

## ADMINISTRATIVE REGULATIONS

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*A cumulative list of effective amendments to the Regulations of Connecticut State Agencies may be found in the Connecticut Law Journal dated December 7, 2010.*

### DEPARTMENT OF PUBLIC HEALTH

#### Notice of Intent to Adopt Regulations

In accordance with the provisions of Section 4-168(a) of the Connecticut General Statutes as amended, notice is hereby given that the Department of Public Health proposes regulations concerning "*Certificates of Need*" under the authority of 20-275(b) of the General Statutes of Connecticut.

**Statement of purpose:** To implement the new Certificate of Need ("CON") process under Public Act 10-179 §§ 83-93. The regulations define certain terms used in Public Act 10-179, 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. The proposed regulations repeal §§ 19a-643-1 through 19a-643-110 and 19a-643-205. Section 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.

Persons wishing to present their views and arguments regarding these regulations are invited to do so in writing within thirty (30) days of publication of this notice. A public hearing will be scheduled if requested by fifteen (15) or more persons, a governmental subdivision or agency, or an association having not less than fifteen (15) members, provided that notice of such request is made within (30) thirty days of publication of this notice to: Commissioner of Public Health, Department of Public Health, 410 Capitol Avenue, MS #13COM, P.O. Box 340308, Hartford, Connecticut 06134-0308; telephone number (860) 509-7101.

In addition, copies of this proposed regulation may be obtained from Melanie Dillon, Department of Public Health, Division of Health Care Access, 410 Capitol Avenue, Hartford, Connecticut 06134-0308; phone (860) 418-7060; e-mail [Melanie.Dillon@CT.gov](mailto:Melanie.Dillon@CT.gov).

J. Robert Galvin, M.D., M.P.H., M.B.A.

Commissioner

**IMPORTANT:** Read instructions on bottom of Certification Page before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations.

## STATE OF CONNECTICUT REGULATION

OF

Department of Public Health

Name of Agency

Concerning

Office of Health Care Access Administrative Regulations

Section 19a-613-1 through 19a-653-4 of the Regulations of Connecticut State Agencies

### SUBJECT MATTER OF REGULATION

**Section 1** The Regulations of Connecticut State Agencies are amended by adding Section 19a-613-1 through 19a-653-4, inclusive, as follows:

(NEW) Sec. 19a-613-1. Description

The Office of Health Care Access (OHCA) division of the Department of Public Health derives its authority primarily from Chapter 368z of the Connecticut General Statutes. The powers of the office are vested in and exercised by a deputy commissioner, appointed as provided in section 19a-612 of the Connecticut General Statutes.

(NEW) Sec. 19a-613-2. Function

The Office of Health Care Access is generally empowered to exercise specified grants of authority over the establishment and operation of health care facilities as defined in Chapter 368z of the Connecticut General Statutes. The Office is responsible for preparing the Statewide Health Care Facilities and Services Plan, administering the Certificate of Need process and collecting inpatient discharge data and financial data from hospitals.

(NEW) Sec. 19a-613-3. Official address and hours.

The principal office of the Office of Health Care Access is located at and all communications should be addressed to the Office of Health Care Access, 410 Capitol Avenue, MS#13HCA, P. O. Box 340308, Hartford, CT 06134-0308. The OHCA office is open from 8:30 a.m. to 4:30 p.m. Monday through Friday except legal holidays.

(NEW) Sec. 19a-613a-4. Public Information

The public may inspect the regulations, decisions and all public records of the Office of Health Care Access at its office. Written requests for public information shall be filed on the FOI request forms available on the office's website.

