

The Connecticut General Assembly

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Memorandum

To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: September 25, 2012

Regulation No:	2012-3B
Agency:	Department of Public Health
Subject Matter:	Certificate of Need
Statutory Authority: (copy attached)	19a-638, 19a-639a, 19a-639b, 19a-639c, 19a-639e, 19a-643

	Yes or No
Mandatory	Y
Federal Requirement	N
Permissive	Y (19a-643 only)

For the Committee's Information:

1. This is a second resubmittal of regulations that were rejected without prejudice at the committee's meeting on February 28, 2012. The regulations were resubmitted on June 15, 2012. The resubmitted regulations were withdrawn on or about July 23, 2012, apparently in response to issues noted in the July 12, 2012 LCO report.

2. Section 4-170 of the general statutes requires that a proposed regulation that is rejected without prejudice and that is *required* by the general statutes be resubmitted not later than

the first Tuesday of the second month following such rejection without prejudice. The department is required by sections 19a-638, 19a-639a, 19a-639b, 19a-639c and 19a-639e of the general statutes to adopt regulations concerning the issuance of a certificate of need. The committee rejected without prejudice the proposed regulations, 2012-003, on February 28, 2012. The regulations were resubmitted on June 15, 2012 (and subsequently withdrawn as noted above), and again resubmitted on September 5, 2012, both of which are outside the applicable timeframe identified in section 4-170 of the general statutes.

3. The former section 19a-639c-2 of the proposed regulations has been deleted in the resubmittal to address substantive concern 2. noted in the February 28, 2012 report. Section 19a-639c-3 of the proposed regulations has been re-numbered as section 19a-639c-2 in the resubmitted proposed regulations.

Substantive Concern:

1. On page 8, section 19a-643-3a, which concerns the issuance of a decision denying an application for a certificate of need and also concerns a request for a public hearing, is inconsistent with the provisions of section 19a-639a of the general statutes. The timeframe for the office to issue a decision, as stated in section 19a-639a of the general statutes, differs from the timeframe described in section 19a-643-3a of the proposed regulations. The timeframes referenced in the proposed regulations appear to be based on versions of sections 19a-639 and 19a-639a of the general statutes that were in effect prior to the enactment of public act 10-179, which substantially amended those sections of the statutes.

2. On page 8, the provision of section 19a-643-3a concerning a request for a hearing is unclear. Specifically, the procedure and timeframe for an applicant to request a hearing is not described. Instead, the applicant is permitted to "request a public hearing in accordance with the regulations of the Office of Health Care Access and chapter 54 of the Connecticut General Statutes". First, the reference to "the regulations of the Office of Health Care Access" is unclear absent a specific citation to the applicable sections of the Regulations of Connecticut State Agencies. Further, section 19a-639a of the general statutes describes the circumstances under which the office shall hold a public hearing on a completed certificate of need application and the timeframe for making a request. Section 19a-641 of the general statutes describes the procedure for an applicant to appeal a final decision made by the office. It is unclear whether this provision of section 19a-643-3a of the proposed regulations relates to a request for a hearing on a completed application before the office issues a decision or a request for a hearing on an appeal of the office's decision to deny the application.

Technical Corrections:

1. Because it is the convention that each section in a proposed regulation contain a separate unit or consecutive units, the formatting of this regulation should be changed, for proper form. On page 1, the introductory language to Sec. 2 should add only "sections 19a-630-1 and 19a-630-2, as follows:". On page 3, before section 19a-638-1, the following introductory language should be added: "Sec. 3. The Regulations of Connecticut

State Agencies are amended by adding sections 19a-638-1 to 19a-638-4, inclusive, as follows:". At the bottom of page 3, before section 19a-639a-1, the following introductory language should be added: "Sec. 4. The Regulations of Connecticut State Agencies are amended by adding sections 19a-639a-1 to 19a-639a-6, inclusive, as follows:". On page 6, before section 19a-639b-1, the following introductory language should be added: "Sec. 5. The Regulations of Connecticut State Agencies are amended by adding sections 19a-639b-1 and 19a-639b-2, as follows:". On page 7, before section 19a-639c-1, the following introductory language should be added: "Sec. 6. The Regulations of Connecticut State Agencies are amended by adding sections 19a-639c-1 and 19a-639c-2, as follows:". On page 7, before section 19a-639e-1, the following introductory language should be added: "Sec. 7. The Regulations of Connecticut State Agencies are amended by adding sections 19a-639e-1 and 19a-639e-2, as follows:".

