

Section 1

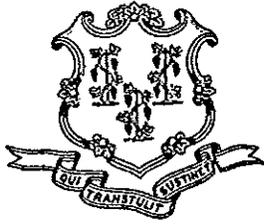
Commissioner's letter

Any further correspondence

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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

February 4, 2013

Pamela B. Booth, Committee Administrator
Legislative Regulation Review Committee
State Capitol, Room 011
Hartford, CT 06106

Re: Regulations Concerning: *Certificate of Need*

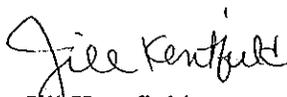
Dear Ms. Booth:

Enclosed for the Committee's consideration is the proposed amendment of the above-captioned regulation.

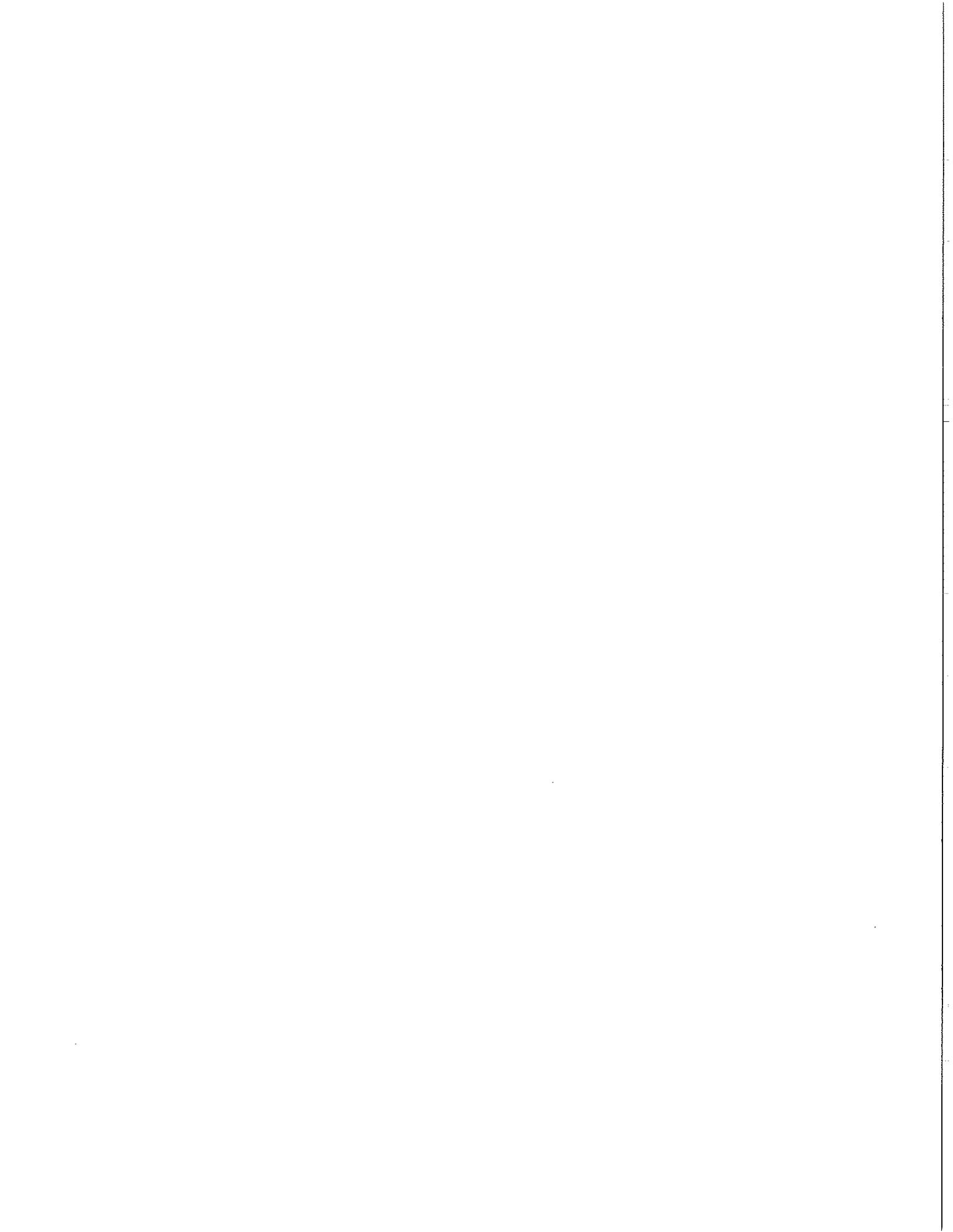
These regulations were **Rejected without Prejudice** by the Legislative Regulations Review Committee on February 28, 2012. The Department has attached a summary of the changes made in an effort to comply with the comments made by the Legislative Commissioner's Office, and we hope the proposed regulations are now satisfactory.

I am available to answer any questions you may have and can be reached at (860) 509-7280 or via e-mail at jill.kentfield@ct.gov. Thank you for your consideration.

Sincerely,


Jill Kentfield
Legislative Liaison

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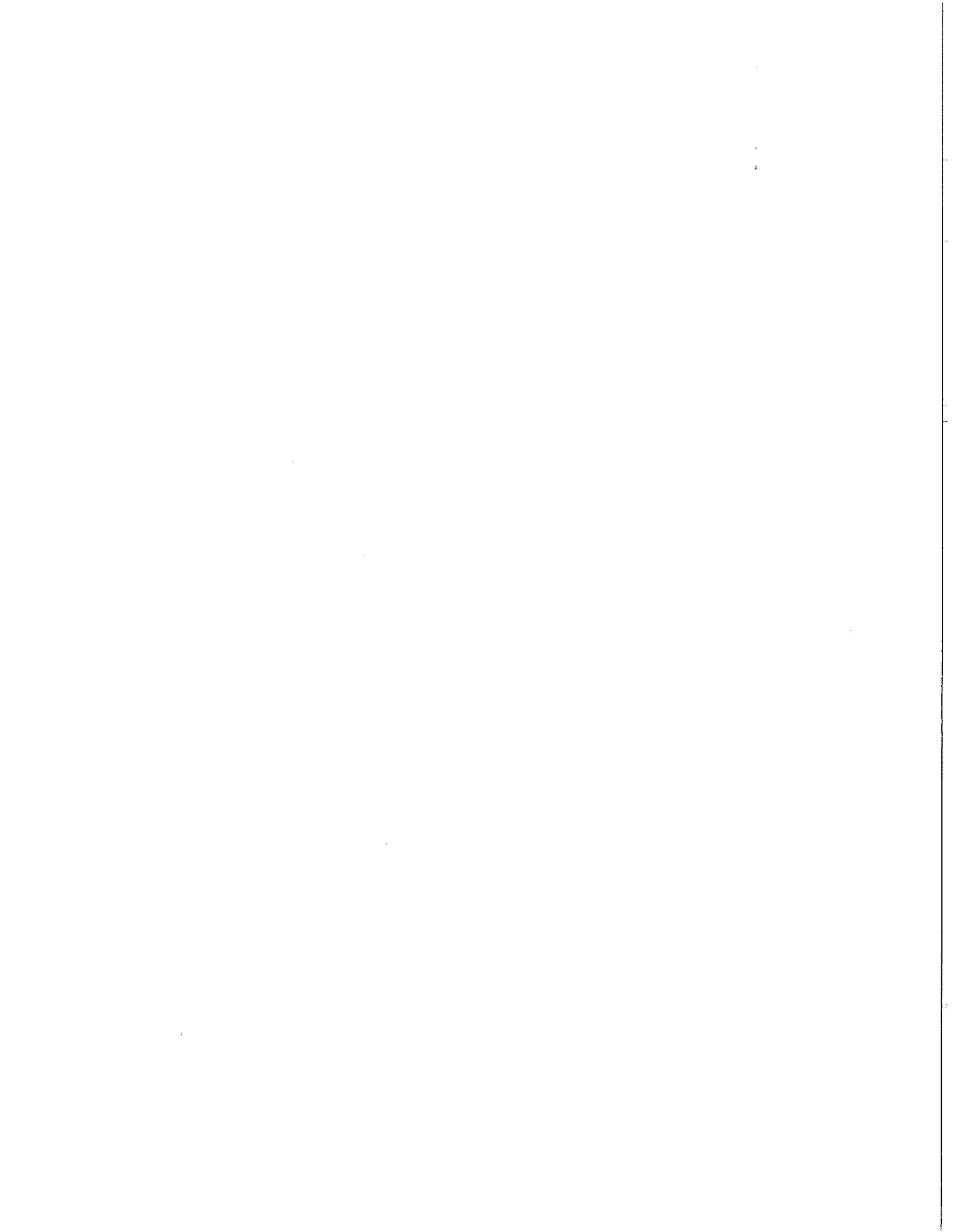


Summary of Comments
 Office of Health Care Access Administrative Regulations
 Sections 19a-613-1 through 19a-653-4 of the Regulations of Connecticut State Agencies

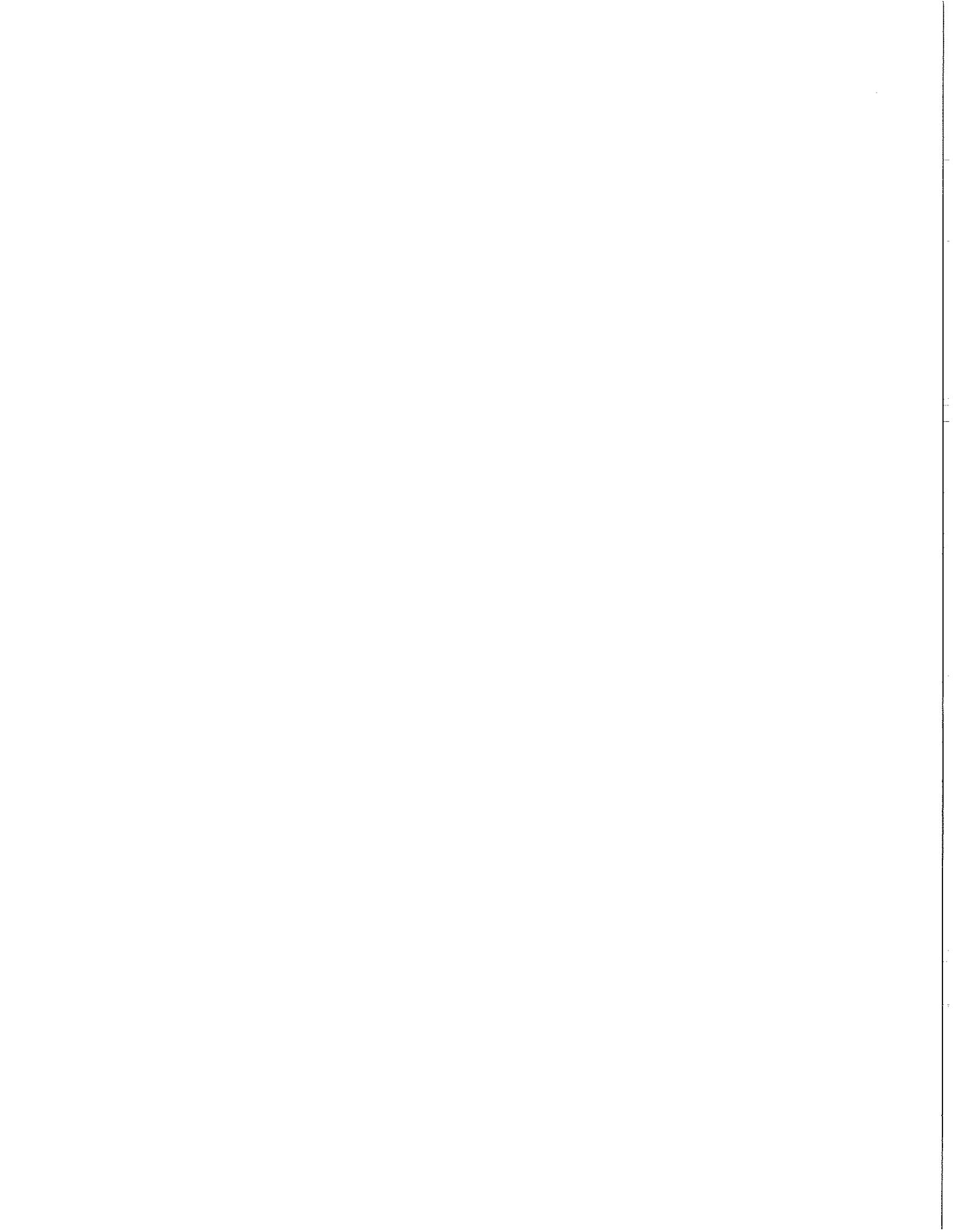
SUBJECT: Proposed regulations necessary to administer the Certificate of Need process under Public Act 10-179 §§ 87, 89-93.

COMMENTERS: Legislative Commissioners' Office 2012-0003C

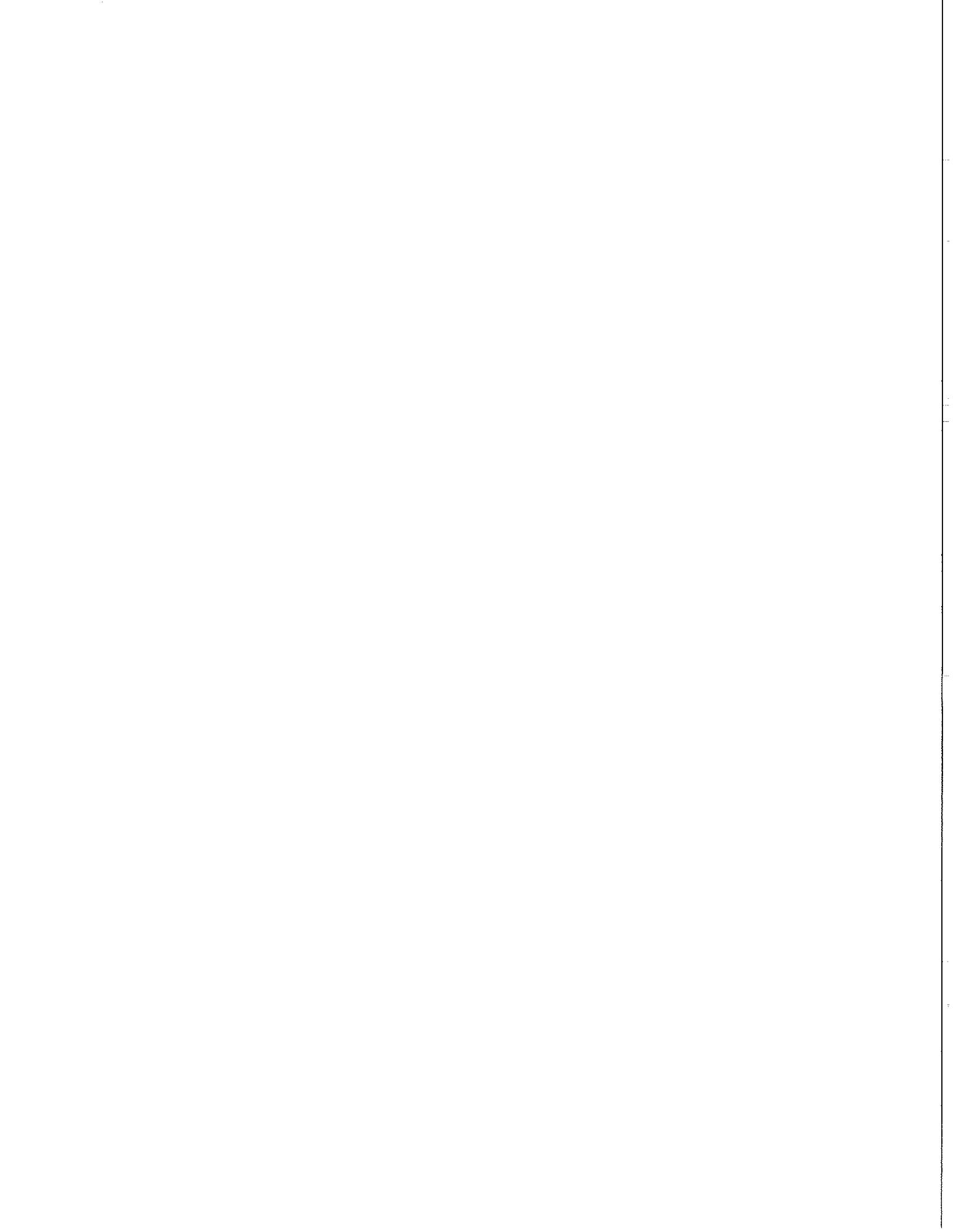
NUMBER	COMMENT	RESPONSE
	<p>Substantive Concerns</p> <p>On page 2, the meaning of sections 19a-630-2(a)(4) and 19a-630-2(a)(5), which are criteria for determining whether an entity is a "central service facility", is unclear.</p>	<p>Section 19a-630-2(a)(4) and 19a-630-2(a)(5) have been revised for clarity</p> <p>Section 19a-630-2(a)(4) includes those facilities such as laboratory, pharmacy or x-ray where the facility is not necessarily run by a physician and services are being performed on and provided to a patient along with decisions being made for the patient by someone other than the patient's physician. The entities resemble a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians. Language is based upon case cite: <u>Comm. On Hospital and Health Care v. Lakoff</u>, 214 Conn. 321 (1990)—in that case, the defendants operated an imaging center that the court held "resembles a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians." Id. 333-34. The court concluded that the imaging center was a "central service facility." Id. 334</p>
	<p>On page 5, the provisions of section 19a-639c-2 conflict with the provision s of sections 19a-639c(a) and 19a-638(c)(2) of the general statutes. Sections 19a-639c and 19a-638 do not provide an exception to the statutory requirements for a health care facility relocation within the same town.</p> <p>Technical Corrections</p>	<p>Yes, OHCA has no statutory authority.... historical policy....recommmend removal/deletion.</p>
1	<p>Throughout the regulations, "Office" should be "office" when referring to the physical location where the Office of Health Care Access conducts</p>	<p>Regulations have been revised to provide more consistency. Most of the time "Office" is referring to the</p>



