

## New York Announces Revisions to the Certificate-of-Need Process

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October 2014

The New York State Department of Health (“NYSDOH”) recently released proposed revisions to its certificate-of-need (“CON”) process.<sup>1</sup> The regulations aim to streamline the administrative process for hospitals, nursing homes, and diagnostic and treatment centers pursuing certain physical improvement projects.<sup>2</sup> The proposed changes are particularly pertinent to entities seeking Delivery System Reform Incentive Payment (“DSRIP”) Program funds. Interested parties may comment on the proposal until December 1, 2014.<sup>3</sup>

By eliminating CON review requirements altogether for some types of projects<sup>4</sup> and limiting review for others, the proposal better aligns the regulatory landscape of the health care industry with that of other industries. Hospitals will likely see their regulatory costs and project lead times substantially reduced since various types of facility and maintenance projects will no longer require CON approval.<sup>5</sup> Fewer regulatory requirements, and therefore reduced expenses, will also assist DSRIP Performing Provider Systems (“PPSs”) become fully operational more quickly. Speed will be crucial for successful PPSs, as the DSRIP application is due in December 2014, and other deliverables must be satisfied in early 2015.<sup>6</sup>

Currently, facility repair and maintenance projects that will cost less than \$6 million do not require a CON application, and those that exceed \$6 million undergo a limited

<sup>1</sup> The full text of the proposed rule is available at <http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac9558781006774852569bd00512fda/728fd7f42cc869ed85257d71004d4b08?OpenDocument> (last visited Oct. 23, 2014).

<sup>2</sup> See 10 N.Y.C.R.R. §§ 710.1(c)(4)-(5).

<sup>3</sup> The preamble to the proposed rule is available at <http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac9558781006774852569bd00512fda/728fd7f42cc869ed85257d71004d4b08?OpenDocument> (last visited Oct. 23, 2014).

<sup>4</sup> Health care entities must still notify the NYSDOH before starting some projects, and that notification must include a written certification from a licensed architect or engineer stating that the project satisfies applicable laws and regulations. 10 N.Y.C.R.R. § 710.1(c)(4)(1).

<sup>5</sup> 10 N.Y.C.R.R. § 710.1(c)(4)(i)(b).

<sup>6</sup> An overview of the DSRIP Program, including the application, is available at [https://www.health.ny.gov/health\\_care/medicaid/redesign/dsrp\\_project\\_plan\\_application\\_draft.htm](https://www.health.ny.gov/health_care/medicaid/redesign/dsrp_project_plan_application_draft.htm) (last visited Oct. 23, 2014).

review CON.<sup>7</sup> Under the proposed changes, facility repair and maintenance projects will not require a CON review regardless of their cost, and those costing less than \$6 million will not require notification either.<sup>8</sup> Similarly, the current requirements for replacing equipment would change. Currently, a health care entity looking to implement a one-to-one replacement of a piece of equipment must undergo a limited review CON for projects costing less than \$6 million, and an administrative CON review for those costing between \$6 and \$15 million.<sup>9</sup> Under the proposal, replacing a piece of equipment with new equipment that “employ[s] substantially equivalent current technology” will now be subject only to a notice requirement, regardless of cost.<sup>10</sup> Additionally, projects to repair deficiencies that have been cited by the NYSDOH will now only require notice to the department, “provided that the construction is limited to correction of the deficiencies,” regardless of cost.<sup>11</sup>

The proposal also updates the CON submission process. Entities with projects that must undergo limited review must submit requests “through the electronic application submission process” that will be posted on the NYSDOH’s website.<sup>12</sup> Once applicants have submitted the required notices to the NYSDOH, applicants will not have to wait for formal approval before beginning the specific project.<sup>13</sup>

Another noteworthy change includes the expansion of the “limited review” process for projects that still require CON approval.<sup>14</sup> Projects that will cost less than \$6 million, but do not qualify to have the CON requirement waived entirely, will undergo a limited review.<sup>15</sup> Furthermore, limited review will now also be available for projects that impact clinical space, such as modifying operating rooms and other specialty care units, or alterations to residential space, such as patient rooms that exceed maintenance level work.<sup>16</sup>

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<sup>7</sup> The Regulatory Impact Statement to the proposed rule (hereinafter “Regulatory Impact Statement”) is available at <http://w3.health.state.ny.us/dbspace/propreqs.nsf/4ac9558781006774852569bd00512fda/728fd7f42cc869ed85257d71004d4b08?OpenDocument> (last visited Oct. 27, 2014).

<sup>8</sup> 10 N.Y.C.R.R. § 710.1(c)(4)(i)(a)-(b). Health care entities must notify the NYSDOH of the project prior to commencement, with a written certification from a New York-licensed architect or engineer, where needed, stating that all statutes and regulations have been satisfied. *Id.* Non-clinical infrastructure projects must also include a “plan to protect patient safety during construction.” 10 N.Y.C.R.R. § 710.1(c)(4)(e).

<sup>9</sup> Regulatory Impact Statement, *supra* note 7.

<sup>10</sup> 10 N.Y.C.R.R. § 710.1(c)(4)(i)(d). The notification must include a written certification from a New York architect or engineer. Once the project is complete, the entity must also submit a certification by a New York architect, engineer, or physicist “that the replacement equipment as installed meets applicable statutes, codes, and regulations; and such other close-out documents as may be required by the department.” *Id.*

<sup>11</sup> 10 N.Y.C.R.R. § 710.1(c)(4)(i)(a).

<sup>12</sup> 10 N.Y.C.R.R. § 710.1(c)(5)(i)(a).

<sup>13</sup> Regulatory Impact Statement, *supra* note 7.

<sup>14</sup> See 10 N.Y.C.R.R. § 710.1(c)(5). Limited review is the least burdensome level of review, and thus the quickest way to operationalize a project that must be reviewed. The entity must submit a narrative summary of the project, including the anticipated cost. The narrative, however, is usually not “subject to financial feasibility or public need” review. Regulatory Impact Statement, *supra* note 7.

<sup>15</sup> 10 N.Y.C.R.R. § 710.1(c)(5).

<sup>16</sup> 10 N.Y.C.R.R. § 710.1(c)(5)(ii)(d). Projects in the clinical space that would qualify as maintenance work, provided that they cost less than \$6 million, would be eligible for the notice-only provision, where no other CON review is required. 10 N.Y.C.R.R. § 710.1(c)(4)(i)(b).

The proposal both alters and simplifies the regulatory burdens facing health care entities. Proper utilization of the new system will allow entities currently covered by the CON requirements to (1) more expeditiously take advantage of changes in technology and advances in equipment; (2) avoid delays in implementation of infrastructure improvements, along with cost creep that is often associated with such delays; and (3) realize quality improvements and anticipated savings more quickly.

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