



Final Decision

Applicant: **The Stamford Hospital**
 One Hospital Plaza
 P.O. Box 9317
 Stamford, CT 06904

Docket Number: **22-32447-CON**

Project Title: **Acquisition of Imaging Equipment**

I. Project Description

The Stamford Hospital (“TSH” or the “Applicant”) seeks authorization to acquire a Single-Photon Emission Computed Tomography/Computed Tomography (“SPECT/CT”) gamma camera for its off-campus location called the Tully Health Center (the “Center”) at 32 Strawberry Hill Court, Stamford, CT 06902.

II. Procedural History

The Applicant published notice of its intent to file a Certificate of Need (“CON”) application in *The Stamford Advocate* (Stamford) on December 21, 22, and 23, 2021. On January 12, 2022, the Health Systems Planning Unit of the Office of Health Strategy (“OHS”) received the CON application from the Applicant for the above-referenced project and deemed the application complete on April 29, 2022. No hearing requests were received from the public per C.G.S. § 19a-639a(e) nor did OHS conduct a hearing pursuant to C.G.S. § 19a-639a(f)(2)¹. On July 28, 2022, the Health Systems Planning Unit requested a sixty-day extension of the review period, until September 26, 2022. Acting Executive Director Kimberly R. Martone considered the entire record in this matter.

III. Provisions of Law

The proposal constitutes the acquisition of a SPECT/CT gamma camera for ~~THS’s~~ the Center, pursuant to C.G.S. § 19-638(a)(10). OHS considered the factors set forth in C.G.S. § 19a- 639(a) in rendering its decision.

¹ Since this application does not concern the “transfer of ownership involving a hospital,” no hearing was required under C.G.S. § 19a-639a(f)(1) either.

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. 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, 728-29 (2013).

IV. Findings of Fact and Discussion

A. Introduction and Background²

1. Stamford Health, Inc., a tax-exempt corporation, is the sole member or ultimate parent of TSH, a not-for-profit acute care hospital located at One Hospital Plaza, Stamford, Connecticut 06904. Ex. A, p. 175
2. TSH provides inpatient, outpatient, and emergency care services on its main campus and outpatient urgent care, imaging, and rehabilitation services at the Center. Ex. A, p. 175
3. TSH currently operates the following nuclear medicine devices:

TABLE A
EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Equipment Description	Days/Hours of Operation	Utilization FY21: 10/2020-09/2021
Stamford Hospital, Nuclear Medicine 1 Hospital Plaza Stamford, CT 06902	Unit 1: GE Infinia Unit 2: GE Infinia Hawkeye SPECT/CT – CT 2 Slice	Monday-Friday 8 AM-4 PM Emergency Call 7 days, 24hrs	1097 <i>Data is not tracked by machine; breakdown between 2 units unavailable.</i>
Tully Health Center 32 Strawberry Hill Court Stamford, CT 06902	Unit 1: Philips Forte Unit 2: Philips Axis	Monday-Friday 8 AM-4 PM	1442 <i>Data is not tracked by machine; breakdown between 2 units unavailable.</i>
Stamford Hospital, Non- Invasive Cardiology 1 Hospital Plaza Stamford, CT 06902	Unit 1: GE Optima 640 – CT 4 Slice	Monday-Friday 7AM -4 PM	875

Ex. C, p.2

4. The Applicant installed the Philips Marconi Axis SPECT gamma camera (the “Axis system”) at the Center in 2002 to provide nuclear medicine procedures. The manufacturer will no longer support the Axis system effective December 31, 2022. Ex. A, p. 9; Ex. D, p. 12

² Use of header descriptions in this document are for organizational purposes only and are not intended as restrictions on the use of information in relation to the CON statutory criteria.

