

Certificate of Need Requirements

Effective date: 9/30/15

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2802 of the Public Health Law, subparagraph (j) of paragraph (3) of subdivision (c) of section 710.1 is amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

(j) [any proposal that does not relate to a change in clinical service, space or equipment or an increase in certified bed capacity, including but not limited to: information systems, exterior building envelope (*e. g.*, windows, roof, wall repairs), parking garages, dietary and solid waste and/or sewage disposal, provided that proposals with a total project cost of up to \$15 million may be reviewed under paragraph (5) of this subdivision] reserved;

Paragraph (4) of subdivision (c) of Section 710.1 is amended to read as follows:

4) Proposals not requiring an application.

(i) The following types of construction projects shall not require prior approval under this Part, regardless of cost, provided that a written notice has been submitted to the Department prior to commencement of construction, together with, where indicated in this paragraph, a written certification by a New York State licensed architect or engineer that the project meets all applicable statutes, codes and regulations; and provided that the hospital shall implement a plan to protect patient safety during construction projects that implicate patient safety, consistent with section 711.2 of this part and other applicable standards, and as otherwise required by the department:

(a) Any proposal for the correction of cited deficiencies, consistent with a plan of correction approved by the department; provided that the construction is limited to the correction of the deficiencies.

~~(i)~~b Any proposal for the repair or maintenance of a medical facility [which is not covered by paragraph (1) of this subdivision], including routine purchases and the acquisition of minor equipment undertaken in the course of a medical facility's inventory control functions, [shall not require the submission of a certificate of need application under this Part if the total project cost does not exceed \$6,000,000, and] provided that for proposals under this clause with a total cost of up to six million dollars, including separate proposals which are programmatically related, no written notice shall be required [together do not exceed \$6,000,000, and further provided that such proposal will not result in increased costs or expenses other than for lease costs, amortization, depreciation, interest, or return of or on equity]. This subparagraph shall not apply to activities requiring a limited review under Article 28 of the Public Health Law pursuant to paragraph (5) of this subdivision.

~~(ii)~~c Any proposal to discontinue a part-time clinic site of a medical facility already authorized to operate part-time clinics pursuant to this Part shall not require the submission of an application pursuant to this Part, but compliance is required with the applicable notice provisions of section 703.6 of this Title.

~~(iii)~~d Any proposal for the replacement of existing equipment, [listed in paragraphs (2) or (3) of this subdivision,] regardless of cost, with another piece of equipment used for similar purposes but employing substantially equivalent current technology which, if subject to approval by the U.S. Food and Drug Administration, has received such

approval. [when such replacement is essential for the continued operation of the facility in compliance with the requirements of this Title or the provision of necessary medical care and services and the equipment to be replaced no longer meets the generally accepted operational standards for such equipment or has exhausted at least 90 percent of the higher of its useful life reported pursuant to Part 86 of this Title or its estimated useful life according to the tables of estimated useful lives in the American Hospital Association's Estimated Useful Lives of Depreciable Hospital Assets, 2008 edition, as incorporated by reference in this clause. Copies of the foregoing publication are available from the American Hospital Association, One North Franklin, Chicago, Illinois 60606-3421, www.aha.org, and a copy is available for inspection and copying at the New York State Department of Health, Regulatory Affairs Unit, Empire State Plaza, Corning Tower, Albany, NY 12237.] The facility's written notice to the department shall[,] [30 days prior to such replacement, notify the department in writing of such proposed replacement with] include a written certification by a New York State licensed architect or engineer that the project meets the applicable statutes, codes and regulations; and a plan to protect patient safety during replacement projects that implicate patient safety, consistent with section 711.2 of this part and other applicable standards, and as otherwise required by the department [a statement of fact indicating when the equipment was purchased or otherwise acquired and that 90 percent of its useful life has been exhausted. At the end of the 30-day notice period the cost of the replacement will be eligible for reimbursement pursuant to Part 86 of this Title. The notice of the proposed replacement should be sent to the department's Division of Health Facility Planning and Division of Health Care Financing]. Upon completion of the project, the facility shall, where

applicable, submit written certification by a New York State licensed architect, engineer and/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.

