STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

February 25, 2015

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: 14-31952-CON
Hartford Hospital	**Acquisition of a PET/CT Camera**

To:

Barbara A. Durdy
Director, Strategic Planning
Hartford Healthcare
181 Patricia Genova Drive
Newington, CT 06111

Dear Ms. Durdy:

This letter will serve as notice of the approved Certificate of Need Application in the above-referenced matter. On February 25, 2015, the Final Decision, attached hereto, was adopted and issued as an Order by the Department of Public Health, Office of Health Care Access.

Kimberly R. Martone
Director of Operations

Enclosure
KRM: amv

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **Hartford Hospital**
181 Patricia M. Genova Drive, Newington, CT 06111

Docket Number: **14-31952-CON**

Project Title: **Acquisition of a Single Photon Emission Computed Tomography/Computed Tomography Camera**

Project Description: Hartford Hospital ("Applicant") is seeking authorization to acquire a new Single Photon Emission Computed Tomography/Computed Tomography ("SPECT/CT") camera, to replace its existing SPECT and Gamma cameras. The total capital expenditure associated with this proposal is $1,000,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in the *Hartford Courant* on July 30, 31 and August 1, 2014. On October 6, 2014, 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 December 29, 2014. 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 Brancifort considered the entire record in this matter.

Findings of Fact and Conclusions of Law

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

1. The Applicant is an 867[1] bed not-for-profit acute care hospital located at 80 Seymour Street, Hartford, CT and a health care facility as defined by Conn. Gen. Stat. § 19a-630. Ex. A, p. 265.

2. The Nuclear Medicine Laboratory at Hartford Hospital utilizes two Philips SPECT[2] cameras and two Philips Argus Gamma[3] cameras to perform planar nuclear medicine and SPECT nuclear medical studies. Ex. A, pp.11-12.

3. The Applicant proposes to acquire a Siemens Symbia Intevo SPECT/CT camera to replace one of its existing Philips SPECT cameras and one of its Philips Gamma cameras currently used for nuclear imaging services in the Nuclear Medicine Laboratory. Ex. A, pp. 8, 10.

4. Both cameras are at the end of their useful life. The SPECT camera is 17 years old and the Gamma camera is 19 years old. Ex. A, p. 7.

5. The proposed equipment is a Siemens Symbia Intevo SPECT/CT camera with a 2-slice CT[4] component for attenuation correction and anatomic detail. Ex. A, p. 8.

6. The SPECT/CT camera has improved iterative reconstruction software that allows for more rapid image acquisition. The proposed SPECT/CT camera's quantitative analysis software eliminates up to 22 time-consuming steps performed on conventional SPECT cameras. Ex. A, p. 7.

7. SPECT images may be distorted due to body tissue density, resulting in low quality scans that appear cloudy or obstructed and confound the ability to interpret studies and diagnose disease. The proposed SPECT/CT camera's CT component provides attenuation and scatter correction, which adds clarity by removing these defects, resulting in improved

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[1] Includes 48 bassinets

[2] A SPECT scan is a type of nuclear imaging test that uses a radioactive substance and a special camera to create 3-D pictures, allowing for the analysis of the function of internal organs. *http://www.mayoclinic.org/tests-procedures/spect-scan/basics/definition/PRC-20020674*

[3] A Gamma camera is a device that uses the emission of light from a crystal struck by gamma rays to produce an image of the distribution of radioactive material in a body organ. The light is detected by an array of light-sensitive electronic components and is converted into electric signals, which are processed to produce the image. *http://medical-dictionary.thefreedictionary.com/gamma+camera*

[4] The non-diagnostic 2-slice CT component of the camera cannot be used as a stand-alone CT scanner, as it is not approved by the FDA for such use.

diagnostic accuracy, fewer false positive results and reduces the need for unnecessary follow-up testing. Ex. A, pp. 7-8, 16.

8. The spatial resolution of the proposed SPECT/CT camera's images is four times better than the images obtained from a SPECT camera. Ex. A, p. 7.

9. The proposed SPECT/CT camera will utilize a lower dose of radiation than the current SPECT camera, thereby reducing radiation exposure to the patient. Ex. A, p. 7.

10. An article, "Clinical SPECT/CT- Time for a New Standard of Care" presented at the 2013 SNMMI[5] session and submitted by the Applicant highlights the technical advances of SPECT/CT and improvements in the camera's attenuation correction. Ex. A, p. 162.