5. TSH seeks approval to replace the existing Axis system with the NM/CT 850ES hybrid SPECT/CT imaging system manufactured by General Electric Healthcare (the “GE system”). Ex. A, p. 35
6. TSH has sufficient funds to purchase the GE system which has a total capital expenditure of \$737,000. Ex. A, p. 23; Exhibit B
7. The proposed GE system has more advanced capabilities than the current Axis system with the primary advancement being the ability to perform attenuation correction, a capability that enhances imaging interpretation and disease diagnoses. Ex. A, p. 12

B. Demonstration of Need

8. The cost of repairing and maintaining the Axis system from fiscal year (“FY”) 2019 to FY2022 (October 2021 to March 2022) totals \$26,993.65 and the machine has been down a total of 58.5 days during that time. Ex. E, p. 9
9. Phillips North America, the manufacturer of the Axis system, notified the Applicant via a letter dated September 20, 2021, that “Effective 12/31/2022, the lifecycle status of AXIS-235276 is being updated to End of Support (EoS), beyond which we expect our ability to support this system may be materially impacted.” Ex. E, p.12
10. Nuclear Medicine, as defined in the following chart, averaged a volume of 1,224 billed encounters for the last three completed fiscal years:

HISTORICAL UTILIZATION BY SERVICE AT TSH					
Machine	Service	Actual Volume [billed encounters] (Last 3 Completed FYs)			
		FY 2019	FY 2020	FY 2021	CFY Volume*
Nuclear Medicine (combined volume of two machines)	BONE SCAN	214	185	216	74
	CARDIAC AMYLOID	5	10	22	8
	GASTRIC EMPTYING	70	54	61	18
	HIDA SCAN	56	50	65	17
	MECKEL SCAN	1	0	1	0
	PARATHYROID SCAN W SPECT	53	39	33	12
	RENAL SCAN W LASIX	24	102	42	11
	SENTINEL NODE	69	26	79	21
	STRESS TEST	591	510	831	182
	THYROID UPTAKE	122	48	91	12
	TUMOR SPECT	0	0	1	0
Total		1205	1024	1442	355

*Months include October through January
Ex. D, p. 2

11. TSH anticipates shifting most of the nuclear medicine volume to the proposed GE system due to its attenuation correction and anatomic localization capabilities:

TABLE B
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment	<u>Actual Procedures (Last 3 Completed FYs)</u>			CFY Volume*	Projected Procedures (First 3 Full Operational FYs)		
	FY19	FY20	FY21	CFY22	FY22	FY23	FY24
Nuclear Medicine	1,205	1,024	1,442	198	1,365	1,365	1,406
Total	1,205	1,024	1,442	198	1,365	1,365	1,406

*Months include – October & November 2021

Ex. C, p. 5

12. The Axis system is so old that the equipment is incapable of utilizing modern software applications (such as Microsoft) which are required to label and accurately process scans. As a result, the images taken on the Axis system are routinely sent to the Philips Forte system for labeling and processing by the nuclear medicine technologist. Ex E, p. 14

Accordingly, the Applicant has satisfied C.G.S. §§ 19a-639(a)(2), (3), and (7).

C. Access

13. The proposed SPECT/CT will serve TSH’s Primary Service Area (“PSA”) of Stamford and Darien; patients from these two towns also represent 71% of the 1,024 procedures performed using existing equipment in FY 2020. Ex. A, pp. 10, 31

OHS TABLE 10
UTILIZATION BY TOWN
FY20

Official Connecticut Town	Volume: (Procedures)
Stamford	652
Norwalk	95
Darien	77
New Canaan	61
Greenwich	23
All Other	116

Ex. A, p. 31

14. The patient population will remain the same following the acquisition of the proposed equipment and is the same patient population currently utilizing the nuclear medicine cameras of the Center. Ex. A, p. 15
15. TSH is a Medicaid provider. Ex. A, p. 20
16. Medicaid beneficiaries are projected to comprise 9% of the payer mix for this service through FY 2024. Ex. A, p. 29
17. TSH does and will continue to accept all governmental payers. Ex. A, p. 29

