

Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Griffin Hospital

Docket Number: 07-31023-CON

Project Title: Establishment of an Outpatient Diagnostic Imaging

Center in Shelton, Connecticut

Statutory Reference: Sections 19a-638 and 19a-639, C.G.S.

Filing Date: May 2, 2008

Hearing Date: June 19, 2008

Intervenor: Advanced Radiology Consultants, LLC

Decision Date: October 3, 2008

Default Date: Not Applicable

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Project Description: Griffin Hospital ("Hospital') proposes the establishment of an outpatient diagnostic imaging center in Shelton, Connecticut. The proposed capital expenditure of the proposal is \$4,319,023.

Nature of Proceedings: On May 2, 2008, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from the Hospital seeking authorization for the establishment of an outpatient diagnostic imaging center ("Center") in Shelton, Connecticut. The proposed capital expenditure of the proposal is \$4,319,023.

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 2 of 16

A notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published on September 26, 2007 in the *The Connecticut Post*. Pursuant to Section 19a-639 of the Connecticut General Statutes ("C.G.S"), three individuals or an individual representing an entity with five or more people had until May 23, 2008, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received one hearing request from the public concerning the Hospital's proposal.

On June 16, 2008, OHCA received a request for Intervenor status with full procedural rights from Advanced Radiology Consultants, LLC. On June 18, 2008, OHCA granted Intervenor status with full rights of cross examination to Advanced Radiology Consultants, LLC.

Pursuant to Section 19a-639, C.G.S., a public hearing regarding the CON application was held on June 19, 2008. On May 21, 2008, the Applicant was notified of the date, time, and place of the hearing. On May 21, 2008, a notice to the public announcing the hearing was published in the *The Connecticut Post*. 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-638, C.G.S.

OHCA's authority to review and approve, modify or deny the CON application 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 fully considered by OHCA in its review.

Findings of Fact

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. Griffin Hospital ("Hospital") is an acute-care hospital located at 130 Division Street, Derby, Connecticut. (August 20, 2007, Letter of Intent, page 2)
- 2. New Haven Radiology Associates ("NHRA") is comprised of 26 Board Certified Radiologists, many with extensive sub-specialty expertise in neurology, musculoskeletal radiology, and interventional radiology, who have served the New Haven area and surrounding communities for over 25 years. (May 2, 2008, Responses to Completeness Letter, page 24)
- 3. In July 2007, Griffin Hospital entered into a professional service agreement with NHRA to provide professional diagnostic imaging services on behalf of Griffin Hospital. (May 2, 2008, Responses to Completeness Letter, page 24)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 3 of 16

4. Griffin Hospital proposes the establishment of an outpatient diagnostic imaging center in Shelton at the Ivy Brook Professional Park ("Center"). (December 18, 2007, Initial CON Application, page 5)

- 5. The imaging modalities to be installed at the proposed center include diagnostic radiography, computed tomography ("CT"), magnetic resonance imaging ("MRI"), and ultrasound. In addition to imaging services, a laboratory drawing station and electrocardiogram services would be located within the Center. Also located within the Center are a Hospital-affiliated otolaryngologist, obstetrician and gynecologist and a Hospital employed internist. (December 18, 2007, Initial CON Application, page 5)
- 6. According to the Hospital, the Center is intended to augment the existing diagnostic imaging services offered at the Hospital by bringing several high-volume modalities into the community to facilitate greater access. (December 18, 2007, Initial CON Application, page 5)
- 7. The Hospital stated that the town of Shelton was selected for the following reasons:
 - Shelton is the largest town in the Hospital's primary service area by population.
 - Shelton's population growth makes it one of Connecticut's fastest growing communities,
 - The proposed Ivy Brook Professional Park is conveniently located just off Route 8 and has ample parking, and
 - The largest primary care practice is just one and half miles from the Ivy Brook Medical Center.