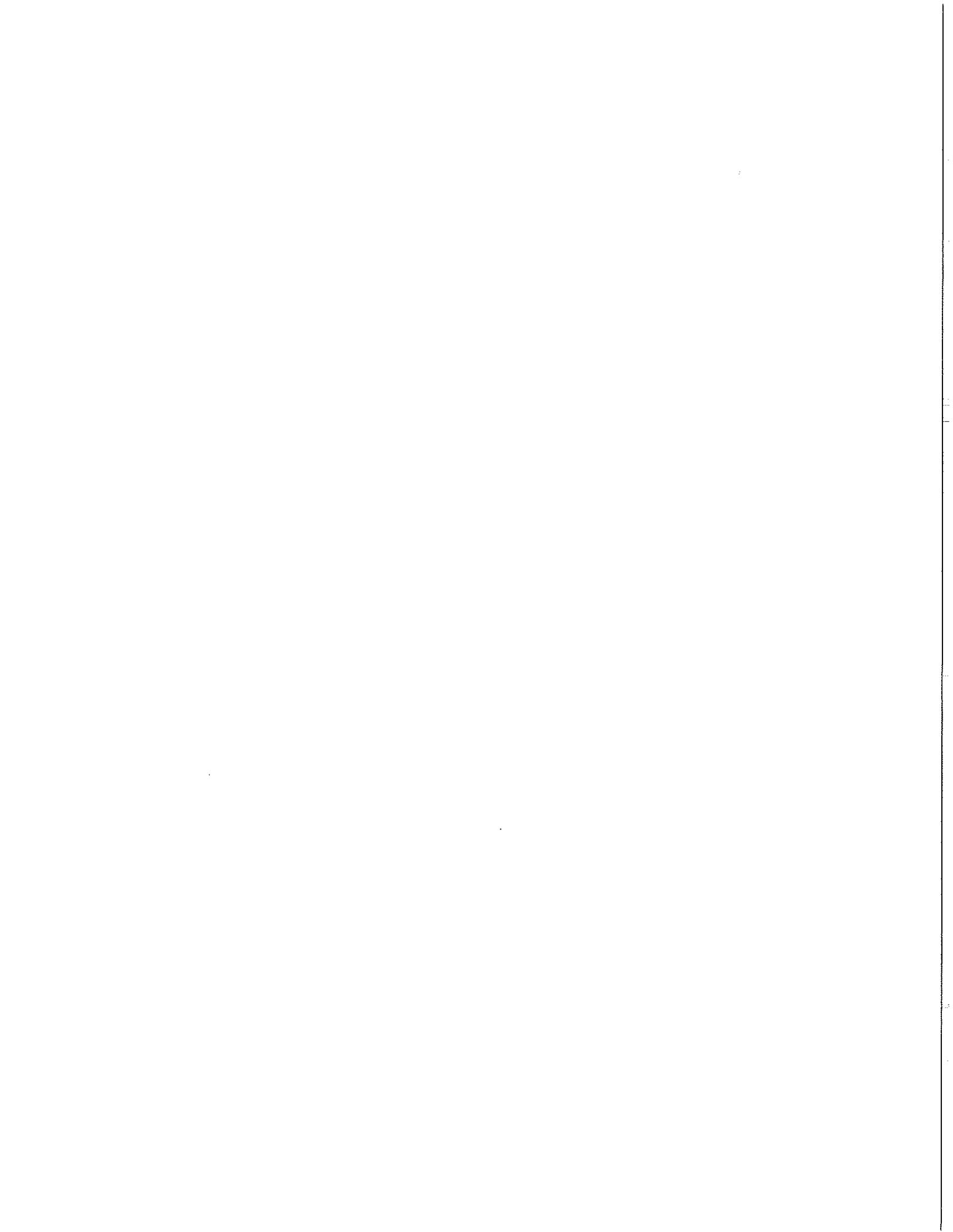
	business, for consistency with the definition of "Office" in section 19a-630-1(f).	division rather than the physical location and therefore only a few of the words were made lower case "office". References to "subsection or subdivision" have been removed for clarity.
2	Throughout the regulations, references to subsections and subdivisions of the general statutes should be deleted, for clarity in the event the statute sections that are referenced are subsequently amended and result in the change of subdivision or subsection designations.	Correction was made for consistency.
3	Throughout the regulations, "Certificate of Need" should be "certificate of need", for consistency.	Capitalization following the introductory language has been corrected.
4	Throughout the regulations, each word in the introductory language following each section number should be capitalized, and each word following a subsection or subdivision designator should be capitalized, for proper form and consistency.	Formatting has been revised accordingly
5	The formatting of the regulation should be corrected. Section 1 should indicate that Sections 19a-613-1 through 19a-613-4, inclusive, are being added, as these sections relate to the description of the Office and its' data collection policies. "Section 2" should be inserted prior to section 19a-630-1, and should indicate that Sections 19a-630-1 through 19a-653-4, inclusive, are being added. The following two sections should be renumbered accordingly. Additionally, as the subject matter of Sections 19a-630-1 through 19a-653-4, inclusive, are certificate of need, "Certificates of Need" should be included in the catch line following "(NEW) Section 19a-630-1"	Deputy commissioner reference has been corrected for clarity
6	On page 1, in the third line of section 19a-613-1, "a deputy commissioner" should be "a deputy commissioner of Public Health", for clarity and, in the fourth line, "19a-612" should be "19a-612d", for accuracy.	Revision has been made accordingly
7	On page 1, in the second line of section 19a-613-2, "Chapter 368z" should be "section 19a-630", for clarity and accuracy.	Correction changing "FOI" to "Freedom of Information" has been made
8	On page 1, in section 19a-613-4, "FOI" should be "Freedom of Information", for proper form.	Addition has been made for proper form.
9	On page 1, in section 19a-630-1, above the line starting with "(a)", introductory language should be added as follows: "As used in sections 19a-630-1 to 19a-653-4, inclusive, of the Regulations of Connecticut State Agencies:", for proper form.	Correction has been made accordingly
10	On page 1, in the first line of section 19a-630-1(a), "as used in subdivisions (8) (9) and (11) of subsection (a) of section 19a-638 of the general statutes" should be deleted, for clarity.	Revision has been made accordingly
11	On page 2, in section 19a-630-2(a)(2), "facility" should be "entity", for consistency and "the individual physician, physicians, practitioner or practitioners" should be "individual physicians or practitioners", for clarity.	Revision has been made accordingly
12	On page 2, in the second line of section 19a-630-2(b), after "(6)", "inclusive, of this section" should be inserted, for clarity.	Revision has been made accordingly
13	On page 2, in section 19a-630-2(b), "whether" should be inserted as the first	Revisions have been made (adding "whether") for



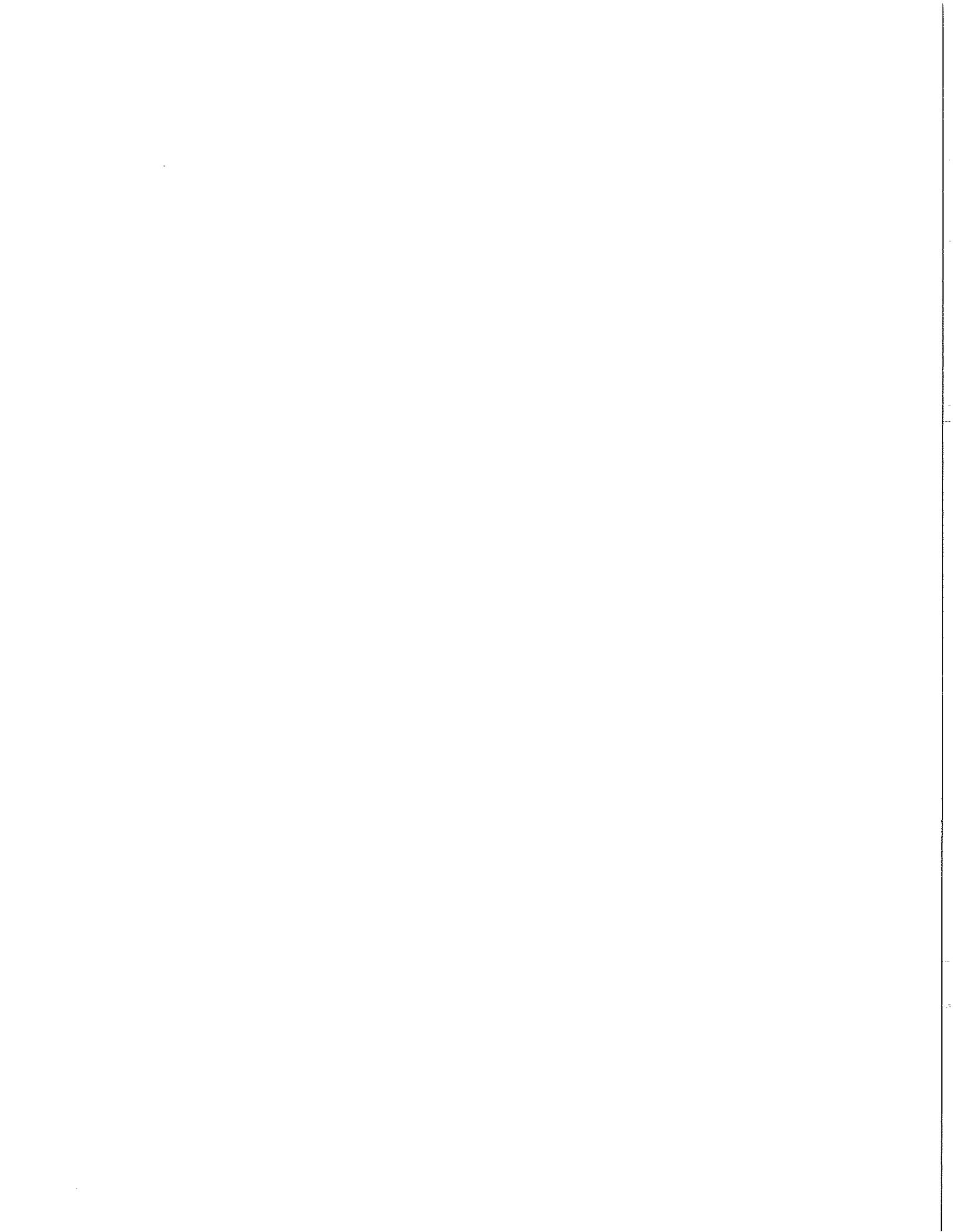
	word of subdivisions (1) through (8), for consistency with the introductory language.	consistency with introductory language
14	On page 2, in section 19a-630-2(b)(2), "no" should be changed to "any", for clarity.	Correction has been made
15	On page 2, in sections 19a-630-2(b)(5) and (6), respectively, "the individual physician, physicians, practitioner or practitioners who provided" and "the physician, physicians, practitioner or practitioners who provided", should be "the individual physicians or practitioners who provide", for clarity.	Revisions have been made accordingly
16	On page 2, in section 19a-630-2(b)(9), "officer" should be "commissioner, the commissioner's designee or the deputy commissioner", for consistency.	Revisions have been made accordingly
17	On page 2, in section 19a-638-1, in the first line, "increases its operating rooms" should be "increases the number of its operating rooms", for clarity, in the third line, "operating room" should be "operating rooms" for accuracy, and, in the fourth line, "operating room(s)" should be "operating room or operating rooms", for proper form.	Revisions have been made accordingly
18	On page 2, in the first and fifth lines 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 and proper form.	Changes have been made accordingly
19	On page 2, in the last line of section 19a-638-3, a period should be inserted after "determination", "and" should be deleted, and "the" should be "The", for clarity. In the same line, "that docket number" should be "the corresponding docket number", for clarity.	Changes have been made accordingly
20	On page 2, in section 19a-638-4, after "determinations" in the first line, the phrase "as to whether a certificate of need is needed" should be inserted, for clarity.	Changes have been made accordingly
21	On page 2, in section 19a-639a-1, in the first line, the first "section" should be deleted, for clarity, in the second line, "application" should be inserted after "certificate of need", for clarity and consistency, and, in the fifth line, "in accordance with subsection (b) of section 19a-639a of the general statutes", should be deleted, for clarity.	Changes have been made accordingly
22	On page 2, in section 19a-639a-1, in subsection (1), "The Applicant" should be "A statement that the applicant", for clarity.	Changes have been made accordingly
23	On page 3, in the first line of section 19a-639a-3(a)(1), "Copies of the notices" should be "A copy of the notice", for consistency.	Changes have been made accordingly
24	On page 3, in the second line of section 19a-639a-3(a)(2), "applicable subdivision" should be "applicable requirement for a certificate of need", for clarity.	Changes have been made accordingly
25	On page 3, in section 19a-639a-3(a)(6), "Application forms for specific types of proposals are available and may be downloaded from the Office's website:" should be "the appropriate application form for the specific type of proposal, as follows, which are available and may be downloaded from the Office's website:", for clarity and consistency with the introductory	Changes have been made accordingly



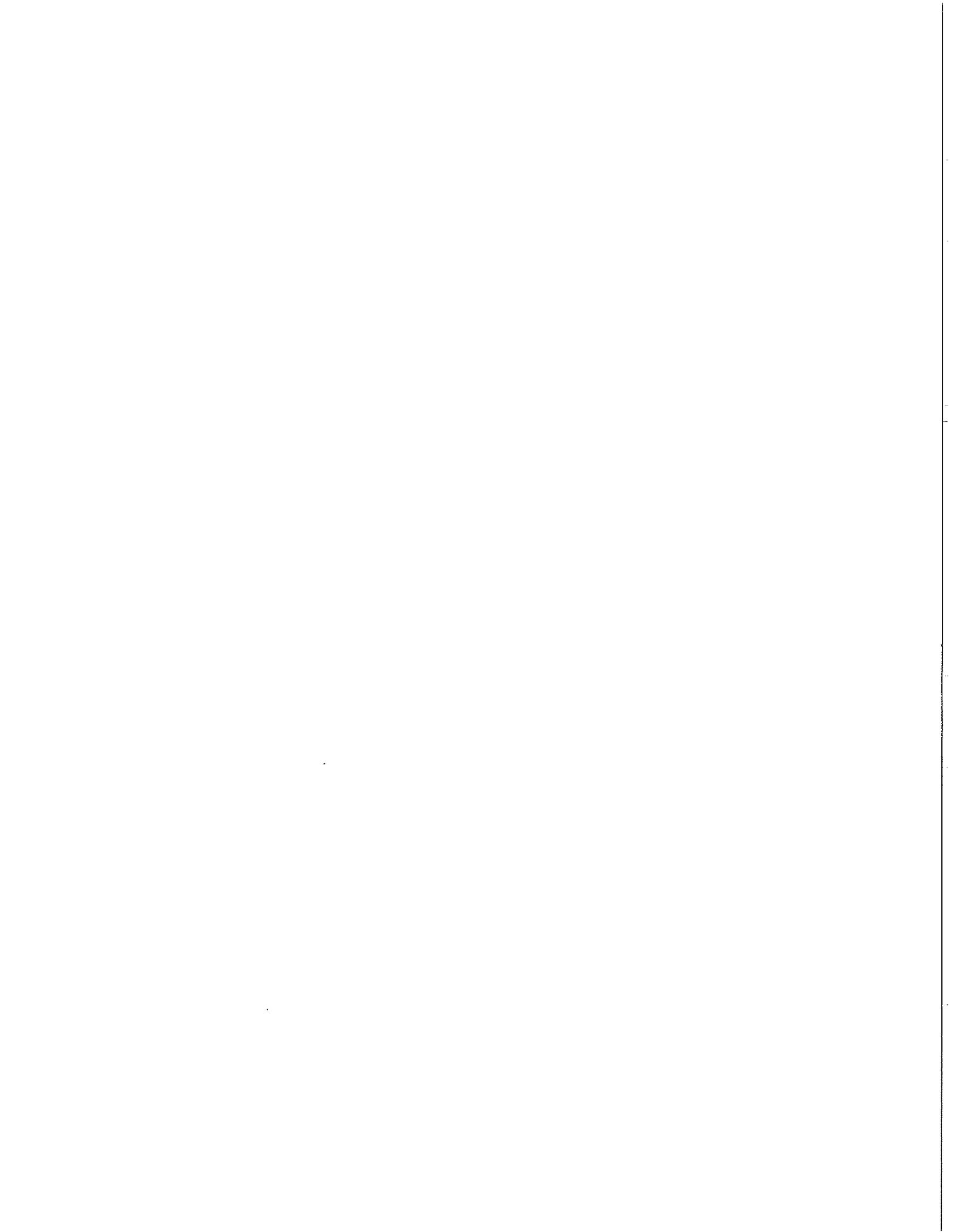
	language.	
26	On page 3, in section 19a-639a-3(a)(6)(A), "of the general statutes" should be inserted after "19a-630", for proper form.	Changes have been made accordingly
27	On page 3, in section 19a-639a-3(a)(6)(I), the subdivisions of subsection (a) of section 19a-638 of the general statutes should either be corrected to "(8), (9) or (11)", or the citation to the subdivisions should be eliminated, for accuracy of reference.	Changes have been made accordingly
28	On page 4, in section 19a-639a-4(b), "the applicant will" in the third line should be "the applicant shall", in accordance with the committee's directive regarding mandates.	Changes have been made accordingly
29	On page 4, in the introductory language of section 19a-639a-5(b), the colon should be deleted, for consistency.	Changes have been made accordingly
30	On page 4, in section 19a-639a-5(b)(2), "will be extended" in the second line should be "shall be extended", in accordance with the committee's directive regarding mandates, and "beyond" in the third line should be "after", for clarity and proper form.	Changes have been made accordingly
31	On page 4, on the sixth line of section 19a-639a-6, "subsection (g) of section 19a-639a of the general statutes" should be deleted, for clarity and accuracy.	Changes have been made accordingly
32	On page 5, in the last line of section 19a-639b-2, "voidance" should be "voiding", for proper form.	Changes have been made accordingly
33	On page 5, in section 19a-639c-1, subsection designations "(a)" and "(b)" should be inserted before each paragraph, for consistency and proper form.	Changes have been made accordingly
34	On page 5, in the second line of section 19a-639c-1, "a request for determination" should be "a letter requesting that the Office make a determination as to whether a certificate of need is required" and, in the third line, "which shall be submitted with such letter," should be inserted after "facility", for accuracy and clarity.	Changes have been made accordingly
35	On page 5, in the sixth line of section 19a-639c-1, "relocation" should be "relocate", for proper form and "Applicant" should be "applicant", for consistency.	Changes have been made accordingly
36	On page 5, in the first and second lines of section 19a-639c-3, "and is either unable to demonstrate or chooses not to demonstrate" should be "and is unable to demonstrate", for consistency with section 19a-639c(a) of the general statutes.	Changes have been made accordingly
37	On page 5, in section 19a-639e-1(a)(3), in the second line, "will" should be "may", for consistency and proper form and "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly
38	On page 5, in section 19a-639e-1(b)(3), in the second line, "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly
39	On page 5, throughout section 19a-639e-2, "service(s)" should be "service or services", for proper form.	Changes have been made accordingly
40	On page 6, in the second line of section 19a-643-1a, "of the Regulations of	Changes have been made accordingly



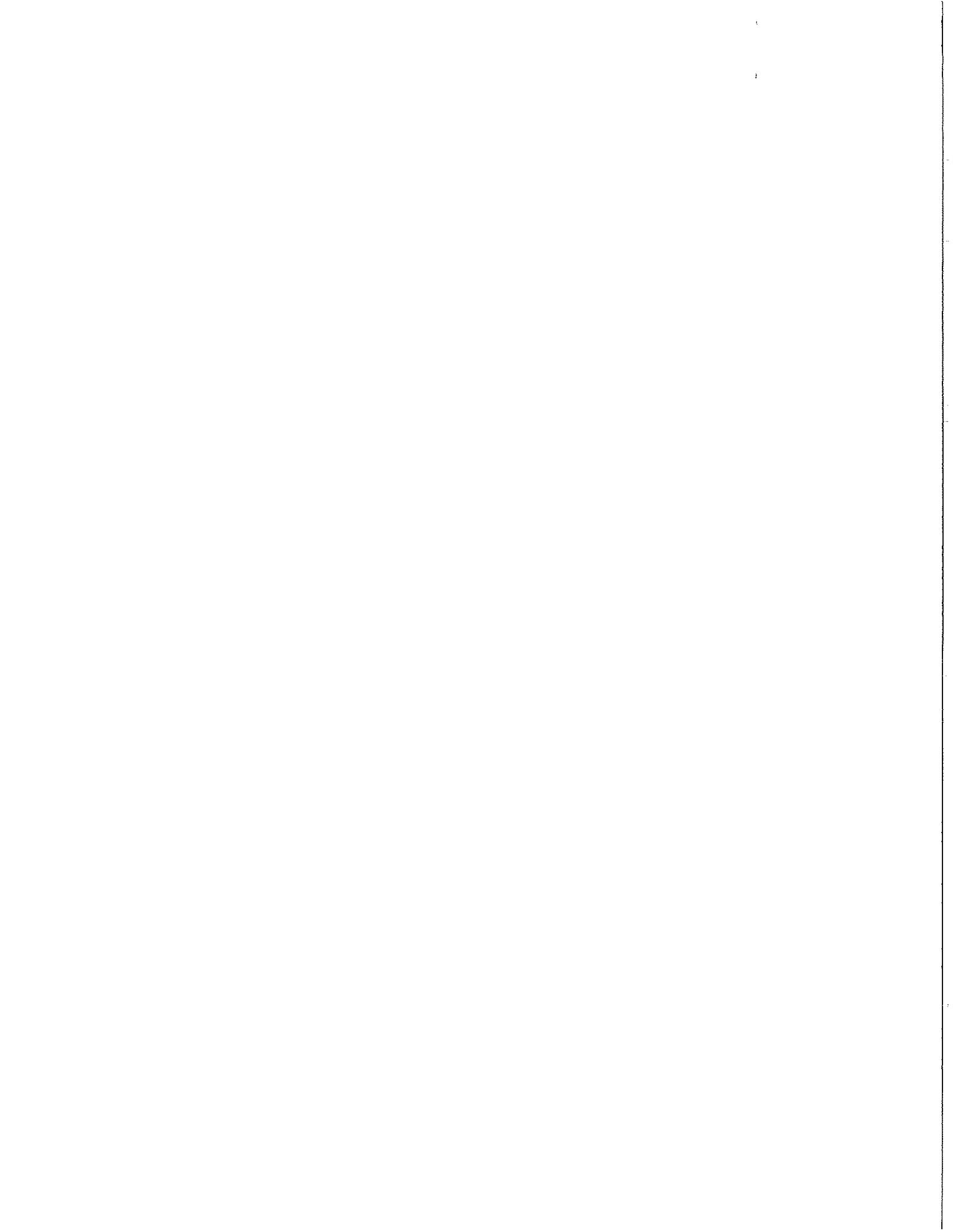
	Connecticut State Agencies" should be inserted after "et seq.", for proper form.	
41	On page 6, in the second line of section 19a-653-1, "this section" should be "section 19a-653 of the general statutes", for clarity and proper form.	Changes have been made accordingly
42	On page 6, in the first line of section 19a-653-2, "of the general statutes" should be inserted after "19a-653", for consistency and proper form.	Changes have been made accordingly
43	On page 6, in the last sentence of section 19a-653-2, "Upon receipt of the request, the Office shall have ten days to notify the facility, institution or person of the date, time and place of the hearing" should be "The Office shall notify the health care facility or person of the date time and place of the hearing, not later than ten days after the Office's receipt of the request.", for clarity and consistency.	Changes have been made accordingly
44	On page 6, in the first line of section 19a-653-3(c), "time extension" should be "extension of time", for consistency, in the third line, "from" should be "beginning on" and "onward" should be deleted, for clarity and, in the fourth line, "at" should be "upon", for clarity.	Changes have been made accordingly
45	On page 6, in Section 2, "Section 2" should be "Sec. 2" and "Section 3" should be "Sec. 3", renumbered as noted in technical correction 5, above	Changes have been made accordingly
46	On page 6, in Section 2, "inclusive" should be inserted after "19a-643-110", for accuracy and clarity.	Changes have been made accordingly, Also added "exclusive of Sections 19a-643-21 and 19a-643-85(c)" – 19a-643-21 allows for the consolidation of the proceeding and 19a-643-85(c) allows for the opportunity of a Public Hearing
47	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.	Section 19a-643-209 (formerly section 19a-643-3a) has been deleted.
48	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	Section 19a-643-209 (formerly section 19a-643-3a) has been revised by adding language which clarifies the hearing request process and specifies the timeframe for requesting a hearing. Specifically, the applicant has 10 days from the date of the denial of the application to request a hearing on an application that has been denied without a hearing. Additionally, specific references to the Regulations of Connecticut State Agencies have been added for purposes of clarity.



