

September 23, 2016

VIA EMAIL AND REGULAR MAIL

Ms. Kimberly Martone
Director of Operations
Office of Health Care Access (OHCA)
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Re: Yale-New Haven Hospital
Replacement of Imaging Equipment

Dear Ms. Martone:

Please find enclosed a Determination Form from Yale-New Haven Hospital (YNHH) regarding its proposed replacement of 5 SPECT cameras with SPECT/CT cameras.

Sincerely,



Nancy Rosenthal
VP, Strategy and Regulatory Planning

Strategy and Regulatory
2 Howe Street
New Haven, CT 06510
Phone: 203-688-5721
Email: nancy.rosenthal@ynhh.org

ynhh.org



State of Connecticut Office of Health Care Access CON Determination Form Form 2020

All persons who are requesting a determination from OHCA as to whether a CON is required for their proposed project must complete this Form 2020. The completed form should be submitted to the Director of the Office of Health Care Access, 410 Capitol Avenue, MS#13HCA, P.O. Box 340308, Hartford, Connecticut 06134-0308.

SECTION I. PETITIONER INFORMATION

If this proposal has more than two Petitioners, please attach a separate sheet, supplying the same information for each Petitioner in the format presented in the following table.

	Petitioner
Full Legal Name	Yale New Haven Hospital
Doing Business As	Yale New Haven Hospital
Name of Parent Corporation	Yale New Haven Health Services Corporation
Petitioner's Mailing Address, if Post Office (PO) Box, include a street mailing address for Certified Mail	789 Howard Avenue New Haven, CT
What is the Petitioner's Status: P for profit and NP for Nonprofit	NP
Contact Person at Facility , including Title/Position: This Individual at the facility will be the Petitioner's Designee to receive all correspondence in this matter.	Nancy Rosenthal VP

Contact Person's Mailing Address, if PO Box, include a street mailing address for Certified Mail	2 Howe Street New Haven, CT 06511
Contact Person's Telephone Number	203-688-5721
Contact Person's Fax Number	n/a
Contact Person's e-mail Address	Nancy.rosenthal@ynhh.org

SECTION II. GENERAL PROPOSAL INFORMATION

- a. Proposal/Project Title: **Replace 5 SPECT Cameras with 5 SPECT/CTs**
- b. Estimated Total Project Cost: **\$2,625000**
- c. Location of proposal, identifying Street Address, Town and Zip Code:
- 1450 Chapel Street (St. Raphael Campus)**
New Haven, CT
- 2 Divine Street**
North Haven, CT
- 111 Goose Lane**
Guilford, CT
- 79 Wawecus Street**
Norwich, CT
- d. List each town this project is intended to serve: **New Haven, North Haven, Guilford, Norwich, and surrounding towns in the local region**
- e. Estimated starting date for the project: **2017 & 2018**

SECTION IV. PROPOSAL DESCRIPTION

Yale-New Haven Hospital (YNHH) currently operates several SPECT nuclear cameras without CT attenuation, and seeks to replace this equipment with SPECT-CT cameras at the following locations:

- 1450 Chapel Street (St. Raphael Campus)
New Haven, CT
Current equipment: Siemens Symbia SPECT & Siemens Siemens E-cam SPECT
- 2 Divine Street
North Haven, CT
Current equipment: GE Ventri SPECT
- 111 Goose Lane
Guilford, CT
Current equipment: GE MyoSite SPECT
- 79 Wawecus Street
Norwich, CT
Current equipment: Philips ADAC Cardio MD SPECT

This equipment is near the end of its useful life and the new SPECT-CT cameras will enable higher quality imaging studies than is currently possible. The CT portion will be used for attenuation purposes only and not as a stand-alone diagnostic scanner.

No new licensure is required for the replacement, and the same population that is currently served by this equipment will continue to be served with an enhanced ability to offer higher quality services.