(May 2, 2008, Responses to Completeness Letter, pages 5 & 6)

8. The Hospital listed the following towns in the proposed primary and secondary service area with their % Market Share Volume Projections:

Table 1: Proposed Primary and Secondary Service Area & % Market Share

Primary Service Area ("PSA") towns	Ansonia	39.4%
	Derby	34.3%
	Shelton	14.1%
Secondary Service Area ("SSA") towns	Milford	0.8%
	Monroe	0.9%
	Orange	1.9%
	Stratford	0.9%
	Trumbull	0.5%

Note: The Hospital based its PSA and SSA towns on its historical volume. While the percentage of Shelton residents that use Griffin's services versus the services of hospitals in surrounding communities (i.e., Griffin's share of the Shelton market) is lower than that of other primary service area towns, the actual number of Shelton residents (effective population) that use Griffin's services is greater than the number of resident users of any other town in the hospital's primary service area.

(December 18, 2007, Initial CON Application, page 15 and Responses to Interrogatories, page 42)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 4 of 16

9. The proposed Center will be linked via the Hospital's electronic record system and central scheduling system to the myriad of services available both on and off the main campus, allowing patients to be pre-registered for other hospital services and ensuring that all physicians and clinicians are able to view reports and results quickly, further optimizing patient care. (May 2, 2008, Responses to Completeness Letter, page 6)

- 10. The proposed Center is not a joint-venturing arrangement with NHRA. The Center, a satellite location of the Hospital's Diagnostic Imaging Services, will be served by the same professional service agreement that already exists between the Hospital and NHRA. (*May 2, 2008, Responses to Completeness Letter, page 10*)
- 11. The Hospital will control the Center and will provide management for all services at the Center. (May 2, 2008, Responses to Completeness Letter, page 10)
- 12. The Diagnostic Imaging Department at the Hospital currently offers patients a full range of diagnostic imaging modalities for inpatients and outpatients, including diagnostic radiography, nuclear medicine, bone densitometry, low dose mammography, ultrasound, positron emission tomography ("PET"), MRI and CT. (December 18, 2007, Initial CON Application, page 11)
- 13. Attachment I shows the existing providers of MRI service in the proposal's primary and secondary service area. (May 2, 2008, Responses to Completeness Letter, page 10)
- 14. The Hospital based the need for the Center on the following:
 - The Hospital's existing CT, MRI and ultrasound equipment on the Hospital's campus are operating at or near capacity, necessitating additional equipment to meet patient demand;
 - In responding to this growth, the Hospital has expanded the capacity of many
 of its outpatient services and acquired additional equipment, expanded
 facilities where possible and extended hours of operation; and
 - The current capacity to provide outpatient imaging services at its main campus is constrained as a result of increased inpatient volume and inpatient utilization of diagnostic imaging.

 (December 18, 2007, Initial CON Application, page 9)
- 15. The Hospital's historical Diagnostic, CT, Ultrasound and MRI volumes for FYs 2006, 2007, 2008 are as follows:

Table 2: Hospital's Historical Diagnostic, CT, Ultrasound, and MRI Volumes

Year	Diagnostic	CT	Ultrasound	MRI	Total
2006	14,506	3,944	4,543	1,802	24,795
2007	15,115	4,110	4,734	1,878	25,836
2008	15,750	4,282	4,933	1,957	26,922

(June 16, 2008, Responses to Interrogatories, page 4)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 5 of 16

16. The following is a description of the Hospital's current diagnostic imaging equipment:

Table 3: Current Diagnostic Equipment

MRI*	Siemens Symphony, 1.5T
CT	GE LightSpeed 16-Slice;
Ultrasound	Philips HDI 5000 Ultrasound
Diagnostic	
Radiography	Konica Express Class I CR System

^{*}Note: Mobile MRI services are currently provided by Alliance Imaging, this system is nine years old, the Hospital offers MRI services six days a week

(December 18, 2007, Initial CON Application, page 9)