(NEW) Sec. 19a-630-1. Definitions

- (1) "Acquisition" as used in subdivisions (8) (9) and (11) of subsection (a) of section 19a-638 of the general statutes means the acquisition through purchase, lease, donation or other comparable arrangement of a computed tomography scanner, magnetic resonance imaging scanner, positron emission tomography scanner, positron emission tomography-computed tomography scanner, linear accelerator or equipment that utilizes technology that has not previously been utilized in the state;
- (2) "Central Service Facility" means a health care facility or institution, person or entity engaged primarily in providing services for the prevention, diagnosis or treatment of human health conditions, serving one or more health care facilities, practitioners or institutions and satisfying the criteria for a central service facility as discussed in section II, below;
- (3) "Day", unless specified otherwise in statute or regulation, means a calendar day;
- (4) "Freestanding Emergency Department" means an emergency department that is not located the main campus of a hospital and is held out to the public (by name, posted signs, advertising or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment;
- (5) "Interventional cardiology" means non-surgical procedures used in the treatment of coronary artery and peripheral vascular disease and performed in the cardiac catheterization laboratory. Procedures include, but are not limited to, angioplasty, valvuloplasty, cardiac ablation, coronary thrombectomy, and congenital heart defect correction. Only those procedures that are authorized pursuant to a Certificate of Need may be performed by a health care facility or provider and several procedures may be authorized under one Certificate of Need. A facility that is authorized to provide open heart surgery is authorized to provide all of the above procedures;

# STATE OF CONNECTICUT REGULATION OF

Department of Public Health  
Name of Agency

- (6) "Office" or "OHCA" means the Office of Health Care Access division of the Department of Public Health, as established by section 19a-612 of the Connecticut General Statutes;
- (7) "Provider" means a any person or entity that provides health care services;
- (8) "Psychiatric residential treatment facility" means a psychiatric residential treatment facility as defined in 42 CFR 483.352;

(NEW) Sec. 19a-630-2. Criteria for Determining if an Entity is a Central Service Facility

(a) An entity shall be a central service facility if it meets one or more of the following criteria: (1) The entity is institutional in nature and practice; (2) patient care is or will be the responsibility of the facility rather than of the individual physician, physicians, practitioner or practitioners; (3) nonmedical personnel, owners or managers can or will be able to influence the operation of the entity to a significant degree; (4) there are physicians from one or more physician practices, partnerships or corporations who practice or will practice there, or who will control a business involving health services; (5) The physician or practitioner is not practicing medicine in the area of his expertise and training, or does not hold a Connecticut license to practice medicine; (6) A partnership with general and managing partners exists.

(b) Additional considerations: In determining whether a particular entity meets any of the criteria in subsection (a) (1) through (6), the commissioner, commissioner's designee or deputy commissioner may consider the following: (1) the entity will is or will be licensed or designated as any type of health care facility or institution by the department; (2) the patients have no prior familiarity with the physician or practitioner or any ongoing relationship with the physician or practitioner; (3) services such as laboratory, pharmacy, x-ray, linear accelerator and imaging , are or will be available with no free choice of the provider of such services by the patient; (4) the entity can continue to function even if the license of its physician or physicians has, have been or may be suspended or revoked, since the entity can simply retain another physician or practitioner; (5) bills and charges are or will be determined by the entity rather than the individual physician, physicians, practitioner or practitioners who provided the care or the service; (6) income distribution is or will be determined by the entity rather than entirely by the physician, physicians, practitioner or practitioners who provided the care of service; (7) there are present interlocking relationships, corporate relationships or entities with other health related corporate relationships, entities or properties; (8) the location and services provided are a small part of a larger entity; and (9) any other information the officer deems relevant or pertinent.

(NEW) Sec. 19a-638-1. Increase in Operating Rooms

Any outpatient surgical facility that increases its operating rooms on and after October 1, 2010, shall file a notification with the office indicating the date on which the operating room was added, the number of operating rooms added and the total number of operating room including the new operating room(s).

(NEW) Sec. 19a-638-2. Replacement of Imaging Equipment

Any health care facility, person or provider that replaces equipment shall notify the office of the date on which the equipment was replaced and the disposition of the replaced equipment pursuant to subdivision (18) of subsection (b) of section 19a-638 of the general statutes. The notification shall also include the docket number of the certificate of need or certificate of need determination and the office shall place the notification in the original file for that docket number.

(NEW) Sec. 19a-638-3. Determinations

All requests for determinations shall be submitted to the office on a Determination Form, which is available on the office's website. The Office will not review a request for determination until a complete form has been submitted and all required information has been provided to the office. Requests for determination may be submitted electronically in PDF format or via facsimile.

(NEW) Sec. 19a-639a-1. Public Notification of a Certificate of Need Application

Pursuant to section subdivision (b) of section 19a-639a of the general statutes, not later than twenty days prior to the submission of a certificate of need, the applicant shall publish notice that an application is to be submitted in a newspaper having substantial circulation in the area where the project is to be located.

