

SIGNIFICANT CHANGES TO CON LAWS PROPOSED

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The Health Care Group at Murtha Cullina is pleased to provide clients and friends with information about topics of interest in the Health Care area.

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The size, shape and tilt of the CON playing field is changing again. A bill has been introduced proposing sweeping changes to the existing Certificate of Need laws. The changes, in Raised Bill No. 5447 (the "Proposed Bill"), significantly change the CON landscape and propose penalties – including loss of the provider's license – for failure to comply.

A public hearing was held on the Proposed Bill on March 12. Deputy Commissioner Vogel addressed the issue of imaging CONs but did not specifically deal with the implications raised by the current language of the Proposed Bill. She did suggest that the time was right for the imaging industry to work closely with OHCA to develop a set of regulations that would address imaging issues in the future. More on this below.

The highlights of the proposed changes are:

- OHCA will be charged with establishing and maintaining an inventory of all health care facilities, providers and services in the state, including health care facilities and providers that are exempt from CON requirements.
- OHCA will be charged with promoting the provision of quality health care in a manner that ensures access for all state residents so as to avoid duplication of health services and improve the availability and financial stability of health care services throughout the state.
- In a dramatic change, the Proposed Bill as currently written will extend the CON requirement to all imaging equipment, but hospitals will be exempt from obtaining a CON for imaging equipment. Everyone else, to include persons, physicians and providers, would have to obtain a CON not only for CTs, MRIs, and positron emission tomography scanners, but for any imaging equipment. At the public hearing, however, Deputy Commissioner Vogel testified that OHCA was primarily concerned with MRI, CT and PET/CT and did not comment on the expansive language of the Proposed Bill. Given her testimony, this seems unlikely to stand as is, but if it does, the ramifications would be profound.
- Replacing existing imaging equipment will be easier. The \$3 million threshold will be dropped. Under the Proposed Bill, even if the imaging equipment originally did not require a CON, you will not have to obtain a CON to replace it, but you will have to notify OHCA of the date of the replacement and how the old equipment was disposed of.
- If a health care facility proposes to relocate, it must demonstrate to OHCA that the population served and payer mix will not change as a result of the move. If it cannot prove this, then it must apply for a CON.
- There is a list of 12 things included and 20 things exempted from the CON process.
- The criteria for awarding a CON have been expanded and made more specific.
- Penalties. If someone fails to comply with the CON laws or the conditions set forth in a CON Order, OHCA may recommend to the Department of Public Health that civil monetary penalties be imposed or that the entity's license be

suspended or revoked. Monetary penalties range from \$100 to \$500 per day for each violation.

Criteria for Need Expanding

The list of criteria to be considered by OHCA in examining need has expanded and been made more specific. The Proposed Bill adds three new concepts that OHCA will take into consideration:

1. Whether the applicant has satisfactorily demonstrated how the proposal will add to the financial strength of the health care system in Connecticut;
2. Whether the applicant has satisfactorily demonstrated how the proposal will improve quality and safety, including, but not limited to, infrastructure development such as entity collaboration, information technology interoperability and benefits reimbursement structure; and,
3. The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

Further, the Proposed Bill authorizes OHCA to revise or add additional criteria as it deems necessary.

These additional factors will introduce an entirely new dynamic into CON applications. It is hard to know yet just how OHCA will apply these need criteria, but it appears that proving need through a straightforward demographics vs. available resources analysis will no longer be sufficient. These new criteria may also prove to be an obstacle for some physicians.

List of Actions that will Require a CON

The Proposed Bill lists twelve specific things that will require a CON:

1. The establishment of a new health care facility.
2. Transfer of ownership of a health care facility.
3. Establishment of a free-standing emergency department.
4. Establishment, expansion or termination of a short-term acute care hospital or children's hospital of inpatient/outpatient behavioral health services, primary care clinics or specialty clinics.
5. Termination of an emergency department by a short-term acute care general hospital.
6. Establishment of an outpatient surgical facility.
7. Increase in the number of operating rooms in an outpatient surgical facility.
8. Establishment of cardiac services, including

inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery.

9. Acquisition of imaging equipment. (See below for more detail.)
10. Acquisition of nonhospital based linear accelerators.
11. Increase in licensed bed capacity of a health care facility.
12. Acquisition of equipment utilizing technology that has not previously been utilized in Connecticut.

New Rules on Acquiring Imaging Equipment

One of the most significant proposed changes is to the rules on acquiring imaging equipment. OHCA has broadened its jurisdiction in this area steadily over the years. At present, a CON is needed if a hospital, physician or other provider wants to acquire a CT scanner, PET scanner, PET/CT scanner, MRI, a linear accelerator or other similar technology that is new to the state.

The Proposed Bill takes this another step. A rather *large* step, perhaps even farther than OHCA wants to go. The bill says that a CON will be needed for:

The acquisition of imaging equipment, including computed tomography scanners, magnetic resonance imaging scanners, positron emission scanners and positron emission tomography-computed tomography scanners, by any person, physician or provider other than a short-term acute care general hospital or children's hospital.

(Emphasis added.) If this language passes as it is now, it will significantly impact who can reasonably acquire imaging equipment in the State. First, on its face it applies to all imaging equipment, not just the high-tech, expensive stuff. This means that if a podiatrist wants to purchase a small X-ray machine for use in his office, he'll need a CON. An OBGYN who wants an ultrasound unit will need a CON. Under this language, all imaging equipment, regardless of type or cost, would fall within OHCA's jurisdiction. Again, at this point it is hard to know if this is the intended result or imprecise drafting.