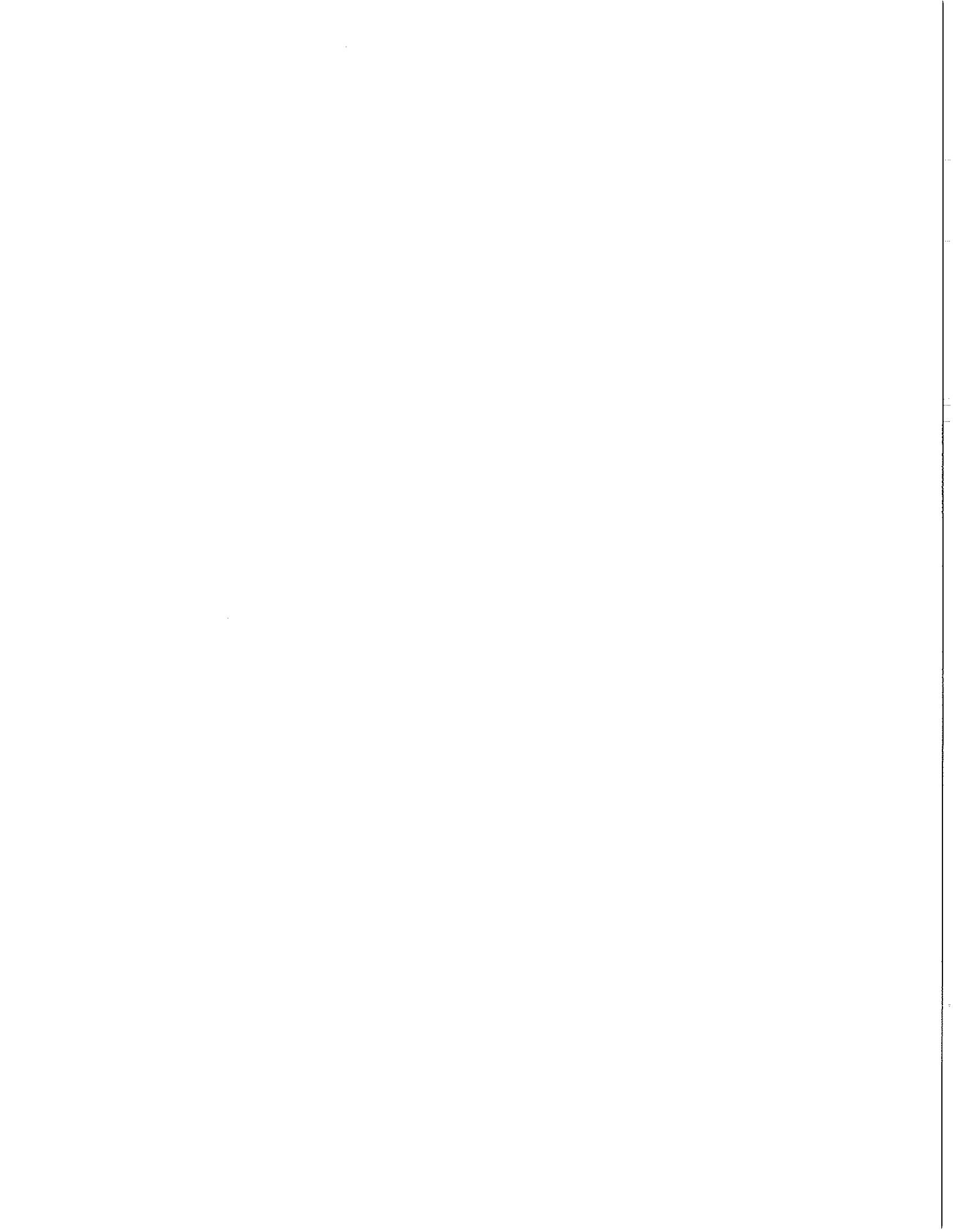
	<p>hold a public hearing on a completed certificate of need application and the timeframe for making a request. Section 19a-641 of the general statutes describes the procedure for an applicant to appeal a final decision made by the office. It is unclear whether this provision of section 19a-643-3a of 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.</p>	
49	On page 1, the introductory language to Sec. 2 should add only "sections 19a-630-1 and 19a-630-2, as follows:"	Changes have been made accordingly
50	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:"	Changes have been made accordingly
51	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:"	Changes have been made accordingly
52	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:"	Changes have been made accordingly
53	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:"	Changes have been made accordingly
54	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:"	Changes have been made accordingly
55	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.	Sections 19a-643-1 to 19a-643-3a have been changed to sections 19a-643-207 to 19a-643-208.
56	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.	Changes have been made accordingly
57	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	Changes have been made accordingly



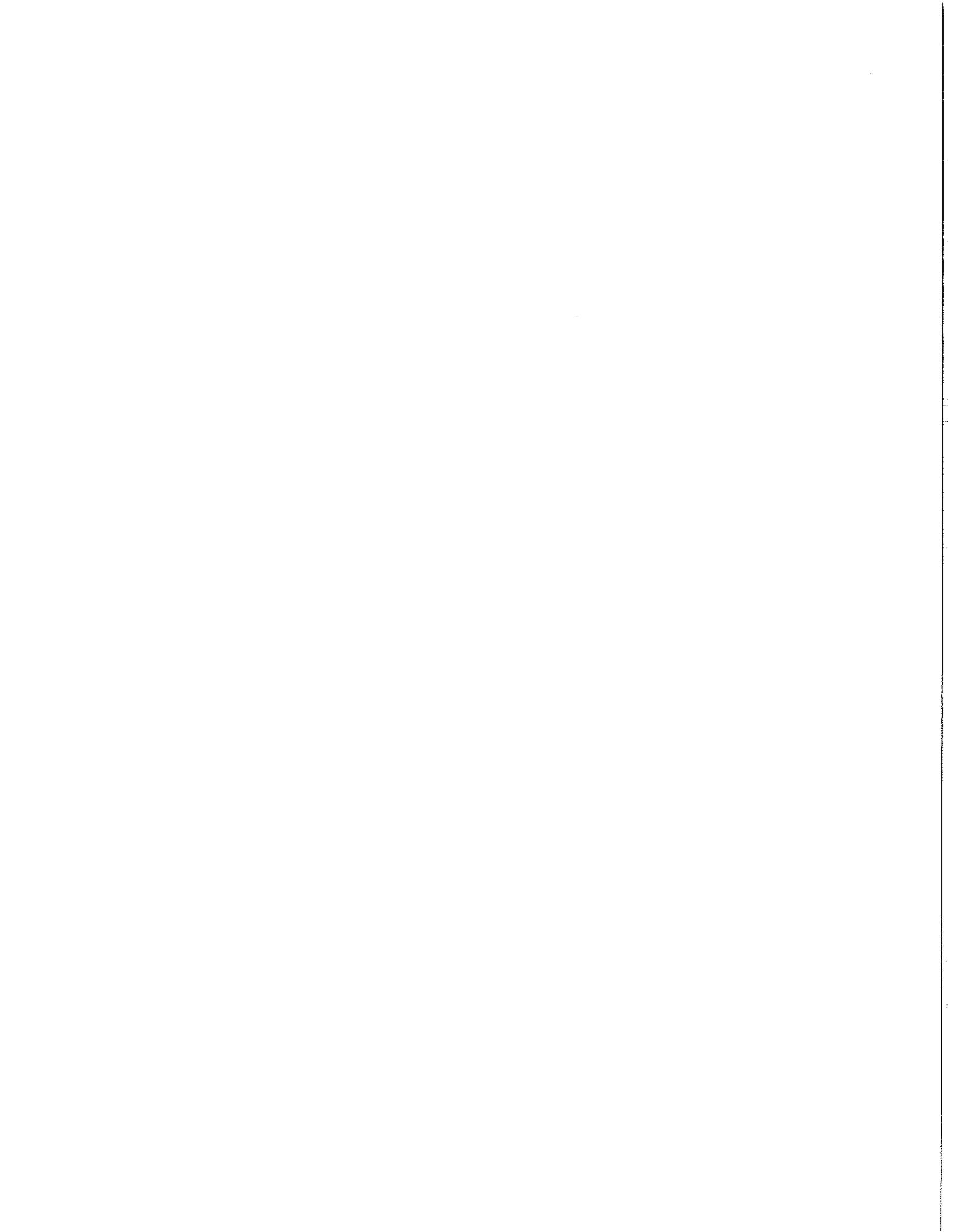
	follows:"	
58	On page 9, Secs. 3, 4 and 5 should be renumbered Secs. 10, 11 and 12, for accuracy and conformity.	Changes have been made accordingly
59	On page 2, in section 19a-630-2(4), "one or more entities who are or may be" should be changed to "the entity that is or may be", for clarity and conformity with the rest of the section.	Changes have been made accordingly
60	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.	Changes have been made accordingly
61	On page 6, in section 19a-639b-1(c), the space between subdivisions (2) and (3) should be deleted, for consistency and proper form.	Changes have been made accordingly
62	On page 8, in section 19a-643-2a, "his designee" should be "the commissioner's designee", for proper form.	Changes have been made accordingly
63	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.	Changes have been made accordingly
64	On page 2, the meaning of section 19a-630-2(b) is unclear. Section 19a-630-2(a) lists criteria for an entity to be deemed a central service facility. The introductory language of subsection (a) provides that the entity "shall be a central service facility" if it meets one or more of the listed criteria. The introductory language of subsection (b) in the same section provides that "in addition to the criteria listed in subsection (a)(1) to (6)", the commissioner may consider the factors listed in subsections (b)(1) to (b)(9). It is not clear whether an entity might satisfy one or more of the criteria in subsection (a) but not be deemed a central service facility because of the factors considered in subsection (b) or, conversely, whether an entity might not satisfy any one of the criteria in subsection (a) but nevertheless be considered a central service facility because of the factors considered in subsection (b).	Section 19a-630-2(b) has been revised by deleting "is a central service facility, in addition to any of the criteria in subsection (a)(1) to (6), inclusive of this section," and adding language which clarifies that this subsection does not include criteria to determine the existence of a Central Service Facility.
65	On page 8, the meaning and intent of section 19a-643-209 are unclear. Connecticut General Statutes section 19a-639a(e) provides, in part, that "[a]ny 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." Conversely, this section of the regulation provides that "an applicant may request a public hearing within ten days of the denial". When construing the intent of this provision, it is plausible that although the Office uses the term "public hearing" in this section of the proposed regulation, the Office is in fact referring to an "administrative hearing" conducted in accordance with the provisions of chapter 54 of the general statutes. If the term "public hearing" is actually intended, then it is not clear that there is statutory authority for a provision which allows the applicant, acting alone, to request a "public hearing" after the review process has been completed and the office has issued a denial on the application. Assuming arguendo that statutory authority exists for the department to permit such a "public	Section 19a-643-209 has been deleted in its entirety.



	<p>hearing", as drafted the proposed regulation does not specify to whom or in what form a request for a "public hearing" shall be made. Further, it is unclear whether such a request is to be made within ten days of the applicant's receipt of the Office's denial or within ten days of the date of the Office's issuance of the denial.</p> <p>The purpose of the Office conducting a "public hearing" after the certificate of need review period has concluded and after the decision has been made on the certificate of need application is unclear and does not appear to be contemplated in the general statutes. Although the term "public hearing" is used in section 19a-643-209, it may be that the Office intends to provide an applicant with the opportunity to contest the denial of the application through an "administrative hearing" conducted in accordance with the provisions of chapter 54 of the general statutes. Under proposed section 19a-643-209, all certificate of need applicants are not entitled to "de novo" review of a denied application. Instead the provision appears to create a system whereby only those applications that did not initially include a "public hearing" are eligible for further review should the Office ultimately deny the application. Further, the interrelationship between this proposed regulatory provision and section 19a-641 of the general statutes is neither explained or self-evident. Section 19a-641 of the general statutes provides that, "Any health care facility or institution and any state health care facility or institution aggrieved by any final decision of said office under the provisions of sections 19a-630 to 19a-639e, inclusive, may appeal from such decision in accordance with the provisions of section 4-183, except venue shall be in the judicial district in which it is located." These proposed regulations contain no reference to the right of appeal pursuant section 19a-641. The public hearing and appeal process set forth in section 19a-643-209 appear to be at variance with the governing statutes. Further clarification from the department is required.</p>	
66	<p>On page 2, in section 19a-630-2(a)(5), "subsection (4) of this section" should be "subdivision (4) of this subsection" for accuracy and proper form.</p>	Changes have been made accordingly
67	<p>On page 3, in section 19a-638-2, the phrase "as defined in section 19a-630-1(e) of the Regulations of Connecticut State Agencies" should be deleted as the phrase is both technically incorrect and unnecessary because of the controlling definition found in section 19a-630-1(5). Additionally, the second occurrence of "section 19a-630-1(e)" should be "section 19a-630-1(5)" for accuracy.</p>	Changes have been made accordingly
68	<p>On page 4, in section 19a-639a-1, the section consists of only one subsection and therefore the designator for subsection "(a)" should be deleted for proper form.</p>	Changes have been made accordingly
69	<p>On page 6, in section 19a-639a-6, the phrase "two weeks" should be "not</p>	Changes have been made accordingly



	less than two weeks" for conformity with the controlling statutory provision. (See Connecticut General Statutes section 19a-639a(f))	
70	On page 7, in section 19a-639b-1(c)(3), subdivision "(3)" should be moved to the line below and aligned with subdivisions (1) and (2) for consistency and proper form.	Changes have been made accordingly
71	On page 7, in section 19a-639b-2, "Non- Transferability" should be "Non-transferability" for proper form.	Changes have been made accordingly
72	On page 8, in section 19a-639e-2(a), "to terminate service or services which were authorized" should be "to terminate a service or services which were authorized" for consistency and proper form.	Changes have been made accordingly
73	On page 8, in section 19a-639e-2(b), "to terminate a service or services which was not authorized" should be "to terminate a service or services which were not authorized" for consistency and proper form.	Changes have been made accordingly
74	On page 9, in section 19a-643-201(b)(23)(A), "October first" should be "October 1st" and "September thirtieth" should be "September 30th" to accurately reflect the official version of the Regulations of Connecticut State Agencies.	Changes have been made accordingly
75	On page 10, in section 19a-643-201(b)(23)(B), "June thirtieth" should be "June 30th" to accurately reflect the official version of the Regulations of Connecticut State Agencies.	Changes have been made accordingly
Other		
		All references to "general statutes" have been changed to "Connecticut General Statutes" for consistency and proper form
		Section 19a-643-21 and 19a-643-85(c) were added in to the regulation as section 19a-643-2a and 19a-643-3a. All obsolete references were revised.
		Section 19a-643-201 (b)(23) was added into the regulation as section 3 and revised to reflect the repeal of 19a-643-205
		Section 19a-639a-3 was revised for ease of readability to the consumer
		All technical corrections noted in report 2012-3A were made

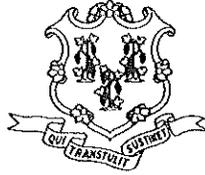


The Connecticut General Assembly

Legislative Commissioners' Office

Edwin J. Maley, Jr.
Commissioner
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Director



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Memorandum

To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: November 27, 2012

Regulation No:	2012-3C
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 third resubmittal of regulations that were rejected without prejudice at the committee's meetings on February 28, 2012 and September 25, 2012. The regulations were also submitted to the committee on June 15, 2012 and subsequently withdrawn on or about July 23, 2012. The resubmittal addresses the substantive concerns and technical corrections noted in the September 25, 2012 report, except as noted below.

2. Sections designated as 19a-643-1a to 19a-643-3a in the previous submittals of the regulations have been renumbered as sections 19a-643-207 to 19a-643-209, in accordance with technical correction number "2" in the September 25, 2012 report.

Substantive Concerns:

1. On page 2, the meaning of section 19a-630-2(b) is unclear. Section 19a-630-2(a) lists criteria for an entity to be deemed a central service facility. The introductory language of subsection (a) provides that the entity "shall be a central service facility" if it meets one or more of the listed criteria. The introductory language of subsection (b) in the same section provides that "in addition to the criteria listed in subsection (a)(1) to (6)", the commissioner may consider the factors listed in subsections (b)(1) to (b)(9). It is not clear whether an entity might satisfy one or more of the criteria in subsection (a) but not be deemed a central service facility because of the factors considered in subsection (b) or, conversely, whether an entity might not satisfy any one of the criteria in subsection (a) but nevertheless be considered a central service facility because of the factors considered in subsection (b).

2. On page 8, the meaning and intent of section 19a-643-209 are unclear. Connecticut General Statutes section 19a-639a(e) provides, in part, that "[a]ny 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." Conversely, this section of the regulation provides that "an applicant may request a public hearing within ten days of the denial". When construing the intent of this provision, it is plausible that although the Office uses the term "public hearing" in this section of the proposed regulation, the Office is in fact referring to an "administrative hearing" conducted in accordance with the provisions of chapter 54 of the general statutes. If the term "public hearing" is actually intended, then it is not clear that there is statutory authority for a provision which allows the applicant, acting alone, to request a "public hearing" after the review process has been completed and the office has issued a denial on the application. Assuming *arguendo* that statutory authority exists for the department to permit such a "public hearing", as drafted the proposed regulation does not specify to whom or in what form a request for a "public hearing" shall be made. Further, it is unclear whether such a request is to be made within ten days of the applicant's receipt of the Office's denial or within ten days of the date of the Office's issuance of the denial.

The purpose of the Office conducting a "public hearing" after the certificate of need review period has concluded and after the decision has been made on the certificate of need application is unclear and does not appear to be contemplated in the general statutes. Although the term "public hearing" is used in section 19a-643-209, it may be that the Office intends to provide an applicant with the opportunity to contest the denial of the application through an "administrative hearing" conducted in accordance with the provisions of chapter 54 of the general statutes. Under proposed section 19a-643-209, all certificate of need applicants are not entitled to "de novo" review of a denied application. Instead the provision appears to create a system whereby only those applications that did not initially include a "public hearing" are eligible for further review should the Office ultimately deny the application. Further, the interrelationship between this proposed

2 Change statute - to clarify that the applicant can request the P.H.

regulatory provision and section 19a-641 of the general statutes is neither explained or self-evident. Section 19a-641 of the general statutes provides that, "Any health care facility or institution and any state health care facility or institution aggrieved by any final decision of said office under the provisions of sections 19a-630 to 19a-639e, inclusive, may appeal from such decision in accordance with the provisions of section 4-183, except venue shall be in the judicial district in which it is located." These proposed regulations contain no reference to the right of appeal pursuant section 19a-641. The public hearing and appeal process set forth in section 19a-643-209 appear to be at variance with the governing statutes. Further clarification from the department is required.

Technical Corrections:

1. On page 2, in section 19a-630-2(a)(5), "subsection (4) of this section" should be "subdivision (4) of this subsection" for accuracy and proper form.
2. On page 3, in section 19a-638-2, the phrase "as defined in section 19a-630-1(e) of the Regulations of Connecticut State Agencies" should be deleted as the phrase is both technically incorrect and unnecessary because of the controlling definition found in section 19a-630-1(5). Additionally, the second occurrence of "section 19a-630-1(e)" should be "section 19a-630-1(5)" for accuracy.
3. On page 4, in section 19a-639a-1, the section consists of only one subsection and therefore the designator for subsection "(a)" should be deleted for proper form.
4. On page 6, in section 19a-639a-6, the phrase "two weeks" should be "not less than two weeks" for conformity with the controlling statutory provision. (See Connecticut General Statutes section 19a-639a(f))
5. On page 7, in section 19a-639b-1(c)(3), subdivision "(3)" should be moved to the line below and aligned with subdivisions (1) and (2) for consistency and proper form.
6. On page 7, in section 19a-639b-2, "Non- Transferability" should be "Non-transferability" for proper form.
7. On page 8, in section 19a-639e-2(a), "to terminate service or services which were authorized" should be "to terminate a service or services which were authorized" for consistency and proper form.
8. On page 8, in section 19a-639e-2(b), "to terminate a service or services which was not authorized" should be "to terminate a service or services which were not authorized" for consistency and proper form.
9. On page 9, in section 19a-643-201(b)(23)(A), "October first" should be "October 1st" and "September thirtieth" should be "September 30th" to accurately reflect the official version of the Regulations of Connecticut State Agencies.

10. On page 10, in section 19a-643-201(b)(23)(B), "June thirtieth" should be "June 30th" to accurately reflect the official version of the Regulations of Connecticut State Agencies.