17. The proposed Center will offer the following imaging equipment:

Table 4: Proposed Diagnostic Equipment at the Center

MRI	Hitachi 1.2 Tesla Oasis boreless high field Open MRI
CT	GE LightSpeed Xtra 16-Slice;
Ultrasound	Philips HDI 5000 Ultrasound
Diagnostic	
Radiography	Konica Express Class I CR System

(December 18, 2007, Initial CON Application, page 12)

- 18. The Hospital states that MRI referral patterns from FY 2005 thru FY 2008 (May) were predominately generated from the following specialties: Medicine (39%), Orthopedic (18%), Surgery (13%), and Neurology (9%) services. (June 16, 2008, Responses to Interrogatories, page 4)
- 19. The Hospital states that CT referral patterns from FY 2005 thru FY 2008 (May) were predominately generated from the following specialties: Emergency Services (39%), Medicine (37%), Surgery (7%), and Pulmonary (3%) services. (June 16, 2008, Responses to Interrogatories, page 4)
- 20. The Hospital indicates that though pediatric requests are not currently one of the strongest referral groups to Griffin Hospital's MRI and CT services, there has been growth in these modalities from FY 2007 to FY 2008 (May). Specifically, there has been 70% growth in MRI referrals (96 pediatric referrals in FY 2007 compared to 259 in FY 2008 projected) during this time period, and 12.6% growth in CT referrals (436 pediatric referrals in FY 2007 compared to 490 in FY 2008 projected. (*June 16, 2008, Responses to Interrogatories, page 5*)
- 21. The proposed Ivy Brook Diagnostic Imaging Center will generate volume referrals from the same physicians who practice or reside in Griffin's primary and secondary service areas. The following specialties have expressed interest: Orthopedics, Internal Medicine, Pediatrics, Geriatrics, Neurology, Cardiology, Radiology, and OB/GYN. (June 16, 2008, Responses to Interrogatories, page 6)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 6 of 16

22. The Hospital states that Valley Orthopedic Specialists, a four member orthopedic group with practices in Ansonia, Oxford, and Shelton, is expected to be one of the strongest referring physician groups for the Center, in addition, Family Health Care, a five member Shelton-based internal medicine group with a large geriatric patient base, will utilize the Center. (June 16, 2008, Responses to Interrogatories, page 6)

- 23. The Hospital expects that referral patterns for pediatric, geriatric, and bariatric populations will be stronger at the proposed Center than at the Hospital's main campus because physicians who treat pediatric, geriatric, and obese patients are more likely to refer patients to the proposed Center for its truly open MRI magnet which will allow children, the elderly, and obese patients easier access into and comfort in the MRI scanner. (June 16, 2008, Responses to Interrogatories, page 6)
- 24. The Hospital also expects referrals from physicians groups that currently do not refer to Griffin Hospital such as:
 - Chapel Pediatrics, a five physician member group that will occupy space in the Ivy Brook building;
 - Pedi-Care, a six member group located approximately three mile from the proposed Center; and
 - Othopedic Sports Medicine, a fourteen member physician practice located approximately two miles from the proposed Center. (June 16, 2008, Responses to Interrogatories, page 8)
- 25. The Hospital testified that an estimated 35% of the total projected volume at the proposed Center will come from bariatric, pediatric and geriatric patients. Bariatric patients (14% or 281), pediatric patients (6% or 122), geriatric patients (15% or 306). (*June 19, 2008, Public Hearing*)
- 26. The Hospital states that the Hitachi Oasis 1.2T open, high field MRI scanner will meet the special needs of any pediatric, geriatric, bariatric, claustrophobic patients residing in the area. The following is a list of benefits for each of the special needs population:

Pediatric Patients

- The superior imaging capability and motion suppression software of the Hitachi Oasis will reduce the need for pediatric sedation, thereby increasing ease of access and reducing anesthesia related risks; and
- The parallel imaging capability of the Hitachi Oasis scanner results in quicker scan times and is particularly useful in pediatric MRI imaging.