(iv)e) Subject to clause (d) of subparagraph (ii) of paragraph 5 of this subdivision, any proposal for a nonclinical infrastructure project, regardless of cost, including but not limited to replacement of heating, ventilating and air conditioning, fire alarm and call bell systems or components thereof, roofs, elevators, parking lots and garages, dietary, and solid waste and/or sewage disposal and upgrades of the exterior building envelope. The facility's written notice to the department shall include a written certification by a New York State licensed architect or engineer that the project meets the applicable statutes, codes and regulations; and shall include a plan to protect patient safety during construction consistent with section 711.2 of this part and other applicable standards, and as otherwise required by the department. Upon completion of the project, the facility shall, where applicable, submit written certification by a New York State licensed architect, engineer and/or physicist that the project as constructed or installed meets applicable statutes, codes and regulations; and such other close-out documents as may be specified by the department.

(iv)f) Notwithstanding anything in this section to the contrary, from time to time the commissioner may, at the commissioner's discretion, approve capital expenditures that may be required in response to new state, municipal, or federal code requirements. Such approval may only be considered when such code changes affect large numbers of hospitals (as such term is defined in Article 28 of the Public Health Law) and where the

commissioner finds that the capital expenditure is unlikely to create any risk to patient safety. Upon such determination, the commissioner shall notify affected hospitals of the opportunity to proceed with such capital expenditures based on a letter of notice to the department. The commissioner may impose a cap on anticipated individual project capital expenditures for such a waiver.

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Paragraph (5) of subdivision (c) of section 710.1 is amended to read as follows:

5) Proposals requiring a limited review. Proposals where total project cost does not exceed \$6,000,000 and for which a certificate of need is not otherwise required under this Part, shall be reviewed under this paragraph, except for proposals covered by paragraph (4) of this subdivision.

(i)(a) Applicants shall submit all such requests for approval of proposals described in this paragraph [directly to the Director of the Bureau of Project Management in the Division of Health Facility Planning,] through the electronic application submission process at the address posted on the department's Web site, including such information and documentation as the department requires to determine whether the proposal is acceptable.

(b) If the proposal involves the addition or decertification of a service or the conversion or decertification of beds subject to review under subparagraph (iv) of this paragraph, a copy shall also be sent to the health systems agency (HSA) having jurisdiction, if any.

The HSA will have 10 days to respond to the department.

(c) If the Department determines that the proposal complies with all pertinent statutory and regulatory requirements, the Department shall notify the applicant, in writing, that the proposal is acceptable and, if applicable, an amended operating certificate will be issued.

(d) If the Department determines that the proposal is not acceptable, the applicant shall be notified in writing of such determination and the bases thereof. If the applicant disagrees with the commissioner's determination, the applicant may submit a certificate of need application to be processed for full review in accordance with this Part.

(e) Applicants that submit proposals subject to review under clause (e) of subparagraph (ii) of this paragraph, or under subparagraph (iv) of this paragraph that do not require an architecture and engineering [review] certification, shall be notified of the Department's determination within 30 days of submission of all necessary information.

(ii) A review shall be conducted of the proposal's compliance with applicable statutes, codes, rules and regulations relating to the structural, architectural, engineering, environmental, safety and sanitary requirement of licensed medical facilities, where the proposal relates to the acquisition, relocation, installation or modification of:

(a) medical equipment involving ionizing radiation or magnetic resonance, including magnetic resonance imagers (MRIs) and CT scanners by a general hospital as defined in Article 28 of the Public Health Law;

(b) facility areas relating to clinical services or surgical or other invasive procedures, not otherwise requiring approval under this section;

(c) inpatient units, including resident rooms in a residential health care facility and other spaces used by residents of residential health care facilities on a daily basis, relating to other than routine maintenance and repairs or routine purchase of equipment;

(d) [systems that impact clinical space, services or equipment, including] heating, ventilating, air conditioning, plumbing, electrical, water supply and fire protection systems[,] [other than routine maintenance and repairs or routine purchases affecting such systems;] that involve 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 residential health care facilities on a daily basis. Projects involving routine maintenance or repairs or routine purchases affecting such systems shall not be subject to this subparagraph.

