



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

July 15, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 13-31815-CON

Yale-New Haven Hospital

**Acquisition of a Portable Computed
Tomography Scanner**

To:

Nancy Rosenthal
Senior Vice President-Health Systems Development
Yale-New Haven Hospital
2 Howe Street
New Haven, CT 06510

Dear Ms. Rosenthal:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On July 15, 2013, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

A handwritten signature in black ink, appearing to read "Kim Martone", written over a horizontal line.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:swl



Office of Health Care Access Certificate of Need Application

Final Decision

Applicants: Yale-New Haven Hospital
20 York Street, New Haven, Connecticut

Docket Number: 13-31815-CON

Project Title: Acquisition of a Portable Computed Tomography
Scanner

Project Description: Yale-New Haven Hospital (“YNHH” or “the Applicant”) is proposing to acquire a Portable Computed Tomography (“P-CT”) scanner to be used for Neurological and Neurosurgical Intensive Care patients at its main campus located at 20 York Street, New Haven, Connecticut.

Procedural History: On January 7, 2013, the Office of Health Care Access (“OHCA”) received the completed Certificate of Need (“CON”) application from YNHH for the above-referenced project and deemed the application complete on March 25, 2013. A notice to the public concerning OHCA’s receipt of YNHH’s intent to file the application with OHCA was published on November 22, 23 and 24, 2012, in *The New Haven Register* (New Haven). 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.

FINDINGS OF FACT

1. YNHH is a 1,407-bed acute care hospital located at 20 York Street in New Haven. Ex. A, p. 65.
2. YNHH is proposing the acquisition of an 8-slice NeuroLogica Ceretom P-CT scanner, which images the head only. Ex. A, p.16.
3. YNHH will utilize the P-CT scanner for patients in its Neuroscience Intensive Care Unit ("NICU"). Ex. A, p.16.
4. YNHH's NICU is comprised of a 14-bed unit that treats patients with a wide variety of neurological and neurosurgical conditions such as brain tumors, intracerebral hemorrhages, severe strokes, refractory seizures, subdural and epidural hematomas and neurological infections. Ex. A, p.16.
5. According to the Applicant, patients with neurological and neurosurgical conditions (hereinafter referred to as "Patients") require frequent Computed Tomography ("CT") imaging to monitor responses to treatment and clinical status, and to assess radiographic correlates to clinical changes. On average, each patient encounter in the NICU requires between 2.0 and 2.3 CT scans during a stay in the intensive care unit. Ex. A, pp. 15-17.
6. The historical practice at YNHH was to transport the Patients from the intensive care unit to the Radiology Department to receive a CT scan. Such transport had been necessary as the marketplace did not offer portable CT scanning, but over the past several years the technology has been developed and perfected and is now available. Ex. A, pp. 15-17.
7. YNHH's NICU is located on the 6th floor of the South Pavilion. A NICU patient requiring a CT scan would be transported to the Radiology Department, located on the 2nd floor of the South Pavilion. Due to the medical condition of NICU patients, most are mechanically ventilated, have invasive monitoring, and are receiving multiple intravenous vasoactive medications. NICU patients must be transported in a hospital bed, a process which requires at least three staff members, including a nurse and respiratory therapist. The transport often must occur during night time hours when the CT scanners have availability but staffing levels are lower. Ex. A, pp. 15-17.
8. According to the Applicant, the current process creates patient safety concerns and logistical difficulties for clinical staff. A NICU patient's transfer to the Radiology Department for a CT scan is time consuming and labor intensive, and staff are off the unit for extended periods of time, which strains the NICU staffing for the care of other patients in the NICU. Ex. A, pp. 15, 18.
9. According to the Applicant, transporting critically ill patients, especially those with neurological injuries or conditions, is inherently risky. Multiple studies have

