

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 Office is open from 8:30 a.m. to 4:30 p.m. Monday through Friday except legal holidays.

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

- (a) "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;
- (b) "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 19a-630-2;
- (c) "Day", unless specified otherwise in statute or regulation, means a calendar day;

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- (d) "Freestanding Emergency Department" means an emergency department that is not located on 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;
- (e) "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;
- (f) "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 general statutes;
- (g) "Provider" means any person or entity that provides health care services;
- (h) "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) one or more partnerships or corporations, other than a group of practicing physicians, whose practice this is or will be and 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;
 - (6) A partnership with general and managing partners exists.
- (b) 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 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).

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(NEW) Sec. 19a-638-2. Establishment of cardiac services

Interventional cardiology procedures, as defined in subsection (5) of section 19a-630-1, 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 interventional cardiology procedures listed in subsection (5) of section 19a-630-1.

(NEW) Sec. 19a-638-3. 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-638-4. 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 shall 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. An applicant shall file the application not later than ninety days after publishing notice in accordance with subsection (b) of section 19a-639a of the general statutes. The notice shall contain 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
- (4) 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 shall reference the applicable subdivision under subsection (a) of section 19a-638 of general statutes;
 - (3) The specific location of the facility, service or equipment;

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- (4) A detailed description of how the proposal relates to 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 services by a short-term acute care general hospital or children's hospital;
 - (F) Termination of surgical services by an outpatient surgical facility or a facility that provides outpatient surgical services as part of the outpatient surgery department of a hospital pursuant to subdivision (6) of subsection (a) of section 19a-638 of the general statutes;
 - (G) Termination of an emergency department by a short-term acute care general hospital;
 - (H) Establishment of cardiac services;
 - (I) Acquisition of any of the equipment enumerated in subdivisions (9), (10) and (12) of subsection (a) of section 19a-638 of the general statutes;
 - (J) Increase in licensed bed capacity; and
 - (K) Increase in operating rooms by an outpatient surgical facility pursuant to subdivision (13) 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 of the general statutes, 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 request for additional information 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 of the general statutes.
 - (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 of the general statutes.

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- (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) Pursuant to section 19a-639a of the general statutes, the ninety day review period for a completed application shall begin on the date the Office posts notice of the completed application on its website. No later than seven days after the thirty day review period for completeness has expired, the Office shall post notice of the completed application on its website. The Office shall also provide notice to the applicant that its application is complete via first class mail, facsimile or electronic mail and this notice shall include the date on which the ninety day review period expires. The posting on the Office 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 for a total of sixty days in accordance with subsection (d) of section 19a-639a of the general statutes. If the Office extends the review period, the Office shall provide notice to the applicant that review has been extended via first class mail, facsimile or electronic mail and this notice shall include the date on which the review period expires.
 - (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 on which the hearing is closed. The Office shall notify the applicant of the date on which the hearing is closed via first class mail, facsimile or electronic mail and this notice shall include the date on which the review period expires.

(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. Expiration and Extension of Certificate of Need

- (a) A certificate of need shall expire 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.

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- (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 either unable to demonstrate or chooses not 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.

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

- (a) Unless otherwise required to file a certificate of need application pursuant to the provisions of subsection (a) of section 19a-638 of the general statutes, 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 later 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.

(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

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- (6) 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.

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.

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Be it known that the foregoing:

Regulations Emergency Regulations

are:

Adopted Amended as hereinabove stated Repealed

By the aforesaid agency pursuant to:

Sections 19a-638(d), 19a-639a(g), 19a-639b(e), 19a-639c(b), 19a-639e(d) and 19a-643 of the General Statutes.

Section of the General Statutes, as amended by Public Act. No. of the Public Acts.

Public Act. No of the Public Acts.

After publication in the Connecticut Law Journal on December 28, 2010 the notice of the proposal to:

Adopt Amend Repeal such regulations

(If applicable): And the holding of an advertised public hearing on

WHEREFORE, the foregoing regulations are hereby:

Adopted Amended as hereinabove stated Repealed

Effective:

When filed with the Secretary of the State.

(OR)

The ____ day of ____ 20__.

In Witness Whereof:	Date	SIGNED (Head of Board, Agency or Commission)	OFFICIAL TITLE, DULY AUTHORIZED <i>Commissioner</i>
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Approved by the Attorney General as to legal sufficiency in accordance with Sec. 4-169, as amended, C.G.S.:	SIGNED	OFFICIAL TITLE, DULY AUTHORIZED
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Approved

Disapproved

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Disapproved in part, (Indicate Section Numbers disapproved only)

Rejected without prejudice.

The Legislative Review Committee in accordance with Sec. 4-170, as amended, of the General Statutes	DATE	SIGNED (Clerk of the Legislative Regulation Review Committee)
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Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications in accordance with Section 4-172, as amended, of the General Statutes.

DATE	SIGNED (Secretary of the State)	BY
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INSTRUCTIONS

One copy of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the Attorney General for his determination of legal sufficiency. Section 4-169 of the General Statutes.

Eighteen copies of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the standing Legislative Regulation Review Committee for its approval. Section 4-170 of the General Statutes.

Each regulation must be in the form intended for publication and must include the appropriate regulation section number and section heading. Section 4-172 of the General Statutes.

Indicate by "(NEW)" in heading if new regulation. Amended regulations must contain new language in capital letters and deleted language in brackets. Section 4-170 of the General Statutes.