Conn. Certificate-Of-Need Law Will Bring Greater Efficiency

By **Conor Duffy, Michael Lisitano and Erin Howard** (July 6, 2023)

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On June 27, Connecticut Gov. Ned Lamont signed into law Public Act 23-171, titled "An Act Protecting Patients and Prohibiting Unnecessary Health Care Costs," a law which makes wide-ranging changes to Connecticut's health care laws.

The act was the product of collaboration between the governor, the state Legislature, the Connecticut Hospital Association and other stakeholders, and accordingly is reflective of current health care priorities for the state.

Among the act's notable changes are a series of updates to Connecticut's certificate-of-need, or CON, laws that affect applicants and the Office of Health Strategy, the state entity responsible for enforcing the CON laws and issuing CON decisions.

Among other updates, the act implements changes to (1) expand current CON public notice requirements, (2) impose new process deadlines on the OHS, (3) newly allow the OHS to benefit from expert consultations when considering certain applications, (4) expand OHS authority to investigate and impose penalties for noncompliance with CON requirements, and (5) clarify certain long-standing CON applicability requirements.

In sum, the changes appear intended to align with current efforts within the state to streamline the potentially lengthy CON process, and impose more exacting deadlines on the OHS in certain circumstances, while also expanding the OHS' ability to investigate and penalize noncompliance with CON laws and CON agreed settlements, and to address complicated health care issues raised in CONs.

All the following changes will take effect Oct. 1.

New OHS Deadlines

The act newly establishes a 30-day deadline for the OHS to respond to CON determination requests, and implements a parallel 30-day deadline for the OHS to respond to facility relocation determination requests.

This change is notable because the CON laws have long allowed parties to submit a request for a determination from the OHS of whether a CON is required for a particular project. However, the OHS has not previously had a specific deadline for responding to determination requests, and consequently the response times for determination requests could vary significantly.

The act newly requires the OHS to make reasonable efforts to limit so-called CON completeness requests to two, and to cease making such requests no later than six months after receiving a CON application.

This appears to be a codification of current practice, under which parties to particularly large or challenging CONs can expect two rounds of completeness questions following submission of a CON application, with the OHS given 30 days to review, and the applicant then given 60 days to respond, which yields up to a six-month process for two such rounds.

The OHS is now required to notify CON applicants within five days of deeming an application complete, in addition to being required to post its deemed complete letter on the OHS CON portal.

This is an interesting change because under current practice, the OHS staff notifies the applicant immediately, usually via email, when an application has been deemed complete by sending a copy of the deemed complete letter.

The act clarifies that the OHS is required to issue a decision on a CON where no public hearing is held within 90 days of deeming the application complete.

This was already the statutory requirement and appears to be a clarifying change for the avoidance of doubt; if a hearing is held, the deadline becomes 60 days after the closure of the hearing record.

New CON Public Notice Requirements

The act expands the current requirement for CON applicants to publish notice of forthcoming applications in a local newspaper to newly require applicants to:

- Publish notice on the applicant's website at least 20 days prior to filing of the application, and the notice must remain on the website for the pendency of the application;

- Request publication of the notice (1) in two locations within the affected community, such as a town hall or library, and (2) on the website of the municipal or local health department, and the postings must remain until a decision on the CON application is rendered, provided that the OHS will not invalidate an applicant's notice if it is changed or removed outside of applicant's control; and

- Provide the notice to the OHS for posting on its website.

The act implements similar notice requirements for notices of CON public hearings, newly requiring applicants to (1) post OHS hearing notices on the applicant's website in a clear, conspicuous and easily accessible location, and (2) request publication of the hearing notice in two locations with the community such as a town hall or library, and on the website of the municipal or local health department.

These changes appear intended to modernize the provision of notice of CON applications and proceedings. It will be interesting to see how these new requirements are enforced by the OHS, which has traditionally required the inclusion of evidence of the newspaper notice

in the CON application bundle submitted to the OHS, and has posted its own notice of public hearings online and elsewhere.

