

Office Of Health Care Access Certificate of Need Application

Proposed Final Decision

Hospital: Hartford Hospital

Docket Number: 02-502

Project Title: Acquisition of 3T MRI Unit at the Institute of Living

Statutory Reference: Sections 19a-638 & 19a-639, Connecticut General

Statutes

Filing Date: April 25, 2002

Hearing: May 30, 2002

Presiding Officer Mary M. Heffernan

Decision Date: June 3, 2002

Default Date: July 24, 2002

Staff Assigned Kim Martone

Sandra Czunas

Project Description: Hartford Hospital ("Hospital") proposes to acquire a 3T MRI Unit at the Institute of Living, at a total proposed capital expenditure of \$3,500,000.

Nature of Proceedings: On April 25, 2002, the Office of Health Care Access ("OHCA") received the Hospital's Certificate of Need ("CON") application seeking authorization to acquire a 3T MRI Unit at the Institute of Living, at a total proposed capital expenditure of \$3,500,000. The Hospital is a health care facility or institution as defined by Section 19a-630, C.G.S.

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A public hearing regarding the CON application was held on May 30, 2002. The Hospital was notified of the date, time, and place of the hearing, and a notice to the public was published prior to the hearing in *The Hartford Courant* and the *Northeast Minority News*. Mary M. Heffernan, Director, Health System Development, was designated by Commissioner Raymond J. Gorman to serve as presiding officer and to render a proposed final decision in this matter. The public hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-639, C.G.S.

The Presiding Officer heard testimony from witnesses for the Hospital and in rendering this proposed final decision, considered the entire record of the proceeding. OHCA's authority to review and approve, modify or deny this proposal is established by Sections 19a-638 & 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 on the Hospital's Current Utilization Statistics Contribution of the Proposal to the Accessibility of Health Care Delivery in the Region Contribution of the Proposal to the Quality of Health Care Delivery in the Region

- 1. Hartford Hospital ("Hospital") is a non-profit acute care hospital located in Hartford. (CON Application, April 15, 2002, page 10)
- 2. The Hospital's Mental Health Network is the Institute of Living ("IOL"). The IOL is one of the first psychiatric hospitals in America and was a pioneer in the introduction of research methods to the study of mental illness. Major areas of current research interest include schizophrenia and other psychotic illnesses, anxiety disorders, cognitive dysfunction and remediation, psychopharmacology, depression, end-of-life issues and caregiver issues. (CON Application, April 15, 2002, page 2)
- 3. The IOL is proposing to utilize non-invasive methods to study the structure, function, and chemistry of the living brain to advance the knowledge of schizophrenia and other neuropsychiatric disorders and their prevention and treatment. (CON Application, April 15, 2002, page 2)
- 4. The Hospital is proposing to acquire a 3T MRI unit to conduct schizophrenia and other neuropsychiatric research to be located at 200 Retreat Avenue in Hartford in a wing of the Neuropsychiatry Research Center. (CON Application, April 15, 2002, page 2)
- 5. The Hospital stated that the proposed 3T MRI unit will be utilized for research purposes. It is not being acquired for clinical purposes. (CON Application, April 15, 2002, page 3)

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6. The Hospital indicated that the proposed research effort will address the causes, symptoms and sequelae of schizophrenia across the course of the illness and throughout the patient's life. It will focus on "translational research", which translates our growing knowledge of the underlying mechanisms of disease into effective clinical treatments. (CON Application, April 15, 2002, page 10)

- 7. The Hospital anticipates that volunteer research subjects will come from the greater Hartford area, within a 20-mile radius. (CON Application, April 15, 2002, page 5)
- 8. The Hospital states it will seek informed consent from volunteer research subjects prior to participating in the proposed research project. (*Testimony provided by Dr. Godfrey Pearlson, May 30, 2002 OHCA Public Hearing, DN:02-502*)
- 9. The Hospital provided the following advantages of the proposed 3T MRI unit:
 - facilitate new research developments into the cause and treatment of schizophrenia;
 - b. shorter imaging time; and
 - c. improved image resolution.

