



Recommendations for Certificate of Need Reform

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Executive Summary

The health care industry has been evolving over time and recent developments in research and technology have shifted both the patient's and the physician's expectations of how and where health care is delivered. Connecticut has relied on a complex Certificate of Need (CON) process to respond to these market changes and through the years the Office of Health Care Access (OHCA) has attempted to streamline and improve the CON process through legislative changes to the statutes governing CON.

This report will provide an overview of the current CON process and make recommendations to reform CON pursuant to Section 2 of Public Act No. 09-3 of the 2009 Special Session of the Connecticut General Assembly. In summary, this report recommends the following:

1. Simplify the CON procedural requirements.
2. Focus CON oversight on "safety net" services and areas of potential over-utilization.
3. Develop CON criteria and standards that will address the financial stability of the health care delivery system and improvement to the quality of patient care.

The goal of the reform presented in this report is to recommend different criteria that encourage the development of a patient-centered delivery system that will strengthen quality health care services and an integrated system approach. This re-alignment will enable OHCA through the CON process, to consider how a specific proposal will strengthen the financial stability of the entire system and how it will preserve access to safety net services.

This report addresses the existing practices and processes that need to be reformed in order to effectively streamline the CON process for the providers and for OHCA. Many bureaucratic processes have been adopted over the years that no longer add value to the outcome. Reform recommendations shift responsibility from OHCA and place it to the applicant (party submitting the CON application). Currently, OHCA expends more energy focusing on the CON procedural requirements than to the actual oversight of the industry. The development of a Statewide Health Care Facilities and Services Plan will provide guidance to the providers of health care services as they contemplate establishing new services or acquiring new technology into the state. It will encourage proactive planning by state government and ensure a financially strong and sustainable health care system in Connecticut.

Current Certificate of Need Process

An approved Certificate of Need is permission from the state for a health care provider or facility to undertake certain services or capital related projects. The Certificate of Need (CON) process in Connecticut commenced 36 years ago as a result of federal efforts in the 1970's in order to contain health care costs. The process was designed as a tool to reduce unnecessary capital expenditures and avoid duplication of services.

Thirty-six of the 50 states have some form of CON regulation and it varies as to the specific requirements and processes. There is no statistical evidence that relates to the effectiveness or cost containment outcomes as a result of CON. It is believed that CON does "control" system growth and over-utilization of profitable services merely by its presence in a state when compared to a non-CON state. For example, Connecticut has not experienced the out-cropping of free-standing services (i.e., single specialty hospitals) as in other states; however, it also cannot be determined that the existing CON regulation has contained health care costs.

On average, 60 CON applications are reviewed and brought to final decision annually with approximately one-third going to hearing. Throughout the years, the statutes have been modified to "exempt" or "waive" specific providers or services from the CON application process. Although this has reduced the number of "full-blown" CON applications, it has created a subset of different forms and processes. In the past year, OHCA issued approximately 30 "Waivers" and 40 "Exemptions"; with an additional 80 "Determinations" as to whether or not a CON was required. Although these legislative remedies have proven to be an excellent short-term fix – an inclusive approach to the process needs to be considered.

The Actual Process:

The three main components of the CON process are the "Letter of Intent"; the CON Application; and the final decision. The timeframes and requirements to each component are outlined in statutes and regulations, a brief review is provided below.

Letter of Intent ("LOI"): applicants must submit specific information for OHCA to consider that an LOI has been filed; OHCA must publish in a local area newspaper the notice of the LOI; OHCA sends the application form; the applicant must wait 60 days during this phase prior to submitting their application.

CON Application: Once the 60-day LOI phase is completed, the applicant has an additional 60 days to submit the application form; once received, OHCA has 10 days to review and send additional questions if necessary; the applicant has an unspecified amount of time to respond to OHCA questions; once OHCA receives the additional information, OHCA has 10 days to review and determine if the application is considered "complete".

Final Decision: OHCA has 90 days to make a final decision once an application is considered complete.

Discussion of CON Reform

The majority of health care services are provided in the outpatient, non-hospital setting yet the majority of current CON regulation focuses on the care provided by hospitals. As the CON statutes have been altered to respond to these changes, the underlining governing criteria has not changed. In other states there has been introduction of criteria and standards that indicate how the state will be reviewing applications for “need” of proposals for imaging equipment, linear accelerators, cardiac services and surgery centers. Such standards enable a more predictive process for the providers and allow the state to become part of a planning process.

