2004, CON application, page 15)

Table 6: Proposed Project Schedule

Renovation Commencement Date	Upon receipt of CON approval
Renovation Completion Date	90 days after CON approval
Commencement of Operation Date	90 days after CON approval

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.:

32. There is no state health plan in existence at this time. *(September 8, 2004, CON application, Page 2)*
33. The Applicant has adduced evidence that the proposal is consistent with the Applicant's long-range plan. *(September 8, 2004, CON application, Page 2)*
34. The Applicant has improved productivity and contained costs by employing group purchasing practices in its procurement of supplies and equipment, and by participating in activities involved with the application of new technology. *(September 8, 2004, CON application, Page 12)*
35. The proposal will not result in any significant change to the Applicant's teaching and research responsibilities. *(September 8, 2004, CON application, Page 13)*
36. There are no distinguishing or unique characteristics of the Applicant's patient/physician mix that relate to the proposal. *(September 8, 2004, CON application, Page 13)*
37. The Applicant has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(September 8, 2004, CON application, Page 13)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for the proposed service on a case by case basis. Certificate of Need ("CON") applications for magnetic resonance imaging 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 current utilization of services and the financial feasibility of the proposed services. Housatonic Valley Radiological Associates, PC, ("Applicant") proposes to acquire a fixed-based, 1.5 tesla strength Magnetic Resonance Imaging ("MRI") replacement unit for its radiology office located in Danbury, Connecticut, at a total capital cost of \$2,165,977. The proposed unit, a Siemen's Magnetom Avanto-MRI System, will be acquired through an operating lease.

The Applicant is a provider of diagnostic imaging services in Fairfield County, with offices located in the towns of Danbury, New Milford and Southbury. The Applicant's practice location at 67 Sandpit Road, Danbury has provided full service outpatient imaging for the past twenty-five (25) years. The imaging services provided at this practice site include general diagnostic x-ray, digital fluoroscopy, ultrasound, spinal CT scanning,

magnetic resonance imaging, vascular studies, diagnostic and screening mammography, minimally invasive biopsies, bone densitometry and echocardiography.

The Applicant has been providing magnetic resonance imaging (“MRI”) services since 1989, and currently operates two mobile MRI scanners. A Siemens Impact 1.0 tesla strength, mobile MRI unit, acquired by the Applicant in 2001, has been used in the Danbury office for basic examinations and cannot be upgraded to handle increasingly complex diagnostic examinations. While the proposed replacement unit will be installed at the Applicant’s 67 Sandpit Road Danbury practice site, the Applicant intends to relocate the existing unit for use to its Southbury practice location. The second MRI unit operated by the Applicant, a 1.0 tesla strength mobile MRI unit, was acquired in April 2000. This unit is currently shared between the Applicant’s New Milford and Southbury practice sites and will be stationed at the New Milford office when the proposed replacement unit becomes operational. The proposed replacement unit will be installed in a separate physical space within the Danbury office, allowing the existing unit to remain in operation until the new unit is fully operational.

The CON proposal is based primarily on the need for additional high-quality MRI capacity. The Applicant is proposing to upgrade the current Danbury office MRI unit in order to gain operating efficiencies and enhance the quality of the current MRI applications; perform additional studies; provide patients and referring physician’s access to rapidly evolving MRI applications; examine more readily individuals who believe they have claustrophobia; examine obese individuals more readily. Furthermore the Applicant’s proposal will improve MRI scheduling and meet projected increases in demand.

The Applicant’s primary service area for the proposed replacement scanner will remain unchanged from the area currently served by the Danbury office operation. In the Applicant’s service area, Danbury Health Systems, Inc., and Northeast Radiology, LLC, provide MRI services. Danbury Health Systems, Inc., on behalf of its affiliates, Danbury Hospital and Danbury Health Care Affiliates, d/b/a Danbury Diagnostic Imaging, provides MRI services at two separate sites. Danbury Hospital has CON authorization for a 3.0 tesla strength MRI unit and operates a 1.5 tesla strength MRI unit. Danbury Diagnostic Imaging located in Danbury operates a, 1.5 tesla strength MRI unit. Northeast Radiology, LLC is in the process of acquiring a 1.5 tesla strength MRI unit for use at its proposed 105 Newton Road, Danbury office site.