Recommendation:

<p>Approval in whole with technical corrections with deletions with substitute pages Disapproval in whole or in part <input checked="" type="checkbox"/> Rejection without prejudice</p>
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Reviewed by: Heather Bannister / William F. O'Shea

Date: November 15, 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 Department of Public Health. The application shall address the guidelines and principles set forth in (1) subsection (a) of section 19a-639, and (2) regulations adopted by the department. 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 department. 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 the office closes the public hearing record.

(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.



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

November 2, 2012

Pamela B. Booth, Committee Administrator
Legislative Regulation Review Committee
State Capitol, Room 011
Hartford, CT 06106

Re: Regulations Concerning: *Certificate of Need*

Dear Ms. Booth:

Enclosed for the Committee's consideration is the proposed amendment of the above-captioned regulation.

These regulations were **Rejected without Prejudice** by the Legislative Regulations Review Committee on February 28, 2012. The Department has attached a summary of the changes made in an effort to comply with the comments made by the Legislative Commissioner's Office, and we hope the proposed regulations are now satisfactory.

I am available to answer any questions you may have and can be reached at (860) 509-7280 or via e-mail at jill.kentfield@ct.gov. Thank you for your consideration.

Sincerely,

Jill Kentfield
Legislative Liaison

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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

I, Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner of the Department of Public Health, an Agency of the State of Connecticut, hereby certify that:

- (1) On December 20, 2010, the Agency gave notice by mail to each joint standing committee of the general assembly having cognizance of the subject matter of the proposed regulations.
- (2) On December 28, 2010, the Agency gave notice in the Connecticut Law Journal of its intention to amend regulations concerning *Certificates of Need*. A true copy of the notice is attached as Exhibit A.
- (3) The Agency gave notice by mail to those persons who requested advance notice of regulation-making proceedings.
- (4) The Agency provided a copy of the proposed regulations to those persons requesting it.
- (5) Following publication of the notice in the Connecticut Law Journal, the Agency prepared a fiscal note, including an estimate of the cost or of the revenue impact on the state or any municipality of the state. A true copy of the fiscal note is attached as Exhibit B.
- (6) All interested persons were given until 4:30 p.m., January 27, 2011 to submit data, views or arguments concerning the proposed regulations and to inspect and copy the fiscal note referred to in paragraph 5.
- (7) The Agency has considered fully all written and oral submissions regarding the proposed regulations and determined that no revision of the fiscal note is needed.

10/19/2012
Date


Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

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Summary of Comments
Office of Health Care Access Administrative Regulations
Sections 19a-613-1 through 19a-653-4 of the Regulations of Connecticut State Agencies

SUBJECT: Proposed regulations necessary to administer the Certificate of Need process under Public Act 10-179 §§ 87, 89-93.

COMMENTERS: Legislative Commissioners' Office

NUMBER	COMMENT	RESPONSE
	<p>Substantive Concerns</p> <p>On page 2, the meaning of 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", is unclear.</p>	<p>Section 19a-630-2(a)(4) and 19a-630-2(a)(5) have been revised for clarity</p> <p>Section 19a-630-2(a)(4) includes those facilities such as laboratory, pharmacy or x-ray where the facility is not necessarily run by a physician and services are being performed on and provided to a patient along with decisions being made for the patient by someone other than the patient's physician. The entities resemble a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians. Language is based upon case cite: <u>Comm. On Hospital and Health Care v. Lakoff</u>, 214 Conn. 321 (1990)—in that case, the defendants operated an imaging center that the court held "resembles a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians." Id. 333-34. The court concluded that the imaging center was a "central service facility." Id. 334</p>
	<p>On page 5, the provisions of section 19a-639c-2 conflict with the provision s of sections 19a-639c(a) and 19a-638(c)(2) of the general statutes. Sections 19a-639c and 19a-638 do not provide an exception to the statutory requirements for a health care facility relocation within the same town.</p> <p>Technical Corrections</p>	<p>Yes, OHCA has no statutory authority.... historical policy... recommend removal/deletion.</p>
1	<p>Throughout the regulations, "Office" should be "office" when referring to the physical location where the Office of Health Care Access conducts</p>	<p>Regulations have been revised to provide more consistency. Most of the time "Office" is referring to the</p>

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	business, for consistency with the definition of "Office" in section 19a-630-1(f).	division rather than the physical location and therefore only a few of the words were made lower case "office". References to "subsection or subdivision" have been removed for clarity.
2	Throughout the regulations, references to subsections and subdivisions of the general statutes should be deleted, for clarity in the event the statute sections that are referenced are subsequently amended and result in the change of subdivision or subsection designations.	Correction was made for consistency.
3	Throughout the regulations, "Certificate of Need" should be "certificate of need", for consistency.	Capitalization following the introductory language has been corrected.
4	Throughout the regulations, each word in the introductory language following each section number should be capitalized, and each word following a subsection or subdivision designator should be capitalized, for proper form and consistency.	Formatting has been revised accordingly
5	The formatting of the regulation should be corrected. Section 1 should indicate that Sections 19a-613-1 through 19a-613-4, inclusive, are being added, as these sections relate to the description of the Office and its' data collection policies. "Section 2" should be inserted prior to section 19a-630-1, and should indicate that Sections 19a-630-1 through 19a-653-4, inclusive, are being added. The following two sections should be renumbered accordingly. Additionally, as the subject matter of Sections 19a-630-1 through 19a-653-4, inclusive, are certificate of need, "Certificates of Need" should be included in the catch line following "(NEW) Section 19a-630-1"	Deputy commissioner reference has been corrected for clarity
6	On page 1, in the third line of section 19a-613-1, "a deputy commissioner" should be "a deputy commissioner of Public Health", for clarity and, in the fourth line, "19a-612" should be "19a-612d", for accuracy.	Revision has been made accordingly
7	On page 1, in the second line of section 19a-613-2, "Chapter 368z" should be "section 19a-630", for clarity and accuracy.	Correction changing "FOI" to "Freedom of Information" has been made
8	On page 1, in section 19a-613-4, "FOI" should be "Freedom of Information", for proper form.	Addition has been made for proper form.
9	On page 1, in section 19a-630-1, above the line starting with "(a)", introductory language should be added as follows: "As used in sections 19a-630-1 to 19a-653-4, inclusive, of the Regulations of Connecticut State Agencies:", for proper form.	Correction has been made accordingly
10	On page 1, in the first line of section 19a-630-1(a), "as used in subdivisions (8) (9) and (11) of subsection (a) of section 19a-638 of the general statutes" should be deleted, for clarity.	Revision has been made accordingly
11	On page 2, in section 19a-630-2(a)(2), "facility" should be "entity", for consistency and "the individual physician, physicians, practitioner or practitioners" should be "individual physicians or practitioners", for clarity.	Revision has been made accordingly
12	On page 2, in the second line of section 19a-630-2(b), after "(6)", "inclusive, of this section" should be inserted, for clarity.	Revision has been made accordingly
13	On page 2, in section 19a-630-2(b), "whether" should be inserted as the first	Revisions have been made (adding "whether") for

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	word of subdivisions (1) through (8), for consistency with the introductory language.	consistency with introductory language
14	On page 2, in section 19a-630-2(b)(2), "no" should be changed to "any", for clarity.	Correction has been made
15	On page 2, in sections 19a-630-2(b)(5) and (6), respectively, "the individual physician, physicians, practitioner or practitioners who provided" and "the physician, physicians, practitioner or practitioners who provided", should be "the individual physicians or practitioners who provide", for clarity.	Revisions have been made accordingly
16	On page 2, in section 19a-630-2(b)(9), "officer" should be "commissioner, the commissioner's designee or the deputy commissioner", for consistency.	Revisions have been made accordingly
17	On page 2, in section 19a-638-1, in the first line, "increases its operating rooms" should be "increases the number of its operating rooms", for clarity, in the third line, "operating room" should be "operating rooms" for accuracy, and, in the fourth line, "operating room(s)" should be "operating room or operating rooms", for proper form.	Revisions have been made accordingly
18	On page 2, in the first and fifth lines 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 and proper form.	Changes have been made accordingly
19	On page 2, in the last line of section 19a-638-3, a period should be inserted after "determination", "and" should be deleted, and "the" should be "The", for clarity. In the same line, "that docket number" should be "the corresponding docket number", for clarity.	Changes have been made accordingly
20	On page 2, in section 19a-638-4, after "determinations" in the first line, the phrase "as to whether a certificate of need is needed" should be inserted, for clarity.	Changes have been made accordingly
21	On page 2, in section 19a-639a-1, in the first line, the first "section" should be deleted, for clarity, in the second line, "application" should be inserted after "certificate of need", for clarity and consistency, and, in the fifth line, "in accordance with subsection (b) of section 19a-639a of the general statutes", should be deleted, for clarity.	Changes have been made accordingly
22	On page 2, in section 19a-639a-1, in subsection (1), "The Applicant" should be "A statement that the applicant", for clarity.	Changes have been made accordingly
23	On page 3, in the first line of section 19a-639a-3(a)(1), "Copies of the notices" should be "A copy of the notice", for consistency.	Changes have been made accordingly
24	On page 3, in the second line of section 19a-639a-3(a)(2), "applicable subdivision" should be "applicable requirement for a certificate of need", for clarity.	Changes have been made accordingly
25	On page 3, in section 19a-639a-3(a)(6), "Application forms for specific types of proposals are available and may be downloaded from the Office's website:" should be "the appropriate application form for the specific type of proposal, as follows, which are available and may be downloaded from the Office's website:", for clarity and consistency with the introductory	Changes have been made accordingly

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	language.		
26	On page 3, in section 19a-639a-3(a)(6)(A), "of the general statutes" should be inserted after "19a-630", for proper form.	Changes have been made accordingly	
27	On page 3, in section 19a-639a-3(a)(6)(I), the subdivisions of subsection (a) of section 19a-638 of the general statutes should either be corrected to "(8), (9) or (11)", or the citation to the subdivisions should be eliminated, for accuracy of reference.	Changes have been made accordingly	
28	On page 4, in section 19a-639a-4(b), "the applicant will" in the third line should be "the applicant shall", in accordance with the committee's directive regarding mandates.	Changes have been made accordingly	
29	On page 4, in the introductory language of section 19a-639a-5(b), the colon should be deleted, for consistency.	Changes have been made accordingly	
30	On page 4, in section 19a-639a-5(b)(2), "will be extended" in the second line should be "shall be extended", in accordance with the committee's directive regarding mandates, and "beyond" in the third line should be "after", for clarity and proper form.	Changes have been made accordingly	
31	On page 4, on the sixth line of section 19a-639a-6, "subsection (g) of section 19a-639a of the general statutes" should be deleted, for clarity and accuracy.	Changes have been made accordingly	
32	On page 5, in the last line of section 19a-639b-2, "voidance" should be "voiding", for proper form.	Changes have been made accordingly	
33	On page 5, in section 19a-639c-1, subsection designations "(a)" and "(b)" should be inserted before each paragraph, for consistency and proper form.	Changes have been made accordingly	
34	On page 5, in the second line of section 19a-639c-1, "a request for determination" should be "a letter requesting that the Office make a determination as to whether a certificate of need is required" and, in the third line, " , which shall be submitted with such letter," should be inserted after "facility", for accuracy and clarity.	Changes have been made accordingly	
35	On page 5, in the sixth line of section 19a-639c-1, "relocation" should be "relocate", for proper form and "Applicant" should be "applicant", for consistency.	Changes have been made accordingly	
36	On page 5, in the first and second lines of section 19a-639c-3, "and is either unable to demonstrate or chooses not to demonstrate" should be "and is unable to demonstrate", for consistency with section 19a-639c(a) of the general statutes.	Changes have been made accordingly	
37	On page 5, in section 19a-639e-1(a)(3), in the second line, "will" should be "may", for consistency and proper form and "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly	
38	On page 5, in section 19a-639e-1(b)(3), in the second line, "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly	
39	On page 5, throughout section 19a-639e-2, "service(s)" should be "service or services", for proper form.	Changes have been made accordingly	
40	On page 6, in the second line of section 19a-643-1a, " of the Regulations of	Changes have been made accordingly	

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	Connecticut State Agencies" should be inserted after "et seq.", for proper form.	
41	On page 6, in the second line of section 19a-653-1, "this section" should be "section 19a-653 of the general statutes", for clarity and proper form.	Changes have been made accordingly
42	On page 6, in the first line of section 19a-653-2, "of the general statutes" should be inserted after "19a-653", for consistency and proper form.	Changes have been made accordingly
43	On page 6, in the last sentence of section 19a-653-2, "Upon receipt of the request, the Office shall have ten days to notify the facility, institution or person of the date, time and place of the hearing" should be "The Office shall notify the health care facility or person of the date time and place of the hearing, not later than ten days after the Office's receipt of the request.", for clarity and consistency.	Changes have been made accordingly
44	On page 6, in the first line of section 19a-653-3(c), "time extension" should be "extension of time", for consistency, in the third line, "from" should be "beginning on" and "onward" should be deleted, for clarity and, in the fourth line, "at" should be "upon", for clarity.	Changes have been made accordingly
45	On page 6, in Section 2, "Section 2" should be "Sec. 2" and "Section 3" should be "Sec. 3", renumbered as noted in technical correction 5, above	Changes have been made accordingly
46	On page 6, in Section 2, "inclusive" should be inserted after "19a-643-110", for accuracy and clarity.	Changes have been made accordingly, Also added "exclusive of Sections 19a-643-21 and 19a-643-85(c)" – 19a-643-21 allows for the consolidation of the proceeding and 19a-643-85(c) allows for the opportunity of a Public Hearing
47	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.	Section 19a-643-209 (formerly section 19a-643-3a) has been revised to refer the reader to Section 19a-639a(d) for the proper timeframes in which the Office shall notify the applicant in writing of the denial of an application.
48	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	Section 19a-643-209 (formerly section 19a-643-3a) has been revised by adding language which clarifies the hearing request process and specifies the timeframe for requesting a hearing. Specifically, the applicant has 10 days from the date of the denial of the application to request a hearing on an application that has been denied without a hearing. Additionally, specific references to the Regulations of Connecticut State Agencies have been added for purposes of clarity.

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	<p>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.</p>	
49	<p>On page 1, the introductory language to Sec. 2 should add only "sections 19a-630-1 and 19a-630-2, as follows:"</p>	Changes have been made accordingly
50	<p>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:"</p>	Changes have been made accordingly
51	<p>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:"</p>	Changes have been made accordingly
52	<p>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:"</p>	Changes have been made accordingly
53	<p>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:"</p>	Changes have been made accordingly
54	<p>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:"</p>	Changes have been made accordingly
55	<p>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.</p>	Sections 19a-643-1 to 19a-643-3a have been changed to sections 19a-643-207 to 19a-643-209.
56	<p>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.</p>	Changes have been made accordingly
57	<p>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</p>	Changes have been made accordingly

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	follows:"	
58	On page 9, Secs. 3, 4 and 5 should be renumbered Secs. 10, 11 and 12, for accuracy and conformity.	Changes have been made accordingly
59	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.	Changes have been made accordingly
60	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.	Changes have been made accordingly
61	On page 6, in section 19a-639b-1(c), the space between subdivisions (2) and (3) should be deleted, for consistency and proper form.	Changes have been made accordingly
62	On page 8, in section 19a-643-2a, "his designee" should be "the commissioner's designee", for proper form.	Changes have been made accordingly
63	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.	Changes have been made accordingly
	Other	
		All references to "general statutes" have been changed to "Connecticut General Statutes" for consistency and proper form
		Section 19a-643-21 and 19a-643-85(c) were added in to the regulation as section 19a-643-2a and 19a-643-3a. All obsolete references were revised.
		Section 19a-643-201 (b)(23) was added into the regulation as section 3 and revised to reflect the repeal of 19a-643-205
		Section 19a-639a-3 was revised for ease of readability to the consumer
		All technical corrections noted in report 2012-3A were made

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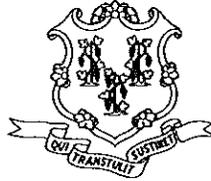
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The Connecticut General Assembly

Legislative Commissioners' Office

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Memorandum

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

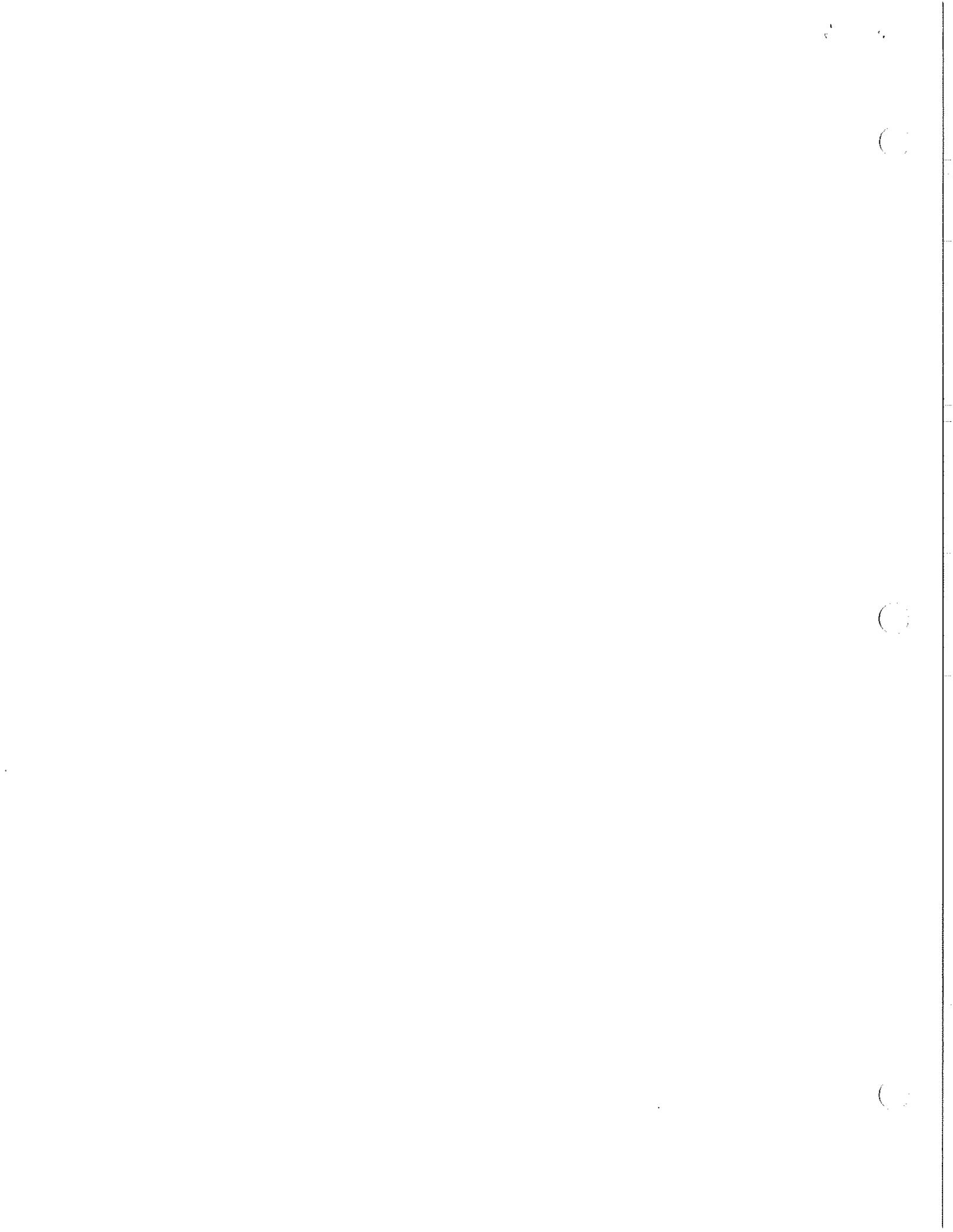
Regulation No:	2012-3B
Agency:	Department of Public Health
Subject Matter:	Certificate of Need
Statutory Authority: (copy attached)	19a-638, 19a-639a, 19a-639b, 19a-639c, 19a-639e, 19a-643

	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.

