

Questions or Assistance?

If you have further questions regarding Certificate of Need Regulations, please feel free to contact one of the following members of our Health Law Practice Group.

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Summary of Proposed Certificate of Need Regulations

The Department of Public Health (“DPH”) recently published official notice of its new proposed Certificate of Need (“CON”) regulations (the “Proposed Regulations”). Copies of the notice and Proposed Regulations are attached. Persons wishing to comment on the Proposed Regulations before they are finalized must do so in writing by January 27, 2010. Upon request, a public hearing may also be held on the Proposed Regulations if requested in writing by January 27, 2010 by at least fifteen (15) people, a governmental subdivision or agency or an association having at least fifteen (15) members. The following provides an overview of the Proposed Regulations:

1. New Definitions of Interest (Sec. 19a-630-1):

- a. 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.
- b. 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 CON may be performed by a health care facility or provider and several procedures may be authorized under one CON. A facility that is authorized to provide open heart surgery is authorized to provide all of the above procedures.

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

- 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; or (6) a partnership with general and managing partners exists.

- b. Additional considerations: In determining whether a particular entity meets any of the criteria in section (a) (1) through (6) above, OHCA may consider the following: (1) The entity is or will be licensed or designated as any type of health care facility or institution by DPH; (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 services; (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 OHCA deems relevant or pertinent.

S&G COMMENT: Under the new CON Statutes, if you establish or transfer the ownership of a Central Service Facility, you will need a CON.

3. Increase in Operating Rooms by Outpatient Surgical Facilities (Sec. 19a-638-1):

Any outpatient surgical facility that increases its operating rooms shall file a notification with OHCA indicating the date on which the operating room was added, the number of operating rooms added and the new total number of operating rooms.

S&G COMMENT: The notice to be filed can be in any format as long as it contains the information required above. A specific notification form has not yet been made available by OHCA.

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

Any health care facility, person or provider that replaces imaging equipment shall notify OHCA of the date on which the imaging equipment was replaced, disposition of the replaced equipment, and the docket # of the CON or CON Determination associated with the replaced imaging equipment.

S&G COMMENT: The Proposed Regulations clarify that you must simply notify OHCA when replacing imaging equipment that was associated with a previous CON or CON Determination.

5. Determinations (Sec. 19a-638-3):

All CON Determination requests must be made with OHCA's Determination Form.

S&G COMMENT: The current form is available on OHCA's website.

6. Content Requirements of Public Notification of a CON Application (Sec. 19a-639a-1):

When publishing notice of its CON Application by newspaper, the applicant's notice must contain at least the following information: (1) The applicant is applying for a CON 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.

S&G COMMENT: The Proposed Regulations clarify that you must include the total capital expenditure for the project in the notice.

7. Meaning of “Newspapers with Substantial Circulation in Town Where Project is to be Located” (Sec. 19a-639a-2):

A list of towns in Connecticut and the corresponding newspapers of substantial circulation in each town are available on OHCA’s website.

S&G COMMENT: OHCA will update the list as necessary.

8. CON Application Requirements (Sec. 19a-639a-3):

- a. The CON application shall consist of the following:
 - i. Copies of the notices of the CON application demonstrating that such notice was published for at least three (3) days in a newspaper having substantial circulation in the town in which the project is going to be located;
 - ii. A description of the project setting forth the proposal in as much detail as possible. The description should reference the applicable subdivision under C.G.S. 19a-638(a);
 - iii. The specific location of the facility, service or equipment;
 - iv. A detailed description of how the proposal satisfies each of the guidelines and principles enumerated in C.G.S. 19a-639 (summarized below):
 - Whether the proposed project is consistent with any applicable regulations;
 - The relationship of the proposed project to the state-wide health care facilities and services plan;
 - Whether there is a clear public need for the proposed health care facility or services;
 - How the proposal will impact the financial strength of the health care system in the state;
 - How the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region;
 - The applicant’s past and proposed provision of health care services to relevant patient populations and payer mix;
 - Satisfactorily demonstrated that the identified population to be served by the proposed project has a need for the proposed services;
 - The utilization of existing health care facilities and health care services in the service area of the applicant; and
 - Satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities.
 - v. All other information as required by the specific provider application form. All supporting

documentation should be attached to the application and referenced as either an attachment or exhibit in the order in which they appear in the application.

- b. One original and four (4) copies of the application shall be submitted to OHCA at 410 Capitol Avenue, MS#13HCA, Hartford, CT 06134. The application shall be accompanied by a \$500 filing fee.
- c. Applications of less than fifty (50) pages (including attachments or exhibits) may be filed electronically in PDF format. All applications exceeding fifty (50) pages must be filed in accordance with subsection (b) above.
- d. Applications shall be deemed received on the date and time at which OHCA receives the document or the complete electronic version of the document. Any documents received after normal business hours (i.e. after 4:30 p.m.) shall be deemed received on the following business day.