The goal of the Certificate of Need reform presented in this report is two-fold: (1) to improve the actual process; and (2) to recommend different criteria that will support and strengthen the quality of health care services and an integrated system approach. This re-alignment will enable OHCA through the CON process, to consider how a specific proposal will strengthen the financial stability of the entire system and how it will preserve access to safety net services. Hospitals remain some of the largest providers of “safety net” health care services to those who are uninsured, underinsured and those covered by government-sponsored programs. The proposed reform to the CON process will allow state government to ensure that citizens have reasonable access to necessary services and to ensure that such access is reliable and sustainable. The services specifically targeted are hospital inpatient and outpatient behavioral health services, the hospital outpatient primary care and specialty care clinics, and emergency department services.

To better balance keeping Connecticut’s health care safety net services intact and ensuring a financially stable health care system this proposal has re-considered the elimination of CONs for hospital-owned imaging equipment and other inpatient and outpatient services. The Board of Directors of each hospital has a fiduciary responsibility to provide quality health care services and ensure they remain fiscally prudent to continue providing charity care and community benefits. Currently, hospitals must file CONs for nearly all large capital expenditures which results in a redundant review since the hospitals perform a thorough analysis to ensure financing. Although recent laws have been passed to lift some of the capital expenditures requirements, this proposal eliminates these projects from CON review.

The areas of concern for potential over-utilization are directed at outpatient imaging and outpatient surgical facilities. Currently these projects require CON authorization and no changes are considered in this report. These would be two health care services that would benefit from inclusion in the Statewide Facilities & Services Plan; however, OHCA does not collect any utilization data at this time. Many states have developed planning criteria and standards for such services and this would be encouraged in the future for Connecticut.

Recommendations

The underlying fundamentals of CON remain the same, which is to reduce duplication and control over-utilization; however, these recommendations will simplify the procedural requirements and change the CON criteria used to analyze the benefit of the application to the system as a whole.

1. **Propose significant legislative changes to improve to the CON procedural requirements, which include streamlining the application process, shifting the accountability to the applicant and removing unnecessary processes.**
2. **Propose legislative changes to when CON authorization is required to the following:**
 - Establish new health care facility;
 - Transfer of ownership of a health care facility;
 - Establish a new or expansion of an Ambulatory Surgery Center;
 - Additional DPH licensed beds;
 - Establish Freestanding Emergency Dept. or terminate an Emergency Dept.;
 - Establish, expand or terminate hospital inpatient or outpatient behavioral health services or outpatient clinics;
 - Establish inpatient or outpatient cardiac services;
 - Acquisition of imaging equipment by providers other than hospitals; and
 - Acquisition of non-hospital based linear accelerators.
3. **Eliminate the existing “Waiver” and “Exemption” administrative processes and propose streamlined legislative changes.**
4. **Adopt a more narrow focused definition of a health care facility to include hospitals licensed by the Department of Public Health under sections 19a-490 to 19a-503, inclusive; specialty hospitals; freestanding emergency departments; and outpatient surgery facilities as defined by section 19a-493b.**
5. **Propose legislative changes to the CON review criteria to include the following:**
 - Demonstrate a clear community need for all citizens;
 - Consistent with the Statewide Facilities & Services Plan;
 - Demonstrate how it will add to the overall system’s financial strength;
 - Demonstrate improvement to both quality and safety (this includes infrastructure development such as, entity collaboration, IT interoperability, continuum of care for patients and benefits reimbursement structure);
 - Provisions of services offered to Medicaid patients and medically indigent; and
 - Demonstrate that it will not result in unnecessary duplication.
6. **Proceed with the development of an “Advisory Committee” to assist OHCA with determining guidelines and standards to the CON application process and incorporate them in the State Health Care Facilities & Services Plan.**

Impact of Recommendations

Impact to number of applications:

Although it is difficult to project how many CON applications would be proposed in a given year or the nature of such proposals, it can be estimated that CON applications will be reduced by 50%. Therefore, the approximately 60 each year, would be reduced to 25 to 30 annually. In addition to CON applications, the number of “Waivers” and “Exemptions” should be reduced to very few if any at all. It is also anticipated to reduce the number of “Determinations” from approximately 80 to 50.

Fiscal Impact:

On average, CON applications generate approximately \$250,000 in revenue each year – this is mostly a result of large capital expenditure projects (i.e., hospital master facility plans). This proposal eliminates these particular projects from CON review and therefore anticipates CON revenue will be closer to approximately \$15,000.

There will be a minor savings in expenses related to advertising the Public Notices of the Letters of Intent by approximately \$10,000

Efficiencies:

These recommendations make sweeping changes to work flow processes. Reducing the number of CON Determination letters, CON Exemptions letters, CON Waiver letters, and reducing the overall number of CON applications will enable OHCA to re-allocate resources to the development of the State Health Care Facilities & Services Plan. Although there will be fewer facilities seeking CON authorization, OHCA will continue its oversight of the health care delivery system through planning tactics such as the utilization study and establishing an inventory of services pursuant to 19a-634.

Special thanks go to the entire staff at OHCA who spent numerous hours researching other states and offering their feedback on CON reform.