2. On page 8, the numbering of sections 19a-643-1a to 19a-643-3a should be changed, since the designation "-1a" would typically follow "-1", "-2a" would follow "-2", etc. The sections should instead be numbered using whichever of the following conventions is preferred by the department: "19a-643-207 to 19a-643-209", using section numbers available at the end of the 19a-643-xx series of regulations; "19a-643-111 to 19a-643-113", or some other of the reserved sections within the 19a-643-xx series of regulations; or "19a-643-A1 to 19a-643-A3", as in the Public Health Code. Also, on page 8, before section 19a-643-1a, the following introductory language should be added: "Sec. 8. The Regulations of Connecticut State Agencies are amended by adding sections 19a-643-207 to 19a-643-209, inclusive, as follows:" (or whichever numbering convention the department prefers), for proper form.

3. On page 8, before section 19a-653-1, the following introductory language should be added: "Sec. 9. The Regulations of Connecticut State Agencies are amended by adding sections 19a-653-1 to 19a-653-4, inclusive, as follows:".

4. On page 9, Secs. 3, 4 and 5 should be renumbered Secs. 10, 11 and 12, for accuracy and conformity.

5. On page 2, in section 19a-630-2(4), "one or more entities who are or may be" should be changed to "the entity that is or may be", for clarity and conformity with the rest of the section.

6. On page 5, in section 19a-639a-3(5), "and" should be inserted after the semicolon, for clarity and accuracy and, in section 19a-639a-3(6), the semicolon should be deleted, for proper form.

7. On page 6, in section 19a-639b-1(c), the space between subdivisions (2) and (3) should be deleted, for consistency and proper form.

8. On page 8, in section 19a-643-2a, "his designee" should be "the commissioner's designee", for proper form.

9. On page 8, in the second sentence of section 19a-643-3a, "will" should be "shall", in accordance with the committee's directive on mandates.

Recommendation:

<p>Approval in whole with technical corrections with deletions with substitute pages Disapproval in whole or in part X Rejection without prejudice</p>

Reviewed by: Heather Bannister / Anne Brennan Carroll

Date: September 12, 2012

Sec. 19a-638. (Formerly Sec. 19a-154). Certificate of need. When required and not required. Request for office determination. Policies, procedures and regulations. (a) A certificate of need issued by the office shall be required for:

- (1) The establishment of a new health care facility;
- (2) A transfer of ownership of a health care facility;
- (3) The establishment of a free-standing emergency department;
- (4) The termination of inpatient or outpatient services offered by a hospital, including, but not limited to, the termination by a short-term acute care general hospital or children's hospital of inpatient and outpatient mental health and substance abuse services;
- (5) The establishment of an outpatient surgical facility, as defined in section 19a-493b, or as established by a short-term acute care general hospital;
- (6) The termination of surgical services by an outpatient surgical facility, as defined in section 19a-493b, or a facility that provides outpatient surgical services as part of the outpatient surgery department of a short-term acute care general hospital, provided termination of outpatient surgical services due to (A) insufficient patient volume, or (B) the termination of any subspecialty surgical service, shall not require certificate of need approval;
- (7) The termination of an emergency department by a short-term acute care general hospital;
- (8) The establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery;
- (9) The acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners, by any person, physician, provider, short-term acute care general hospital or children's hospital, except as provided for in subdivision (22) of subsection (b) of this section;
- (10) The acquisition of nonhospital based linear accelerators;
- (11) An increase in the licensed bed capacity of a health care facility;

(12) The acquisition of equipment utilizing technology that has not previously been utilized in the state;

(13) An increase of two or more operating rooms within any three-year period, commencing on and after October 1, 2010, by an outpatient surgical facility, as defined in section 19a-493b, or by a short-term acute care general hospital; and

(14) The termination of inpatient or outpatient services offered by a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended.