Geriatric Patients

- 270 degrees of true openness which will drastically reduce patient anxiety and motion resulting in quality diagnostic images;
- 70% of scans can be performed feet first, allowing patients an even higher comfort and confidence level while always being in visual contact with the operator;

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 7 of 16

- Open access for loved ones to be present and close for comfort and/or assistance;
- Quiet gradients provide advanced technology to reduce sounds and lessen patient anxiety; and
- RADAR, the Hitachi proprietary motion suppression software, ideal for those patients with neurodegenerative disorders such as Parkinson's Disease, suppresses the effect of patient motion to limit artifacts which can compromise diagnostic results.

Bariatric Patients

- The specifications of the Hitachi Oasis can meet the unique diagnostic imaging needs of bariatric patients:
- The unit's table top in the upright position has no weight limit and accommodates 500 pound patients during raising and lowering;
- The 80cm large coil comfortably fits almost all bariatric patients. For those larger than this, the unit boasts an inherent body coil which will produce quality MRI images;
- The Hitachi Oasis will be the only true open MRI unit in the surrounding area that can perform scans requiring a 1.0T magnet strength or greater; and
- The strongest open magnet currently available in the area to service obese patients is 0.3T.

(June 16, 2008, Responses to Interrogatories, pages 19 - 28)

- 27. The Hospital states that the projected FY 2009 MRI volume for the proposed Center is 1,622 scans. The Hospital anticipates that 512 outpatient MRI or 31.6% scans will shift from the Hospital to the proposed Center in FY 2009. The reduction in MRI volume at the Hospital's main campus resulting from the shift of some volume to the proposed Center will create capacity for anticipated hospital and outpatient MRI volume growth. It is expected that the Hospital inpatient MRI scan volume will increase from the current 623 inpatient scans in FY 2007 to over 1,000 in 2012. (June 16, 2008, Responses to Interrogatories, page 28)
- 28. The Hospital provided the following table showing the capacity for each existing MRI providers in their service area:

Table 5: Capacity of each existing MRI provider

Table 3. Capacity of each existing with provider							
	Advanced Radiology		R Russo & Associates		Milford	Dx	
MRI Locations	Shelton	Stratford	Orange	Shelton	Stratford	Hospital	Imaging Milford
Ave hrs/day day	9	14.9	8	8.5	14.3	9.4	9.0
Days per week	5	7	5.5	5	5.5	5.5	5
Operational hrs/wk	45	104	44	43	79	52	45
Days per year	260	364	286	260	286	286	260
Number of units	1	1	1	1	1	1	1
Est. min/procedure	60	45	60	60	45	45	60
Type of equipment	1.0T	1.5T	0.3T	0.3T	1.5T	1.5T	0.3T
			Open	Open			Open

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 8 of 16

Capacity per day	9	20	10	9	19	13	9
CAPACITY/YEAR (TOTAL SCANS)	2,340	7,231	2,288	2,210	5,453	3,585	2,340
Total est. exams/day	9	20	8	9	19	11	9
Total utilization prior year (2007)	2,299	5,094	2,066	N/A	N/A	3,087	1,061
% Exams Est. Day Shift	100%	100%	100%	100%	100%	100%	100%
Total Exams Est. Day Shift	9	20	8	9	19	11	9
UTLIZATION/% CAPACITY	98%	70%	90%	N/A	N/A	83%	45%

(June 16, 2008, Responses to Interrogatories, page 34)