(CON Application, April 15, 2002, page 4 and Responses to Completeness received on April 25, 2002, page 22)

- 10. The Hospital anticipates that within 3-5 years the research initiatives associated with this proposal will result in more effective understanding, diagnosis, treatment, and prevention of illness episodes in populations with schizophrenia or other severe psychiatric disorders. (CON Application, April 15, 2002, page 4)
- 11. According to an article titled "Multivoxel 3D Proton Spectroscopy in the Brain at 1.5 Versus 3.0 T: Signal-to-Noise Ratio (SNR) and Resolution Comparison" by Gonen et al in the *American Journal of Neuroradiology* 22:1727-1731, October 2001, improvements of about 20-50% can be realized in SNR per unit time and spectral resolution through the use of a 3T MRI. These advantages allow shorter examinations and better quantification. (Responses to Completeness received on April 25, 2002, page 15)
- 12. According to the article titled "Diffusion-Tensor MR Imaging at 1.5 and 3.0 T: Initial Observations" by Hunsche et al in *Radiology* November 2001, diffusion-tensor magnetic resonance imaging at 3.0 T offers better image resolution (MR) or shorter imaging time than that at 1.5 T because of a 40% increase in SNR. (Responses to Completeness received on April 25, 2002, page 22)
- 13. Research department staff works regular business hours, from 8:30 a.m.-5:00 p.m., Monday through Friday. The Hospital stated the staff most likely will also utilize the off hours, including weekends and holidays to conduct research. (CON Application, April 15, 2002, page 5)

14. Based on past experience in the establishment of a research center and funded research projects of this kind, the Hospital projects the following volume statistics for the first three years of operation with the 3T MRI unit as follows:

Projected Number of Scans: FYs 2003-2005

| Scans | Year 2003 | Year 2004 | Year 2005 |
|-----------|-----------|-----------|-----------|
| Research | 570 | 1,425 | 1,900 |
| Clinical* | 30 | 75 | 100 |
| Total | 600 | 1,500 | 2,000 |

^{*}The Hospital estimates the potential clinical use would never be more than 10% and the projected budget is based on 5%. All clinical (non-research) scans will be performed on an ambulatory basis. (CON Application, April 15, 2002, pages 3, 8, and 286)

- 15. The Hospital has established a collaborative research effort with Yale University Department of Psychiatry, as follows:
 - The Hospital will contract with Yale for the services of Dr. Godfrey Pearl as Director of Research to help in the development of a Schizophrenia Research Center at the IOL.
 - The Director will be responsible for the administration and management of the Research Center.

(Responses to Completeness received on April 25, 2002, page 3)

16. The Hospital stated that discussions are currently under way with various departments of the University of Connecticut School of Medicine to establish a collaborative research effort. (CON Application, April 15, 2002, page 5 and Responses to Completeness received on April 25, 2002, page 1)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition

Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services

17. The proposal has a total capital expenditure of \$2,760,500 which includes:

Total Capital Expenditure

| Project Components | Cost |
|---------------------------|-------------|
| Fixed Equipment | \$2,099,367 |
| Moveable Equipment | 50,000 |
| Construction/Renovation | 1,350,633 |
| Total Capital Expenditure | \$3,500,000 |

(CON Application, April 15, 2002, page 11)

18. The proposal will be financed entirely through charitable contributions earmarked specifically for the research of schizophrenia and other neuropsychiatric disorders. (CON Application, April 15, 2002, page 2)

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19. The 3T MRI unit and associated support areas will be located in 5,117 square feet of space located on the first floor of the White Hall building. (CON Application, April 15, 2002, page 2)

- 20. The Hospital projects revenue under expenses incremental to the project of (\$400,100), (\$474,643), and (\$474,643) for the first three years of operation of the 3T MRI unit due to non-cash depreciation expenses. (CON Application, April 15, 2002, page 285)
- 21. The Hospital projects overall revenue over expenses with the project of \$19,090,227, \$19,463,189, and \$19,882,209 in FY 2003, FY 2004, and FY 2005, respectively. *(CON Application, April 15, 2002, page 285)*
- 22. The Hospital indicated that the proposal will not generate direct patient care revenues, and research subjects will not be billed for these research efforts. The Hospital will only bill patients for pre-operative clinical purposes (i.e. brain mapping prior to neurosurgery), ruling out neurological conditions, or Hospital patients whose clinical need would be better met by a 3T magnet. (CON Application, April 15, 2002, pages 10&11)
- 23. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs associated with the Hospital's proposal. (CON Application, April 15, 2002, page 285)

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

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

- 24. There is no State Health Plan in existence at this time. (CON Application, April 15, 2002, page 3)
- 25. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. (CON Application, April 15, 2002, page 3)
- 26. The Hospital has improved productivity and contained costs by participating in energy conservation, group purchasing, reengineering and application of technology. (CON Application, April 15, 2002, page 9)
- 27. The unique patient/physician mix characteristics related to this proposal is the IOL is the largest private not-for-profit behavioral health provider in the State of Connecticut. (CON Application, April 15, 2002, page 10)
- 28. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. (CON Application, April 15, 2002, page 7 and Appendix E)

