

HEALTH LAW

Expert Analysis

New York Revises Certificate-of-Need Review Requirements

The New York State Department of Health recently proposed revisions to the Certificate-of-Need (CON) regulations that are intended to simplify the CON process for so-called “construction” applications. This column summarizes these changes.

Background

For decades, New York has had one of the most pervasively regulated health care delivery systems of any state. When New York became the first state to adopt a CON process in 1964, it was expected to enable the Health Department to engage in state-wide and regional planning of the state’s health care infrastructure. The Health Department’s website summarizes the purposes of the CON process:

New York’s Certificate of Need (CON) process governs establishment, construction, renovation and major medical equipment acquisitions of health care facilities, such as hospitals, nursing homes, home care agencies, and diagnostic and treatment centers.

The objectives of the CON process are to promote delivery of high quality health care and ensure that services are aligned with community need. CON provides the Department of Health oversight in limiting investment in duplicate beds, services and medical equipment which, in turn, limits associated health care costs.¹

By
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New York’s CON process applies to the establishment, closure, merger, or change of ownership of licensed facilities such as hospitals, nursing homes, ambulatory surgery centers, diagnostic and treatment centers, home health agencies and other providers.² The CON process also applies to construction, renovation, expansion, consolidation, or reduction of facilities, programs and services, and the acquisition of major medical equipment by those providers.³ However, over the years various studies have shown that the CON process has not contained health care costs and may actually have contributed to increased costs.

Both the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice have repeatedly criticized state CON processes as being harmful to competition and a factor in escalating health care costs.⁴ Various federal laws enacted in the 1970s that required states to have a review process and that funded local health planning agencies were subsequently repealed.

Although many states that had statutory CON requirements have repealed them or let them sunset, about 36 states still have some form of CON process. New York has never seriously considered doing away with its CON process. However, as the process became more cumbersome, as

approvals took longer, and as the costs to hospitals and other providers increased, the Health Department has undertaken periodic efforts to modify the CON process.

Construction

New York Public Health Law (PHL) Section 2802 requires CON approval for a variety of so-called “construction” projects. Construction is defined in PHL §2801(5):

“Construction” means the erection, building or substantial acquisition, alteration, reconstruction, improvement, extension or modification of a hospital, including its equipment; the inspection and supervision thereof; and the studies, surveys, designs, plans, working drawings, specifications, procedures and other actions necessary thereto.

The Department of Health is modifying and streamlining the CON process, eliminating CON review altogether for some types of projects.

The general regulations implementing the CON review process for construction applications are found at 10 NYCRR §710.1. For many years, CONs were necessary for significant additions to or renovations of health care facilities, the purchase of major medical equipment such as an MRI or linear accelerator, and many other improvements and initiatives by hospitals and health care facilities. They required the filing of a lengthy and complicated CON application, review by Health Department staff, and

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then approval by the former State Hospital Review and Planning Council, which in 2010 was merged with the Public Health Council into what is now the Public Health and Health Planning Council (PHHPC).⁵

Revisions

As the Regulatory Impact Statement of the Department of Health's proposed regulations explains, construction projects subject to Health Department approval have to undergo one of three levels of review. "Full CON Review" is required for projects of generally greater complexity and higher cost, such as a top-to-bottom renovation of a large hospital. These require the review and approval of the PHHPC. "Administrative Review," while it requires the submission of a CON application, involves Health Department review of financial feasibility and public need, but does not require PHHPC approval. "Limited Review" is for projects not subject to financial feasibility or public need review. These require the submission of a narrative describing the construction project, and where needed, architecture/engineering drawings or certification, and are reviewed and approved by Health Department staff.

The Health Department is modifying and streamlining the CON process by moving certain categories of CON applications into Administrative Review without the need for PHHPC approval, and eliminating CON review altogether for some other types of projects.⁶

The following proposals or projects will no longer require a CON application:

- Any proposal for the correction of deficiencies cited by the Health Department, consistent with a plan of correction approved by the Health Department, provided that the construction is limited to the correction of deficiencies.

- Any proposal for the repair or maintenance of a medical facility including routine purchases and the acquisition of minor equipment undertaken in the course of the medical facility's inventory control functions. For proposals with a total cost of up to \$6 million, no written notice to the Health Department will be required.

- Any proposal to discontinue a part-time clinic site if a medical facility is already authorized to operate part-time clinics, provided applicable requirements for notice to the Health Department are complied with.

- Any proposal for the replacement of existing equipment regardless of cost with another piece of equipment (approved by the U.S. Food and Drug Administration) used for similar purposes but employing substantially equivalent current technology. Written notice to the Health Department of such replacement must include a written certification by a New York State licensed architect or engineer that the project meets applicable statutes, codes and regulations, and a plan to protect patient safety during replacement projects that implicate patient safety; and subsequent notification to the Health Department from such architect or engineer and/or a New York licensed medical physicist (in the case of radiation-producing medical equipment) that the replacement equipment as installed meets applicable statutes, rules and regulations, as well as such other close-out-documents as the Health Department may require.

Hospitals and other licensed providers are likely to welcome these modifications to the CON requirements for construction applications. The Health Department has a reduced staff and limited resources, and there is simply no need for the elaborate vetting of projects that was formerly the case.

- Any proposal for a non-clinical infrastructure project, regardless of costs, including replacement of heating, ventilating or air conditioning; replacement of fire alarm and call bell systems; addition or replacement of roofs, elevators, parking lots and garages; new dietary, solid waste or sewage disposal facilities; and upgrades of the exterior building envelope. Written notice to the Health Department of completion must include written certification by a New York-licensed architect or engineer as above.

The new regulations also change which proposals and projects are subject to Limited Review (i.e., no CON required; review and approval by the Health Department but not by the PHHPC). Formerly, a variety of projects were eligible for limited review

where the project cost did not exceed \$6 million. Under the revised regulations, projects eligible for limited review now can be submitted electronically to the Health Department, and will include:

- The acquisition, relocation, installation or modification of resident rooms in a residential health care facility (RHCF) and other spaces used by RHCF residents on a daily basis; and

- The modification or alteration of clinical space, services or equipment such as operating rooms, treatment and procedure rooms, and intensive care, cardiac care and other special care units (such as airborne infection isolation rooms and protective environment rooms), laboratories and special procedure rooms, and patient or resident rooms or other spaces used by residents of RHCFs on a daily basis.

Conclusion

Hospitals and other licensed providers are likely to welcome these modifications to the CON requirements for construction applications. The Health Department has a reduced staff and limited resources, and there is simply no need for the elaborate vetting of projects that was formerly the case.

The Affordable Care Act and New York's own extensive Medicaid reform efforts are incentivizing hospitals and other providers to do what state health planning previously tried to accomplish through law and regulation. More hospitals are consolidating, and the resulting systems are doing more of their own regional planning, phasing out unneeded inpatient beds, eliminating or reducing duplicative or unnecessary services, and effecting a more appropriate allocation of resources and equipment. These latest revisions to the CON process should facilitate these trends.

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1. <https://www.health.ny.gov/facilities/cons/>.

2. N.Y. Public Health Law (PHL) §2801-a.

3. *Id.* §2802.

4. See, e.g., Department of Justice and Federal Trade Commission, "Improving Health Care: A Dose of Competition," July 2004.

5. See, Serbaroli, "State's New Council on Health and Health Planning," *New York Law Journal*, July 27, 2010, p. 3.

6. Proposed Rule Making: Certificate of Need (CON) Requirements, *NYS Register*, Oct. 15, 2014, pp. 22-24.