- 29. The Hospital states that since there is no other truly open, bore-less high field MRI in the Hospital's service areas, the addition of the 1.2 Tesla MRI will have little to no impact on other local providers. (June 16, 2008, Responses to Interrogatories, page 34)
- 30. The Hospital states that the proposed Hitachi 1.2T Oasis Boreless High Field Open MRI by virtue of its boreless design, weight accommodation, and fast and quiet scan times, will easily accommodate bariatric, pediatric, geriatric, and claustrophobic patients. The technology offered by the Oasis allows for the option of scanning without the need for contrast, an expensive and potentially harmful component of the exam, making it a prudent choice when considering cost-effectiveness and patient safety. (December 18, 2007, Initial CON Application, page 11)
- 31. The proposed GE LightSpeed Xtra 16-Slice CT scanner will have the following mechanical characteristics and imaging capabilities:
 - The system's gantry size is 80 cm, which makes it ideal for bariatric and claustrophobic patients;
 - The system comes with a new detector design which includes DAS (Digital Acquisition System) technology that reduces radiation dose by 30% compared to the Hospital's current CY scanner technology;
 - This system allows for the scanner's table to be lowered to 18 inches from the floor which makes it ideal for pediatric, geriatric, and bariatric patients; and
 - The system has extensive pediatric radiation dose reduction algorithms which will help to ensure that pediatric patients will receive a radiation dose that is as low as reasonable achievable.
 - (May 2, 2008, Responses to Completeness Letter, page 13)
- 32. The proposed Center will use similar ultrasound and diagnostic radiography equipment currently utilized at the Hospital's main campus ensuring familiar operation by technologists. (*December 18, 2007, Initial CON Application, page 13*)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 9 of 16

33. The following tables provide the scanning capacity for the Applicant's proposed MRI and CT imaging equipment:

Table 5A: MRI Scanner Capacity

	Proposed Imaging Equipment
Number of MRI Scanners	1
Average # Hours/Week Scanner Operates	45
Weeks/Year Operational**	52
Targeted Utilization as % of Capacity	85%
Annual Total Capacity for Scans in Hours	2,340
Average Scan Time in Hours	.75
Annual Capacity - # MRI Scans/Scanner	3,120
Actual & Projected/Actual # MRI scans	1,622
% Total MRI Capacity	52%

Table 5B: CT Scanner Capacity

	Proposed Imaging Equipment
Number of CT Scanners	1
Average # Hours/Week Scanner Operates	45
Weeks/Year Operational**	52
Targeted Utilization as % of Capacity	85%
Annual Total Capacity for Scans in Hours	2,340
Average Scan Time in Hours	.5
Annual Capacity - # MRI Scans/Scanner	4,680
Actual & Projected/Actual # MRI scans	3,349
% Total MRI Capacity	72%

(February 12, 2008, Responses to Completeness Letter, page 4 and May 2, 2008, Responses to Completeness Letter, page 15)

34. The Applicant projected the following volume for each type of imaging equipment at the proposed Center from FYs 2009 through 2011:

Table 6: Projected Volume at the proposed Center

Ivy Brook Diagnostic Radiology Center	FY 2009	FY 2010	FY 2011
Number of MRI scans	1,622	1,712	1,802
Number of CT scans	3,349	3,746	3,944
Number of Ultrasound scans	4,088	4,316	4,543
Number of X-Ray scans	13,056	13,781	14,506

(February 21, 2008, Responses to Completeness Letter, page 6)

35. The Hospital testified that the proposed Hitachi 1.2 Tesla Oasis Boreless High Field Open MRI received Food and Drug Administration ("FDA") approval in November 2007, and currently there are only 11 such Open MRIs in operation throughout the United States. (*June 19, 2008, Public Hearing*)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 10 of 16

36. Dr. Kathleen Minnick, General and Laparoscopic Surgical Associates, testified that the advantage of the Hitachi OASIS in its application to breast imaging would benefit not only the population at large, but in particular, elderly, claustrophobic or obese women who have difficulty with traditional MRI machines. (*June 16, 2008, Prefile Testimony, page 5*)