[(e) equipment or facility space, where the proposal does not relate to a change in clinical service, space or equipment, or an increase in certified bed capacity, and is not subject to paragraph (3) of this subdivision and, notwithstanding any inconsistent provision of this paragraph, whose cost does not exceed \$15,000,000 including but not limited to:

information systems, exterior building envelope (e.g., windows, roof, wall repairs), parking garages, dietary, and solid waste and/or sewage disposal;]

[(f)]e)the relocation of an extension clinic within the same service area, defined as (1) one or more postal zip code areas in each of which twenty-five (25) percent or more of the extension clinic's patients reside, or (2) the area within one mile of the current location of such extension clinic, which does not entail an increase in services or clinical capacity;

and

([g]f) Notwithstanding anything in this Title to the contrary, the reallocation, relocation or redistribution of linear accelerators as replacements for cobalt units and related services from one hospital to another hospital within the same established Article 28 network.

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REGULATORY IMPACT STATEMENT

Statutory Authority:

Paragraph (1) of section 2802 of the Public Health Law details procedures for the submission of applications for approval of construction projects for general hospitals, nursing homes, diagnostic and treatment centers and other health care facilities defined as hospitals in section 2801. Subparagraphs (1-a) and (1-b) of section 2802, as amended by Chapter 174 of the Laws of 2011, set forth the types of construction projects that do not require prior approval and for which written notice suffices for submission of the required construction application.

Legislative Objectives:

Article 28 of the Public Health Law seeks to protect and promote the health of the inhabitants of the State by assuring the efficient, accessible, and affordable provision of health services of the highest quality and that such services are properly utilized. Section 2802 seeks to ensure that the application process furnishes the Department with sufficient information to determine whether construction projects proposed by facilities subject to Article 28 are consistent with this standard.

Construction projects subject to Article 28 approval undergo one of three levels of review:

Limited Review: This level of review requires only the submission of a narrative describing the construction activity to be undertaken, the cost of the construction and where applicable, architecture/engineering drawings or certification. Limited review

construction projects are generally not subject to review for financial feasibility or public need.

Administrative Certificate of Need (CON) review: This process requires submission of a CON application, which has considerably more detailed forms and schedules than the documents required for limited review. The process also involves review for financial feasibility and public need.

Full CON review: Full review construction projects generally require the submission of the same forms and schedules as administrative review applications but, because of their generally greater complexity and higher costs, usually involve a more detailed review for financial feasibility and public need. They also require review by the Public Health and Health Planning Council for submission of a recommendation by the PHHPC to the Commissioner.

The amended section 2802 provides that a notice process, as opposed to a CON application, is sufficient in the case of construction projects, regardless of cost, that involve only non-clinical infrastructure, facility repair and maintenance, and the one-for-one replacement of equipment. The proposed rule changes would amend paragraphs (4) and (5) of subdivision (c) of section 710.1 to remove CON review requirements for repair and maintenance projects and equipment replacement projects costing more than \$6 million. The proposed revisions would also remove the requirement in paragraph (3) of subdivision (c) of section 710.1 that non-clinical infrastructure projects exceeding \$15

million be subject to administrative review. In lieu of the submission of administrative or full review CON applications, the amended rules would require the submission of only a written notice and, where applicable, specified certifications and a plan for patient safety during project construction (additional close-out certifications would be required, where applicable, upon completion of the project). Once the notice and required accompanying documents were submitted, the applicant would also not have to await formal approval from the Department to commence the proposed project.

Current Requirements:

Under paragraph (4) of subdivision (c) of section 710.1, projects for facility repair and maintenance costing under \$6 million do not require an application, while those over \$6 million require a limited review application. Projects for one-for-one replacement of non-medical and most medical equipment for which the total project costs are under \$6 million are currently subject to limited review. Those between \$6 million and \$15 million require administrative CON review. Projects for one-for-one equipment replacement of certain types of major medical equipment, e.g., MRI's, therapeutic radiology devices, CT scanners and cardiac catheterization equipment, regardless of cost, do not require an application, but only notification to the Department, and documentation that the equipment to be replaced is depreciated or no longer operable. Under section 710.1(c)(5), projects involving non-clinical infrastructure, including but not limited to windows, roof and wall repairs, parking garages, dietary, and solid waste and/or sewage disposal, whose costs are under \$15 million are subject only to limited review. Under 710.1(c)(3), non-clinical infrastructure projects that exceed \$15 million are subject to

administrative CON review. Non-clinical infrastructure projects that exceed this amount are not subject to full review, regardless of cost.