# STATE OF CONNECTICUT REGULATION OF

Department of Public Health  
Name of Agency

The notification must contain at least the following information: (1) The Applicant is applying for a Certificate of Need pursuant to section 19a-638 of the general statutes; (2) a description of the scope and nature of the project; (3) the street address where the project is to be located; and (3) the total capital expenditure for the project.

(NEW) Sec. 19a-639a-2. Newspapers with Substantial Circulation in Town Where Project is to be Located

A list of towns in Connecticut and the corresponding newspapers of substantial circulation in each town are available on the office's website. The office will update the list as necessary.

(NEW) Sec. 19a-639a-3. Certificate of Need Application

(a) The application shall consist of the following:

- (1) Copies of the notices of the certificate of need application demonstrating that such notice was published for at least three days in a newspaper having substantial circulation in the town in which the project is going to be located pursuant to subsection (b) of section 19a-639a of the general statutes;
- (2) A description of the project setting forth the proposal in as much detail as possible. The description should reference the applicable subdivision under subsection (a) of section 19a-638 of general statutes;
- (3) The specific location of the facility, service or equipment;
- (4) A detailed description of how the proposal satisfies each of the guidelines and principles enumerated in section 19a-639 of the general statutes and any supporting documentation;
- (5) All other information as required by the specific application form, which is available on the office's website. The application form should be filled out in its entirety and all supporting documents should be attached to the application and referenced as either an attachment or exhibit in the order in which they appear in the application;
- (6) Application forms for specific types of proposals are available and may be downloaded from the office's website:
  - (a) Establishment of a new health care facility as defined in section 19a-630;
  - (b) Establishment of an outpatient surgical facility;
  - (c) Establishment of a freestanding emergency department;
  - (d) Transfer of ownership of a health care facility;
  - (e) Termination of inpatient or outpatient mental health or substance service by a short-term acute care general hospital or children's hospital;
  - (f) Termination of an emergency department by a short-term acute care general hospital;
  - (g) Establishment of cardiac services;
  - (h) Acquisition of any of the equipment enumerated in subdivisions (8), (9) and (11) of subsection (a) of section 19a-638 of the general statutes;
  - (i) Increase in licensed bed capacity; and
  - (j) Increase in operating rooms by an outpatient surgical facility pursuant to subdivision (12) of subsection (a) of the section 19a-638 of the general statutes.

(b) One original and four copies of the application shall be submitted to the office at 410 Capitol Avenue, MS#13HCA, Hartford, CT 06134. The application shall be accompanied by the \$500 filing fee pursuant to subsection (a) of section 19a-639a of the general statutes. If the application including attachments or exhibits does not exceed 50 pages, it may be filed electronically in accordance with subsection (c) of this section.

(c) Applications of less than 50 pages may be filed electronically in PDF format. All applications exceeding 50 pages must be filed in accordance with subsection (b) of this section.

(d) Applications shall be deemed received on the date and time at which the office receives the document or the complete electronic version of the document. Any documents received after normal business hours shall be deemed received on the following business day.

(NEW) Sec. 19a-639a-4. Certificate of Need - Completeness Review

(a) Pursuant to subsection (c) of section 19a-639a, the office shall have thirty days to review the application and request additional information as necessary to complete the application. The applicant shall have sixty days from the date of the request to provide responses to the completeness questions and said responses may be filed electronically in PDF format or via facsimile. If the applicant fails to respond within the sixty day time frame, the application shall be deemed withdrawn in accordance with subsection (c) of section 19a-639a.

# STATE OF CONNECTICUT REGULATION OF

Department of Public Health  
Name of Agency

(b) Upon receipt of the responses, the office shall have thirty days to review the responses and make a determination with respect to whether the application is complete or if further information is needed. If additional information is sought, the applicant will have another sixty days to respond. If the applicant fails to respond within the sixty day time frame, the application shall be deemed withdrawn in accordance with subsection (c) of section 19a-639a.

(c) The review cycle described above shall continue until the office deems an application complete.