As required by Section 34 of Public Act No. 15-146 (P.A. 15-146 §34), the Department of Public Health (DPH) recently issued a report to the joint standing committee of the General Assembly which examines and makes recommendations on the ability to eliminate Certificate of Need (CON) approval or to create an expedited approval process under certain circumstances. A copy is attached here. On page 5 of this report, the Commissioner recommends that CON authorization should not be required to replace a SPECT camera with a SPECT-CT.

The purpose of letter is seek guidance from the Office of Health Care Access (OHCA) with respect to whether a CON is still required to replace a SPECT camera with a SPECT-CT when the CT portion will be used only for attenuation purposes and not as a stand-alone diagnostic scanner. YNHH hopes to minimize its administrative burden and that of the State of Connecticut when processing this relatively routine replacement of existing and aging equipment.

SECTION V. AFFIDAVIT

(Each Petitioner must submit a completed Affidavit.)

Petitioner: Yale-New Haven Hospital

Project Title: Replace 5 SPECT Cameras with 5 SPECT/CTs

I, Nancy Rosenthal, VP
(Name) (Position – CEO or CFO)

of Yale-New Haven Health System being duly sworn, depose and state that the
(Organization Name)

information provided in this CON Determination form is true and accurate to the best of my
knowledge.

[Signature] 9.26.2016
Signature Date

Subscribed and sworn to before me on September 26, 2016

[Signature]
Notary Public/Commissioner of Superior Court

My commission expires: _____

MATHEW L SCHLAGER
NOTARY PUBLIC - State of Connecticut
My Commission Expires
August 31, 2019



**Report to the Joint Standing Committee
Of the Connecticut General Assembly
Certificate of Need Requirements**

Public Act 15-146

**Raul Pino, MD, MPH
Acting Commissioner
Connecticut Department of Public Health**

January 1, 2016

Report for Public Act 15-146 Section 34

I. Introduction

Section 34 of Public Act No. 15-146 (P.A. 15-146 §34) requires the Department of Public Health (DPH) Commissioner to report to the joint standing committee of the General Assembly on the certificate of need (CON) requirements under chapter 368z of the Connecticut General Statutes by January 1, 2016. The purpose of this report is to examine and make recommendations on the ability to eliminate Certificate of Need (CON) approval or to create an expedited approval process under certain circumstances.

II. Certificate of Need Overview

Connecticut was one of 15 states that initiated the CON program in 1973. From 1974 through 1986, the specifics of the program were largely influenced by the federal National Health Planning and Resources Development Act (Public Law 93-641), which established minimum requirements regarding the type of services subject to CON review, review procedures and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1987 but Connecticut retained its CON program. Thirty-six (36) states and the District of Columbia now maintain CON programs although the scope and focus of these programs may vary state to state.¹

CON programs have been designed to control health care costs and provide for planning for new services and facilities. Connecticut's CON program is administered through the Office of Health Care Access (OHCA) at the Connecticut Department of Public Health (DPH). The program is a regulatory and planning tool used to shape the health care system by ensuring the appropriate, coordinated allocation and distribution of health care resources. It is intended to maintain or promote equitable access for all Connecticut residents, including those on Medicaid, ensure quality and help prevent costly duplication of services by limiting market entry to those facilities and services that are found to be needed. CON, together with OHCA's Statewide Health Care Facilities and Services Plan,² reflects the state's efforts to coordinate health planning, in part, to address continuing changes in Connecticut's health care system environment. OHCA's other responsibilities include health care data collection, analysis and reporting, and hospital financial review and reporting.

