

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Department of Public Health Final Decision

Applicant: Connecticut Children's Medical Center

Docket Number: 17-32148-CON

Project Title: Acquisition of a 3.0 Tesla Magnetic Resonance Imaging Scanner

Project Description: Connecticut Children's Medical Center (or "Applicant") seeks authorization to acquire a new 3.0 Tesla Magnetic Resonance Imaging scanner to be located at its hospital campus at 282 Washington Street in Hartford, CT.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in the *Hartford Courant* (Hartford) on December 23, December 24 and December 25, 2016. On February 21, 2017, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on July 12, 2017. OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a. Deputy Commissioner Addo considered the entire record in this matter.



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Findings of Fact and Conclusions of Law

1. Connecticut Children's Medical Center ("CCMC" or "Applicant") is a 187-bed non-profit children's hospital located at 282 Washington Street in Hartford, Connecticut. Ex. A, pp. 10-11.
2. CCMC serves as the primary teaching hospital for the Department of Pediatrics at the University of Connecticut School of Medicine. Ex. A, pp. 11-12.
3. The Applicant performs approximately 4,400 imaging studies annually using a single, 1.5 Tesla ("1.5T") Magnetic Resonance Imaging ("MRI") scanner. Ex. A, p. 11.
4. In order to increase pediatric patients' access to high quality care, improve patient safety, and to reduce anesthesia and sedation wait times, the Applicant proposes to acquire a higher strength Philips Ingenia 3.0 Tesla ("3T") Omega MRI scanner. Ex. A, pp.11, 293.
5. Higher strength magnetic scanners such as the 3T are the current standard of care for diagnostic imaging in the United States for orthopedic, neurologic, cardiac, gastrointestinal and urologic conditions. Two-thirds of free-standing children's hospitals in the United States have this technology. Ex. A, pp. 11, 16-17.
6. The acquisition of the 3T scanner is intended to:
 - a. decrease the length of sedation required to acquire images;
 - b. reduce the Applicant's reliance upon computed tomography (CT) scanners for the evaluation of urgent/emergency conditions, thereby decreasing radiation exposure;
 - c. improve access to all patients regardless of their ability to pay, and
 - d. improve spatial resolution and post imaging processing.¹ Ex. A, pp. 13-14, 81.
7. Approximately 50% of the Applicant's patients require sedated MRI studies since many children under the age of 10 and those with developmental delays require anesthesia in order to remain still throughout the procedure.² Ex. A, pp. 12, 18-19.
8. Outpatients scheduled to receive scans risk postponement of their appointments so that the Applicant can accommodate emergency scans and inpatient examinations. The Applicant's wait times for non-emergent, sedated studies currently average between 10 and 15 days. Ex. A, pp. 11, 14.

¹ The term "spatial resolution" relates to the number of pixels that make up an image; specifically, more pixels of a smaller size equate to a sharper image and better diagnostic capability. The phrase "post-image processing" refers to computer-based manipulation of the imaging data to show additional detail that is not apparent to the eye based upon anatomy alone. Ex. A, p. 309.

² When assessing the need for an MRI scanner, the 2012 Statewide Health Care Facilities and Services Plan allows for consideration of unique patient populations and the complexity of scanning procedures, including the impact on available scanner access due to lengthy procedures. These guidelines have not yet been formally adopted into regulation.

9. According to the Journal of Neurosurgical Pediatrics, “The risk of developing a radiation-induced malignancy is relative to a patient’s cumulative radiation exposure and increases with exposure at younger ages.” It recommends employing an MRI rather than a CT-scanner to eliminate exposure to radiation and minimize sedation risks.³ Ex. A p. 98.
10. Children are more sensitive to radiation than adults, have a longer life expectancy than adults with a larger window for exposure to radiation damage and may receive a higher radiation dose than necessary if CT settings are not adjusted for their smaller body size, according to the National Cancer Institute.⁴ Ex. A, p. 107.
11. In *MR Imaging at 3.0T in Children*, The Hospital for Sick Children and the University of Toronto list among the advantages of 3.T over 1.5T MRI scans the acquisition of good-quality images even with a small field of view and a shorter acquisition time, the latter of which is beneficial for children who many not be able to cooperate for long and require additional patient monitoring. As with adults, the 3T offers a doubled signal-to-noise ratio, improved spatial resolution and improved contrast-to-noise ratio, resulting in clearer images and improved diagnostics.⁵ Ex. A, p. 81.
12. The Applicant’s historical volume, as shown below, has increased since 2014, however the number of scans that can be performed on the 1.5T is constrained by the longer time required to perform pediatric scans and the limited possible scheduling hours due to the requirement that patients fast before procedures.