Secondly, the proposal exempts hospitals from this requirement. This is a substantial change, giving hospitals a competitive edge over competing physician-owned imaging centers.

Further, any replacement of imaging equipment—including imaging equipment that was not acquired through the CON process—can be done by simply giving

OHCA notice. No CON is required. The notice must specify the date on which the equipment is replaced and how the old equipment was disposed of. Again, this appears to apply to all imaging equipment.

In light of Deputy Commissioner Vogel's testimony, this section of the bill will probably be changed. Her testimony stressed OHCA's concerns with MRI, CT and PET/CT equipment, and stressed the need for new regulations to enable a "meaningful planning approach" to the growth of outpatient imaging in the state. One observer has suggested that the Proposed Bill is really intended to persuade the industry to participate in the creation of a new regulatory scheme. It is too early to tell what will happen with the proposed exemption of hospitals from these requirements.

Procedural Changes Relating to Notification

Other changes involve the procedure for applications.

- There would be a flat application fee of \$500.
- There will be no more Letters of Intent. At least twenty days prior to filing the CON application with OHCA, the applicant must publish in a newspaper the fact that it intends to file the application. The notice must be published for at least three consecutive days. OHCA will not accept the CON filing without proof of the published notice.
- OHCA would have 30 days in which to review CON applications. For the first time, there would be a specified limit (60 days) on how long the Applicant would have to reply to requests for information.
- Requests for a public hearing must be made within 30 days after the CON application is deemed complete (i.e., posted on OHCA's website). OHCA will have more discretion in whether to hold a hearing.
- The current waiver and exemption process would be dropped.

Relocating a Facility

Any health care facility seeking to relocate must submit a letter to OHCA demonstrating that the population to be served and the payor mix will not change. If OHCA is not convinced, it may require the health care facility to apply for a CON.

Termination of Services

A health care facility that proposes to terminate a service obtained through a CON must apply to modify its CON at least 60 days before the termination. OHCA can hold public hearings and request additional information.

A health care facility terminating all services offered by the facility must notify OHCA at least 60 days prior to the termination and surrender its CON.

A health care facility terminating a facility or service for which a CON was not obtained must notify OHCA at least 60 days prior to the termination.

Penalties

No new statute is complete without new penalties. The Proposed Bill allows the Department of Public Health to suspend or revoke the license of any person, provider or health care facility or to assess a civil monetary penalty if: (i) the entity fails to obtain a CON when required; (ii) fails to comply with any conditions in the CON Order; or (iii) fails to file any information requested by OHCA.

The penalty provisions allow for a hearing. Monetary penalties imposed will not be less than \$100 nor more than \$500 for each violation, and in the event of a continuing violation, each day of continuance is deemed to be a new violation.

If the provider does not pay the civil penalty, that is grounds for suspension or revocation of that provider's license. Further, OHCA may decline to issue a CON to any such person until the payment of the civil penalty has been made.

Exemptions from CON Process

The Proposed Bill collects all of the exemptions from the OHCA CON process and puts them in one place. They include:

1. Health care facilities owned and operated by the federal government.
2. The establishment of offices for a licensed private practitioner, unless imaging equipment is going to be acquired.
3. Health care facility operated by a religious group that treats patients only through spiritual means through prayer for healing.
4. Residential care homes, nursing homes and rest homes.
5. An assisted living services agency as defined in 19a-490.
6. Home health agencies as defined in 19a-490.
7. Hospice services as defined in 19a-122b.
8. Outpatient rehabilitation facilities.
9. Outpatient chronic dialysis services.
10. Transplant services.
11. Free clinics as defined in 19a-630.
12. School-based health centers, community health centers as defined in 19a-490a, and federally qualified health centers.

13. Mental health and substance abuse providers not affiliated with a health care facility.
14. Health care facilities operated by a nonprofit educational institution exclusively for students, faculty and staff of the institution, and their dependents.
15. Outpatient clinics or programs operated exclusively by or contracted to be operated by a municipality, municipal agency, municipal board of education or health district as set forth in 19a-241.
16. Replacement of existing imaging equipment. (See discussion, above.)
17. Acquisition of cone-beam dental imaging equipment by a licensed dentist.
18. Termination of inpatient or outpatient services offered by a hospital, except as required by the new Section a of 19a-639e.
19. The partial or total elimination of services by an outpatient surgical facility, except as provided by 19a-639e, as amended.
20. Termination of services for which the DPH has requested the facility to relinquish its license.

No doubt there will be changes to the Proposed Bill before final passage, and there is a fair chance it will not even come out of Committee this year, but it is clear that substantial changes to the CON laws are coming.

Power Breakfast:

Controlling Costs and Enhancing Your Green Profile

They say breakfast is the most important meal of the day. This one certainly will be! We invite you to breakfast with energy industry professionals who will provide the latest information on opportunities for project funding and cost savings, as well as insights into the trends and changes in Connecticut's deregulated energy environment.

Date: Tuesday, April 6, 8:00 a.m. to 10:00 a.m.

Place: Murtha Cullina LLP
CityPlace I, 185 Asylum Street, Hartford

If you would like more information, or to reserve your place, please contact Jackie Rowe at 860.240.6140 or jrowe@murthalaw.com.

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