A summary of recent changes in Connecticut's CON program is presented in this section to provide a perspective on the comments and recommendations put forth in this report. In 2009, DPH proposed recommendations for CON reform with the goals of simplifying CON procedural requirements; focusing CON oversight on "safety net" services and areas of potential over-utilization; developing CON criteria and standards to address the financial stability of the health care delivery system; and improving the quality of patient care. Following these recommendations and to be responsive to impending shifts in the health care delivery system

¹ NCLS: Certificate of Need: State Health Laws and Programs <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>

² Connecticut Statewide Health Care Facilities and Services Plan <http://www.ct.gov/dph/cwp/view.asp?a=3902&q=558152>

resulting from the federal Patient Protection and Affordable Care Act (Public Law 111-148), Connecticut's CON program underwent considerable change in 2010 (Public Act 10-179).³ Current CON application activity reflects federal health care reform changes that have significantly affected Connecticut's health care facilities and providers, their administrative costs and the services they provide. ⁴ CON applications emanating from changes in reimbursement, insurance coverage, models of care, transparency and innovation require OHCA to provide an unprecedented in-depth level of review and analysis.

Conn. Gen. Stat. §19a-638 requires CON authorization for⁵:

- 1) The establishment of:
 - a. a new health care facility,
 - b. a freestanding emergency department;
 - c. an outpatient surgical facility; or
 - d. cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery;
- 2) The termination of:
 - a. inpatient or outpatient services offered by a hospital, including mental health and substance abuse services;
 - b. surgical services except if the termination is due to (A) insufficient patient volume, or (B) the termination of any subspecialty surgical service; or
 - c. inpatient or outpatient services offered by a state-owned facility that provides services eligible for Medicare or Medicaid reimbursements;
- 3) A transfer of ownership of a health care facility or group practice;
- 4) The acquisition of:
 - a. certain imaging equipment;
 - b. nonhospital based linear accelerators; or
 - c. equipment utilizing technology that has not previously been utilized in the state; and
- 5) An increase:
 - a. in the licensed bed capacity of a health care facility; or
 - b. of two or more operating rooms within any three-year period.

Pursuant to Conn. Gen. Stat. §19a-638, any person, health care facility or institution may request a written determination from OHCA if there is uncertainty whether or not a CON is required for a particular circumstance. The determination process minimizes the submission of applications when a CON is not required and provides confirmation to those who are required to file a CON. OHCA provides a determination form on its website (www.ct.gov/ohca) to assist potential applicants.

³ CT Public Act 10-179 <https://www.cga.ct.gov/2010/ACT/Pa/pdf/2010PA-00179-R00SB-00494-PA.pdf>

⁴ Connecticut Statewide Health Care Facilities and Services Plan 2012, p.11
http://www.ct.gov/dph/lib/dph/ohca/hc_facilities_advisory_body/ohcastatewide_facilities_and_services_chapter_2overarching_issues.pdf

⁵ Conn. Gen. Stat. §19a-638 https://www.cga.ct.gov/current/pub/chap_368z.htm#sec_19a-638

Overall, CON program changes have improved CON's utility as a planning tool by better aligning health care resources with community needs; simplifying procedural requirements; focusing oversight on preserving access to "safety net" services; avoiding potential areas of over-saturation or over-utilization; and improving criteria to address the financial stability of the health care delivery system and enhance quality of patient care. In some recent CON approvals, OHCA has used agreed settlements, where appropriate, to promote applicants' involvement in implementing recommendations made in hospital Community Health Needs Assessments. The agreed settlements are designed, in part, to help ensure uninterrupted provision of and access to quality essential inpatient and outpatient services.

OHCA is mindful of the evolving health care environment and the impact of health care reform changes on providers of health care services. OHCA has continued to simplify and make improvements to the CON administrative process. OHCA's Certificate of Need website page has been updated to make information more accessible to applicants and Connecticut residents. Application forms were revised in November 2014 to be consistent, aligned with statutory criteria and to improve application completeness and efficiency. In August 2015, OHCA created a CON guidebook for applicants to improve responsiveness and facilitate the decision process. To streamline its internal processes, OHCA developed an analyst toolkit in November 2015 that includes a decision checklist, a standardized decision format and application review guidance. OHCA staff is also available to respond to applicant questions and provide assistance in understanding the application completion process.