The Applicant has an established referral pattern and patient base for the proposed service. The Applicant anticipates that most of the patient volume for the proposed replacement unit will come from the Applicant’s existing patient/referral base. The Applicant states that scan times will be faster with the proposed 1.5 tesla strength unit. This will allow the Applicant to increase patient throughput. The estimated annual MRI capacity for the proposed replacement unit will be 5,304 scans based on the anticipated throughput of 30 minutes per scan and the anticipated 2,652 hours of scheduled operation for the proposed scanner annually. The Applicant projects incremental MRI scans at its Danbury office to be 1,253 in Year 1, 1,566 in Year 2 and 1,910 in Year 3. The incremental increase is due to recovery of claustrophobic patients, introduction of new procedures on the brain, head,

neck and body, and an estimated 10% annual growth within the industry per American College of Radiology (“ACR”) projections. Based on the foregoing, OHCA finds that the Applicant’s projected utilization and need for the proposal appears to be reasonable.

The Applicant intends to pursue American College of Radiology (“ACR”) accreditation for the proposed replacement scanner. The Applicant’s MRI services, as well as its other radiological services, are ACR accredited. The Applicant maintains a Quality Assurance Plan. The MRI examinations to be performed using the proposed replacement unit will be supervised and interpreted by radiologists within the practice group.

The total capital cost of \$2,165,977 for the replacement proposal will be funded by an equity contribution of \$452,791 from the Applicant’s operating funds and by lease financing of \$1,713,186 through an operating lease. The Applicant projects that its incremental MRI scans will be 1,253 in Year 1, 1,566 in Year 2 and 1,910 in Year 3 as a result of the implementation of the replacement proposal. The Applicant projects incremental revenue over expense of \$48,820 in Year 1, \$147,225 in Year 2 and \$297,516 in Year 3 due to the CON proposal. The Applicant’s MRI scan volume projections and the financial projections appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Housatonic Valley Radiological Associates, PC, to acquire a fixed-based, 1.5 tesla strength MRI replacement unit for its radiology office located in Danbury, Connecticut, at a total capital cost of \$2,165,977 is hereby GRANTED.

Order

Housatonic Valley Radiological Associates, PC, (Applicant") is hereby authorized to acquire a fixed-based, 1.5 tesla strength Magnetic Resonance Imaging ("MRI") replacement unit for its radiology office located in Danbury, Connecticut, at a total capital cost of \$2,165,977, subject to the following conditions:

1. This authorization shall expire on January 10, 2006. Should the Applicant's MRI replacement unit project not be completed by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
2. The Applicant shall not exceed the approved total capital cost of \$2,165,977. In the event that the Applicant learns of potential cost increases or expects that final project costs will exceed those approved, the Applicant shall file with OHCA a request for approval of the revised CON project budget.
3. If the Applicant intends to operate the authorized fixed-based, 1.5 tesla strength MRI replacement unit at a location other than 67 Sandpit Road, Danbury, Connecticut, the Applicant is required to seek OHCA CON determination as to whether operation of the approved replacement MRI unit at any different location requires CON authorization.
4. This authorization requires the removal of the Applicant's existing Siemens mobile, 1.0 tesla strength MRI scanner from its Danbury practice location, no later than three months after the replacement MRI scanner has become operational.
5. The Applicant is required to request a Certificate of Need Determination specific to the relocation of the Siemens mobile MRI unit currently in operation at the Danbury practice location prior to any relocation of that unit to any other Housatonic Valley Radiological Associates or affiliated radiology practice location.

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

January 11, 2005

Signed by Cristine A. Vogel
Commissioner

CAV: jah