- 37. Mr. Charmel, President and CEO of Griffin Hospital, testified to the following:
 - a. Physical space constraints within the Hospital's Radiology Department limits the ability to expand services within the Hospital;
 - b. The Hospital is operating a mobile MRI six days per week and the mobile pad is utilized by a mobile PET scanner on the seventh day;
 - c. This particular MRI scanner is the first truly open, bore-less MRI, the Hitachi magnet offers significant advantages when serving the pediatric population;
 - d. The Hospital's Diagnostic Imaging Department served over 8,000 pediatric patients last year;
 - e. The Hospital chose the town of Shelton as a site for the proposed Center, since it's the largest town in the Hospital's primary service area; (June 16, 2008, Prefile Testimony of Patrick A. Charmel, President and CEO of Griffin Health Services Corporation)

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

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

38. The total capital expenditure and cost associated with this proposal are \$1,651,421 and \$3,635,202, respectively, and consist of the following:

Table 7: Total Proposed Capital Cost

Total Capital Expenditure/ Cost Itemization				
Major Medical Equipment (Purchase)	\$25,508			
Non-Medical Equipment (Purchase)*	\$300,000			
Construction/Renovation	\$1,325,913			
Total Capital Expenditure	\$1,651,421			
Medical Equipment (Lease-FMV)	\$2,667,602			
Total Capital Cost	\$4,319,023			

^{*}Computers, Telecommunications, Furniture, Non-ferrous fire extinguisher (June 16, 2008, Responses to OHCA's Interrogatories, page 2)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 11 of 16

39. The cost of the proposed medical equipment proposed for lease is as follows:

Table 8: Proposed Leased Medical Equipment

Medical Equipment	Cost
MRI Scanner	\$1,620,000
CT Scanner	\$683,820
Ultrasound	\$50,133
CR System	\$100,280
Radiographic Room	\$106,300
PACS Work Station	\$107,069
Total	\$2,667,602

(June 16, 2008, Response to OHCA's Interrogatories, Appendix C, page 103))

- 40. Project Financing will consist of \$1,651,421 in funded depreciation and \$2,667,602 in lease financing. (December 18, 2007, Initial CON Application, pages 37 & 38 and June 16, 2008, Responses to Interrogatories, pages 38 & 94)
- 41. The Applicant provided a Master Lease with GE Finance Corporation under which the lease financing will fall. (*December 18, 2007, Initial CON Application, Appendix 13*)
- 42. The proposed Center will be located in an existing building. The cost to the applicant is the fit out of 4,489 usable square feet. Use of building common areas will be included in the lease but are not included in the fit out cost. (*December 18*, 2007, *Initial CON Application*, page 34)
- 43. The charges for the proposed services will be consistent with the Hospital's existing chargemasters for diagnostic radiography, MRI, CT and ultrasound which are on file with OHCA. (*December 18, 2007, Initial CON Application, page 40*)
- 44. The Hospital experienced the following increases/decreases between FY 2006 and FY2007:

Table 9: Hospital's Historical Financials (Increases/Decreases)

Activity	FY2006	FY2007	Increase/(Decrease)
Cash and Cash Equivalents	\$7,938,174	\$1,995,748	(\$5,942,426)
Long-term debt, net of current portion	\$23,533,843	\$56,342,426	\$32,808,583
Total Non-Operating Revenue	\$1,546,531	\$229,504	(\$1,317,027)

(Source: FY2006 FY2007 Griffin Hospital Audited Financial Statements

- 45. The Hospital states that the decreased of \$5.9 million in the Cash and Cash Equivalents activity was due to changes in cash policy. The Hospital took some of the Cash and Cash equivalent out and invested it on equities and bonds.

 (June 19, 2008, Public Hearing, Docket number: 07-31023)
- 46. The Hospital states that the increased in Long Term debt was due to the issuance of CHEFA Series C and D bonds for the building of the ambulatory care pavilion, cancer center, and internal renovations. (May 1, 2008, Second Completeness Letter, Page 26)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 12 of 16

47. The Hospital states that the decreased in Non – Operating Revenue was due to the fact that a non-operating expense of \$970,000 is recorded in the Non-Operating Revenue line. *May 1, 2008, Second Completeness Letter, Page 26*)