III. An Expedited CON Process

P.A. 15-146 §34 specifically requests the Commissioner of Public Health to examine and make recommendations to eliminate the requirements to obtain CON approval or to create an expedited approval process for certain services, equipment purchases and ownership transfers, including:

- 1) ancillary capital expenditures not related to direct patient care or services;
- 2) repairs to facilities damaged by floods, storms or other unexpected occurrences; and
- 3) facility improvements necessary to comply with building codes or other legal requirements.

The Public Act does not provide a definition for an expedited approval process. For the purposes of this report, the following definition of expedited approval will be used: the process by which certain types of certificate of need applications, as specified in section 19a-638(c) of the general statutes, are subject to shorter review cycle requirements as specified in section 19a-639a of the general statutes.

CON approval is not currently required for 1) ancillary capital expenditures not related to direct patient care or services; 2) repairs to facilities damaged by floods, storms or other unexpected occurrences; and 3) facility improvements necessary to comply with building codes or other legal requirements therefore, an approval process for these particular situations cannot be eliminated or expedited.

It should be noted that there are no existing statutory barriers to an expedited CON review and approval process. Whenever possible and as resources allow, OHCA renders CON decisions before the 90 day statutory timeframe. However, OHCA is limited by the resources currently at its disposal and the relative unpredictability of CON application submissions and volume at any given time. Unlike some other states that specify set time periods when certain types of CON applications can be filed, Connecticut CONs are provider driven, as applications are filed without any predictable pattern. This unpredictability, coupled with competing priorities and other OHCA statutory responsibilities, makes scheduling and workload difficult to manage, especially with limited resources. Additional staff would be required to facilitate expedited reviews for CON applications.

With the appropriate resources, the following applications would be recommended for an expedited approval process:

- 1) the termination of inpatient or outpatient services offer by a hospital (19a-638(a)(5).(DPH currently holds hearings for terminations of service in the affected community to provide an opportunity for public comment);
- 2) the acquisition of imaging equipment, i.e., computed tomography (CT) scanners, magnetic resonance imaging (MRI) scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners (19a-638(a)(10);
- 3) the relocation of a health care facility that does not satisfy the requirements of section 19a-639c; and
- 4) the transfer of ownership of ambulatory surgery centers.

Abbreviated timeframes would be recommended for issuing decisions for those projects subject to an expedited review as long as sufficient resources were made available. It is suggested that the proposed change include an expedited review process that would provide for a forty-five day review period with a decision issued within forty-five days of the date an application is deemed complete. This would be a fifty percent reduction in time within which OHCA currently is required to issue a decision. OHCA's authority to conduct a public hearing would be maintained, however, even for an application under expedited review. Additionally, a graduated fee scale based on the complexity of a CON application is recommended, whereby the fee for an expedited CON application would be lower than for a more complex application, such as the transfer of ownership of a hospital. For example, Oregon has a separate fee schedule for expedited review CON applications.

* It is also recommended no CON authorization be required to replace a SPECT camera or to replace a SPECT with a SPECT-CT, as current law allows MRI, CT, PET and PET-CT scanners to be replaced without a CON. Instead, this could be handled through the notification process specified under Conn. Gen. Stat. section 19a-638(a)(18) and section 19a-638-3 of the Regulations of Connecticut State Agencies.⁶ This will assist OHCA in maintaining an accurate

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⁶ Statewide Health Care Facilities And Services Inventory
<http://www.ct.gov/dph/cwp/view.asp?a=3902&q=557564&dphNav=|56694|>

inventory of imaging equipment within the State. The elimination of the CON requirement for the acquisition of temporary imaging equipment is also recommended.