11. The proposed SPECT/CT camera will be installed at the same location as the existing Phillips SPECT camera. The existing SPECT camera and Gamma camera will be removed prior to installation of the new SPECT/CT camera. Ex. A, p. 11.

12. The population that will be served by the proposed SPECT/CT camera is the same population that is currently served by the existing cameras and therefore, there will be no impact on existing providers or duplication of services. Ex. A, pp. 10-11, 13.

13. The majority of the patients referred to the Hartford Hospital Nuclear Medicine Laboratory are within the Applicant's primary and secondary service areas. There will be no change in referral patterns as a result of this proposal. Ex. A, pp. 10, 144.

14. The proposed SPECT/CT camera will perform the same diagnostic nuclear medicine studies that are currently being performed by the Phillips SPECT camera and the Argus Gamma camera. Ex. A, p.11.

[5] Society of Nuclear Medicine and Molecular Imaging (SNMMI)

15. The Applicant's historical utilization for the Hartford Hospital Nuclear Medicine Laboratory is as follows:

TABLE 1
APPLICANT'S HISTORICAL UTILIZATION
FISCAL YEARS 2011-2013

Scanner	FY 2011	FY 2012	FY 2013	Change FY 2011-2013
Phillips Solus SPECT*	620	625	620	0%
Philips Brightview SPECT	620	625	620	0%
Philips Argus Gamma-1*	448	469	448	0%
Phillips Argus Gamma-2	448	469	448	0%
Total	**2,136**	**2,187**	**2,136**	**0%**

*Cameras to be replaced
Note: Hartford Hospital does not track the number of scans performed on each of the cameras. Volumes presented assume equal utilization of both SPECT cameras for SPECT studies and all four cameras for planar studies.
The Applicant's Fiscal Year covers the period of October 1st - September 30th.
Ex. A, pp. 11-12

16. The Applicant projects stable utilization, as follows:

TABLE 2
APPLICANT'S PROJECTED UTILIZATION
FISCAL YEARS 2014-2017

	Fiscal Years			
Equipment	**2014*** **	**2015**	**2016**	**2017**
Phillips Solus SPECT*	920	-	-	-
Phillips Brightview SPECT	1,220	900	900	900
Phillips Argus Gamma-1*	-	-	-	-
Phillips Argus Gamma-2	-	340	340	340
Siemens Symbia Intevo SPECT/CT**	-	900	900	900
Total MRI Scans	2,140	2,140	2,140	2,140

*Cameras to be replaced
**Proposed new SPECT/CT
***Annualized based on October 1, 2013-June 15, 2014
Ex. A, pp. 11-12.

17. Due to manufacturer cessation[6], the two Argus Gamma cameras were out of service for the entire year of 2014, and the Solus SPECT camera was out of service for 3 months. During that time, patients requiring nuclear medicine studies were either accommodated by other Hartford Hospital cameras or were sent elsewhere. Ex. A, pp. 11-12.

18. The proposal's total capital expenditure is itemized below:

[6] A cessation order letter instructs the users of a device to cease using the equipment due to risk of serious injury.

TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE

Imaging Equipment (SPECT/CT Camera)	$585,000
Construction/Renovation	$415,000
Total Capital Expenditure	**$1,000,000**

Ex. A, p. 15.

19. The proposed acquisition will be funded from the Applicant's operating capital. Ex. A, p. 16.

20. Small incremental losses are projected from FY 2015 through FY 2017. They are solely due to the added depreciation[7] expense resulting from replacing fully depreciated units with the proposed SPECT/CT camera.

TABLE 4
HARTFORD HOSPITAL'S PROJECTED INCREMENTAL REVENUES AND EXPENSES WITH THE PROPOSAL
FISCAL YEARS 2015-2017

	FY 2015	FY 2016	FY 2017
Revenue from Operations	-	-	-
Total Operating Expenses*	$144,867	$144,867	$144,867
Gain/(Loss) from Operations	**($144,867)**	**($144,867)**	**($144,867)**

*Operating expenses represent the change in depreciation amount.
Ex. A, p. 302.