- 48. The Hospital is projecting an incremental gain from operations as a result of this proposal as follows: \$4,754,340 in FY 2009, \$5,125,943 in FY 2010, \$5,982,893 in FY 2011, and \$6,574,758 in FY 2012. (June 16, 2008, Responses to Interrogatories, pages 108 & 110)
- 49. The Hospital projects there will be no change in the service's payer mix attributable to the proposal. The service's current and three-year projected payer mix is as follows:

Table 10: Outpatient Diagnostic Imaging Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare	31%	31%	31%	31%
Medicaid	10%	10%	10%	10%
Champus	0%	0%	0%	0%
Total Government	41%	41%	41%	41%
Commercial Insurers	53%	53%	53%	53%
Uninsured	4%	4%	4%	4%
Workers Compensation	2%	2%	2%	2%
Total Non-Government	59%	59%	59%	59%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%

(February 21, 2008, First Completeness Responses, page 10 and Appendix 3)

- 50. There is no State Health Plan in existence at this time. (December 18, 2007, Initial CON Application, page 14)
- 51. The proposal is consistent with the Hospital's long-range plan. (December 18, 2007, Initial CON Application, page 14)
- 52. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, application of technology and reengineering. (December 18, 2007, Initial CON Application, page 31)
- 53. The Hospital has provided an explanation of the changes to the Hospital's teaching and research responsibilities that be caused by the implementation of the proposed project. (December 18, 2007, Initial CON Application, page 31)
- 54. The proposal will not result in any change to patient / physician mix of the Hospital. (December 18, 2007, Initial CON Application, page 32)
- 55. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. (December 18, 2007, Initial CON Application, Appendix 5, page 274-319)
- 56. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. (May 1, 2008, Second Completeness Letter Responses, Appendix 3, page 169)

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 13 of 16

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 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 proposed services.

Griffin Hospital ("Hospital") an acute-care hospital located at 130 Division Street in Derby, Connecticut, proposes to establish a comprehensive outpatient diagnostic imaging center in Shelton at the Ivy Brook Professional Park ("Center"). The Hospital currently provides all aspects of diagnostic imaging services for both inpatients and outpatients which include diagnostic radiography, nuclear medicine, bone densitometry, low dose mammography, ultrasound, positron emission tomography ("PET"), MRI and CT. The proposed Center will include diagnostic radiography, computed tomography ("CT"), magnetic resonance imaging ("MRI"), and ultrasound. In addition to imaging services, a laboratory drawing station and electrocardiogram services would be located within the Center. Also located within the Center are a Hospital-affiliated otolaryngologist, obstetrician and gynecologist and a Hospital employed internist.

The proposed Center will be linked via the Hospital's electronic record system and central scheduling system to the myriad of services available both on and off the main campus, allowing patients to be pre-registered for other hospital services and ensuring that all physicians and clinicians are able to view reports and results quickly, further optimizing patient care. New Haven Radiology Associates ("NHRA") a 26 Board Certified Radiologists group with extensive sub-specialty expertise in neurology, musculoskeletal radiology, and interventional radiology will provide the professional diagnostic imaging services at the proposed Center.

One of the imaging modalities proposed for the new Center is the Hitachi 1.2 Tesla Oasis boreless high field Open MRI ("Open MRI"). According to the Hospital the Open MRI received FDA approval in November, 2007, and currently there are only 11 such Open MRIs in operation throughtout the United States. The Hospital states that the proposed Hitachi 1.2T Oasis Boreless High Field Open MRI by virtue of its boreless design, weight accommodation, and fast and quiet scan times, will meet the special needs of bariatric, pediatric, geriatric, and claustrophobic patients residing in the area. The technology offered by the Oasis allows for the option of scanning without the need for contrast, an expensive and potentially harmful component of the exam, making it a prudent choice when considering cost-effectiveness and patient safety. It also has motion suppression software, for those patients with neurodegenerative disorders such as Parkinson's Disease, which suppresses the effect of patient motion to limit artifacts which can compromise diagnostic results. Currently, there is no other truly open, bore-less high field MRI in operation in the State of Connecticut. The proposed Open MRI provides a level of quality that cannot be met by current technology in the service area therefore projecting the volume of patients that will benefit from the introduction of this new technology is difficult and more than

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 14 of 16

likely under-stated. OHCA acknowledges that this "new to the market" technology addresses the unmet need of the pediatric, bariatric, and geriatric population; however, the exact (or even a confident estimate) of this market remains undetermined.