APPLICANT'S CURRENT & PROJECTED PAYER MIX AT TULLY HEALTH CENTER

Payer	Most Recently Completed FY 21		Projected					
			FY 22		FY 23		FY 24	
	Volume	%	Volume	%	Volume	%	Volume	%
Medicare	733	51%	682	50%	682	50%	703	50%
Medicaid	126	9%	120	9%	120	9%	127	9%
TRICARE	0	0%	0	0%	0	0%	0	0%
Total Government	859		802		802		830	
Commercial Insurers: In-Network	535	37%	520	38%	520	38%	534	38%
Commercial Insurers: Out-of-Network*								
Uninsured	0	0%	0	0%	0	0%	0	0%
Self-pay	45	3%	40	3%	40	3%	42	3%
Workers Compensation	3	0.2%	3	0.2%	3	0.2%	3	0.2%
Total Non-Government	583		563		563		579	
Total Payer Mix	1442	100%	1365	100%	1365	100%	1406	100%

Ex. A, p. 29

18. TSH anticipates shifting most of nuclear medicine volume to the proposed GE system due to its attenuation correction and anatomic localization capabilities. Ex. A, p. 37

With respect to C.G.S. §§ 19a-639(a)(5) and (6), the Applicant has satisfactorily demonstrated that the Proposal will maintain accessibility of health care delivery in the region. Subsections (a)(10) and (a)(12) are not applicable as the Proposal does not reduce access to services by Medicaid or indigent patients and will not result in any consolidation.

D. Quality

19. TSH is licensed by the Department of Public Health (“DPH”) as a General Hospital. The license is active and in good standing. Ex. A, p. 12

20. Stamford Health Inc., the parent of TSH, participates in the Connecticut Department of Social Services’ (“DSS”) Person-Centered Medical Home (“PCMH”) Glide Path program which provides financial and technical support for practices and clinics pursuing PCMH recognition. This program provides enhanced reimbursement to participants for services such as outpatient Medicaid visits at the Center. Ex. A, p. 18

21. The proposed GE system will provide the following advanced capabilities that will result in benefits to patients and clinicians:

- a) Attenuation correction: CT component of the proposed GE system can remove shadows and attenuation artifacts resulting from overlapping tissue for patients needing cardiac imaging³, as an example. Ex. A, pp. 9-10
- b) Increased number of incidental findings⁴ which can be critical in early detection of pathologies. Ex. E, p. 1
- c) Improved anatomic localization which allows clinicians to accurately detect and monitor abnormalities in patients. Ex. E, p. 1

With respect to subsection C.G.S. § 19a-639(a)(5), the Applicant has satisfactorily demonstrated that the Proposal will maintain quality healthcare delivery in the region.

E. Financial Soundness

22. TSH has sufficient resources to purchase the GE system, fund construction and renovation, and remove the Axis system. The proposal which has a total capital expenditure of \$737,000 and is broken down into the following categories:

Total Proposal Capital Expenditure	
Category	Cost
Equipment: GE NM/CT 850ES	\$ 440,000
Land/Building	-
Construction/Renovation	\$ 287,000
Other: Removal of old equipment	\$ 10,000
Total Capital Expenditure	\$ 737,000

Ex. A, p. 23; Ex. B

23. TSH has budgeted for the GE system and allocated funds in the operating budget for 2021.
Ex. A, p.p. 11, 14, 23
24. The GE system comes with a one-year warranty which will keep repair costs down in the first year of ownership. Ex. E, p. 10

The Applicant has previously allocated funds to purchase the GE system and has demonstrated that they have sufficient resources available to fund the project. Thus, the Applicant has demonstrated that the Proposal is financially feasible in accordance with C.G.S. § 19a-639(a)(4).

F. Cost to Consumers

³ Aju P. Pazhenkottil, Jelena-Rima Ghadri, Rene N. Nkoulou, Mathias Wolfrum, Ronny R. Buechel, Silke M. Küest, Lars Husmann, Bernhard A. Herzog, Oliver Gaemperli, Philipp A. Kaufmann. Improved Outcome Prediction by SPECT Myocardial Perfusion Imaging After CT Attenuation Correction. Journal of Nuclear Medicine Feb 2011, 52 (2) 196-200; DOI: 10.2967/jnumed.110.080580 Accessed online June 2, 2022.