(b) A certificate of need shall not be required for:

(1) Health care facilities owned and operated by the federal government;

(2) The establishment of offices by a licensed private practitioner, whether for individual or group practice, except when a certificate of need is required in accordance with the requirements of section 19a-493b or subdivision (9) or (10) of subsection (a) of this section;

(3) A health care facility operated by a religious group that exclusively relies upon spiritual means through prayer for healing;

(4) Residential care homes, nursing homes and rest homes, as defined in subsection (c) of section 19a-490;

(5) An assisted living services agency, as defined in section 19a-490;

(6) Home health agencies, as defined in section 19a-490;

(7) Hospice services, as described in section 19a-122b;

(8) Outpatient rehabilitation facilities;

(9) Outpatient chronic dialysis services;

(10) Transplant services;

(11) Free clinics, as defined in section 19a-630;

(12) School-based health centers, community health centers, as defined in

section 19a-490a, not-for-profit outpatient clinics licensed in accordance with the provisions of chapter 368v and federally qualified health centers;

(13) A program licensed or funded by the Department of Children and Families, provided such program is not a psychiatric residential treatment facility;

(14) Any nonprofit facility, institution or provider that has a contract with, or is certified or licensed to provide a service for, a state agency or department for a service that would otherwise require a certificate of need. The provisions of this subdivision shall not apply to a short-term acute care general hospital or children's hospital, or a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended;

(15) A health care facility operated by a nonprofit educational institution exclusively for students, faculty and staff of such institution and their dependents;

(16) An outpatient clinic or program operated exclusively by or contracted to be operated exclusively by a municipality, municipal agency, municipal board of education or a health district, as described in section 19a-241;

(17) A residential facility for persons with intellectual disability licensed pursuant to section 17a-227 and certified to participate in the Title XIX Medicaid program as an intermediate care facility for the mentally retarded;

(18) Replacement of existing imaging equipment if such equipment was acquired through certificate of need approval or a certificate of need determination, provided a health care facility, provider, physician or person notifies the office of the date on which the equipment is replaced and the disposition of the replaced equipment;

(19) Acquisition of cone-beam dental imaging equipment that is to be used exclusively by a dentist licensed pursuant to chapter 379;

(20) The partial or total elimination of services provided by an outpatient surgical facility, as defined in section 19a-493b, except as provided in subdivision (6) of subsection (a) of this section and section 19a-639e;

(21) The termination of services for which the Department of Public Health has requested the facility to relinquish its license; or

(22) Acquisition of any equipment by any person that is to be used exclusively for scientific research that is not conducted on humans.

(c) (1) Any person, health care facility or institution that is unsure whether a certificate of need is required under this section, or (2) any health care facility that proposes to relocate pursuant to section 19a-639c shall send a letter to the office that describes the project and requests that the office make a determination as to whether a certificate of need is required. In the case of a relocation of a health care facility, the letter shall include information described in section 19a-639c. A person, health care facility or institution making such request shall provide the office with any information the office requests as part of its determination process.

(d) The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the commissioner holds a public hearing prior to implementing the policies and procedures and prints notice of intent to adopt regulations in the Connecticut Law Journal not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted. Final regulations shall be adopted by December 31, 2011.