Based on the foregoing reasons, OHCA finds that the Hospital has provided evidence to support the need for the proposed Center and that the proposal will improve the accessibility and quality of diagnostic imaging services while at the same time filling an unmet need for a certain subpopulation (pediatric, bariatric, geriatric, claustrophobic and patients with neurodegenerative disorders) in the greater Shelton region.

The proposed total capital expenditure of \$4,319,023 will be financed entirely through funded depreciation and lease financing. The Hospital projects an incremental gain from operations related to the proposal of \$4,754,340, \$5,125,943, \$5,982,893 and \$6,573,758 in FYs 2009, 2010, 2011, 2012, respectively. Although OHCA cannot draw any conclusions, the Hospital's financial projections appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 15 of 16

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Griffin Hospital ("Hospital") to establish an outpatient diagnostic imaging center in Shelton at the Ivy Brook Professional Park at a total capital cost of \$4,319,023, is hereby **GRANTED**, subject to the following conditions:

- 1. This authorization shall expire on October 2, 2010. Should the Hospital's imaging center not be fully implemented by that date, including MRI and CT scanning being available to patients, the Hospital must seek further approval from OHCA to implement the project beyond that date.
- 2. The Hospital will acquire a Hitachi 1.2 Tesla Oasis Boreless High Field Open MRI and a GE LightSpeed Xtra 16-Slice CT scanner for the outpatient diagnostic imaging center in Shelton.
- 3. The Hospital shall submit a written report that focuses on the utilization of the MRI in general and specifically the sub-population targeted in this proposal on a biannual basis for the first two full years of operation of the MRI unit. Each bi-annual utilization report shall be submitted to OHCA by no later than one month following the end of each bi-annual reporting period. The bi-annual period for this reporting shall be based on the service operational year and not on a calendar or fiscal year. Unless otherwise notified by OHCA, at each meeting the Hospital shall present a written report to OHCA including but not limited to the following information:
 - Number of MRI scan volume by diagnoses for the Center;
 - MRI scan volume for the Center by town of origin;
 - MRI scan volume for the Center for each sub-population (pediatric, bariatric, geriatric and claustrophobic);
 - Significant findings regarding referral patterns and patient migration patterns that may assist OHCA in determining how to better quantify "un met need" in a given population;
 - Significant findings regarding Breast MRI studies;
 - Other data that is relevant to this proposal and/or when specifically requested by OHCA
- 4. The Hospital shall schedule bi-annual meeting with OHCA to be held during the first two years of operation of the MRI services in order to discuss the utilization results reported in conjunction with condition # 3 above and any other pertinent matters related to the operation of this Center. Such meetings will be scheduled and held within 45 days subsequent to the filing of the bi-annual data required in condition # 3.

Griffin Hospital October 3, 2008 Final Decision; Docket Number: 07-31023-CON Page 16 of 16

With respect to the acquisition of the CT and MRI equipment, the Hospital shall notify OHCA regarding the following information in writing by no later than 30 days after the equipment becomes operational:

- a) The name of the manufacturer of the CT and MRI scanner equipment;
- b) The model name and description of the CT and MRI scanner equipment;
- c) The initial date of the operation of the CT and MRI scanner equipment.
- 6. The Hospital shall not exceed the approved total capital cost of \$4,319,023. In the event that the Hospital learn of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law.

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

Signed by Commissioner Vogel on October 3, 2008				
Date	Cristine A. Vogel Commissioner			
CAV: pf				