**TABLE 1
HISTORICAL (ACTUAL) NUMBER OF SCANS BY FISCAL YEAR**

Scanner	FY 2014	FY 2015	FY 2016	FY 2017	Change FY 2014- FY 2017
TOTAL 1.5T	4,165	4,374	4,490	4,320*	3.7%

*FY 2017 annualized based on data from 10/1/2016 through 6/30/2017.
Ex. A, p. 11; Ex. C, p. 309.

13. The Applicant estimates that the 3T scanner will be operational by January 2018. Ex. A. p. 10.

³ Eric Thompson, M.D. et al., *Results of a North American Survey of rapid-sequence MRI utilization to evaluate cerebral ventricles in children*, 13 J NEUROSURG PEDIATRICS 636-640 (June 2014).

⁴ National Cancer Institute, *Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers* (June 2012).

⁵ Govind B. Chavhan, M.D. et al., *MR Imaging at 3.0T in Children: Technical Differences, Safety Issues, and Initial Experience*, 29 RADIOGRAPHICS 1451-1466 (2009).

14. As shown in the table below, the Applicant projects an overall 37% increase in scans from FY 18 through FY 21.

**TABLE 2
PROJECTED NUMBER OF SCANS BY FISCAL YEAR**

Scanner	FY 2018	FY 2019	Change*	FY 2020	Change*	FY 2021	Change*	FY18-21 Change
Total 3T Scans	750	1,450	93%	2,125	47%	2,675	26%	257%
Total 1.5T Scans	4,490	4,490	0%	4,490	0%	4,490	0%	0%
TOTAL	5,240	5,940	13%	6,615	11%	7,165	8%	37%

* The Applicant projects declining year-over-year percent increases on the 3T as it reduces its existing backlog of patients and stabilizes the number of scans it must refer elsewhere due to 1.5T scanner capacity issues. Ex. A, pp. 23, 33; Ex. E p. 314.

15. The Applicant attributes the aforementioned projections due to:
- advancements within existing and future service lines requiring diagnostic imaging;⁶
 - additional complex cases in sub-specialty care,
 - rotation away from CT imaging to minimize radiation exposure; and
 - reductions in the back-log of patients waiting for scans. Ex. A, pp. 23; Ex. C, p. 310.
16. The Applicant anticipates that by FY21, with the addition of the 3.0T, it will be able to provide 225 MRI scans per year to children who would otherwise receive a CT-scan. Ex. E, p. 314.
17. The Applicant currently must refer approximately 1,500 patients per year elsewhere to receive their scans. Ex. C, p. 308.
18. By performing the scans in-house, coordination of care will improve by reducing invasive, high-risk testing; eliminating the risks associated with transferring patients to other facilities; and maintaining the image and results within the patient’s electronic medical record. Ex. A, p.21.
19. The Applicant has a backlog of between 175 and 225 MRI scans to perform on non-emergent patients. Ex. E, p. 314.
20. While other hospitals provide pediatric as well as adult MRI scans, CCMC is the only freestanding children’s general hospital in Connecticut. Ex. A, p. 35.
21. CCMC solely treats children and has a special team assembled for those children requiring MRIs that require sedation, consisting of a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist, and Pediatric Radiologist. The team’s focus is trifold: to ensure

⁶ A service line is a group of condition-specific, related services, defined by their integrated functions and overlapping patient need, integrated to create a coordinated patient experience. Ex. A., p 310.

sedation is performed safely, to minimize the child and its family’s anxiety, acquire quality imaging with minimal movement to prevent the need for re-scans. Ex. A, p. 12.