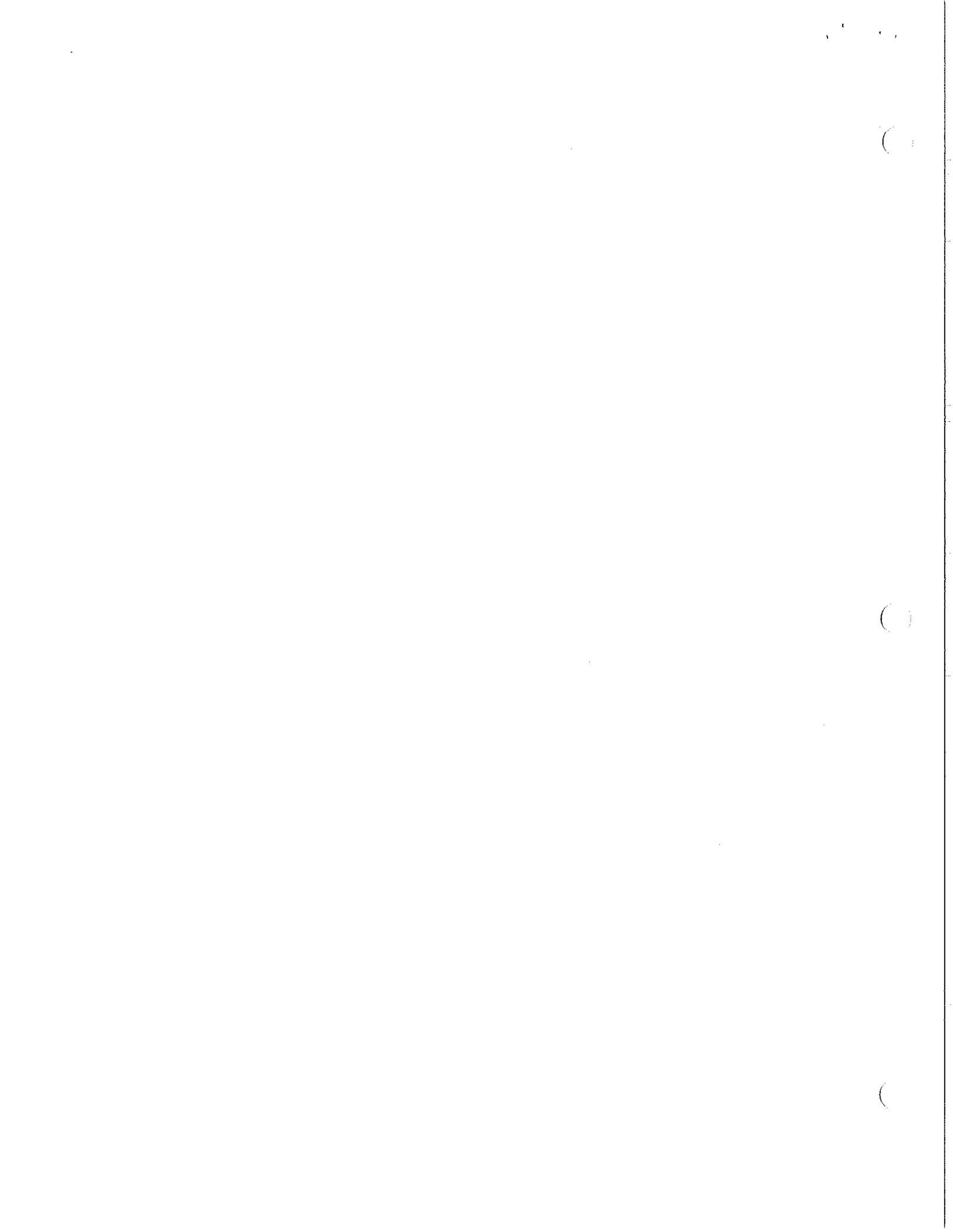
5. On page 2, in section 19a-630-2(4), "one or more entities who are or may be" should be changed to "the entity that is or may be", for clarity and conformity with the rest of the section.

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 <input checked="" type="checkbox"/> Rejection without prejudice</p>
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Reviewed by: Heather Bannister / Anne Brennan Carroll

Date: September 12, 2012

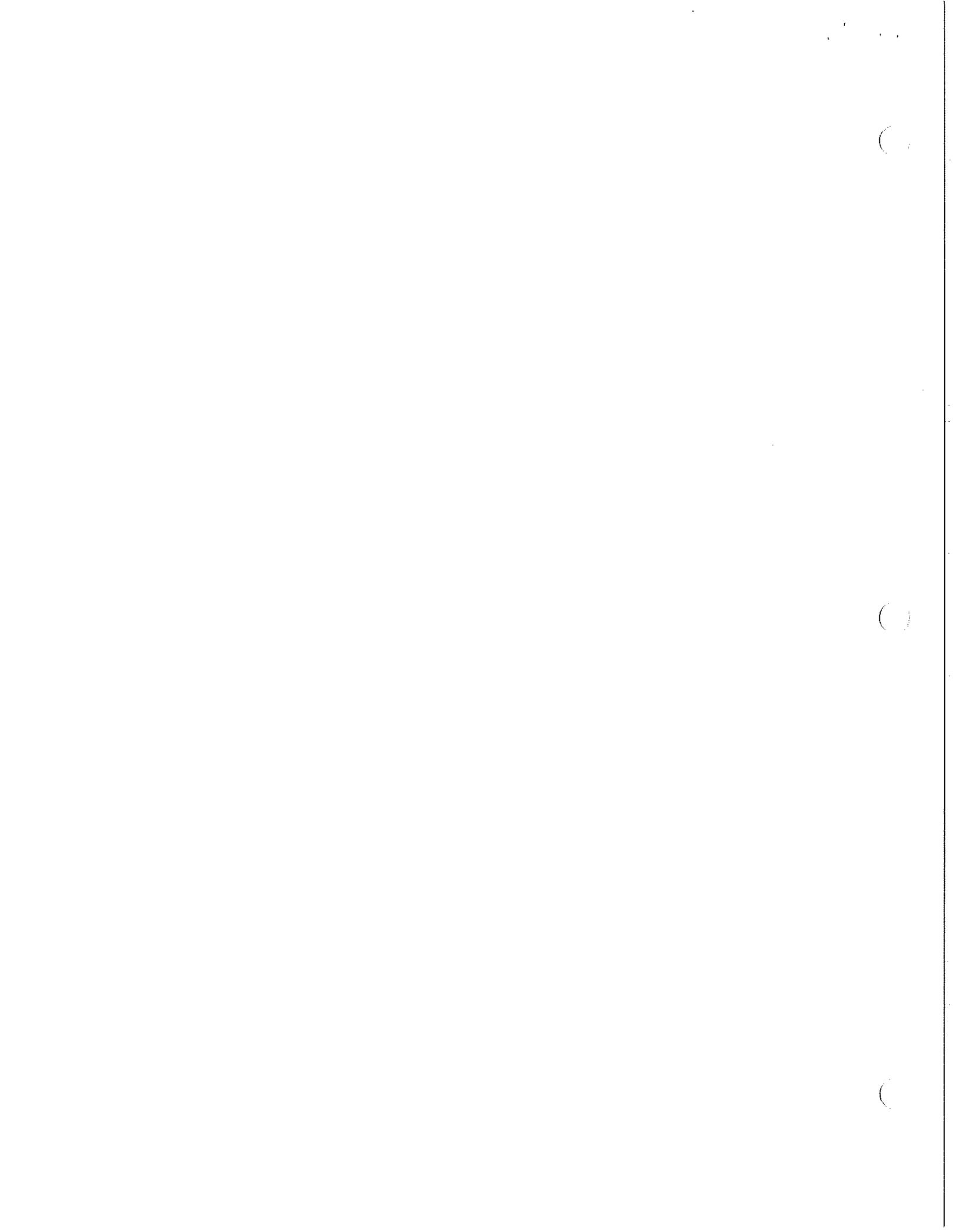
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Sec. 19a-638. (Formerly Sec. 19a-154). Certificate of need. When required and not required. Request for office determination. Policies, procedures and regulations. (a) A certificate of need issued by the office shall be required for:

- (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;

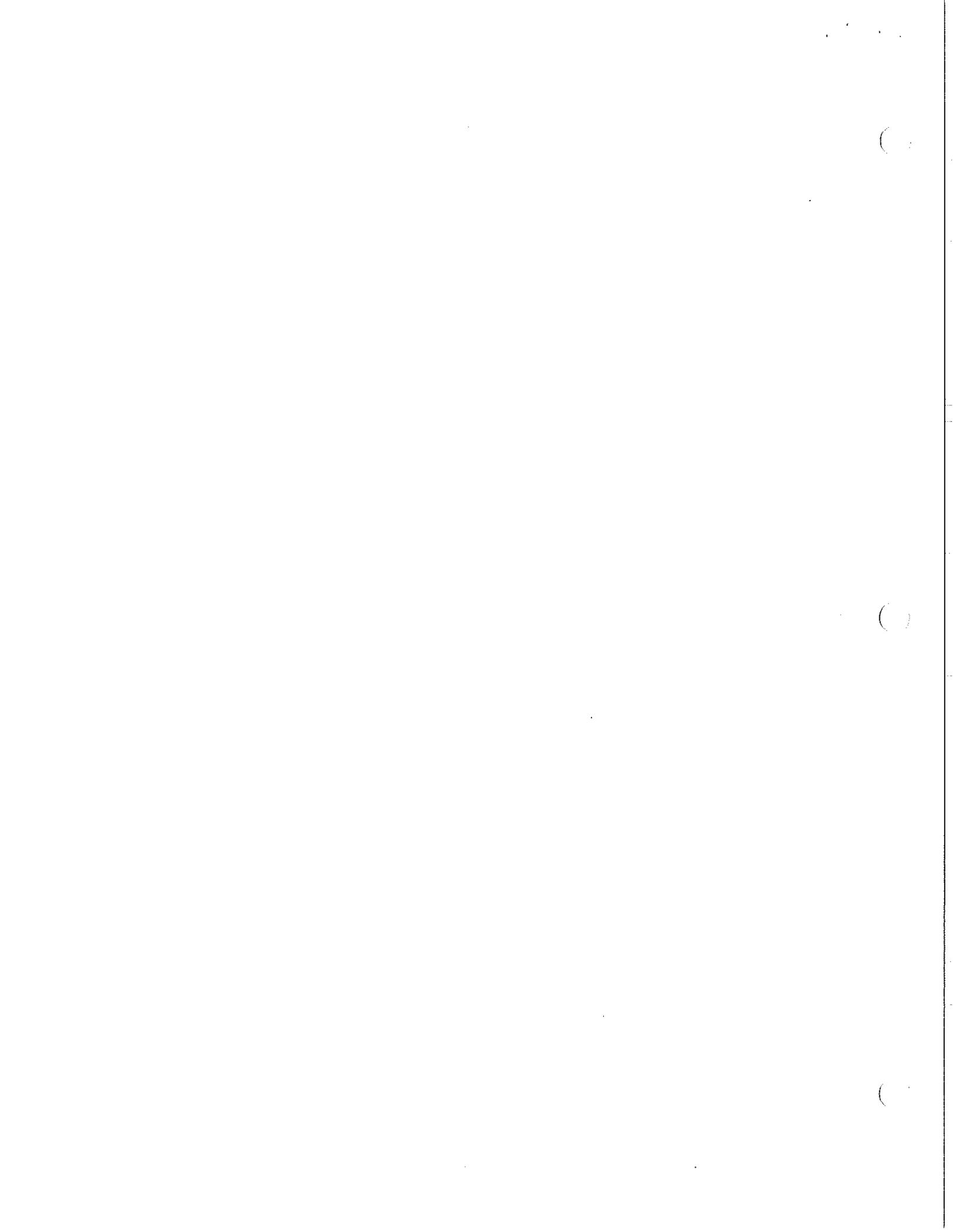
(8) Outpatient rehabilitation facilities;

(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

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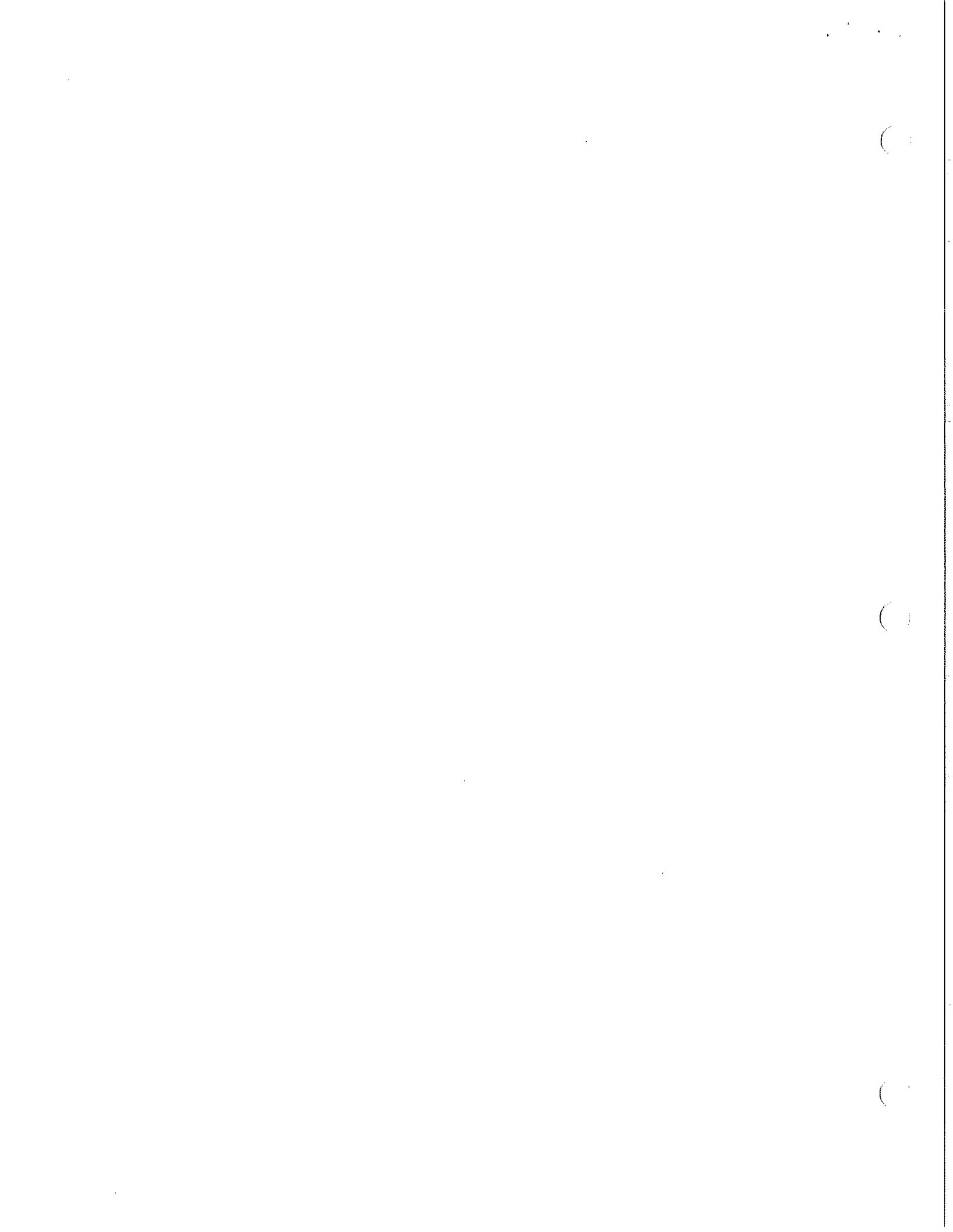
(22) Acquisition of any equipment by any person that is to be used exclusively for scientific research that is not conducted on humans.

(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



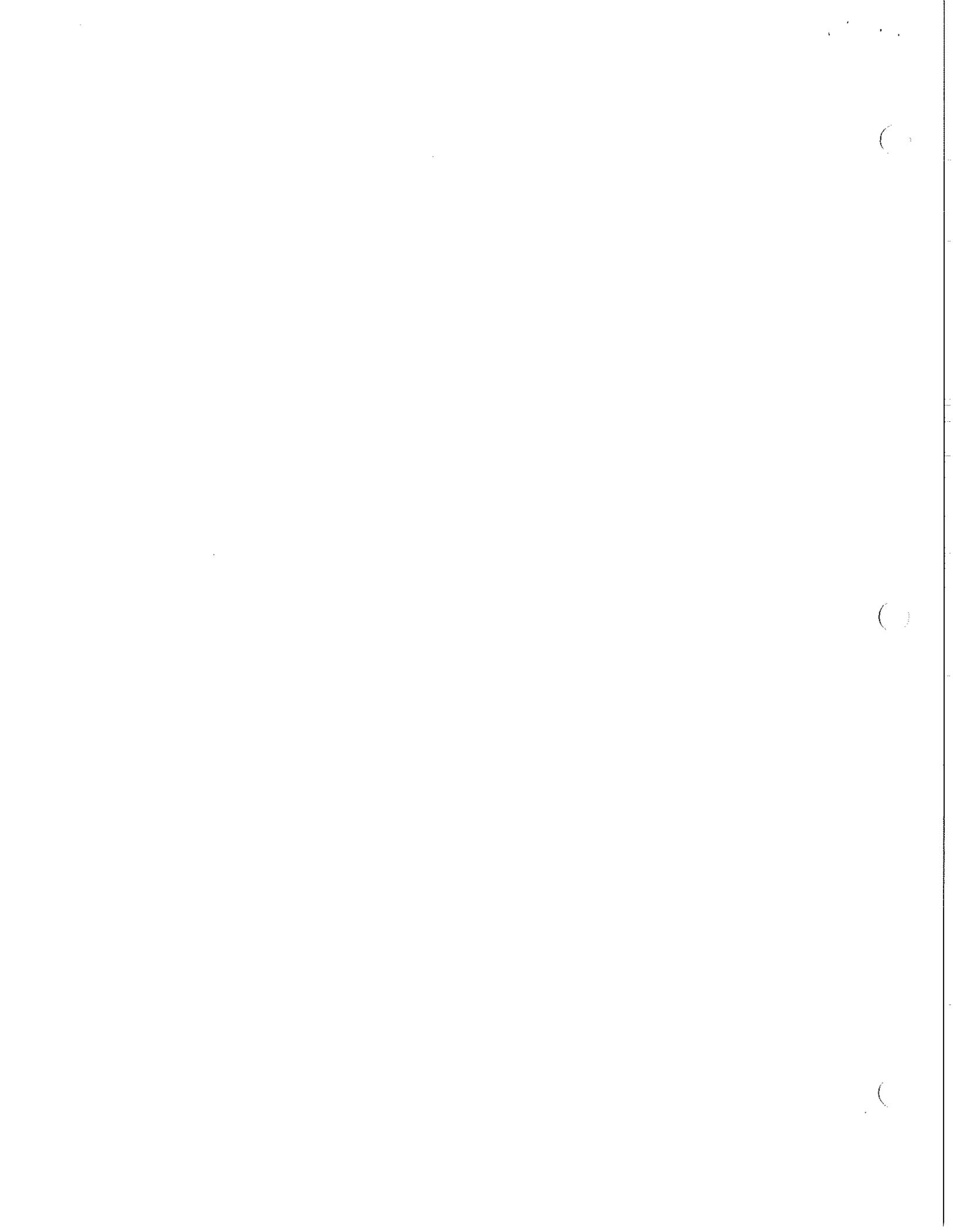
subsection. The office shall not accept the applicant's certificate of need application for filing unless the application is accompanied by the application fee prescribed in subsection (a) of this section and proof of compliance with the publication requirements prescribed in this subsection.