Needs and Benefits:

Whether undertaken on an ongoing or occasional basis, the construction projects involving repair and maintenance, non-clinical infrastructure and equipment replacement addressed by the amended Section 2802 typically require relatively rapid implementation, lest services to patients be disrupted or operational inefficiencies occur. The proposed amendments seek to ensure that these essential activities can be undertaken more rapidly than often occurs under the current requirements for limited review and administrative or full CON review set forth in section 710.1.

The proposed changes would amend paragraphs (3), (4) and (5) of subdivision (c) of section 710.1 to expand the range of projects that do not require limited review or administrative or full CON review. The following would no longer require these types of prior approval, regardless of cost:

- correction of cited deficiencies, provided that the construction is limited to the correction;
- projects for repair or maintenance;
- replacement of any type of equipment, medical or non-medical. This is in contrast to current rules, which exempt only certain types of major medical devices from prior approval;
- non-clinical infrastructure projects.

All projects affected by the new rules would require the submission of a written notice and, where applicable, a plan for patient safety during project construction, and

architect/engineer certification that the proposed project complies with the medical facilities construction code set forth in 10 NYCRR Parts 711 through 715. For those repair/maintenance, equipment replacement and non-clinical infrastructure projects currently subject to administrative CON review, and for the relatively few such projects requiring full CON review, the proposed changes would remove the need for applicants to submit the more elaborate and detailed CON application forms and schedules currently required. For all projects affected by the new rules, the proposed changes would also remove the requirement for the applicant to await Department approval of the proposed project before commencing construction. Applicants would therefore be able to proceed with their projects as soon as their written notices were submitted and receipt of the individual notice acknowledged by NYSE-CON, the electronic CON application processing mechanism. Upon completion of the project, the facility would be required to submit, as applicable, written certification by an architect, engineer and/or physicist, stating that the project had been completed in compliance with all applicable codes and regulations.

Although under the proposed rules the applicant would no longer need to await Department approval before commencement of the proposed project, it would remain the responsibility of the applicant to construct and operate the project in full compliance with the medical facilities construction code (Parts 711 through 715), the hospital code (Part 405) and any other applicable regulations. Any violations thereof would be fully cited in the course of routine surveys, complaint investigations or other surveillance and enforcement activities.

The submission of written notices rather than CON applications, together with the absence of a need to await formal Department approval of proposed projects, whether currently subject to CON review or limited review, would enable hospitals, nursing homes and diagnostic and treatment centers to take prompt advantage of changes in equipment and technology and allow them to update their facility equipment and infrastructure more readily. These new provisions would also help health facility operators avoid increases in construction costs that can occur while projects are pending Department approval, as well as prevent delays in the attainment of savings associated with proposed improvements to their facilities and services. For the Department, the simpler receipt of written notices would enable staff to focus more fully on larger-scale CON projects that warrant in-depth review and analysis.

COSTS:

Costs to State Government Other than the Department of Health:

There are no costs to State government.

Costs to Local Government:

There are no costs to local governments. For those local governments that operate Article 28 facilities, the proposed rules would reduce the costs associated with the preparation of administrative review CON and full review CON applications for affected projects. They would also eliminate the costs associated with delays in construction that can occur while projects await Department approval.

Costs to Private Regulated Parties:

Because the proposed amendments simplify the Article 28 review process for construction projects, these changes carry no costs for private regulated parties. The

proposed rules actually would reduce the costs associated with the preparation of administrative review CON and full review CON applications for affected projects. They would also eliminate the costs associated with delays in construction that can occur while projects await Department approval.

Costs to the Department of Health:

There would be no additional costs to the Department of Health because CON review is an established function of the agency.