S&G COMMENT: On October 25, 2010, DPH published notice regarding the formation of the State-Wide Health Care Facilities and Services Plan Advisory Board (the "Advisory Board"), which is charged with establishing and maintaining the state-wide health care facilities and services plan. More information about the Advisory Board including, its members and upcoming meetings, can be found at <http://www.ct.gov/ohca/cwp/view.asp?a=3990&q=469574>. In addition, please note that provider specific CON application forms are available on OHCA's website.

9. CON Completeness Review (Sec. 19a-639a-4):

- a. OHCA shall have thirty (30) days to review the application and request additional information as necessary to complete the application. The applicant shall have sixty (60) 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 (60) day time frame, the application shall be deemed withdrawn.
- b. Upon receipt of the responses, OHCA shall have thirty (30) 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 (60) days to respond. If the applicant fails to respond within the sixty (60) day time frame, the application shall be deemed withdrawn.

S&G COMMENT: This review cycle shall continue until OHCA deems an application complete.

10. CON Review Period Sec. (19a-639a-5):

- a. The review period will begin on the date on which OHCA publishes notice on its website that the application has been deemed complete. OHCA shall publish notice on its website no later than seven (7) days beyond the expiration of the thirty (30) day review period. Additionally, OHCA 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.

- b. OHCA may extend the review period for good cause for a total of sixty (60) days. Where a public hearing is held on the CON, the review period will be extended for another sixty (60) days beyond the date of the hearing.

S&G COMMENT: We interpret section (a) above to mean that OHCA will publish notice on its website no later than seven (7) days before the expiration of the thirty (30) day review period.

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

OHCA 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 (2) weeks prior to the date of the hearing. OHCA 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 on the CON. Additionally, OHCA shall post notice of the public hearing on its website.

12. Voidance and Extension of CON (19a-639b-1):

- a. A CON shall be void two (2) years from the date of issuance by OHCA unless the applicant has requested an extension of the CON at least thirty (30) days in advance of the expiration of the CON.
- b. At a minimum, a request for an extension of a CON shall contain the following:
 - i. A detailed description of any change in the cost, configuration, services or scope of the project;
 - ii. 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;
 - iii. An estimated timetable for commencement and completion of all remaining components of the project; and
 - iv. 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:
 - i. Site procurement: The applicant must have made progress toward permanent acquisition of the intended site for the project.
 - ii. Financial status: The applicant must be able to provide documentation regarding finalizing any necessary loans or lease purchase arrangements.

- iii. The applicant must provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.

S&G COMMENT: An Extension of CON form has not yet been made available by OHCA.

13. Non-Transferability of the CON (Sec. 19a-639b-2):

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

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

Any health care facility that proposes to relocate its facility shall submit a request for determination with OHCA's form which is available on its website. Based upon the information submitted by the applicant, OHCA shall determine whether there has been substantial change in the payer mix or the population served by the health care facility that proposes to relocate. The applicant shall provide the percentages of total patient volume by payer source prior to the relocation and following the relocation.

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

No determination is required for relocation of a health care facility within the same town.

16. CON for Relocation (Sec. 19a-639c-3):

Any health care facility that proposes to relocate its facility and is unable to demonstrate to the satisfaction of OHCA that the relocation will not result in a substantial change in the payer mix or population served shall file a CON for the establishment of a new health care facility.

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

- a. Any health care facility that was authorized through a CON shall provide notice that it is terminating services not later than sixty (60) 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 CON and intends to close the facility shall notify OHCA not later than sixty (60) 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.

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

- a. Any health care facility that intends to terminate services which were authorized pursuant to a CON shall file a modification of the original CON on the form available on OHCA's website. The applicant shall provide the following information to OHCA: (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 CON shall notify OHCA not later than sixty (60) 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.

20. Civil Penalties (Sec. 19a-653-1 - 4):

DPH, prior to the imposition of any civil penalty, shall notify any facility, institution or person subject to such civil penalty in accordance with C.G.S. 19a-653.

S&G COMMENT: The new CON Statutes and Proposed Regulations clarify that civil penalties can be imposed upon any person or healthcare facility that fails to obtain the required CON Approval for a project. The civil penalty can be up to \$1,000 per day for each day a person or healthcare facility conducts any activities that required prior approval from OHCA.

21. Repeal of Sections 19a-643-1 through 19a-643-110 of the Regulations of Connecticut State Agencies:

Authorizes the repeal of all the previous CON regulations.

S&G COMMENT: There are certain subject areas that are in the existing regulations that are not covered by the new CON Statutes or Proposed Regulations. One such example is the processes and procedures applicable to CON hearings.

22. Repeal of Section 19a-643-205 of the Regulations of Connecticut State Agencies:

Repeals section 19a-643-205, which requires acute care general or children's hospitals to submit to OHCA by March 31st of each year the hospital operating budget approved by the hospital's governing body for the fiscal year that commenced on October 1st, or July 1st for John Dempsey Hospital of the University of Connecticut Health Center, of the previous calendar year.

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