22. The total capital expenditure for the purchase of the 3T MRI is \$3,960,846, approximately \$822,000 of which, the Applicant will use for construction/renovation. The Applicant will make the purchase using cash from operations. Ex. A, p. 3.

23. The Applicant anticipates operational gains associated with the acquisition and utilization of the new scanner. Ex. A, p. 23.

**TABLE 3
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2018	FY 2019	FY 2020	FY 2021
Revenue from Operations	\$736,896	\$1,452,957	\$2,171,920	\$2,788,745
Total Operating Expenses*	\$709,435	\$1,306,373	\$1,359,073	\$1,369,477
Gain/Loss from Operations	\$27,461	\$146,584	\$812,847	\$1,419,268

* Includes salaries, fringe benefits, professional and contracted services, supplies and drugs and depreciation
Ex. A, p. 32.

24. As shown in the table below, Applicant’s current payer mix consists of nearly 46% of patients covered by Medicaid and 53% covered by commercial insurers.

**TABLE 4
APPLICANT’S CURRENT & PROJECTED PAYER MIX**

Payer	FY 2015		FY2016		Projected									
					FY 2017		FY 2018		FY2019		FY2020		FY 2021	
	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%
Medicare*	7	0.2%	12	0.3%	2	0.3%	15	0.3%	17	0.3%	19	0.3%	20	0.3%
Medicaid*	2,013	45.9%	2,060	45.9%	324	45.9%	2,404	45.9%	2,726	45.9%	3,035	45.9%	3,289	45.9%
CHAMPUS & TriCare	47	1.1%	34	0.8%	6	0.8%	45	0.9%	50	0.8%	56	0.8%	61	0.9%
Total Government	2,067	47%	2,106	47%	332	47%	2,464	47.1%	2,793	47%	3,110	47%	3,370	47.1%
Commercial Insurers	2,289	52.3%	2,369	52.8%	372	52.7%	2,761	52.7%	3,130	52.7%	3,486	52.7%	3,775	52.7%
Uninsured/Self Pay	18	0.4%	15	0.3%	2	0.3%	15	0.3%	17	.03%	19	0.3%	20	0.3%
Workers Compensation	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total Non-Government	2,307	52.7%	2,384	53.1%	374	53%	2,776	53%	3,147	53%	3,505	53%	3,795	53%
Total Payer Mix	4,374	99.9%	4,490	100.1%	706	100%	5,240	100%	5,940	100.1%	6,615	100%	7,165	100.1%

*FY 2017 data is based on months 10/1/2016 through 6/30/2017.

Ex. A, p. 34.

25. Due to its specialized, child-focused services, the Applicant's primary service area spans 42 towns throughout Connecticut. Ex. A, pp 29.
26. No change in access for the patient population served by this proposal is projected and, in particular, for Medicaid patients. Ex. A, pp. 21, 34.
27. The Applicant anticipates no significant change in the amount of incoming referrals received, but expects to retain more of its existing outpatient business. Ex. A, p. 29.
28. There will be no change to the Applicant's pricing structure or cost to consumers as a result of this proposal. Ex. A, p. 21.
29. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
30. This CON application is consistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2)); Ex. A, pp. 18.
31. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3)); Ex. A, pp. 18.
32. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)); Ex. A, pp. 22-23.
33. The Applicant has satisfactorily demonstrated that the proposal will improve quality, and maintain accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5)); Ex. A, pp. 17-20.
34. The Applicants have shown that there would be no significant change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients. (Conn. Gen. Stat. § 19a-639(a)(6)); Ex. A, pp. 24, 34.
35. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7)); Ex. A, pp. 24-25.
36. The utilization of existing health care facilities and health care services in the Applicant's service area supports this application. (Conn. Gen. Stat. § 19a-639(a)(8)); Ex. A, p. 35.
37. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)); Ex. A, p. 30.
38. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)); Ex. A, p. 34.

39. The Applicant has demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)); Ex. A, p. 30.

40. The Applicants have satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or access to care. (Conn. Gen. Stat. § 19a-639(a)(12)); Ex. A, p. 21.

