My name is Jennifer Cox and I am a healthcare attorney at the firm of Cox & Osowiecki, LLC in Hartford. I appreciate the opportunity to testify on behalf of the Connecticut Hospital Association (CHA) concerning HB 5447, An Act Concerning The Certificate Of Need Process.

Connecticut's current Certificate of Need (CON) system, like every regulatory scheme developed over decades, is not elegantly drafted, has a "patchwork" feel and, in places, could use some modernizing housekeeping changes to make it easier to read and easier to use. CHA appreciates the desire to streamline and update the CON statutes, but has serious concerns that the bill, as drafted, constitutes a major shift in power from the legislature to an agency, does little to clarify the rights and obligations of healthcare providers, and creates many unknowns that will cause confusion.

The bill has two major structural flaws and many confusing passages and terms. The first structural flaw is that it shifts policy making powers that must remain with the legislature into the hands of an agency, the Office of Health Care Access (OHCA). The second is that it takes a snapshot in time of how the CON process works today and attempts to cement that process for all time, creating a gap in the oversight of future developments in healthcare services.

The first structural concern is the massive shift in power from the legislature to OHCA. While CHA appreciates the desire to streamline some of OHCA's operational processes, reducing red tape could be achieved without wholesale transfer and delegation of powers from the legislature to OHCA. Examples of this extensive delegation of powers are found in Section 6 of the bill, which grants the agency extraordinary powers to make discretionary determinations of the criteria for CON approval, and in Section 10, which requires entities that are not subject to CON – either now or in the future – to make filings with OHCA.

The criteria to be used in reviewing CONs, and the entities subject to the CON process and agency oversight, are all policy decisions. Policy decisions need to remain legislative decisions and should not be made discretionary decisions of any agency.

The bill relies too heavily on use of the state-wide facilities plan to fill in the gaps that would be created in the new CON system, including allowing the state-wide facilities plan to dictate CON criteria without legislative input and without following the regulatory rule-making process. Currently, the state health plan, required under section 19a-7, is one factor OHCA must consider when assessing CON applications. The bill seeks to change this process to instead have the state-wide facilities plan, required under section 19a-634, become a method for setting CON criteria, with no other governmental
vetting or review. The state-wide facilities plan is designed to be a high-level blueprint through which OHCA is able to utilize its expertise to provide a "big picture" view of healthcare needs and resources in Connecticut. The bill would shift that purpose from a blueprint that encourages facilities to meet the needs of patients in long-term planning to a method for dictating what criteria should be used to decide CON. Setting CON criteria should be left to the legislature, with refinement through the regulatory rule-making process.

Additionally, many of the criteria that would be used to review CON applications are vague and lack sufficient definitions. This places tremendous discretionary power in OHCA's hands, and essentially shifts the criteria setting process and reach of CON, both traditional legislative functions, to OHCA. Even if that shift in power could survive legal challenge, which is questionable, it will cause substantial confusion. The result would replace a system that all involved understand, with a system that relies heavily on an agency's subjective decisions.

The second structural concern is that the bill relies on a snapshot in time of "right now" to set long-term CON policy, freezing in place the current trends in CON decisions for the future. That is not sufficiently flexible to respond to the healthcare market or breakthroughs in medicine. For example, a CON will continue to be needed to establish cardiac services in any location and behavioral health services at hospitals, but the CON process will no longer provide oversight of other types of care services, or developing services, in non-cardiac areas such as oncology, orthopedics, and neurology.

While retaining CON control over cardiac services accurately reflects the current landscape, it does not make sense to ignore other areas of medicine or future medical developments. Deregulating new or expanded non-cardiac services will place existing services in jeopardy by suddenly introducing competitors and other market forces that were not contemplated when the services were undertaken.

We know that medical breakthroughs that will save lives and improve quality of life are being discovered in countless labs and through ongoing research. Five or ten years from now there could be a breakthrough resulting in a simple-to-perform procedure that deploys existing technology, for example, to clean plaque from the brain before it causes a stroke. If this hypothetical procedure can be performed with little or no anesthesia, and is an interventional therapy (i.e. a guide wire is used to access the brain or spinal cord), it would be exempt from the new CON process, even though a similar procedure for cardiac services would continue to be governed by CON. The only real difference in the two scenarios is that one has already been invented, and one is tomorrow's innovation. It has been 35 years since the first angioplasty of a conscious patient, and we are still debating, for good reasons, which facilities should have a CON to perform these services. Cutting edge medical innovations and developments can be discovered and invented in bursts, practically overnight, but then follow very long timelines while being introduced in facilities on a wider basis. We do not yet know what they are, or how long they will take to reach the field, but the CON system needs to be flexible enough to allow for reasonable planning and cost containment. The bill fails to account for such developing and yet-to-be invented services.

In addition to these two structural flaws, the bill contains numerous undefined terms, vague passages, and significant curtailment of due process. The bill's limitations on due process rights include eliminating hearings when requested by providers or the public, and holding them if, and only if, OHCA so desires. This is a major change to current practice that might create efficiency, but at the cost of removing any forum for providers, advocates, interested persons or concerned public citizens to voice their thoughts and provide valuable insight to the ever changing landscape of medical care. The practical effects of this bill will be years of legislative debates and protracted litigation to define terms
and test the constitutionality of the shift in policy-making powers from the legislature to OHCA. The bill's vagueness and missing due process measures will be problematic, and the likelihood of mass confusion will cause significant dollars to shift from treating patients to paying lawyers and consultants to learn a whole new process.

If changes to the CON system are needed to improve efficiency, the entire provider community eagerly awaits the opportunity to sit down and discuss how to streamline the process without creating confusion, adding administrative costs, or delaying innovation. Businesses, including healthcare providers, need clarity and predictability to do their work. This bill falls short of providing that necessary framework.

Thank you for your consideration of our position.

For additional information, contact CHA Government Relations at (203) 294-7310.