

# HEALTH LAW BULLETIN

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## The New York State Department of Health Proposes Amendments to the Certificate of Need Process

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The Department of Health has recently undertaken a comprehensive review of the Certificate of Need (“CON”) process.

Public Health Law Article 28 governs the establishment and construction of health care facilities and the addition of certain health care facility services and equipment. One of its corresponding regulations, Title 10 NYCRR Part 710 establishes criteria governing the types of medical facility construction projects, including service changes and equipment acquisitions, which require review and the level of review applicable to each type of project.

The two most intensive levels of review are full review and administrative review. These types of review consider several elements: public need, financial feasibility, character and competence, architectural and engineering standards, and legal matters. Projects subject to full review are reviewed by both Department of Health (“DOH”) staff and the State Hospital Review and Planning Council (“SHRPC”). SHRPC makes a recommendation to either the Commissioner of Health or, for projects that involve the establishment or a change of ownership of a facility, to the Public Health Council (“PHC”) for a final determination. Administrative reviews require only a staff recommendation to the Commissioner for a final decision. Less costly and less complex projects may be subject to prior limited review or limited architectural review and are exempt from Council review.

In most cases, the projected cost of a project is the primary determinant of its level of review. However, certain types of CON applications are subject to full re-

view regardless of cost. For example, applications involving the establishment of an operator of a health care facility or applications involving the addition of highly complex services require SHRPC review regardless of cost.

The DOH has proposed regulatory amendments that would raise the project cost thresholds that establish the level of review, reduce the level of review for the acquisition by hospitals of certain medical equipment, combine limited architectural review and prior review into a single review category, and eliminate SHRPC review of certain project amendments.

Specifically, the proposed amendments will raise the project cost threshold for full review from \$10 million to \$15 million and the threshold for administrative review from \$3 million to \$6 million. In addition, the proposed amendments maintain the sliding threshold for administrative review of projects with a cost of up to 10 percent of operating costs, but raise the cap on projects eligible for administrative review under the sliding threshold from \$25 million to \$50 million for general hospitals. Under the proposal, facilities that are financed with publicly-backed debt would be eligible for administrative review under the sliding threshold.

The CON review process also applies to purchases of certain medical equipment. Currently, the acquisition of MRIs, CT scanners, and lithotripters are subject to administrative review. However, the DOH has determined that a rigorous CON review of these types of equipment in general hospital settings is not longer necessary, and the goals of CON review

can be accomplished by a less intensive review, except for the purchase of an MRI or CT scanner by a diagnostic and treatment center which would remain subject to administrative review. In addition, the DOH has determined that the acquisition of lithotripters should no longer be regulated by the CON process; but, the addition of lithotripsy as a service will remain subject to a limited review.

Importantly, the proposed amendments will eliminate full review of non-clinical and health information technology projects regardless of cost. Non-clinical and health information technology projects with a total cost of up to \$15 million will be subject to limited review, and such projects with a cost in excess of \$15 million will be subject to administrative review.

Finally, the proposed regulatory revisions will permit administrative review of amendments to projects that experience: a change in financing where the project is no more costly on a present value basis over the expected life of the project than 10% of approved costs or \$15 million, whichever is less, an increase in total construction costs of up to \$6 million and up to 10% or \$15 million, whichever is less, or a reduction of scope of construction which accounts for 15% or more of projected costs, if there is a corresponding reduction in construction costs, which may include consideration of fixed costs.



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