Sec. 19a-639a. Certificate of need application process. Issuance of decision. Public hearings. Policies, procedures and regulations. (a) An application for a certificate of need shall be filed with the office in accordance with the provisions of this section and any regulations adopted by the office. The application shall address the guidelines and principles set forth in (1) subsection (a) of section 19a-639, and (2) regulations adopted by the office. The applicant shall include with the application a nonrefundable application fee of five hundred dollars.

(b) Prior to the filing of a certificate of need application, the applicant shall publish notice that an application is to be submitted to the office in a newspaper having a substantial circulation in the area where the project is to be located. Such notice shall (1) be published (A) not later than twenty days prior to the date of filing of the certificate of need application, and (B) for not less than three consecutive days, and (2) contain a brief description of the nature of the project and the street address where the project is to be located. An applicant shall file the certificate of need application with the office not later than ninety days after publishing notice of the application in accordance with the provisions of this

subsection. The office shall not accept the applicant's certificate of need application for filing unless the application is accompanied by the application fee prescribed in subsection (a) of this section and proof of compliance with the publication requirements prescribed in this subsection.

(c) Not later than five business days after receipt of a properly filed certificate of need application, the office shall publish notice of the application on its web site. Not later than thirty days after the date of filing of the application, the office may request such additional information as the office determines necessary to complete the application. The applicant shall, not later than sixty days after the date of the office's request, submit the requested information to the office. If an applicant fails to submit the requested information to the office within the sixty-day period, the office shall consider the application to have been withdrawn.

(d) Upon determining that an application is complete, the office shall provide notice of this determination to the applicant and to the public in accordance with regulations adopted by the office. In addition, the office shall post such notice on its web site. The date on which the office posts such notice on its web site shall begin the review period. Except as provided in this subsection, (1) the review period for a completed application shall be ninety days from the date on which the office posts such notice on its web site; and (2) the office shall issue a decision on a completed application prior to the expiration of the ninety-day review period. Upon request or for good cause shown, the office may extend the review period for a period of time not to exceed sixty days. If the review period is extended, the office shall issue a decision on the completed application prior to the expiration of the extended review period. If the office holds a public hearing concerning a completed application in accordance with subsection (e) or (f) of this section, the office shall issue a decision on the completed application not later than sixty days after the date of the public hearing.

(e) The office shall hold a public hearing on a properly filed and completed certificate of need application if three or more individuals or an individual representing an entity with five or more people submits a request, in writing, that a public hearing be held on the application. Any request for a public hearing shall be made to the office not later than thirty days after the date the office determines the application to be complete.

(f) The office may hold a public hearing with respect to any certificate of need

application submitted under this chapter. The office shall provide not less than two weeks' advance notice to the applicant, in writing, and to the public by publication in a newspaper having a substantial circulation in the area served by the health care facility or provider. In conducting its activities under this chapter, the office may hold hearing on applications of a similar nature at the same time.

(g) The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the commissioner holds a public hearing prior to implementing the policies and procedures and prints notice of intent to adopt regulations in the Connecticut Law Journal not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted. Final regulations shall be adopted by December 31, 2011.

Sec. 19a-639b. Certificate of need. Validity, extension, revocation and nontransferability. Policies, procedures and regulations. (a) A certificate of need shall be valid only for the project described in the application. A certificate of need shall be valid for two years from the date of issuance by the office. During the period of time that such certificate is valid and the thirty-day period following the expiration of the certificate, the holder of the certificate shall provide the office with such information as the office may request on the development of the project covered by the certificate.

(b) Upon request from a certificate holder, the office may extend the duration of a certificate of need for such additional period of time as the office determines is reasonably necessary to expeditiously complete the project. Not later than five business days after receiving a request to extend the duration of a certificate of need, the office shall post such request on its web site. Any person who wishes to comment on extending the duration of the certificate of need shall provide written comments to the office on the requested extension not later than thirty days after the date the office posts notice of the request for an extension of time on its web site. The office shall hold a public hearing on any request to extend the duration of a certificate of need if three or more individuals or an individual representing an entity with five or more people submits a request, in writing, that a public hearing be held on the request to extend the duration of a certificate of need.