- identified complications that may occur during intra-hospital transport. For intensive care unit patients, transport off the unit increases the risk of injury or complication since the patients are likely to be in a more remote part of the hospital with fewer resources, equipment and staff in the event of an emergency. Ex. A, p.17.
10. According to a journal article submitted by the Applicant, transport of patients within the hospital to a radiology suite is associated with logistical and safety issues and may require a significant amount of care provider time. Together, these factors can increase risk of secondary neurological injury. The Use of a Portable Health CT Scanner in the Intensive Care Unit, *Journal of Neuroscience Nursing*, 2010. Ex. A, p. 48.
 11. The aforementioned journal article also indicates that most providers prefer using a P-CT scanner because they believe that it improves patient safety. The article concludes that P-CT scanning should improve patient care because enhanced patient safety is likely to result from use of this point-of-care technology. The Use of a Portable Health CT Scanner in the Intensive Care Unit, *Journal of Neuroscience Nursing*, 2010. Ex. A, pp. 52, 54.
 12. A study submitted by the Applicant concludes that P-CT can be reliably and consistently performed at the patient's bedside in the ICU and should lead to decreased transportation related morbidity and improve rapid decision making. Experience With Use of a Second Generation Portable Head CT Scanner in the Neuroscience Intensive Care Unit, Andrew P. Carlson, MD and Howard Yanos, MD, Department of Neurosurgery, University of New Mexico Health Sciences Center, Albuquerque, NM, USA. Ex. A, p. 57.
 13. Another study submitted by the Applicant indicates that P-CT may be helpful in reducing the risks associated with transporting NICU patients in need of follow up head CT scans, particularly for those patients with severe brain injuries. Repeat imaging requiring transport of these patients from the NICU to the radiology department carries an inherent risk and can affect patient outcome adversely or lead to unexpected events that may compromise patient care. Portable head CT scan and its effect on intracranial pressure, cerebral perfusion pressure, and brain oxygen, *Journal of Neurosurgery*, December 17, 2010. Ex. A, p. 62.
 14. The proposed P-CT scanner allows for the required CT scanning to be performed by the patient's bedside. Patients no longer have to be transported, clinicians do not have to leave the unit, and scans can be safely and effectively obtained. Ex. A, p. 15.
 15. The proposed patient populations are those NICU patients currently being treated at YNHH. YNHH's specialized NICU serves as a major referral location for critically ill neurological and neurosurgical patients. Ex. A, p. 20.

16. YNHH reports the following historical CT scanner volume for NICU Patients:

Table 1: Historical CT Scanner Volume for NICU Patients

	FY 2010	FY 2011	FY 2012	FY 2013*
CT Scans	2,087	2,371	1,883	2,298
Percentage change		13.6%	(22.7%)	22.0%

*FY 2013 annualized based on actual 4-month volume.

Note: Volumes fluctuate as the patient mix in the NICU varies from year to year and the frequency and quantity of CT scans varies by diagnosis and patient condition.

Ex. A, pp. 21 & 22, Ex. B, p. 81.

17. YNHH's annualized and projected CT Scanner utilization for NICU Patients is as follows:

Table 2: Projected CT Utilization (NICU patients only)

	FY 2013*	FY 2014	FY 2015	FY 2016
P-CT Scans	2,298	2,479	2,479	2,479

*Historical volumes between 2010 and 2012 were averaged to estimate 2013; 122 scans were added to account for one additional scan per day for 4 months of FY 2013. This additional scan per day represents NICU patients who needed but did not receive a CT scan because clinical condition precluded transport to Radiology Department.

FY 2013 annualized based on actual 4-month volume.

FY 2014-2016 projections were based on the following calculations:

FY 2014: Avg. of 2010-2012 plus additional 365 scans (1 additional per day).

FY 2015-2016: Projections held flat since NICU is fully occupied.

Ex. A, p. 21-23, Ex. B, p. 81.

18. YNHH is the only provider in the service area that offers neuroscience intensive care services. No other Connecticut provider offers P-CT services to this population. Ex. A, p. 19.
19. The populations to be served by the proposed P-CT scanner are NICU patients at YNHH. During FY 2012, approximately 50% of YNHH's NICU patients came from the following towns: New Haven (13.5%), Hamden (6.1%), Milford (5.1%), West Haven (4.6%), Branford (4.4%), East Haven (4.0%), Waterbury (4.0%), Bridgeport (3.2%), Madison (2.7%) or Stratford (2.7%). In addition, the NICU treated patients from 53 additional Connecticut towns, as well as out-of-state patients. Ex. A, pp.15-19 and pp. 41-45.

20. The current and projected payer mix for YNHH's NICU population is projected to remain unchanged:

Table 3: Current and Projected NICU Patient Payer Mix

Payer	Current	Projected
Non-Government	45%	45%
Medicare	36%	36%
Medicaid	18%	18%
Other Government	1%	1%
Total Government	55%	55%
Total	100%	100%

Ex. A, pp. 25-26.

21. The total capital expenditure for the acquisition of the P-CT scanner by YNHH is \$436,860 which will be funded through an equity contribution. Ex. A, p. 25.
22. YNHH does not project any incremental revenue from this proposal, only incremental expenses. The projected incremental losses from this proposal for FYs 2014 through 2016 are (\$204,000), (\$206,000) and (\$212,000), respectively. Ex. A, pp. 27 & 72.
23. The projected operating losses incremental to the proposal are related to the depreciation expense of the P-CT scanner and the incremental staff (0.7 FTEs) expense to provide a CT technologist on the NICU to operate the P-CT scanner. Ex. C, p. 82.
24. YNHH projects overall operating gains, which include the P-CT scanner:

Table 4: YNHH's Overall Financial Projections (in thousands)

Description	2014	2015	2016
Incremental Revenue from Operations	\$2,480,865	\$2,597,291	\$2,726,806
Incremental Total Operating Expense	\$2,403,664	\$2,508,757	\$2,630,714
Overall Gain from Operations	\$77,201	\$88,534	\$96,092

Ex. A, p. 72.