(NEW) Sec. 19a-639a-5. Certificate of Need - Review Period

(a) The review period will begin on the date on which the office publishes notice on its website that the application is complete with subsection (d) of section 19a-639a of the general statutes. The office shall publish notice on its website as expeditiously as possible and in no instance more than seven days beyond the expiration of the thirty day review period. Additionally, the office shall provide notice that the application is complete to the applicant via first class mail, facsimile or electronic mail. The notice to the applicant shall also notify the applicant of the date on which the review period expires. The notice on the website shall serve as notice to any interested members of the public.

(b) Extensions of the Review Period:

- (1) The Office may extend the review period for good cause as defined in section 19a-630-1 of the Regulations of Connecticut State Agencies for a total of sixty days in accordance with subsection (d) of section 19a-639a of the general statutes.
- (2) Where a public hearing is held pursuant to subsections (e) or (f) of section 19a-639a of the general statutes, the review period will be extended for another sixty days beyond the date of the hearing.

(NEW) Sec. 19a-639a-6. Notice of Public Hearing

The office shall provide notice of the date, time and place of the public hearing in a newspaper having substantial circulation in the town in which the project is to be located two weeks prior to the date of the hearing pursuant to subsection (f) of section 19a-639a of the general statutes. The office shall also provide a copy of the notice via first class mail, facsimile or electronic mail to the applicant and any individuals or entities that have requested a hearing pursuant to subsection (g) of section 19a-639a of the general statutes. Additionally, the office shall post the notice of public hearing on its website.

(NEW) 19a-639b-1. Voidance and Extension of Certificate of Need

(a) A certificate of need shall be void two years from the date of issuance by the office unless the applicant has requested an extension of the certificate of need at least thirty days in advance of the expiration of the certificate of need pursuant to subsection (b) of section 19a-639b of the general statutes.

(b) At a minimum, a request for an extension of a certificate of need shall contain the following:

- (1) A detailed description of any change in the cost, configuration, services or scope of the project;
- (2) A detailed description and documentation of any progress on the project including preparation of construction drawings, securing of necessary funds and building permits and commencement of any construction;
- (3) An estimated timetable for commencement and completion of all remaining components of the project; and
- (4) Documentation of an extenuating circumstance, including, but not limited to, delays occasioned by negotiations with vendors or contractors, beyond the control of the applicant that prevented the applicant from completing the project by the expiration date.

(c) The following criteria shall be used to determine whether an extension will be granted to the applicant:

- (1) Site procurement: The applicant must have made progress toward permanent acquisition of the intended site for the project.

# STATE OF CONNECTICUT REGULATION OF

Department of Public Health  
Name of Agency

- (2) Financial status: The applicant must be able to provide documentation regarding finalizing any necessary loans or lease purchase arrangements.
- (3) The applicant must provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.

(NEW) Sec. 19a-639b-2. Non-Transferability of the Certificate of Need

A certificate of need is non-transferable. A certificate of need or rights thereunder may not be sold, assigned, leased, transferred, mortgaged, or pledged. Any attempt to transfer a certificate of need shall result in the immediate voidance of the certificate of need.

(NEW) Sec. 19a-639c-1. Relocation of a Health Care Facility

Pursuant to section 19a-639c of the general statutes, any health care facility that proposes to relocate its facility shall submit a request for determination. A form for the relocation of a health care facility is available on the office's website.

Based upon the information submitted by the applicant, the office shall determine whether there has been substantial change in the payer mix or the population served by the health care facility that proposes to relocation. The Applicant shall provide the percentages of total patient volume by payer source prior to the relocation and following the relocation.

(NEW) Sec. 19a-639c-2. Relocation within the same town

For a relocation of a health care facility within the same town, the office shall not require the submission of information concerning the payer mix or population served as it will be presumed that the proposed relocation will not result in a substantial change in the payer mix or population served. Accordingly, no determination is required for relocation of a health care facility within the same town.

(NEW) Sec. 19a-639c-3. Certificate of Need for Relocation

Any health care facility that proposes to relocate its facility and is unable to demonstrate to the satisfaction of the office that the relocation will not result in a substantial change in the payer mix or population served shall file a certificate of need for the establishment of a new health care facility pursuant to subdivision (1) of subsection (a) of section 19a-638 of the general statutes.