(c) In the event that the office determines that: (1) Commencement, construction

or other preparation has not been substantially undertaken during a valid certificate of need period; or (2) the certificate holder has not made a good-faith effort to complete the project as approved, the office may withdraw, revoke or rescind the certificate of need.

(d) A certificate of need shall not be transferable or assignable nor shall a project be transferred from a certificate holder to another person.

(e) The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the commissioner holds a public hearing prior to implementing the policies and procedures and prints notice of intent to adopt regulations in the Connecticut Law Journal not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted. Final regulations shall be adopted by December 31, 2011.

Sec. 19a-639c. Proposed relocation of a health care facility. Policies, procedures and regulations. (a) Any health care facility that proposes to relocate a facility shall submit a letter to the office, as described in subsection (c) of section 19a-638. In addition to the requirements prescribed in said subsection (c), in such letter the health care facility shall demonstrate to the satisfaction of the office that the population served by the health care facility and the payer mix will not substantially change as a result of the facility's proposed relocation. If the facility is unable to demonstrate to the satisfaction of the office that the population served and the payer mix will not substantially change as a result of the proposed relocation, the health care facility shall apply for certificate of need approval pursuant to subdivision (1) of subsection (a) of section 19a-638 in order to effectuate the proposed relocation.

(b) The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the commissioner holds a public hearing prior to implementing the policies and procedures and prints notice of intent to adopt regulations in the Connecticut Law Journal not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted. Final regulations shall be adopted by December 31, 2011.

From 2012 Supplement

Sec. 19a-639e. Proposed termination of service by a health care facility. Policies, procedures and regulations. (a) Unless otherwise required to file a certificate of need application pursuant to the provisions of subsection (a) of section 19a-638, any health care facility that proposes to terminate a service that was authorized pursuant to a certificate of need issued under this chapter shall file a modification request with the office not later than sixty days prior to the proposed date of the termination of the service. The office may request additional information from the health care facility as necessary to process the modification request. In addition, the office shall hold a public hearing on any request from a health care facility to terminate a service pursuant to this section if three or more individuals or an individual representing an entity with five or more people submits a request, in writing, that a public hearing be held on the health care facility's proposal to terminate a service.

(b) Any health care facility that proposes to terminate all services offered by such facility, that were authorized pursuant to one or more certificates of need issued under this chapter, shall provide notification to the office not later than sixty days prior to the termination of services and such facility shall surrender its certificate of need not later than thirty days prior to the termination of services.

(c) Any health care facility that proposes to terminate the operation of a facility or service for which a certificate of need was not obtained shall notify the office not later than sixty days prior to terminating the operation of the facility or service.

(d) The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the commissioner holds a public hearing prior to implementing the policies and procedures and prints notice of intent to adopt regulations in the Connecticut Law Journal not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted. Final regulations shall be adopted by December 31, 2011.

Sec. 19a-643. (Formerly Sec. 19a-160). Regulations. (a) The Department of Public Health shall adopt regulations, in accordance with the provisions of chapter

54, to carry out the provisions of sections 19a-630 to 19a-639e, inclusive, and sections 19a-644 and 19a-645 concerning the submission of data by health care facilities and institutions, including data on dealings between health care facilities and institutions and their affiliates, and, with regard to requests or proposals pursuant to sections 19a-638 to 19a-639e, inclusive, by state health care facilities and institutions, the ongoing inspections by the office of operating budgets that have been approved by the health care facilities and institutions, standard reporting forms and standard accounting procedures to be utilized by health care facilities and institutions and the transferability of line items in the approved operating budgets of the health care facilities and institutions, except that any health care facility or institution may transfer any amounts among items in its operating budget. All such transfers shall be reported to the office within thirty days of the transfer or transfers.

(b) The Department of Public Health may adopt such regulations, in accordance with the provisions of chapter 54, as are necessary to implement this chapter.