25. 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))
26. The Applicant's proposal is in accordance with OHCA's Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
27. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

28. The Applicant has satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
29. The Applicant has satisfactorily demonstrated that its proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))
30. The Applicant has satisfactorily demonstrated that there would be no change to the provision of health care services to the relevant population and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))
31. The Applicant has satisfactorily identified the population to be served by its proposal and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))
32. The Applicant's historical utilization of CT scans for NICU patients supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
33. The Applicant has satisfactorily demonstrated that its proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

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 General Statutes § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services, 288 Conn. 790 (2008)*.

YNHH is proposing the acquisition of a P-CT scanner which images the head only, and is used exclusively for neuroscience intensive care unit (NICU) patients. *FF2&3*.

YNHH's 14-bed NICU treats patients with a wide variety of neurological and neurosurgical conditions such as brain tumors, intracerebral hemorrhages, severe strokes, refractory seizures, subdural and epidural hematomas and neurological infections. *FF4*. CT imaging has become an increasingly important diagnostic tool for these patients, who often require frequent imaging to monitor treatment responses and clinical status. *FF5*.

Prior to the acquisition of the P-CT scanner, the patients were transported in their hospital bed from the NICU located on the 6th floor to the Radiology Department on the 2nd floor, a process requiring multiple staff, including the patient's nurse and a respiratory therapist. *FF6&7*. This particular patient population requires special care during transport, as most of YNNH's NICU patients are mechanically ventilated, have invasive monitoring and are receiving multiple intravenous vasoactive medications. Moreover, such transport often occurs at night, when CT scanners are available, but staffing levels are lower. *FF7*.

The transportation process creates patient safety concerns and many logistical difficulties for clinical staff, as it is time consuming, labor intensive and creates issues for the care of other intensive care patients since NICU staff are off the unit for extended periods of time. *FF8*. Studies have identified issues that can occur during intra-hospital transport, which may include increased risk of second neurological injury or complications, since patients are likely to be in more remote areas of a hospital with fewer resources, equipment and staff in the event of an emergency. *FF9&10*. Studies also indicate that improved patient care and safety are likely to result from this point-of-care technology, and that most providers prefer using a P-CT scanner for this reason. *FF11*. Additionally, these studies note that CT scanning at a patient's bedside should lead to decreased transportation related morbidity, improve rapid decision making and reduce risk related to follow up scans. *FF13*. The P-CT scanner allows for the required CT scanning to be performed by the patient's bedside. Patients no longer have to be transported, clinicians do not have to leave the unit, and scans can be safely and effectively obtained. *FF14*.

YNHH is the only provider in the service area that offers neuroscience intensive care services. Additionally, there is no other provider in Connecticut that offers P-CT scanner services. *FF18*. Based on the unique patient population, its special imaging needs, and the fact that only YNHH will offer this bedside scanning service for NICU patients, OHCA finds there to be sufficient need for the proposed P-CT scanner. Moreover, OHCA finds

the projected utilization of the P-CT scanner to be reasonable, as each patient requires between 2.0-2.3 CT scans during their stay in the NICU and historical volume, although fluctuating due to variations in patient mix and diagnosis, has averaged more than 2,000 scans annually. *FF5&16*. In light of historical P-CT utilization, YNHH has demonstrated a sufficient basis to support its projected volume, which takes into account P-CT scans for those NICU patients with clinical conditions too serious to transport to the Radiology Department. *FF17*.

The total capital expenditure associated with this proposal is \$436,860 to be funded through YNHH's equity. *FF21*. Although there are projected annual losses incremental to the proposal, they are primarily associated with depreciation of the proposed scanner and the incremental staff expense to provide a CT technologist. *FF22&23*. YNHH, however, is projecting an overall operational gain, which includes the P-CT scanner, for the next three years. *FF24*. Based on YNHH's overall financial projections, OHCA finds this proposal to be financially feasible.

Based on the foregoing, OHCA finds that the Applicant has demonstrated that there is a need for the proposed acquisition and that the quality of care will likely be improved due to increased patient safety.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Yale-New Haven Hospital for the acquisition of a Portable Computed Tomography scanner to be utilized for its patients in the Neuroscience Critical Care Unit is hereby **APPROVED**.

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

Date

7/15/13



Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner

*** TX REPORT ***

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

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AGENCY: YALE-NEW HAVEN HOSPITAL

FROM: STEVEN LAZARUS

DATE: 7/15/13 TIME: _____

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Comments: DN: 13-31815-CON Notice of Final Decision

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