(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



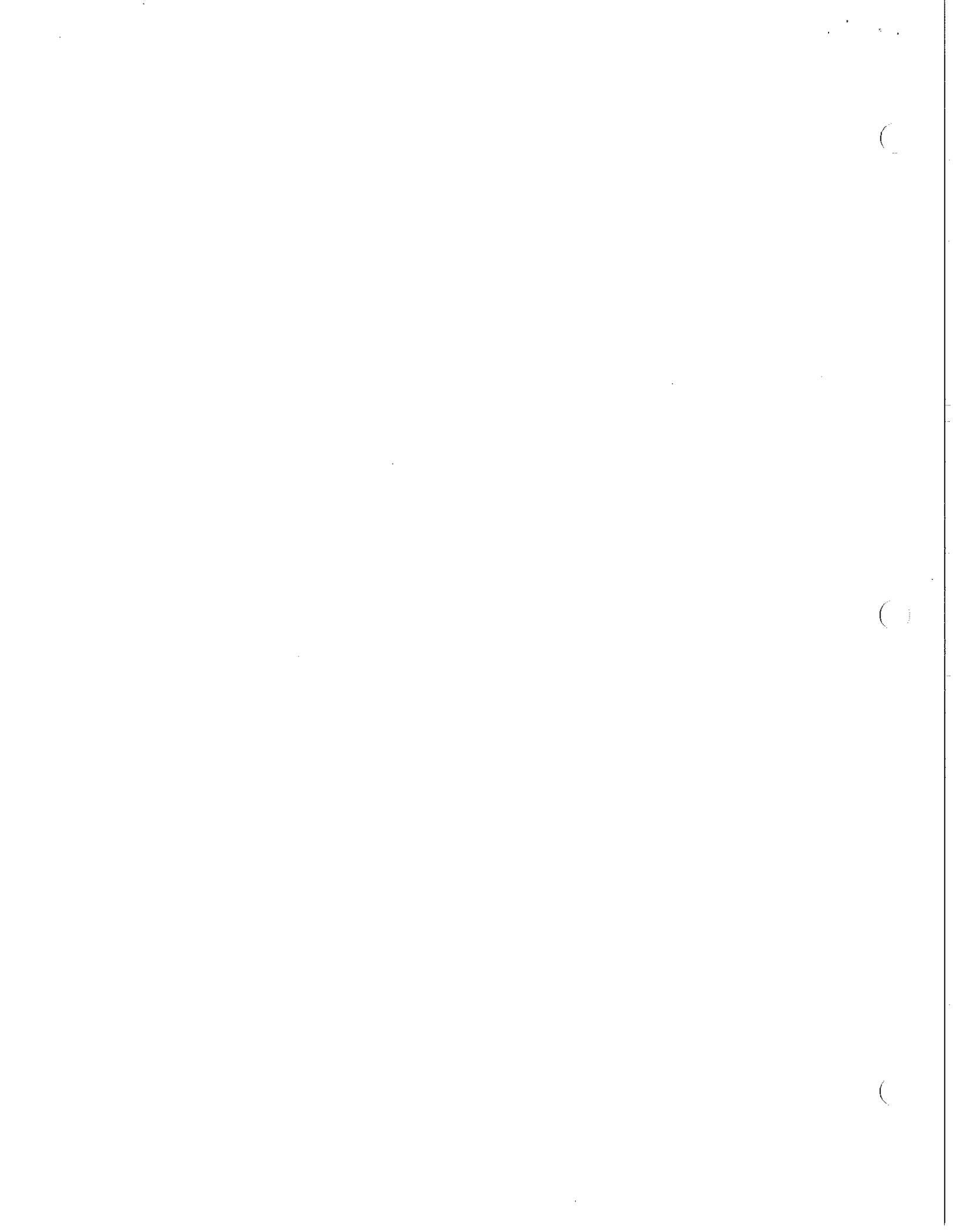
application submitted under this chapter. The office shall provide not less than two weeks' advance notice to the applicant, in writing, and to the public by publication in a newspaper having a substantial circulation in the area served by the health care facility or provider. In conducting its activities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



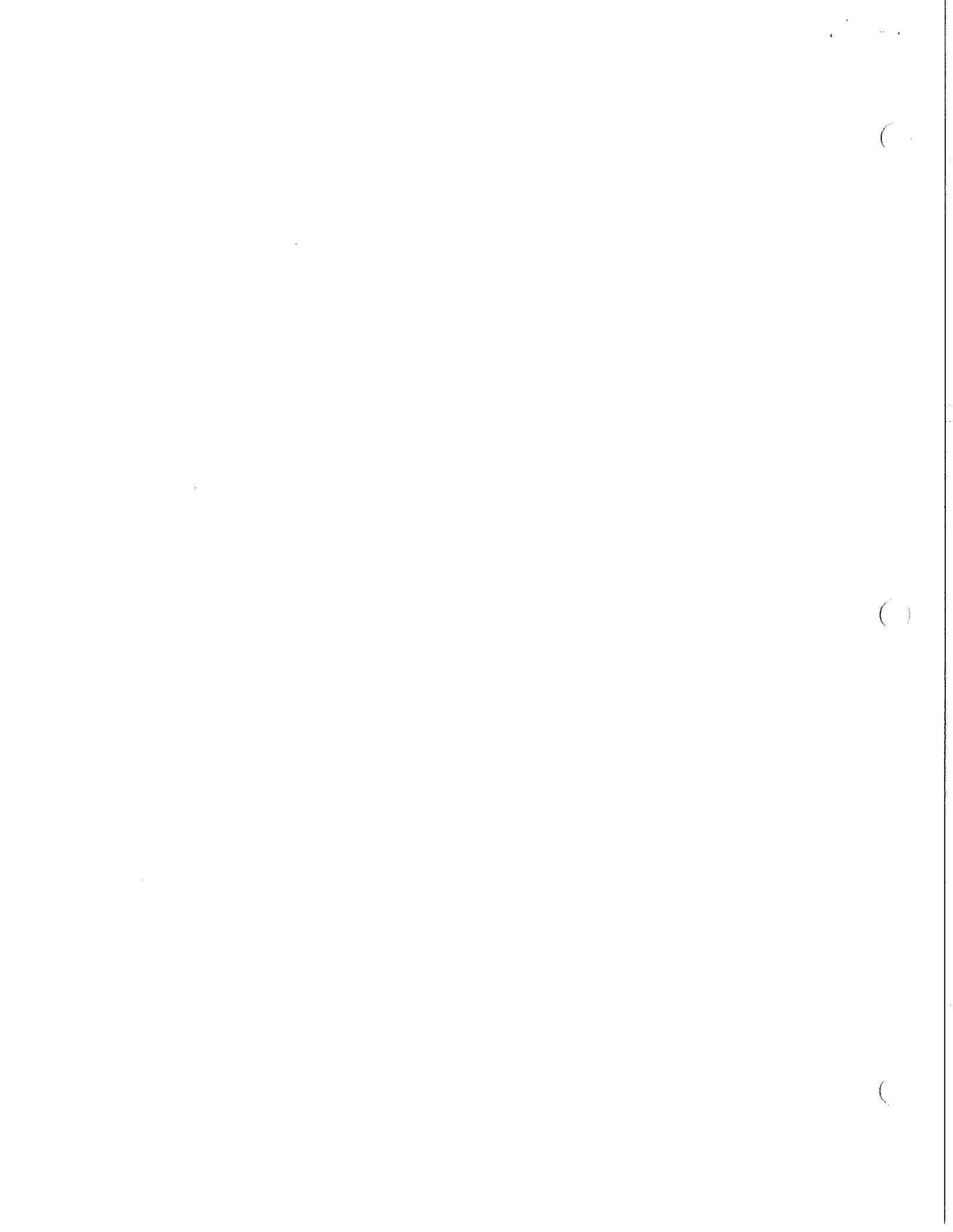
or other preparation has not been substantially undertaken during a valid certificate of need period; or (2) the certificate holder has not made a good-faith effort to complete the project as approved, the office may withdraw, revoke or rescind the certificate of need.

(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

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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.

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The Connecticut General Assembly

Legislative Commissioners' Office

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Commissioner
William A. Hamzy
Commissioner

Larry G. J. Shapiro
Director



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Memorandum

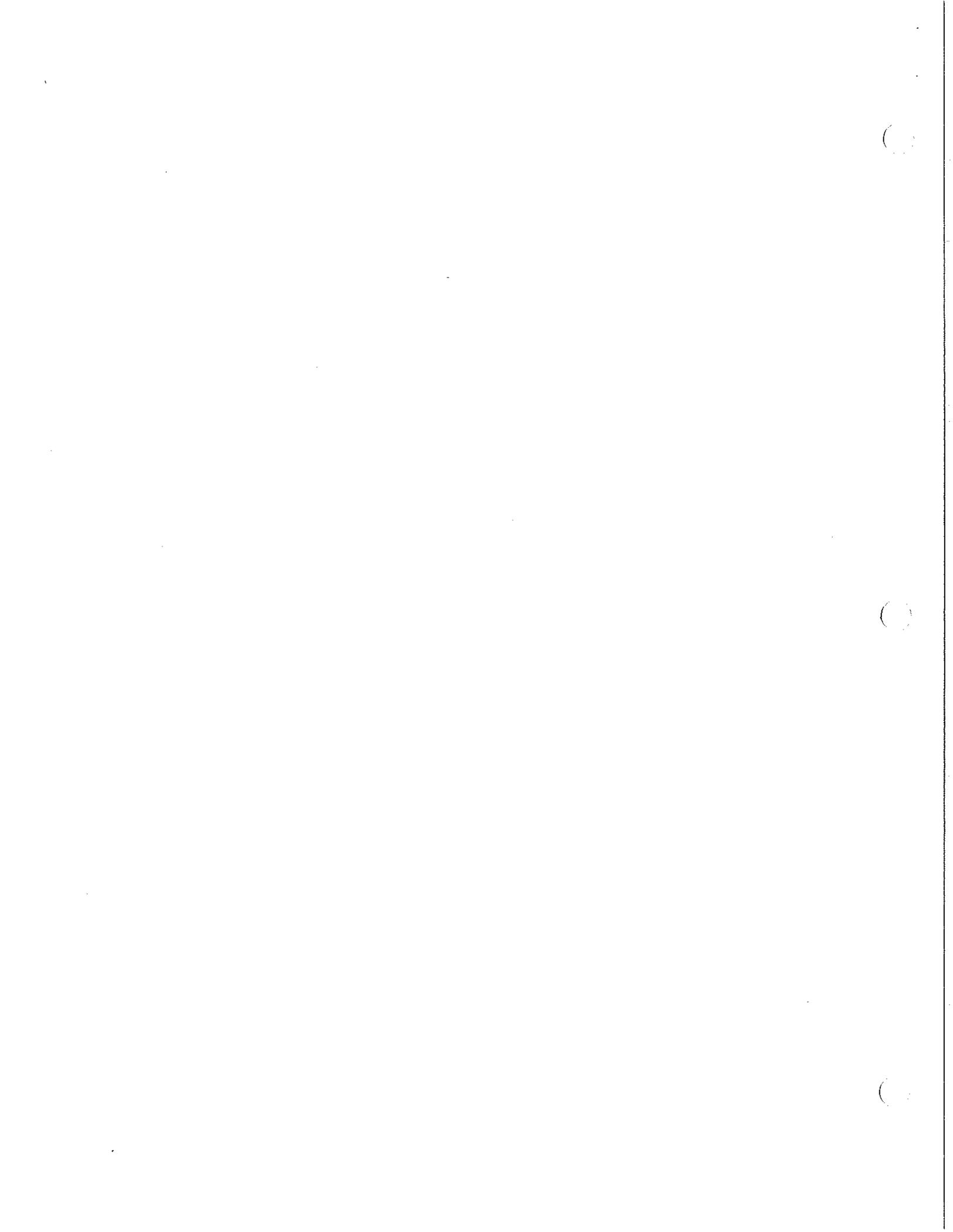
To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: July 24, 2012

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
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.

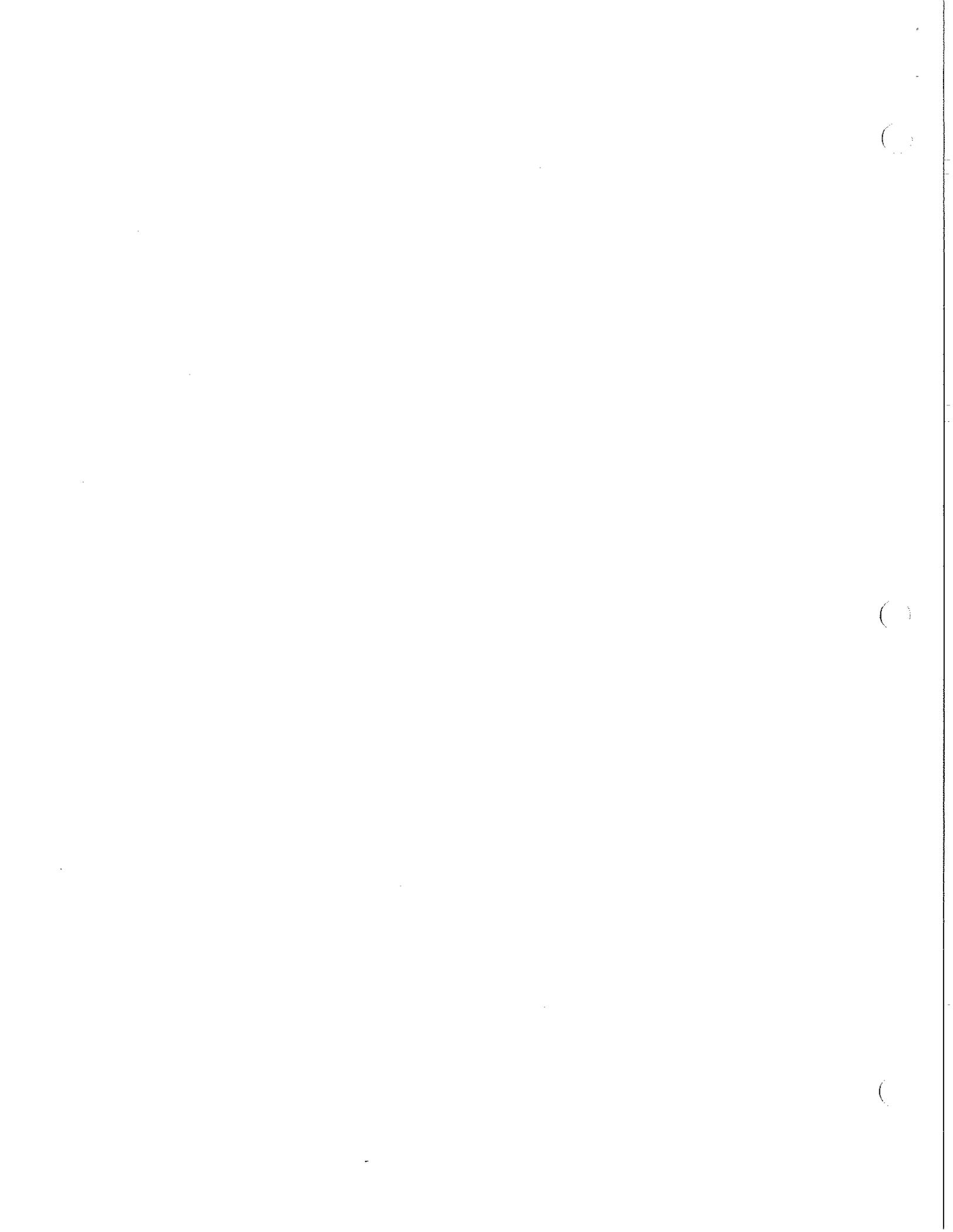
3. The former section 19a-639c-2 of the proposed regulations has been deleted in the resubmittal to address substantive concern "2." noted in the February 28, 2012 report. Section 19a-639c-3 of the proposed regulations has been re-numbered as section 19a-639c-2 in the resubmitted proposed regulations.

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-463-110, 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:

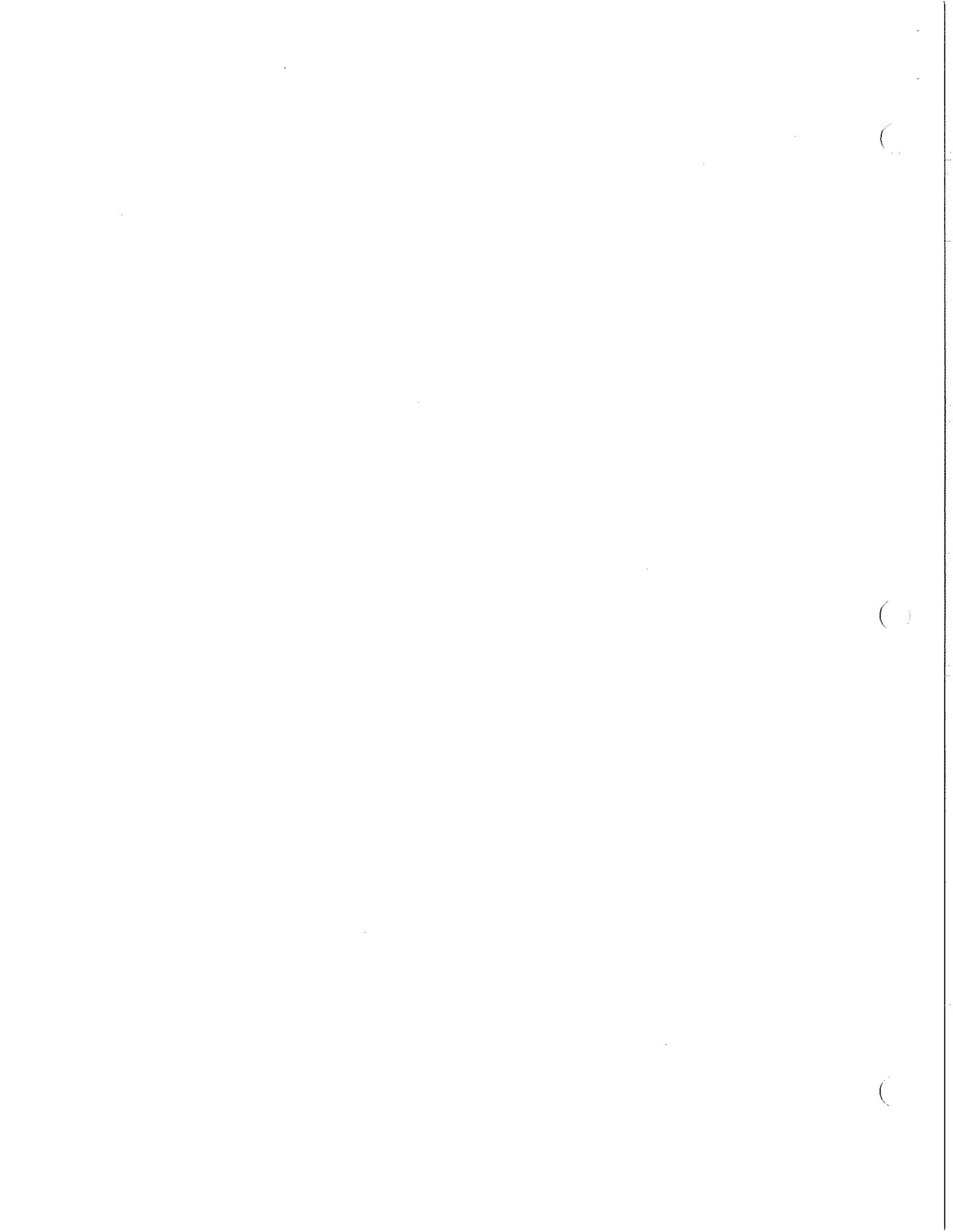
1. Throughout the regulations, the comma after "and" in a series should be deleted, for proper form and consistency.
2. On page 1, "Section 1. The Regulations Of Connecticut State Agencies Are Amended By Adding Section 19a-613-1 Through 19a-613-4, Inclusive, As Follows:" should be "Section 1. The Regulations 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.

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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.

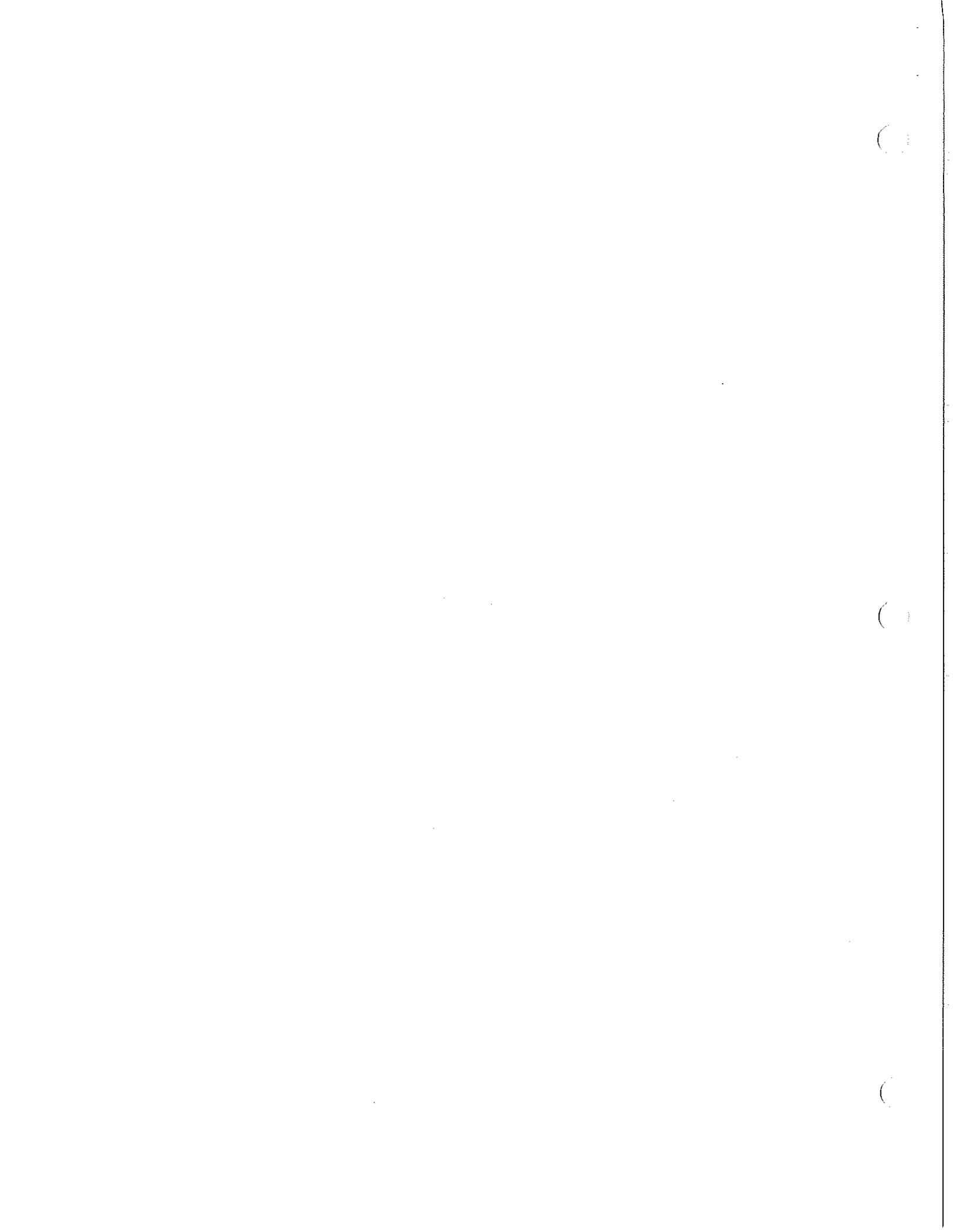


Recommendation:

<p>Approval in whole with technical corrections with deletions with substitute pages Disapproval in whole or in part <input checked="" type="checkbox"/> 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

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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.