21. The Applicant projects overall operational gains for the next three consecutive years.

TABLE 5
HARTFORD HOSPITAL'S OVERALL PROJECTED REVENUE AND EXPENSES
WITH THE PROPOSAL

	FY 2015	FY 2016	FY 2017
Revenue from Operations	$1,068,231	$1,082,740	$1,223,660
Total Operating Expenses	$1,016,076	$1,024,555	$1,065,253
Gain/(Loss) from Operations	**$52,154**	**$58,185**	**$60,406**

Note: figures are in thousands
Ex. A, p. 302

[7]A method of allocating the cost of a tangible asset over its useful life

22. The Applicant's patient population mix will remain unchanged as a result of this proposal.

TABLE 6
PATIENT POPULATION MIX

	FY 2014	FY 2015	FY 2016	FY 2017
Medicare*	39%	39%	39%	39%
Medicaid*	16%	16%	16%	16%
CHAMPUS &TriCare	1%	1%	1%	1%
Total Government	**56%**	**56%**	**56%**	**56%**
Commercial Insurers*	43%	43%	43%	43%
Uninsured	1%	1%	1%	1%
Total Non-Government	**44%**	**44%**	**44%**	**44%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity
Ex. C, p. 308.

23. There will be no change in access for the patient population served by this proposal. Ex. A, p. 10

24. 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))

25. The CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

26. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

27. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

28. The Applicant has satisfactorily demonstrated that access to services will be maintained and the quality of health care delivery and cost effectiveness will be improved. (Conn. Gen. Stat. § 19a-639(a)(5))

29. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))

30. The Applicant has identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))

31. The Applicant's historical utilization in the area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

32. 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))

33. 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))

34. The Applicant has satisfactorily demonstrated that the proposal will not result in a negative impact on the diversity of health care providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))

35. The Applicant has satisfactorily demonstrated that its proposal will not result in any consolidation. (Conn. Gen. Stat. § 19a-639(a)(12))

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. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727, 739-40 (2013).*

The Applicant, Hartford Hospital, an 867 bed not-for-profit acute care hospital, is seeking authorization for the acquisition of one SPECT/CT camera to replace one of two SPECT cameras and one of two Gamma cameras currently used in the hospital's Nuclear Medicine Laboratory. *FF1, 3.* The Applicant's existing Phillips Solus SPECT camera and Philips Argus Gamma camera were manufactured in 1997 and 1995, respectively, and are at the end of their useful life. *FF4*

The Applicant's Nuclear Medicine Laboratory uses both cameras to perform planar nuclear medicine and SPECT nuclear medical studies. *FF2.* During the scanning process, factors relating to different tissue densities may produce artifacts which confound the ability to interpret studies and diagnose disease. The proposed camera's CT component provides attenuation and scatter correction, which adds clarity by removing defects, resulting in improved diagnostic accuracy, fewer false positives and reduces the need for unnecessary follow-up testing. *FF7* The proposed SPECT/CT camera is capable of producing images that are four times better than the existing SPECT camera. *FF8* In addition, the proposed SPECT/CT camera will use a lower dose of radiation than the existing SPECT camera, thus reducing patients' radiation exposure. *FF9* Thus, the Applicant's proposal to replace the SPECT camera and Gamma camera with a single SPECT/CT camera will benefit its patient population by providing a higher quality, safer and more cost-effective option for nuclear testing. As a result, the Applicant has satisfactorily demonstrated not only that there is a clear public need for its proposal, but also that the quality of health care delivery and cost effectiveness will be improved.

The population to be served by the proposed SPECT/CT camera is the same population that is currently being served. Existing providers will not be impacted by this proposal as there will be no changes to referral patterns. *FF12* As a result, there will be no change in the payer mix or access provided to Medicaid recipients or indigent persons. *FF23* Consequently, this proposal will result in continued access for the patient population currently served with the added benefit of new and more technologically advanced equipment. Therefore, the Applicant has satisfactorily demonstrated that its proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons or result in a negative impact on the diversity of health care providers in the area.

The Applicant has projected stable demand for SPECT/CT imaging services from FY2015 through FY2017. *FF16* A review of the historical utilization indicates that the Applicant's projections are reasonable and achievable. The total capital expenditure associated with this proposal is $1,000,000 and will be funded from the Applicant's operating capital. *FF18-19* Despite slight incremental losses resulting from the added depreciation expenses, the Applicant will realize overall operational gains. *FF20-21* Therefore, the Applicant has demonstrated that its proposal is financially feasible.

The Applicant has satisfactorily shown that access to care will be maintained, quality of care will be improved and the overall enhancements in quality will improve the cost effectiveness of nuclear testing. All of these benefits are consistent with the overall goals of the Statewide Health Care Facilities and Services Plan.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Hartford Hospital for the acquisition of one SPECT-CT camera 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
Office of Health Care Access

Feb. 25, 2015
Date

Janet M. Brancifort
Janet M. Brancifort, MPH
Deputy Commissioner