Rationale

Hartford Hospital proposes to acquire a 3T MRI unit to conduct schizophrenia and other neuropsychiatric research at 200 Retreat Avenue in Hartford in a wing of the Neuropsychiatry Research Center at the Institute of Living. The IOL is proposing to utilize non-invasive methods to study the structure, function, and chemistry of the living brain to advance the knowledge of schizophrenia and other neuropsychiatric disorders and their prevention and treatment. The Hospital's proposed research effort will address the causes, symptoms and sequelae of schizophrenia across the course of the illness and throughout the patient's life. It will focus on "translational research", which translates our growing knowledge of the underlying mechanisms of disease into effective clinical treatments.

The proposed 3T MRI unit will facilitate new research developments into the cause and treatment of schizophrenia. The Hospital anticipates that within 3-5 years the research initiatives associated with this proposal will result in more effective understanding, diagnosis, treatment, and prevention of illness episodes in these populations. As published professional articles have documented, the 3T MRI unit offers shorter imaging times and better image resolution. Improvements of about 20-50% can be realized in SNR per unit time and spectral resolution. These advantages allow shorter examinations and better quantification. Diffusion-tensor magnetic resonance imaging at 3.0 T offers better image resolution (MR) or shorter imaging time than that at 1.5 T because of a 40% increase in SNR.

The Hospital has established a collaborative research effort with Yale University Department of Psychiatry. The Hospital will contract with Yale for the services of a Director of Research to help in the development of a Schizophrenia Research Center at the IOL. The Director will be responsible for the administration and management of the Research Center. The Hospital states it will seek informed consent from volunteer research subjects prior to participating in the proposed research project. Discussions are currently under way with various departments of the University of Connecticut School of Medicine to establish a collaborative research effort. The Hospital's proposal will advance the current research of schizophrenia and other neurological disorders, especially with the collaboration of other respected research centers. Therefore, OHCA finds that the Hospital's research effort will improve access to possible future treatments of these disorders, thereby improving the quality of life for these populations.

Based on past experience in the establishment of a research center and funded research projects of this kind, the Hospital projects to perform 600, 1,500, and 2,000 total MRI scans on the 3T MRI unit in the first three years of operation. The Hospital estimates the potential clinical use would never be more than 10%, and the projected budget is based on 5%. All clinical (non-research) scans will be performed on an ambulatory basis. Therefore, the Hospital's volume statistics appear to be realistic.

The proposal is financially feasible. The proposal has a total capital expenditure of \$3,500,000, which will be financed entirely through existing charitable contributions earmarked specifically for the research of schizophrenia and other neuropsychiatric disorders. The 3T MRI unit and associated support areas will be located in 5.117 square feet of space located on the first floor of the White Hall building. The Hospital projects a loss of revenues incremental to the project of \$400,100, \$474,643, and \$474,643 for the first three years of operation of the 3T MRI unit due to non-cash depreciation expenses. The Hospital projects an excess of revenues with the project of \$19,090,227, \$19,463,189, and \$19,882,209 in FYs 2003, 2004, and 2005, respectively. The Hospital's proposal will not generate direct patient care revenues, and research subjects will not be billed for these research efforts. The Hospital will only bill patients for preoperative clinical purposes (i.e. brain mapping prior to neurosurgery), ruling out neurological conditions, or Hospital patients whose clinical need would be better met by a 3T magnet. Based on the above factors, the financial projections appear to be reasonable and achievable. Therefore, the Hospital's proposal is in the best interests of consumers and payers.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Hartford Hospital to acquire a 3T MRI Unit at the Institute of Living, at a total proposed capital expenditure of \$3,500,000, is hereby GRANTED.

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Order

Hartford Hospital is hereby authorized to acquire a 3T MRI Unit at the Institute of Living, at a total proposed capital expenditure of \$3,500,000, subject to the following conditions:

- 1. The Hospital shall submit to OHCA copies of its research policies and research protocol associated with this project, including informed consent, as approved by the Hospital's Institutional Review Committee.
- 2. This authorization shall expire on June 24, 2003, unless the Hospital presents evidence to OHCA that the 3T MRI equipment has become operational by that date.
- 3. The Hospital shall not exceed the approved capital expenditure of \$3,500,000. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA, a request for approval of the revised project budget.

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

By Order of the Office of Health Care Access

Date Signed: Mary M. Heffernan Presiding Officer

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