Local Government Mandates:

The proposed amendments do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposed amendments impose no new reporting requirements, forms or other paperwork.

Duplication:

There are no relevant State or Federal rules that duplicate, overlap or conflict with the proposed amendments.

Alternatives Considered:

The Department considered no alternatives because the proposed amendments reflect a statutory mandate.

Federal Standards:

Because there are no Federal rules affecting Certificate of Need, the proposed amendments do not exceed any minimum standards of the Federal government.

Compliance Schedule:

The proposed rules would take effect upon publication of a Notice of Adoption in the New York State Register. Because applications for construction under Article 28 may be submitted at any time, there is no schedule of compliance.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS
For
SMALL BUSINESSES AND LOCAL GOVERNMENTS

A regulatory flexibility analysis is not required for this proposal since it will not impose any adverse economic impact or reporting, record keeping or other compliance requirements on small businesses or local governments. The proposed rules simplify the application process for the approval of certain types of projects for construction, repair and maintenance and purchases of replacement equipment by hospitals, nursing homes, clinics and other health care providers.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A rural area flexibility analysis is not required for this proposal since it will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on rural areas. The proposed rules simplify the application process for the approval of certain types of projects for construction, repair and maintenance and purchases of replacement equipment by hospitals, nursing homes, clinics and other health care providers.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A job impact statement is not submitted because this proposed rule will have no adverse impact on jobs or employment opportunities. The proposed rules simplify the application process for the approval of certain types of projects for construction, repair and maintenance and purchases of replacement equipment by hospitals, nursing homes, clinics and other health care providers. Because these rules represent only a change in application procedures, they will have no impact on jobs and employment opportunities, in the health care sector or elsewhere.

ASSESSMENT OF PUBLIC COMMENT

In commenting on the proposed rules, the Healthcare Association of New York State (HANYs) states that the proposed 710.1(c)(5)(ii)(d) is contrary to statute in its retention of limited review for the installation, replacement or modification of heating, ventilation and air conditioning systems and for other infrastructure projects that involve the modification or alteration of clinical space. It is HANYs' position that the reference in PHL 2801 section 1-a to "non-clinical infrastructure," which includes heating, ventilation and air conditioning (HVAC), plumbing, electrical and other systems, exempts such projects from approval by the State, regardless of the area of the hospital involved.

The Department agrees that PHL 2801 section 1-a exempts non-clinical infrastructure projects from CON review regardless of the area of the hospital involved, except when such projects also involve changes to actual clinical space, services or equipment. Accordingly, the proposed language of 710.1(c)(5)(ii)(d) retains the requirement for limited review of the installation, modification or replacement of HVAC, plumbing, electrical, water supply and fire protection systems "that involve *modification or alteration* of clinical space, services or equipment" (emphasis added). Projects for the modification or alteration of such spaces, services or equipment, even to accommodate infrastructure changes, cannot be deemed nonclinical, involving as they do areas, devices and services that have a direct impact on patient care. The Department therefore disagrees with HANYs' suggestion that the proposed 710.1(c)(5)(ii)(d) be modified.

The Department wishes to emphasize that infrastructure projects that involve clinical areas but which do not propose to modify or alter clinical space, services or equipment would be exempt from review and subject only to submission of a notice under the proposed rules, as intended by PHL 2801 section 1-a. For example, a hospital's proposed installation of a new HVAC system for the entire facility would obviously affect operating rooms, outpatient clinics and patient rooms, as well as the hospital's nonclinical areas. However, unless the project involved the modification or alteration of clinical space, services or equipment, it would be considered nonclinical and would require only the submission of a notice, as provided for in PHL 2801 section 1-a. We note that the Department has already received notices for several such projects, some from facilities of considerable size, and has imposed no review requirements on these undertakings.

The Department also received comments on the proposed rules from Mid-Hudson Medical Group, P. C. Although as a professional corporation, physicians in this organization are not subject to Article 28 of the Public Health Law, they wrote in support of the proposed rules on behalf of those among their membership who have affiliated ambulatory surgery centers, which are subject to Article 28 requirements, stating that the replacement of a CON requirement with a notice requirement would permit operators of Article 28 facilities to implement needed projects more quickly.