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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;

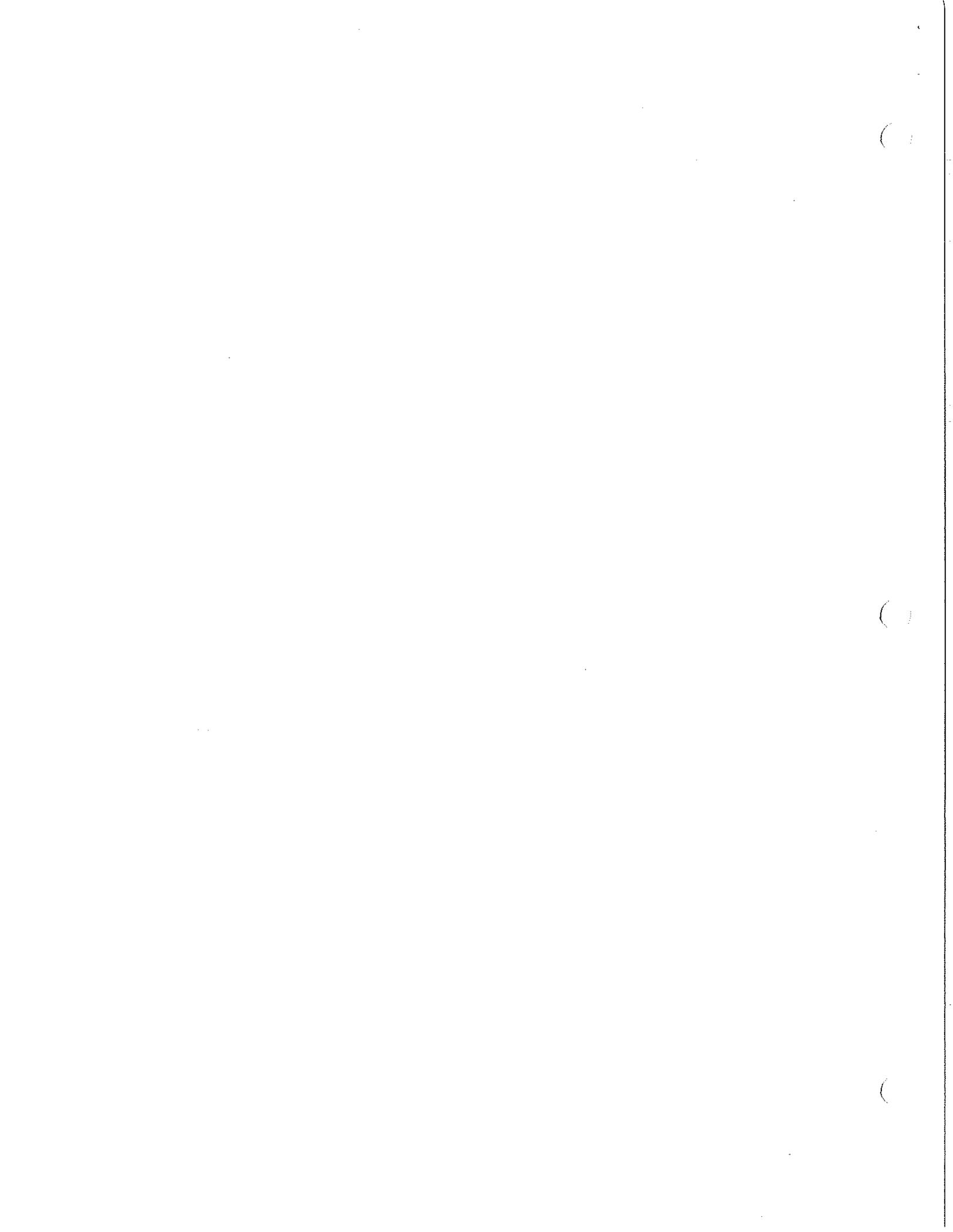
(7) The termination of an emergency department by a short-term acute care general hospital;

(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

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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

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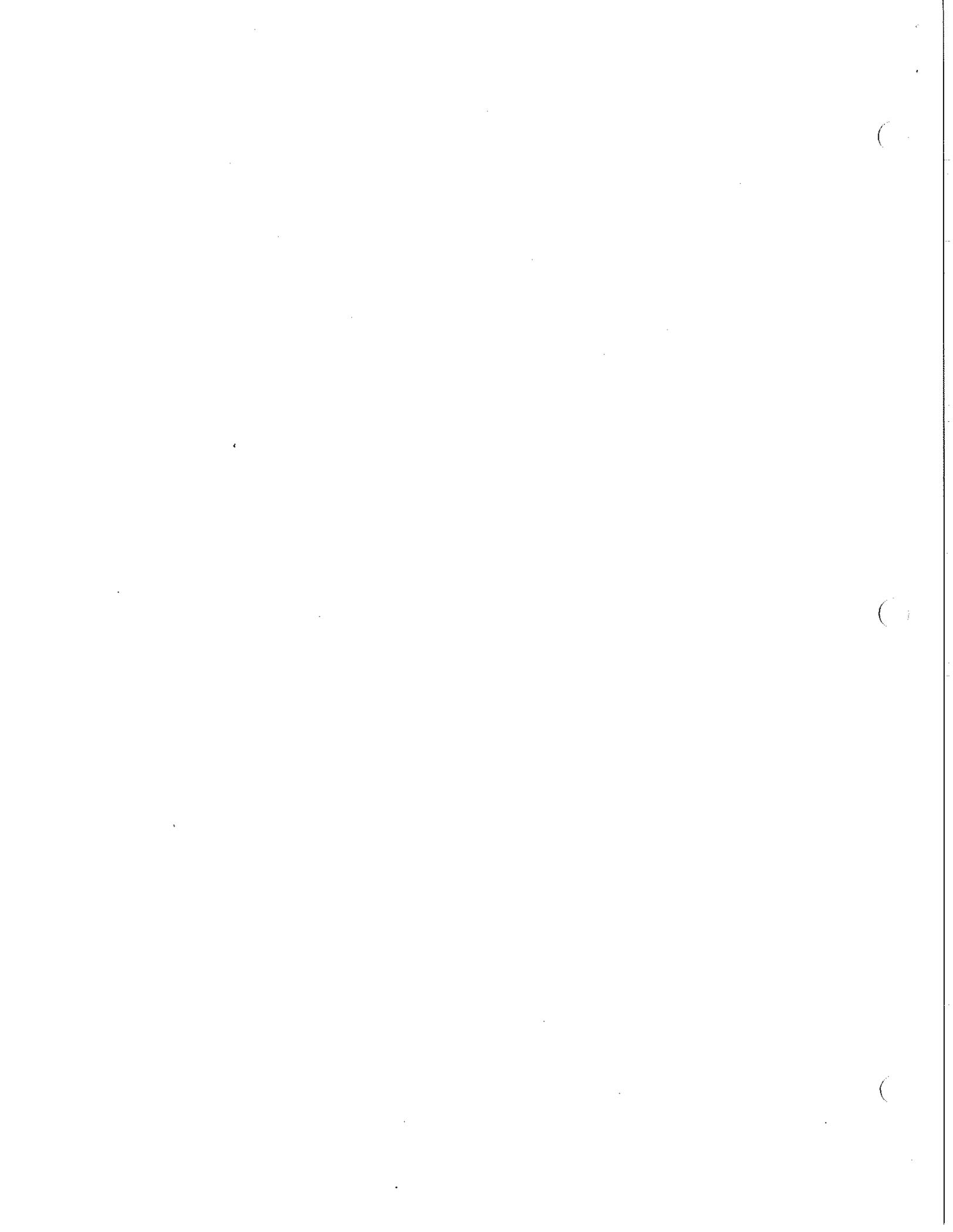
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(22) Acquisition of any equipment by any person that is to be used exclusively for scientific research that is not conducted on humans.

(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.





STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

August 24, 2012

Pamela B. Booth, Committee Administrator
Legislative Regulation Review Committee
State Capitol, Room 011
Hartford, CT 06106

Re: Regulations Concerning: *Certificate of Need*

Dear Ms. Booth:

Enclosed for the Committee's consideration is the proposed amendment of the above-captioned regulation.

These regulations were **Rejected without Prejudice** by the Legislative Regulations Review Committee on February 28, 2012. The Department has attached a summary of the changes made in an effort to comply with the comments made by the Legislative Commissioner's Office, and we hope the proposed regulations are now satisfactory.

I am available to answer any questions you may have and can be reached at (860) 509-7280 or via e-mail at jill.kentfield@ct.gov. Thank you for your consideration.

Sincerely,

Jill Kentfield
Legislative Liaison

Phone: (860) 509-7280, Fax: (860) 509-7100
Telephone Device for the Deaf (860) 509-7191
410 Capitol Avenue - MS # 13COM
P.O. Box 340308 Hartford, CT 06134
An Equal Opportunity Employer

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Summary of Comments
Office of Health Care Access Administrative Regulations
Sections 19a-613-1 through 19a-653-4 of the Regulations of Connecticut State Agencies

SUBJECT: Proposed regulations necessary to administer the Certificate of Need process under Public Act 10-179 §§ 87, 89-93.

COMMENTERS: Legislative Commissioners' Office

NUMBER	COMMENT	RESPONSE
	<p>Substantive Concerns</p> <p>On page 2, the meaning of 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", is unclear.</p>	<p>Section 19a-630-2(a)(4) and 19a-630-2(a)(5) have been revised for clarity</p> <p>Section 19a-630-2(a)(4) includes those facilities such as laboratory, pharmacy or x-ray where the facility is not necessarily run by a physician and services are being performed on and provided to a patient along with decisions being made for the patient by someone other than the patient's physician. The entities resemble a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians. Language is based upon case cite: <u>Comm. On Hospital and Health Care v. Lakoff</u>, 214 Conn. 321 (1990)—in that case, the defendants operated an imaging center that the court held "resembles a hospital type of diagnostic service in that patients are referred to the center for particular tests rather than to specific physicians." Id. 333-34. The court concluded that the imaging center was a "central service facility." Id. 334</p>
	<p>On page 5, the provisions of section 19a-639c-2 conflict with the provision s of sections 19a-639c(a) and 19a-638(c)(2) of the general statutes. Sections 19a-639c and 19a-638 do not provide an exception to the statutory requirements for a health care facility relocation within the same town.</p> <p>Technical Corrections</p>	<p>Yes, OHCA has no statutory authority.... historical policy....recommend removal/deletion.</p>
1	<p>Throughout the regulations, "Office" should be "office" when referring to the physical location where the Office of Health Care Access conducts</p>	<p>Regulations have been revised to provide more consistency. Most of the time "Office" is referring to the</p>

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COMMENTERS: Legislative Commissioners' Office

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	business, for consistency with the definition of "Office" in section 19a-630-1(f).	division rather than the physical location and therefore only a few of the words were made lower case "office". References to "subsection or subdivision" have been removed for clarity.
2	Throughout the regulations, references to subsections and subdivisions of the general statutes should be deleted, for clarity in the event the statute sections that are referenced are subsequently amended and result in the change of subdivision or subsection designations.	Correction was made for consistency.
3	Throughout the regulations, "Certificate of Need" should be "certificate of need", for consistency.	Capitalization following the introductory language has been corrected.
4	Throughout the regulations, each word in the introductory language following each section number should be capitalized, and each word following a subsection or subdivision designator should be capitalized, for proper form and consistency.	Formatting has been revised accordingly
5	The formatting of the regulation should be corrected. Section 1 should indicate that Sections 19a-613-1 through 19a-613-4, inclusive, are being added, as these sections relate to the description of the Office and its' data collection policies. "Section 2" should be inserted prior to section 19a-630-1, and should indicate that Sections 19a-630-1 through 19a-653-4, inclusive, are being added. The following two sections should be renumbered accordingly. Additionally, as the subject matter of Sections 19a-630-1 through 19a-653-4, inclusive, are certificate of need, "Certificates of Need" should be included in the catch line following "(NEW) Section 19a-630-1"	Deputy commissioner reference has been corrected for clarity
6	On page 1, in the third line of section 19a-613-1, "a deputy commissioner" should be "a deputy commissioner of Public Health", for clarity and, in the fourth line, "19a-612" should be "19a-612d", for accuracy.	Revision has been made accordingly
7	On page 1, in the second line of section 19a-613-2, "Chapter 368z" should be "section 19a-630", for clarity and accuracy.	Correction changing "FOI" to "Freedom of Information" has been made
8	On page 1, in section 19a-613-4, "FOI" should be "Freedom of Information", for proper form.	Addition has been made for proper form.
9	On page 1, in section 19a-630-1, above the line starting with "(a)", introductory language should be added as follows: "As used in sections 19a-630-1 to 19a-653-4, inclusive, of the Regulations of Connecticut State Agencies:", for proper form.	Correction has been made accordingly
10	On page 1, in the first line of section 19a-630-1(a), "as used in subdivisions (8) (9) and (11) of subsection (a) of section 19a-638 of the general statutes" should be deleted, for clarity.	Revision has been made accordingly
11	On page 2, in section 19a-630-2(a)(2), "facility" should be "entity", for consistency and "the individual physician, physicians, practitioner or practitioners" should be "individual physicians or practitioners", for clarity.	Revision has been made accordingly
12	On page 2, in the second line of section 19a-630-2(b), after "(6)", "inclusive, of this section" should be inserted, for clarity.	Revision has been made accordingly
13	On page 2, in section 19a-630-2(b), "whether" should be inserted as the first	Revisions have been made (adding "whether") for

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	word of subdivisions (1) through (8), for consistency with the introductory language.	consistency with introductory language
14	On page 2, in section 19a-630-2(b)(2), "no" should be changed to "any", for clarity.	Correction has been made
15	On page 2, in sections 19a-630-2(b)(5) and (6), respectively, "the individual physician, physicians, practitioner or practitioners who provided" and "the physician, physicians, practitioner or practitioners who provided", should be "the individual physicians or practitioners who provide", for clarity.	Revisions have been made accordingly
16	On page 2, in section 19a-630-2(b)(9), "officer" should be "commissioner, the commissioner's designee or the deputy commissioner", for consistency.	Revisions have been made accordingly
17	On page 2, in section 19a-638-1, in the first line, "increases its operating rooms" should be "increases the number of its operating rooms", for clarity, in the third line, "operating room" should be "operating rooms" for accuracy, and, in the fourth line, "operating room(s)" should be "operating room or operating rooms", for proper form.	Revisions have been made accordingly
18	On page 2, in the first and fifth lines 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 and proper form.	Changes have been made accordingly
19	On page 2, in the last line of section 19a-638-3, a period should be inserted after "determination", "and" should be deleted, and "the" should be "The", for clarity. In the same line, "that docket number" should be "the corresponding docket number", for clarity.	Changes have been made accordingly
20	On page 2, in section 19a-638-4, after "determinations" in the first line, the phrase "as to whether a certificate of need is needed" should be inserted, for clarity.	Changes have been made accordingly
21	On page 2, in section 19a-639a-1, in the first line, the first "section" should be deleted, for clarity, in the second line, "application" should be inserted after "certificate of need", for clarity and consistency, and, in the fifth line, "in accordance with subsection (b) of section 19a-639a of the general statutes", should be deleted, for clarity.	Changes have been made accordingly
22	On page 2, in section 19a-639a-1, in subsection (1), "The Applicant" should be "A statement that the applicant", for clarity.	Changes have been made accordingly
23	On page 3, in the first line of section 19a-639a-3(a)(1), "Copies of the notices" should be "A copy of the notice", for consistency.	Changes have been made accordingly
24	On page 3, in the second line of section 19a-639a-3(a)(2), "applicable subdivision" should be "applicable requirement for a certificate of need", for clarity.	Changes have been made accordingly
25	On page 3, in section 19a-639a-3(a)(6), "Application forms for specific types of proposals are available and may be downloaded from the Office's website:" should be "the appropriate application form for the specific type of proposal, as follows, which are available and may be downloaded from the Office's website:.", for clarity and consistency with the introductory	Changes have been made accordingly

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	language.		
26	On page 3, in section 19a-639a-3(a)(6)(A), "of the general statutes" should be inserted after "19a-630", for proper form.	Changes have been made accordingly	
27	On page 3, in section 19a-639a-3(a)(6)(I), the subdivisions of subsection (a) of section 19a-638 of the general statutes should either be corrected to "(8), (9) or (11)", or the citation to the subdivisions should be eliminated, for accuracy of reference.	Changes have been made accordingly	
28	On page 4, in section 19a-639a-4(b), "the applicant will" in the third line should be "the applicant shall", in accordance with the committee's directive regarding mandates.	Changes have been made accordingly	
29	On page 4, in the introductory language of section 19a-639a-5(b), the colon should be deleted, for consistency.	Changes have been made accordingly	
30	On page 4, in section 19a-639a-5(b)(2), "will be extended" in the second line should be "shall be extended", in accordance with the committee's directive regarding mandates, and "beyond" in the third line should be "after", for clarity and proper form.	Changes have been made accordingly	
31	On page 4, on the sixth line of section 19a-639a-6, "subsection (g) of section 19a-639a of the general statutes" should be deleted, for clarity and accuracy.	Changes have been made accordingly	
32	On page 5, in the last line of section 19a-639b-2, "voidance" should be "voiding", for proper form.	Changes have been made accordingly	
33	On page 5, in section 19a-639c-1, subsection designations "(a)" and "(b)" should be inserted before each paragraph, for consistency and proper form.	Changes have been made accordingly	
34	On page 5, in the second line of section 19a-639c-1, "a request for determination" should be "a letter requesting that the Office make a determination as to whether a certificate of need is required" and, in the third line, ", which shall be submitted with such letter," should be inserted after "facility", for accuracy and clarity.	Changes have been made accordingly	
35	On page 5, in the sixth line of section 19a-639e-1, "relocation" should be "relocate", for proper form and "Applicant" should be "applicant", for consistency.	Changes have been made accordingly	
36	On page 5, in the first and second lines of section 19a-639c-3, "and is either unable to demonstrate or chooses not to demonstrate" should be "and is unable to demonstrate", for consistency with section 19a-639c(a) of the general statutes.	Changes have been made accordingly	
37	On page 5, in section 19a-639e-1(a)(3), in the second line, "will" should be "may", for consistency and proper form and "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly	
38	On page 5, in section 19a-639e-1(b)(3), in the second line, "that intends to close" should be inserted after "facility", for clarity.	Changes have been made accordingly	
39	On page 5, throughout section 19a-639e-2, "service(s)" should be "service or services", for proper form.	Changes have been made accordingly	
40	On page 6, in the second line of section 19a-643-1a, "of the Regulations of	Changes have been made accordingly	

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	Connecticut State Agencies" should be inserted after "et seq.", for proper form.	
41	On page 6, in the second line of section 19a-653-1, "this section" should be "section 19a-653 of the general statutes", for clarity and proper form.	Changes have been made accordingly
42	On page 6, in the first line of section 19a-653-2, "of the general statutes" should be inserted after "19a-653", for consistency and proper form.	Changes have been made accordingly
43	On page 6, in the last sentence of section 19a-653-2, "Upon receipt of the request, the Office shall have ten days to notify the facility, institution or person of the date, time and place of the hearing" should be "The Office shall notify the health care facility or person of the date time and place of the hearing, not later than ten days after the Office's receipt of the request.", for clarity and consistency.	Changes have been made accordingly
44	On page 6, in the first line of section 19a-653-3(c), "time extension" should be "extension of time", for consistency, in the third line, "from" should be "beginning on" and "onward" should be deleted, for clarity and, in the fourth line, "at" should be "upon", for clarity.	Changes have been made accordingly
45	On page 6, in Section 2, "Section 2" should be "Sec. 2" and "Section 3" should be "Sec. 3", renumbered as noted in technical correction 5, above	Changes have been made accordingly
46	On page 6, in Section 2, "inclusive" should be inserted after "19a-643-110", for accuracy and clarity.	Changes have been made accordingly, Also added "exclusive of Sections 19a-643-21 and 19a-643-85(c)" -- 19a-643-21 allows for the consolidation of the proceeding and 19a-643-85(c) allows for the opportunity of a Public Hearing
Other		All references to "general statutes" have been changed to "Connecticut General Statutes" for consistency and proper form
		Section 19a-643-21 and 19a-643-85(c) were added in to the regulation as section 19a-643-2a and 19a-643-3a. All obsolete references were revised.
		Section 19a-643-201 (b)(23) was added into the regulation as section 3 and revised to reflect the repeal of 19a-643-205
		Section 19a-639a-3 was revised for ease of readability to the consumer
		All technical corrections noted in report 2012-3A were made

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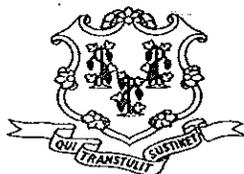
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The Connecticut General Assembly

Legislative Regulation Review Committee

Senator Andrew Roraback
Co-Chair



Representative Paul Davis
Co-Chair

March 5, 2012

Subject: Proposed Regulation 2012-003

Jewel Mullen, MD, Commissioner
Department of Public Health
410 Capitol Avenue/MS#13COM
Hartford, CT 06106

Dear Commissioner Mullen, MD:

Proposed Regulation

2012-003 Department of Public Health "CERTIFICATION OF NEED" The Regulations of Connecticut State Agencies is amended Sections 19a-613-1 through 19a-653-4, inclusive. Sections 19a-643-1 through 19a-643-110 and 19a-643-1 through 19a-643-205 are repealed.

