

The Connecticut General Assembly

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Memorandum

To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: July 24, 2012

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| Regulation No: | 2012-3A |
| Agency: | Department of Public Health |
| Subject Matter: | Certificate of Need |
| Statutory Authority: (copy attached) | 19a-2a, 19a-638 |

| | Yes or No |
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| Mandatory | Y (19a-638) |
| Federal Requirement | N |
| Permissive | Y (19a-2a) |

For the Committee's Information:

1. This is a resubmittal of regulations that were rejected without prejudice at the committee's meeting on February 28, 2012. The resubmittal addresses one of the two substantive concerns noted in the February 28, 2012 report. A new substantive concern has been added relating to the department's new proposal on the repeal of certain regulations. The resubmittal addresses the technical corrections noted in the February 28, 2012 report, except as noted below.

2. Section 4-170 of the general statutes requires that a proposed regulation that is rejected without prejudice and that is required to be adopted 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 section 19a-638(d) of the general statutes to adopt regulations concerning the issuance of a certificate of need, which is the subject of the proposed regulations. The committee rejected without prejudice the proposed regulations, 2012-003, on February 28, 2012. Therefore, pursuant to section 4-170 of the general statutes, the department was required to resubmit the proposed regulations not later than Tuesday, April 3, 2012. The regulations were resubmitted on June 15, 2012, which is 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.

4. The department's resubmittal of these regulations suggests that the department discussed the substantive concerns contained in the February 28, 2012 report with the Office of the Attorney General. (See "Summary of Comments", page 1, attached to department's letter to the committee dated June 15, 2012.) However, the resubmitted regulations do not include an updated certification page but instead contain the original certification page, signed by Joseph Rubin, Assistant Attorney General on December 5, 2011.

Substantive Concerns:

1. On page 2, sections 19a-630-2(a)(4) and 19a-630-2(a)(5), which are criteria for determining whether an entity is a "central service facility", are unclear and require the reader to speculate as to the meaning of the provisions. This substantive concern was previously noted in the February 28, 2012 report. Specifically, with respect to section 19a-630-2(a)(4), it is not clear whether the clause "whose practice this is or will be and who will control a business involving health services" refers to "partnerships or corporations" or alternatively to "a group of practicing physicians". With respect to section 19a-630-2(a)(5), the use of "physician or practitioner" presumably refers to a physician or practitioner who is an owner, a partner or a manager of a central service facility, however the reader is left to infer that this is the actual meaning of the provision. After these regulations were rejected without prejudice on February 28, 2012, the department appears to have consulted with the Office of the Attorney General concerning this substantive concern. (See "Summary of Comments", page 1, attached to department's letter to the committee dated June 15, 2012.) The Office of the Attorney General apparently has advised the department that these provisions do not require substantive revisions.

2. On page 9, in Section 3, the department proposes to repeal sections 19a-643-1 to 19a-643-110, inclusive, except for sections 19a-643-21 and 19a-643-85(c). The proposed regulations rejected without prejudice by the committee on February 28, 2012 included a repeal of sections 19a-643-1 to 19a-643-110, inclusive, without exception. The department's notice of intent to adopt regulations published in the Connecticut Law Journal on December 28, 2010 and the department's statement of purpose in both the initially-

submitted proposed regulations and this resubmittal of the regulations all state: "The proposed regulations repeal sections 19a-643-1 through 19a-643-110 . . ." For the first time in this process, the department now indicates that sections 19a-643-21 and 19a-643-85(c) are to be excepted from the repeal of the series of sections. The department's decision to retain these 2 existing sections of regulations while repealing the rest of the series creates technical and substantive issues with the resubmitted proposed regulations. If these sections are to be retained, technically it would be preferable to have the sections renumbered, for example, the department might elect to renumber these sections as 19a-643-2a and 19a-643-3a, as both sections seem to address rules of practice. In addition, substantive issues preclude retaining section 19a-643-85(c) as a stand alone provision in its present form. First, the section specifically requires that notice be given as provided in section 19a-643-48, yet the department is proposing to repeal 19a-643-48 in the resubmitted proposed regulations. Second, 19a-643-85(c) also contains an obsolete reference to a waiver of a hearing under section 19a-639 of the general statutes. Section 19a-639 of the general statutes was substantially revised in 2010 and no longer includes any provision concerning a waiver of hearing. If section 19a-643-85(c) is to be retained, revisions to the provisions are needed.