Expanded OHS Oversight and Enforcement Authorities

The act newly permits the OHS — for applications submitted on and after Oct. 1 — to retain an independent consultant with subject matter expertise to review CON applications that cannot reasonably be conducted by the OHS without expert consultation. The applicant will be responsible for paying for such consultant, which must be limited to a reasonable amount per application.

This is a significant change in the CON laws which has the potential to alter how CONs — particularly on contentious matters — are currently reviewed and adjudicated.

It will be interesting to see whether the availability of a health care consultant at the applicant's cost will lead the OHS to commonly use such consultants, and consequently whether a precedent will be established requiring use of a consultant on certain types of CONs.

It will also be interesting to see what a reasonable amount of compensation for such a consultant will mean in practice, and how that affects this new option for the OHS and potential cost for CON applicants, not all of whom are large entities with significant resources.

The act lowers the threshold at which, and expands the circumstances in which, the OHS may impose civil monetary penalties under the CON laws, providing that a person or facility that negligently — formerly this standard was "willfully" — fails to seek CON approval when required shall be subject to civil penalties of up to $1,000 per day, and newly providing that such penalty shall also be available for the OHS to impose on any person or facility that negligently fails to comply with an agreed settlement.

This change lowers the legal standard for the OHS to seek to penalize violations of CON laws, and expressly expands the OHS authority to impose such penalties for violations of CON agreed settlements.

The change to the legal standard appears intended to address, in part, recent unresolved investigatory efforts of the OHS that have been challenged by counterparties on the basis that the alleged violations were not done willfully. The change to expressly reference agreed settlements comes as more CON matters are resolved via agreed settlements.

The act also provides that in response to a proposed imposition of a civil penalty, the alleged violator may opt to comply with the enumerated conditions of the agreed settlement within 15 business days as an alternative to requesting (1) a hearing or (2) an extension to file required data during such time period; however, it is unclear based on the text whether such compliance will be sufficient to avoid imposition of the proposed civil penalty.

The act also newly permits the OHS to issue notices when the OHS has a reasonable belief of a CON law violation, which notice includes a reference to the basis of the alleged violations, a short and plain statement of the claims and description of the alleged violations, and a statement allowing the recipient to request a hearing within 10 business days.

If a hearing is requested, it will be conducted consistent with other CON public hearings

under the Connecticut Administrative Procedure Act, with a preponderance of evidence standard for finding CON violations, and with the OHS authorized to issue a cease-and-desist order, enforceable by the Connecticut attorney general, upon a finding of a violation or in the event an alleged violator does not request a hearing.

These changes similarly appear to be intended to memorialize current processes and expressly permit the OHS to order CON violators to cease-and-desist from carrying on activities in violation of CON laws.

Clarifying When CON Applications Are Required

The act modifies the CON law concerning replacement of imaging equipment to specify that a CON is not required when replacing CT and MRI scanners that were previously acquired through a CON, including when the replacement has dual modalities or functionalities as long as the applicant already offers similar imaging services, and to no longer merely reference "imaging equipment";

The act also adds a carveout to the current CON requirement for acquisition of a nonhospital-based linear accelerator, stating that a CON is not required when replacing nonhospital-based linear accelerators that were previously acquired through a CON.

These changes appear to be clarifying to specify the OHS' intention of what is covered by a CON for replacement of imaging equipment.

Takeaways

As noted above, the act includes updates to the CON laws likely to be viewed favorably by health care organizations and other entities subject to CON laws in Connecticut, as well as updates likely to be viewed favorably by the OHS as it seeks to more efficiently oversee and carry out its CON duties under law.

In particular, the changes to OHS' enforcement authorities and the lowering of the legal standard for imposing penalties appear to give the OHS stronger ground to stand on to enforce the CON laws and to punish violators, and may give the OHS more leverage over agreed settlement negotiations and investigations.

Health care organizations would be well advised to closely study the text of the changes, and any corresponding guidance issued by the OHS, to assess their potential effects.

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