The above captioned regulation was **Rejected Without Prejudice** by the Legislative Regulation Review Committee on 2/28/2012. The action was based on the recommendations of the Legislative Commissioners' Office. The necessary corrections are listed on the attached pages.

The regulation should be corrected and then resubmitted to the Legislative Regulation Review Committee with a summary of the changes listed by paragraph. If this is a mandated regulation then the regulation must be resubmitted to this office no later than the 1st Tuesday of the second month following the regulation's rejection.

Sincerely,

Handwritten signature of Pamela B. Booth in cursive.

Pamela B. Booth, Administrator
Legislative Regulation Review Committee

Enclosures (2)

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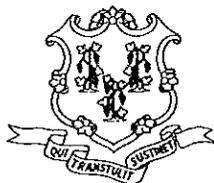
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The Connecticut General Assembly

Legislative Commissioners' Office

Edwin J. Maley, Jr.
Commissioner
William A. Hamzy
Commissioner

Larry G. J. Shapiro
Director



Legislative Office Building
Suite 5500
Hartford, Connecticut
06106-1591
(860) 240-8410
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e-mail: lco@cga.ct.gov

Memorandum

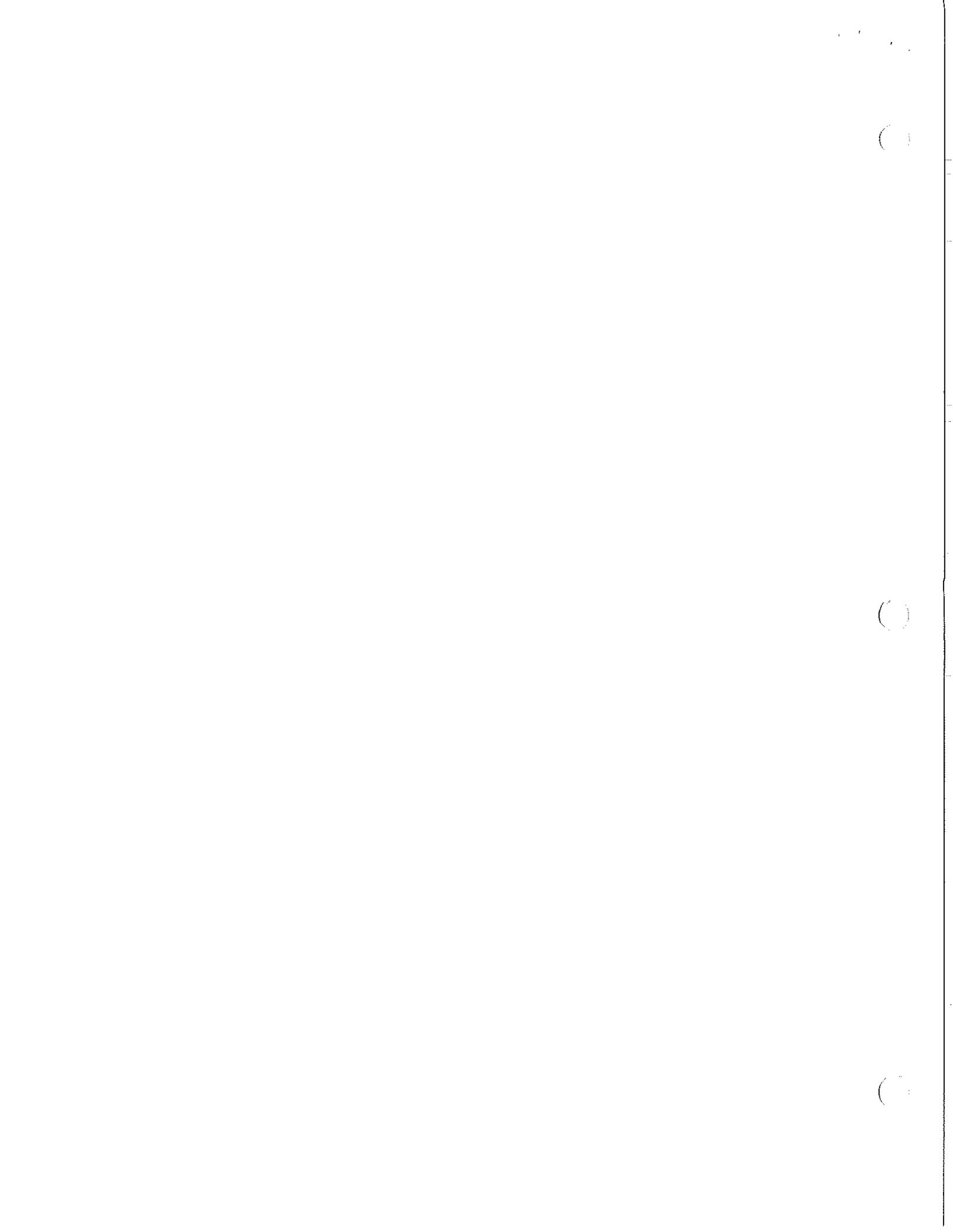
To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: February 28, 2012

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

	Yes or No
Mandatory	Y
Federal Requirement	N
Permissive	N

For the Committee's Information:

1. Section 19a-638 of the general statutes requires the department to adopt final regulations concerning the department's policies and procedures relating to the issuance of a certificate of need by December 31, 2011. The department submitted proposed regulations to the committee on or about December 27, 2011. Final regulations will not have been "adopted" until the committee approves the proposed regulations, which will occur not earlier than the committee's meeting on February 28, 2012.



2. Section 4-168(a)(1)(C) of the general statutes requires that an agency's notice of intent to adopt regulations include a reference to the statutory authority for the proposed regulation. The department's notice of intent states that the proposed regulations are issued under the authority of section 20-275(b). Section 20-275(b) concerns licensing of electrologists. Section 19a-638 gives the department the authority to adopt regulations concerning the issuance of certificates of need.

3. The certification page indicates that this regulation is being amended when, in fact, it is a new regulation being adopted.

Substantive Concerns:

1. On page 2, the meaning of 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", is unclear.

2. On page 5, the provisions of section 19a-639c-2 conflict with the provisions of sections 19a-639c(a) and 19a-638(c)(2) of the general statutes. Sections 19a-639c and 19a-638 do not provide an exception to the statutory requirements for a health care facility relocating within the same town.

Technical Corrections:

1. Throughout the regulations, "Office" should be "office" when referring to the physical location where the Office of Health Care Access conducts business, for consistency with the definition of "Office" in section 19a-630-1(f).

2. Throughout the regulations, references to subsections and subdivisions of the general statutes should be deleted, for clarity in the event the statute sections that are referenced are subsequently amended and result in the change of subdivision or subsection designations.

3. Throughout the regulations, "Certificate of Need" should be "certificate of need", for consistency.

4. Throughout the regulations, each word in the introductory language following each section number should be capitalized, and each word following a subsection or subdivision designator should be capitalized, for proper form and consistency.

5. The formatting of the regulation should be corrected. Section 1 should indicate that Sections 19a-613-1 through 19a-613-4, inclusive, are being added, as these sections relate to the description of the Office and its' data collection policies. "Section 2" should be inserted prior to section 19a-630-1, and should indicate that Sections 19a-630-1 through 19a-653-4, inclusive, are being added. The following two sections should be renumbered accordingly. Additionally, as the subject matter of Sections 19a-630-1 through 19a-653-4, inclusive, are certificates of need, "Certificates of Need" should be included in the catch line following "(NEW) Section 19a-630-1"

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6. On page 1, in the third line of section 19a-613-1, "a deputy commissioner" should be "a deputy commissioner of Public Health", for clarity and, in the fourth line, "19a-612" should be "19a-612d", for accuracy.
7. On page 1, in the second line of section 19a-613-2, "Chapter 368z" should be "section 19a-630", for clarity and accuracy.
8. On page 1, in section 19a-613-4, "FOI" should be "Freedom of Information", for proper form.
9. On page 1, in section 19a-630-1, above the line starting with "(a)", introductory language should be added as follows: "As used in sections 19a-630-1 to 19a-653-4, inclusive, of the Regulations of Connecticut State Agencies:", for proper form.
10. On page 1, in the first line of section 19a-630-1(a), "as used in subdivisions (8) (9) and (11) of subsection (a) of section 19a-638 of the general statutes" should be deleted, for clarity.
11. On page 2, in section 19a-630-2(a)(2), "facility" should be "entity", for consistency and "the individual physician, physicians, practitioner or practitioners" should be "individual physicians or practitioners", for clarity.
12. On page 2, in the second line of section 19a-630-2(b), after "(6)", "inclusive, of this section" should be inserted, for clarity.
13. On page 2, in section 19a-630-2(b), "whether" should be inserted as the first word of subdivisions (1) through (8), for consistency with the introductory language.
14. On page 2, in section 19a-630-2(b)(2), "no" should be changed to "any", for clarity.
15. On page 2, in sections 19a-630-2(b)(5) and (6), respectively, "the individual physician, physicians, practitioner or practitioners who provided" and "the physician, physicians, practitioner or practitioners who provided", should be "the individual physicians or practitioners who provide", for clarity.
16. On page 2, in section 19a-630-2(b)(9), "officer" should be "commissioner, the commissioner's designee or the deputy commissioner", for consistency.
17. On page 2, in section 19a-638-1, in the first line, "increases its operating rooms" should be "increases the number of its operating rooms", for clarity, in the third line, "operating room" should be "operating rooms" for accuracy, and, in the fourth line, "operating room(s)" should be "operating room or operating rooms", for proper form.
18. On page 2, in the first and fifth lines 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 and proper form.

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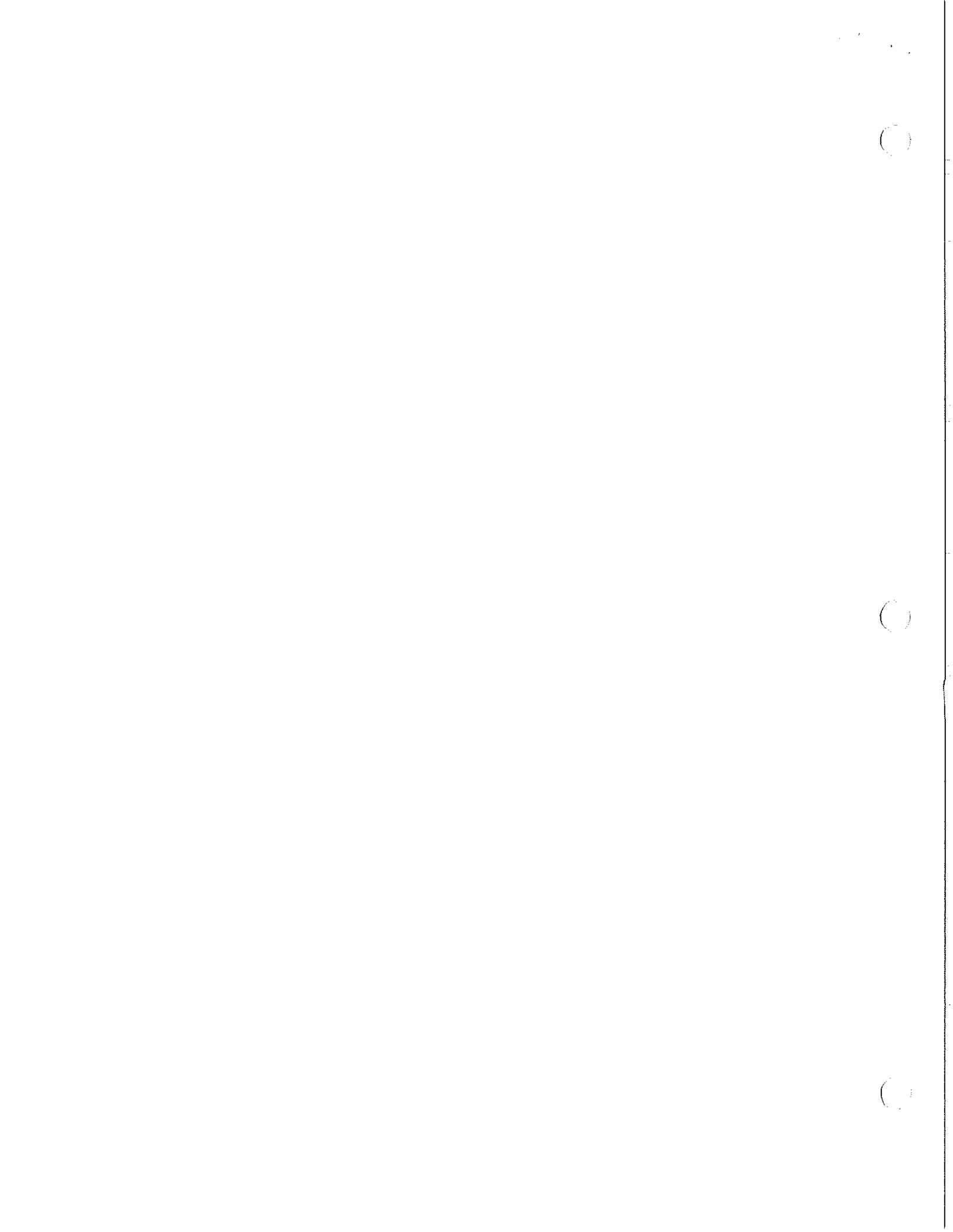
19. On page 2, in the last line of section 19a-638-3, a period should be inserted after "determination", "and" should be deleted, and "the" should be "The", for clarity. In the same line, "that docket number" should be "the corresponding docket number", for clarity.
20. On page 2, in section 19a-638-4, after "determinations" in the first line, the phrase "as to whether a certificate of need is needed" should be inserted, for clarity.
21. On page 2, in section 19a-639a-1, in the first line, the first "section" should be deleted, for clarity, in the second line, "application" should be inserted after "certificate of need", for clarity and consistency, and, in the fifth line, "in accordance with subsection (b) of section 19a-639a of the general statutes", should be deleted, for clarity.
22. On page 2, in section 19a-639a-1, in subsection (1), "The Applicant" should be "A statement that the applicant", for clarity.
23. On page 3, in the first line of section 19a-639a-3(a)(1), "Copies of the notices" should be "A copy of the notice", for consistency.
24. On page 3, in the second line of section 19a-639a-3(a)(2), "applicable subdivision" should be "applicable requirement for a certificate of need", for clarity.
25. On page 3, in section 19a-639a-3(a)(6), "Application forms for specific types of proposals are available and may be downloaded from the Office's website:" should be "the appropriate application form for the specific type of proposal, as follows, which are available and may be downloaded from the Office's website:", for clarity and consistency with the introductory language.
26. On page 3, in section 19a-639a-3(a)(6)(A), "of the general statutes" should be inserted after "19a-630", for proper form.
27. On page 3, in section 19a-639a-3(a)(6)(I), the subdivisions of subsection (a) of section 19a-638 of the general statutes should either be corrected to "(8), (9) or (11)", or the citation to the subdivisions should be eliminated, for accuracy of reference.
28. On page 4, in section 19a-639a-4(b), "the applicant will" in the third line should be "the applicant shall", in accordance with the committee's directive regarding mandates.
29. On page 4, in the introductory language of section 19a-639a-5(b), the colon should be deleted, for consistency.
30. On page 4, in section 19a-639a-5(b)(2), "will be extended" in the second line should be "shall be extended", in accordance with the committee's directive regarding mandates, and "beyond" in the third line should be "after", for clarity and proper form,
31. On page 4, on the sixth line of section 19a-639a-6, "subsection (g) of section 19a-639a of the general statutes" should be deleted, for clarity and accuracy.

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32. On page 5, in the last line of section 19a-639b-2, "voidance" should be "voiding", for proper form.
33. On page 5, in section 19a-639c-1, subsection designations "(a)" and "(b)" should be inserted before each paragraph, for consistency and proper form.
34. On page 5, in the second line of section 19a-639c-1, "a request for determination" should be "a letter requesting that the Office make a determination as to whether a certificate of need is required" and, in the third line, ", which shall be submitted with such letter," should be inserted after "facility", for accuracy and clarity.
35. On page 5, in the sixth line of section 19a-639c-1, "relocation" should be "relocate", for proper form and "Applicant" should be "applicant", for consistency.
36. On page 5, in the first and second lines of section 19a-639c-3, "and is either unable to demonstrate or chooses not to demonstrate" should be "and is unable to demonstrate", for consistency with section 19a-639c(a) of the general statutes.
37. On page 5, in section 19a-639e-1(a)(3), in the second line, "will" should be "may", for consistency and proper form and "that intends to close" should be inserted after "facility", for clarity.
38. On page 5, in section 19a-639e-1(b)(3), in the second line, "that intends to close" should be inserted after "facility", for clarity.
39. On page 5, throughout section 19a-639e-2, "service(s)" should be "service or services", for proper form.
40. On page 6, in the second line of section 19a-643-1a, "of the Regulations of Connecticut State Agencies" should be inserted after "et seq.", for proper form.
41. On page 6, in the second line of section 19a-653-1, "this section" should be "section 19a-653 of the general statutes", for clarity and proper form.
42. On page 6, in the first line of section 19a-653-2, "of the general statutes" should be inserted after "19a-653", for consistency and proper form.
43. On page 6, in the last sentence of section 19a-653-2, "Upon receipt of the request, the Office shall have ten days to notify the facility, institution or person of the date, time and place of the hearing" should be "The Office shall notify the health care facility or person of the date time and place of the hearing, not later than ten days after the Office's receipt of the request.", for clarity and consistency.
44. On page 6, in the first line of section 19a-653-3(c), "time extension" should be "extension of time", for consistency, in the third line, "from" should be "beginning on" and "onward" should be deleted, for clarity and, in the fourth line, "at" should be "upon", for clarity.



45. On page 6, in Section 2, "Section 2" should be "Sec. 2" and "Section 3" should be "Sec. 3", renumbered as noted in technical correction 5, above.

46. On page 6, in Section 2, "inclusive" should be inserted after "19a-643-110", for accuracy and clarity.

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Recommendation:

<p>Approval in whole with technical corrections with deletions with substitute pages Disapproval in whole or in part <input checked="" type="checkbox"/> Rejection without prejudice</p>
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Reviewed by: Heather Bannister / Anne Brennan Carroll

Date: February 15, 2012

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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

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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.

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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;

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(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

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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

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(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.

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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
Office of Government Relations

December 27, 2011

Pamela B. Booth, Committee Administrator
Legislative Regulation Review Committee
State Capitol
Room 011
Hartford, CT 06106

Regulations Concerning: *Certificate of Need*

Dear Ms. Booth:

Enclosed for the Committee's consideration is the proposed above-captioned regulation. It is authorized by section 4-168 of the Connecticut General Statutes.

Statement of Purpose: (A) The purpose of the regulations is to implement the new Certificate of Need ("CON") process under Public Act 10-179 §§ 83-93. (B) The regulations define certain terms used in Public Act 10-179, and establish policies regarding the increase in operating rooms, replacement of imaging equipment, determinations, relocations and terminations. The regulations also establish procedures for CON applications, including public notice, the contents of the application, the review period and public hearings regarding CON applications. Finally, the regulations establish the process for assessment of civil penalties. (C) The proposed regulations repeal §§ 19a-643-1 through 19a-643-110 and 19a-643-205. Sections 19a-643-1 through 19a-643-110 are the existing administrative regulations and rules of practice and the majority of them no longer apply under Public Act 10-179. Section 19a-643-205 concerns the filing of budgets by hospitals, which is no longer required under Public Act 10-179.

I am available to answer any questions you may have. Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Jill Kentfield".

Jill Kentfield, Legislative Liaison
Office of Government Relations



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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



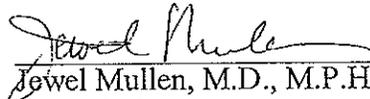
Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel Malloy
Governor

I, Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner of the Department of Public Health, an Agency of the State of Connecticut, hereby certify that:

- (1) On December 20, 2010, the Agency gave notice by mail to each joint standing committee of the general assembly having cognizance of the subject matter of the proposed regulations.
- (2) On December 28, 2010, the Agency gave notice in the Connecticut Law Journal of its intention to amend regulations concerning *Certificates of Need*. A true copy of the notice is attached as Exhibit A.
- (3) The Agency gave notice by mail to those persons who requested advance notice of regulation-making proceedings.
- (4) The Agency provided a copy of the proposed regulations to those persons requesting it.
- (5) Following publication of the notice in the Connecticut Law Journal, the Agency prepared a fiscal note, including an estimate of the cost or of the revenue impact on the state or any municipality of the state. A true copy of the fiscal note is attached as Exhibit B.
- (6) All interested persons were given until 4:30 p.m., January 27, 2011 to submit data, views or arguments concerning the proposed regulations and to inspect and copy the fiscal note referred to in paragraph 5.
- (7) The Agency has considered fully all written and oral submissions regarding the proposed regulations and determined that no revision of the fiscal note is needed.

11/18/11
Date _____



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner



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