⁴ Joanne Coward, Julie Nightingale, Peter Hogg. The Clinical Dilemma of Incidental Findings on the Low-Resolution CT Images from SPECT/CT MPI Studies. Journal of Nuclear Medicine Technology Sep 2016, 44 (3) 167-172; DOI: 10.2967/jnmt.116.174557. Accessed online June 2, 2022.

25. Approximately 9% of TSH's procedure volume will be comprised of Medicaid beneficiaries. TSH does not anticipate any changes in payer mix through FY 2024. Ex. A, p. 29

26. Patient costs⁵ for imaging services will not be affected, and there will be no change to TSH's fee structure associated with these imaging services as a result of the proposal:

Average cost of Nuclear Medicine Procedures AT TULLY HEALTH CENTER Per Commercially INSURED patient

Historical	Projected			
FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
\$1,971	\$2,030	\$2,091	\$2,154	\$2,219

Ex. A, p 21

27. The growth in patient costs for imaging services is based on anticipated annual rate increases of approximately 3%. Ex. A, p. 24 These increases in cost are in line with the allowed cost growth benchmarks of FY 21 of 3.4%, FY 22 of 3.2% and slightly above the CGB of 2.9% for FY 23⁶.

28. TSH will continue to implement their financial assistance policy system-wide which includes the Center. Ex. A, pp. 20, 157-164

29. The Applicant provided charity care worth approximately \$40,000 and \$41,000 for the years ended September 30, 2020, and 2019, respectively. For the years ended September 30, 2020, and 2019, the estimated cost of charity care was \$9,000 and \$9,500, respectively. Ex. A, p.189

Based on the Applicant's provision of services to relevant populations, the acceptance of various insurance payers – including Medicaid – and their commitment to maintaining the current fee structure and the Applicant has satisfied C.G.S. §§ 19a-639(a)(5) and (6).

G. Existing Providers

30. There are currently two other existing providers.

**OHS TABLE 11
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS**

Facility's Provider Name, Street Address and Town
Greenwich Hospital – 5 Perryridge Rd, Greenwich, CT 06830
Norwalk Hospital - 34 Maple St, Norwalk, CT 06850

Ex A., p. 31 table 11

⁵ Cost is defined as the total dollar amount paid by the insurer plus patient out-of-pocket costs (e.g., deductibles, co-pays)

⁶ [Cost Growth and Quality Benchmarks, and Primary Care Target \(ct.gov\)](https://www.ct.gov/cgb/cost-growth-and-quality-benchmarks-and-primary-care-target)

31. The Applicant anticipates that there will be no impact on existing providers or patient referrals as this proposal is a replacement with updated technology that is compatible with Microsoft software. Ex. A, p. 17

The Applicant's acquisition of the replacement GE system will not negatively impact the utilization or diversity of existing health care facilities in the service area. The Proposal seeks only to replace an older unit at the end of its service life. Replacing this older unit will allow the applicant to continue providing existing services. As such, C.G.S. §§ 19a-639(a)(8), (9), and (11) are satisfied.

V. Conclusion

Based upon the foregoing, the Applicant has met its burden in satisfying C.G.S. §§ 19a-639(a)(2)-(9) and (a)(11). C.G.S. §§ 19a-639(a)(10) and (a)(12) are not germane to the application as the Proposal does not reduce access to services by Medicaid or indigent patients and will not result in any consolidation. Lastly, OHS currently has no applicable policies or standards adopted in regulations, so C.G.S. § 19a-639(a)(1) cannot be applied.

Order

Based upon the foregoing Findings and Discussion, the Applicant's request to acquire a Single-Photon Emission Computed Tomography/Computed Tomography ("SPECT/CT") gamma camera for TSH is hereby **APPROVED** under C.G.S. § 19a-639(a). All of the foregoing constitutes the final Order of the Office of Health Strategy in this matter.

By Order of the
Office of Health Strategy

September 23, 2022

Date

Kimberly R. Martone
Acting Executive Director