Technical Corrections:

1. Throughout the regulations, the comma after "and" in a series should be deleted, for proper form and consistency.
2. On page 1, "Section 1. The Regulations Of Connecticut State Agencies Are Amended By Adding Section 19a-613-1 Through 19a-613-4, Inclusive, As Follows:" should be "Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 19a-613-1 to 19a-613-4, inclusive, as follows:" and "Section 2. The Regulations Of Connecticut State Agencies Are Amended By Adding Section 19a-630-1 Through 19a-653-4, Inclusive." should be "Sec. 2. The Regulations of Connecticut State Agencies are amended by adding sections 19a-630-1 to 19a-653-4, inclusive, as follows:", for proper form.
3. On page 1, in section 19a-630-1, the introductory language beginning with "as" should be "As used in sections 19a-630-1 to...". The phrase is not part of the section catchline and should be moved to the beginning of the next line, for consistency and proper form.
4. On page 2, in section 19a-630-2(b), "(1) through (6)," should be "(1) to (6), inclusive, of this section," for proper form and on page 3, in section 19a-630-2(b)(6), ", inclusive of this section," should be deleted for clarity.
5. On page 3, at the end of the last line of section 19a-638-1, "new operating rooms" should be "new operating room or operating rooms", for accuracy and clarity.
6. On page 3, at the end of the second sentence of section 19a-638-2, "subsection (5) of section 19a-630-1" should be "section 19a-630-1(e) of the Regulations of Connecticut State Agencies", for accuracy.

7. On page 3, in the first line of section 19a-639a-1, the introductory language beginning with "Pursuant to" is not part of the catchline and should be moved to the beginning of the next line, for consistency and proper form.
8. On pages 3 and 4, in sections 19a-639a-1(2), (3) and (4), the first word in each of these subdivisions should be capitalized, for consistency and proper form.
9. On page 4, in section 19a-639a-3(a)(1), "three days" should be "three consecutive days", for consistency with the provisions of section 19a-639a(b)(1)(B) of the general statutes.
10. On page 4, in section 19a-639a-3(a)(2) "of general statutes" should be "of the general statutes", for proper form.
11. On page 5, in section 19a-639a-3(c), "of less than 50 pages" should be "not exceeding 50 pages", for consistency
12. On page 5, in section 19a-639a-5(a), "No late than" should be "Not later than", for accuracy.
13. On pages 5 and 6, in section 19a-639a-5(b)(2), the references to "hearing is closed" should be "public hearing record is closed", for consistency with changes made to section 19a-639a(d) in section 2 of PA 12-170.
14. On page 6, in section 19a-639b-1, all occurrences of "must" should be "shall", in accordance with the committee's directive on mandates and in 19a-639b-1(c), the space between subdivisions (2) and (3) should be deleted, for consistency and proper form.
15. On page 6, in the catchline of section 19a-639c-1, "Relocation Of A Health Care Facility" should be inserted after "19a-639c-1" and deleted from section 19a-639c-1(a), for consistency and proper form.
16. On page 7, in section 19a-639e-1(b)(3), "may be obtain" should be "may obtain", for accuracy.
17. On page 8, in section 19a-639e-2(b)(3), "the patient" should be "the patients", for consistency.
18. On page 8, in section 19a-643-1a, "et seq" should be "et seq.," for proper form.
19. On page 8, in section 19a-653-2, the period after "(NEW)" should be deleted, for consistency and proper form.
20. In section 19a-643-201(b)(23), which is not part of the proposed regulations, the reference to section 19a-643-205 should be bracketed because of the repeal of section 19a-64-205 in Section 4 on page 9.