(NEW) Sec. 19a-639e-1. Termination of a Health Care Facility

(a) Any health care facility that was authorized through a certificate of need shall provide notice that it is terminating services not later than sixty days prior to the termination. The notification shall contain the following: (1) The name and location of the health care facility; (2) reason for closing the facility; (3) other facilities where patients will be able to obtain the services that are currently provided by the facility; and (4) date on which the facility will be closed. .

(b) Any health care facility that was not authorized through a certificate of need and intends to close the facility shall notify the office not later than sixty days prior to the termination of the facility. The notification shall contain the following: (1) The name and location of the health care facility; (2) reason for closing the facility; (3) other facilities where patients may be obtain the services that are currently provided by the facility; and (4) date on which the services will no longer be provided or on which the facility will be closed.

(NEW) Sec. 19a-639e-2. Termination of Services Provided by a Health Care Facility

(a) Any health care facility that intends to terminate services which were authorized pursuant to a certificate of need shall file a modification of the original certificate of need on the forms available on the office's website. The applicant shall provide the following information to the office: (1) The service(s) that the facility will no longer provide; (2) the reasons that the facility will no longer provide the service(s); (3) other facilities where the patients may obtain the service(s) which the facility will no longer provide; and (4) the date on which the service(s) will be terminated.

(b) Any health care facility that intends to terminate a service which was not authorized pursuant to a certificate of need shall notify the office not late than sixty days prior to the termination of the service. The notification shall contain the following: (1) The service(s) that the facility will no longer provide; (2) the reason that the facility will no longer provide the service(s); (3) other facilities where the patient may obtain the service(s) which the facility will no longer provide; and (4) the date on which the service(s) will be terminated.

**STATE OF CONNECTICUT  
REGULATION  
OF**

*Department of Public Health*  
Name of Agency

(NEW) Sec. 19a-643-1a. Rules of Practice

The Office of Health Care Access division of the Department of Public Health shall follow the Rules of Practice under section 19a-9-1, et seq.

(NEW) Sec. 19a-653-1. Notification of a Civil Penalty

The commissioner or the commissioner's designee, prior to the imposition of any civil penalty under this section, shall notify any facility, institution or person subject to such civil penalty in accordance with subsection (b) of section 19a-653 of the general statutes.

(NEW). Sec. 19a-653-2. Civil Penalty - Request for Hearing

Pursuant to subsection (c) of section 19a-653, any health care facility or person to whom the notice of civil penalty was addressed may request a hearing to contest the imposition of the civil penalty. 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.

(NEW) Sec. 19a-653-3. Civil Penalty - Request for Extension of Time

(a) A request for an extension of time within which to file required data or information shall contain the following: (1) the reason why the health care facility or person was unable to comply with the original due date; and (2) the date on which the information or data will be filed.

(b) In reviewing the request for an extension of time, the office shall consider the following: (1) any extenuating circumstances that prevented compliance with the original due date; (2) demonstration of a good faith effort to comply with the appropriate statute, act, order, or regulations; (3) past history of compliance with the submission of data or information requirements; (4) the length of the delay in filing; (5) the degree of incompleteness or inaccuracy; and (5) any other relevant criteria.

(c) If the request for a time extension is granted, it shall be granted to a date certain. Failure to submit the required data or information by that extended date may result in the imposition of a civil penalty from the day after the extended due date onward. The civil penalty shall become effective at the expiration of the time extension and OHCA shall provide notice of the same to the person or health care facility.

(NEW) Sec. 19a-653-4. Rescission of Civil Penalty

Upon receipt of the data or information or the filing of a certificate of need, the office may rescind the civil penalty in whole or in part.

**Section 2** Sections 19a-643-1 through 19a-643-110 of the Regulations of Connecticut State Agencies are repealed.

**Section 3** Section 19a-643-205 of the Regulations of Connecticut State Agencies is repealed.

STATE OF CONNECTICUT  
REGULATION  
OF

Department of Public Health  
Name of Agency

**Statement of Purpose:**

The purpose of the regulations is to implement the new Certificate of Need (“CON”) process under Public Act 10-179 §§ 83-93. The regulations define certain terms used in Public Act 10-179, 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. The proposed regulations repeal §§ 19a-643-1 through 19a-643-110 and 19a-643-205. Section 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.