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

CCMC, a 187-bed free-standing children's hospital in Hartford, currently utilizes a single 1.5T MRI scanner to conduct approximately 4,400 MRI scans annually. CCMC seeks to acquire a Phillips Ingenia 3T Omega MRI scanner for its main campus, at a cost of \$3.96 million. *FF1-FF4*, 23.

Recent studies indicate that higher strength MRI scanners, such as the 3T MRI scanner, are the current standard of care for the majority of free-standing children's hospitals in the United States. Not only will the proposed scanner produce sharper and more detailed images, the acquisition and utilization of the new scanner will reduce the length of sedation required to complete imaging, and decrease radiation exposure associated with the utilization of CT scans. *FF5-6*.

As with adults, the 3T offers a doubled signal-to-noise ratio, improved spatial resolution and improved contrast-to-noise ratio, resulting in clearer images and improved diagnostics. An added benefit to children is that, the 3T maintains good-quality images even with a small field-of-view in a shorter time. *FF12*. Limiting the acquisition time is of particular importance when scanning children as children under the age of 10 and those with special needs often have difficulty remaining still for the duration of the procedure. Approximately 50% of the Applicant's patients require sedation. *FF7*.

CT scanners are often employed for the evaluation of urgent conditions when MRI scanning is unavailable. *FF6*. MRIs eliminate the exposure to radiation resulting from CT scans. Children are more sensitive to radiation than adults and due to their longer life expectancies they have a larger window of exposure to radiation damage and may additionally receive a higher radiation dose than necessary if CT settings are not adjusted for their smaller body size, according to the National Cancer Institute. *FF10*. It is therefore recommended that MRIs be performed on children. *FF11*. The Applicant anticipates that by FY21, it will, on its second MRI, perform approximately 225 MRI scans on children that would have otherwise received CT-scans. *FF16*. As a result, image quality will be improved and childhood exposure to radiation will be minimized due to the proposal.

CCMC is the sole general children's hospital in Connecticut. It has a special team assembled for those children requiring MRIs that require sedation, consisting of a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist, and Pediatric Radiologist. The teams' focus is trifold: to ensure sedation is performed safely, to minimize the child and its family's anxiety, acquire quality imaging with minimal movement to prevent the need for re-scans. *FF20*.

Currently, the Applicant must refer approximately 1,500 patients per year to other facilities and it has a backlog of between 175 and 225 scans to perform. *FF17*, 19. With the introduction of the second MRI, CCMC will be able to accommodate these patients in its specialty care setting. By performing the scans in-house, the risks associated with transferring patients to other facilities will be reduced, and

coordination of care will be improved due to patients' imaging results and electronic medical records remaining with CCMC. As such, the proposal will increase access to quality care.

Furthermore, the Statewide Healthcare Facilities and Services Plan takes into consideration the "unique patient populations" and "complexity of scanning procedures" when assessing a hospital's need for a new or additional MRI. As the only freestanding general children's hospital, CCMC serves a unique patient population. Due to the nature of scanning children and their specialized sedation needs and increased risk of radiation from other imaging techniques, CCMC may also be considered to provide complex scanning. *FF11, 20-21.*

The Applicant expects to retain more of its existing outpatient business as a result of increased capacity following the acquisition. Notwithstanding, the Applicant's proposal should have minimal to no effect on upon existing providers due to the size and scope of its primary service area and the specialized population it serves. As the proposed scanner will be used in the same location as the existing 1.5T MRI scanner, the Applicant will continue to serve the same patient population, including Medicaid and indigent patients. Moreover, access to care will be maintained and the proposal will not affect patient cost. All of these benefits are consistent with the Statewide Health Care Facilities and Services Plan. *FF15-FF19.*

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application requesting authorization to acquire a 3T MRI Scanner, at Connecticut Children's Hospital in Hartford, Connecticut, is hereby APPROVED.

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

By Order of the
Department of Public Health
Office of Health Care Access



9/13/2017
Date

Yvonne T. Addo, MBA
Deputy Commissioner