Recommendation:

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| <p>Approval in whole with technical corrections with deletions with substitute pages Disapproval in whole or in part X Rejection without prejudice</p> |
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Reviewed by: Heather Bannister / William F. O'Shea

Date: July 12, 2012

Sec. 19a-2a. Powers and duties. The Commissioner of Public Health shall employ the most efficient and practical means for the prevention and suppression of disease and shall administer all laws under the jurisdiction of the Department of Public Health and the Public Health Code. The commissioner shall have responsibility for the overall operation and administration of the Department of Public Health. The commissioner shall have the power and duty to: (1) Administer, coordinate and direct the operation of the department; (2) adopt and enforce regulations, in accordance with chapter 54, as are necessary to carry out the purposes of the department as established by statute; (3) establish rules for the internal operation and administration of the department; (4) establish and develop programs and administer services to achieve the purposes of the department as established by statute; (5) contract for facilities, services and programs to implement the purposes of the department as established by statute; (6) designate a deputy commissioner or other employee of the department to sign any license, certificate or permit issued by said department; (7) conduct a hearing, issue subpoenas, administer oaths, compel testimony and render a final decision in any case when a hearing is required or authorized under the provisions of any statute dealing with the Department of Public Health; (8) with the health authorities of this and other states, secure information and data concerning the prevention and control of epidemics and conditions affecting or endangering the public health, and compile such information and statistics and shall disseminate among health authorities and the people of the state such information as may be of value to them; (9) annually issue a list of reportable diseases, emergency illnesses and health conditions and a list of reportable laboratory findings and amend such lists as the commissioner deems necessary and distribute such lists as well as any necessary forms to each licensed physician and clinical laboratory in this state. The commissioner shall prepare printed forms for reports and returns, with such instructions as may be necessary, for the use of directors of health, boards of health and registrars of vital statistics; (10) specify uniform methods of keeping statistical information by public and private agencies, organizations and individuals, including a client identifier system, and collect and make available relevant statistical information, including the number of persons treated, frequency of admission and readmission, and frequency and duration of treatment. The client identifier system shall be subject to the confidentiality requirements set forth in section 17a-688 and regulations adopted thereunder. The commissioner may designate any person to perform any of the duties listed in subdivision (7) of this section. The commissioner shall have authority over

directors of health and may, for cause, remove any such director; but any person claiming to be aggrieved by such removal may appeal to the Superior Court which may affirm or reverse the action of the commissioner as the public interest requires. The commissioner shall assist and advise local directors of health in the performance of their duties, and may require the enforcement of any law, regulation or ordinance relating to public health. When requested by local directors of health, the commissioner shall consult with them and investigate and advise concerning any condition affecting public health within their jurisdiction. The commissioner shall investigate nuisances and conditions affecting, or that he or she has reason to suspect may affect, the security of life and health in any locality and, for that purpose, the commissioner, or any person authorized by the commissioner, may enter and examine any ground, vehicle, apartment, building or place, and any person designated by the commissioner shall have the authority conferred by law upon constables. Whenever the commissioner determines that any provision of the general statutes or regulation of the Public Health Code is not being enforced effectively by a local health department, he or she shall forthwith take such measures, including the performance of any act required of the local health department, to ensure enforcement of such statute or regulation and shall inform the local health department of such measures. In September of each year the commissioner shall certify to the Secretary of the Office of Policy and Management the population of each municipality. The commissioner may solicit and accept for use any gift of money or property made by will or otherwise, and any grant of or contract for money, services or property from the federal government, the state or any political subdivision thereof or any private source, and do all things necessary to cooperate with the federal government or any of its agencies in making an application for any grant or contract. The commissioner may establish state-wide and regional advisory councils.

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.