P.A. 15-146 §34 requires recommendations for expedited automatic approval of certain CON applications in circumstances where DPH does not notify the applicant within thirty days of its intent to review such application. CON programs are aimed at improving access to health care services as well as restraining health care costs. Laws authorizing such programs are one mechanism by which state governments seek to reduce overall health and medical costs. To allow for the automatic approval of a CON application based solely on the extinguishment of a time deadline would deprive OHCA of the opportunity to conduct a thorough review of the request contained in the CON application, thereby usurping OHCA's authority and diminishing its mission to ensure cost-effective access to health care services for the public.

Currently, CON laws allow for the relocation of imaging equipment without CON approval. They also permit the relocation of a health care facility without CON authorization as long as an applicant can satisfactorily demonstrate that the current payer mix and population served will not substantially change as a result of the relocation. Current statute does not, however, permit the relocation of a hospital service without CON approval, despite the fact that OHCA does not regulate the establishment of new hospital services, except cardiac services. In addition, there is no existing definition for the relocation of a hospital service. This may become more important, as health care reform continues to evolve and affect where and how hospitals provide services.

IV. Summary

Many statutory and administrative changes have been made to the CON application process over the last several years in response to a changing health care environment. These changes have helped improve the process while maintaining the intended function of CON: to promote access, to ensure quality, to help control costs and to serve as a planning tool. OHCA understands and acknowledges the health care industry's need for responsiveness and timeliness in CON decision making. OHCA can and does accelerate CON application review and decision rendering whenever possible, however limited resources and the hearing process precludes OHCA from doing it on a systematic basis. To ensure that all CON applications, whether expedited or not, are given appropriate and adequate review, are in the best interest of Connecticut's citizens served by our health care system, the recommendations made in this report for an expedited review process for specific applications would require additional staff.

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

October 4, 2016

VIA EMAIL ONLY

Nancy Rosenthal
VP, Strategy and Regulatory Planning
Yale New Haven Hospital
2 Howe Street
New Haven, CT 06511

RE: Certificate of Need Determination Report Number 16-32124-DTR
Replacement of Imaging Equipment

Dear Ms. Rosenthal:

On September 28, 2016, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") Determination request on behalf of Yale New Haven Hospital ("Petitioner") with respect to the replacement of five (5) single photon emission computed tomography ("SPECT") cameras with five (5) single-photon emission computed tomography/computed tomography ("SPECT-CT") cameras.

The Petitioner currently operates SPECT cameras at locations in the following towns: New Haven, CT; North Haven, CT; Guilford, CT; and Norwich, CT. Petitioner contends that its equipment has reached the end of its useful life and that the new SPECT-CT cameras will enable higher quality imaging studies than is currently possible. Petitioner requests guidance as to whether a CON is required to replace a SPECT camera with a SPECT-CT camera.

Pursuant to Conn. Gen. Stat. § 19a-638(a)(10), a certificate of need is required for the "acquisition of computed tomography scanners..." SPECT-CT cameras combine computed tomography with the technology currently utilized by the Petitioner to enhance imaging.



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410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer

Therefore, the Petitioner's request to replace its SPECT cameras with SPECT-CT cameras constitutes an acquisition of imaging equipment, and a *CON is required*.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kim Martone', with a stylized flourish at the end.

Kimberly R. Martone
Director of Operations

cc: Rose McLellan, License and Applications Supervisor, DPH, DHSR

Olejarz, Barbara

From: Olejarz, Barbara
Sent: Tuesday, October 04, 2016 2:36 PM
To: 'Rosenthal, Nancy'
Cc: Hansted, Kevin; Martone, Kim; Riggott, Kaila
Subject: Determination
Attachments: 32124-1.pdf

Tracking:	Recipient	Delivery
	'Rosenthal, Nancy'	
	Hansted, Kevin	Delivered: 10/4/2016 2:36 PM
	Martone, Kim	Delivered: 10/4/2016 2:36 PM
	Riggott, Kaila	Delivered: 10/4/2016 2:36 PM

10/4/16

Please see attached determination for Report Number: 16-32124-DTR for Replacement of Imaging Equipment.

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov

