

ADDENDUM
STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
ANNUAL MEETING
AGENDA

February 6, 2025

*Immediately following the Committee on Codes, Regulations and Legislation Meeting
(Codes scheduled to begin at 9:30 a.m.)*

90 Church Street, 4th Floor CR 4 A/B, New York, New York 10007

VI. REGULATION

Report of the Committee on Codes, Regulations and Legislation

Patsy Yang, Dr.P.H., Vice Chair of the Committee on Codes, Regulations and Legislation

For Discussion

24-12 Repeal and Replace of 710.1 of Title 10 NYCRR (Approval of Medical Facility Construction)

SUMMARY OF EXPRESS TERMS

Governor Hochul recognized in her 2024 State of the State that health care providers face administrative barriers when seeking to modernize and invest in their facilities, including specifically the Certificate of Need process. Governor Hochul thus directed the Department to review and amend the Certificate of Need process, including raising the cost thresholds for projects subject to a more detailed review and streamlining the application and approval processes, including for routine services.

The regulatory proposal would repeal and replace section 710.1 of Part 710 of Title 10 of the New York Codes, Rules, and Regulations (NYCRR). Generally, the proposal modernizes the Certificate of Need review process for construction of health care facilities. It reorders subdivisions and paragraphs logically, combining redundant language pertaining to all review levels in general paragraphs up front. Language pertaining to requirements, processes and practices that are obsolete have been removed.

This proposal will increase the cost thresholds that generally determine the level of review for projects as directed in the 2024 State of the State and revises review levels for specific types of projects to reflect the advances and evolving trends in healthcare. A detailed description follows below:

710.1(a) remains unchanged, specifying that medical facilities shall be planned to achieve efficiency and economy of operation and care of high quality.

710.1(b) includes definitions of “general hospital,” “total project cost(s),” “total basic cost(s) of construction”

Pertinent elements of 710.1(d), (e), (f) and (g) have been moved into a new 710.1(c), with subsequent paragraphs re-ordered accordingly. New subdivision 710.1(c) is organized to begin with general requirements and then detail the different levels of certificate of need review beginning with the most rigorous and ending with the most streamlined.

710.1(c)(1) covers the types of proposals requiring a Certificate of Need application, which remains largely unchanged from the current regulation except for the overall total project costs thresholds will shift from over \$15 million for a general hospital and \$6 million for all other facilities to over \$30 million for a general hospital and \$8 million for all other facilities. Project cost thresholds were last raised in 2017; construction costs have more recently increased substantially. The amounts included in the proposal reflect an appropriate balance between the increased construction costs for large-scale projects and the desire to maintain sufficient oversight while reducing administrative barriers.

710.1(c)(2) delineates general tenants of Certificate of Need review that pertain to all projects. These have been consolidated and clarified where necessary from the current regulation. The one major change from the current regulation is that the total project cost threshold under which architectural self-certification is allowed has been raised from \$15 million to \$30 million. The amounts included in the proposal reflect an appropriate balance between the recognition of increased construction costs for large-scale projects and the desire to maintain sufficient oversight while reducing administrative barriers.

710.1(c)(3) describes proposals requiring a Full Review including a recommendation from the Public Health and Health Planning Council. Specifically, it raises the total project cost thresholds subject to Full Review for general hospitals to the greater of \$60 million (currently \$30 million) or 10% of a facility's operating costs, not to exceed \$150

million, and for all other facility types subject to certificate of need review, projects that exceed the greater of \$20 million (currently \$15 million) or 10% of a facility's operating costs, not to exceed \$30 million. For projects adding beds, converting beds to a higher level of care, or otherwise changing the number of beds, only those that add or otherwise change more than 10% of existing beds will be subject to Full Review regardless of cost. Conversion of beds to a lower level of care if less than 10% of existing beds which be subject to Administrative or Limited review. Lung transplant services are added to those that require a full review certificate of need while several other services have been removed including Therapeutic Radiology, Cardiac Catheterization, Bone Marrow Transplantation, Burn Care, Acquired Immune Deficiency Syndrome (AIDS) centers, and Epilepsy Services.

710.1(c)(4) describes proposals eligible for Administrative Review. Specifically, it raises the total project cost thresholds for general hospitals subject to Administrative Review to greater than \$30 million (currently \$15 million) but not exceeding the greater of \$60 million or 10% of a facility's operating costs not to exceed \$150 million and for other facility types, greater than \$8 million (currently \$6 million) but not exceeding the greater of \$20 million or 10% of a facility's operating costs not to exceed \$30 million. The amounts included in the proposed regulation reflect an appropriate balance between the recognition of increased construction costs for large-scale projects and the desire to maintain sufficient oversight.

In addition, references to specific services have been removed from the regulation. These include services that either no longer need to be separated out or that better fit within the general review requirements, including but not limited to: Diagnostic Cardiac

Catheterization service; changes in bed capacity at an acquired immune deficiency syndrome (AIDS) center; addition of skilled nursing facility beds for individuals with acquired immune deficiency syndrome (AIDS); acquisition of magnetic resonance imaging (MRI) machines; addition of adult day health care services; and acquisition of computed tomography (CT) scanners.

710.1(c)(4) also makes any project funded primarily by state grants eligible for Administrative Review to avoid subjecting projects for modernization of the States health care infrastructure to duplicative levels of review.

Finally, 710.1(c)(4) removes projects involving Emergency Room space from requiring Administrative Review in order to reduce approval times and support providers in meeting heightened demand for such services.

710.1(c)(5) describes proposals eligible for Limited Review. Specifically, it raises the total project cost threshold eligible for Limited Review to \$30 million (currently \$15 million) for general hospitals and \$8 million (currently \$6 million) for all other facility types.

Other changes include exempting from review the addition or renovation of exam rooms in facilities where such space already exists within or adjacent to previously certified space regardless of project cost as exam rooms pose minimal risk as they are used for limited scope of services with minimal physical environmental standards. Such projects would require only notice to the Department. The proposed regulations would also make mobile van extension clinics eligible for Limited Review as they have fewer generally accepted design and construction standards than traditional brick and mortar buildings.

These proposed regulations reflect an appropriate balance between the recognition of reducing administrative barriers and approval times and the desire to maintain sufficient oversight.

The previous 710.1(c)(6) delineating cardiac catheterization proposals requiring limited review was removed. Projects covered therein will be assigned a review level under general provisions of the new section, e.g., project cost thresholds and impact on the facility's operating certificate.

The new 710.1(c)(6) describes proposals that do not require a Certificate of Need Application and require only written notice to the State Department of Health. Notices will be required for non-clinical projects greater than \$12 million instead of the previous \$6 million. Also, any project that is otherwise eligible for Limited Review, but is architecturally self-certified by the applicant, will now also be eligible for notice only as long as it does not involve a change in the beds or services which would require an update to the applicant's operating certificate.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, section 710.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby repealed and replaced, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Section 710.1 General provisions.

(a) Medical facilities shall be planned to achieve efficiency and economy of operation and care of high quality.

(b) For purposes of this Part, the following terms shall have the following meanings:

(1) “General hospital” means a general hospital as defined in subdivision 10 of section 2801 of the Public Health Law.

(2) “Total project cost(s)” means total costs for construction, including but not limited to costs for demolition work, site preparation, design and construction contingencies, total costs for real property, for fixed and movable equipment, architectural and/or engineering fees, construction manager and/or consultant fees, construction loan interest costs, and other financing, professional and ancillary fees, charges, and allowances. Such costs shall include the cost of all capital items associated with an acquisition, lease arrangement and/or construction. If any acquisition is to be financed through a leasing arrangement, the relevant cost shall be the cost of the asset, not the lease amount.

(3) “Total basic cost(s) of construction” means total project cost(s) less capitalized amounts of construction loan interest cost(s) and other financing fees and charges.

(c) The erection, building, acquisition, alteration, reconstruction, improvement, extension, or modification of a medical facility, including its equipment and services shall be governed by the following:

(1) Proposals requiring a certificate of need application. Any proposal which involves any of the following shall be the subject of an application submitted for review pursuant to the requirements of this Part and Article 28 of the Public Health Law:

(i) the initial construction or acquisition of a building for use as a hospital as defined in subdivision 1 of section 2801 of Public Health Law;

(ii) any other construction, addition or replacement proposal involving a total project cost in excess of \$30,000,000 for a general hospital or \$8,000,000 for all other facilities, except non-clinical and health information technology projects subject to paragraph (6) of this subdivision;

(iii) a conversion of beds or a change in the certified bed capacity of a facility, regardless of cost;

(iv) the addition, modification, change in the method of delivery of, decertification of a licensed service, or the addition or deletion of approval to operate part-time clinics, regardless of costs. The addition or deletion of part-time clinic services operated by the State Department of Health (other than as an extension of an article 28 hospital operated by the State Department of Health) or by the health department of a city or county as such terms are defined in section 614 of the Public Health Law shall not be subject to approval pursuant to this Part; or

(v) the initial acquisition or addition of any equipment, regardless of cost, utilized in the provision of a service listed in paragraph (3) of this subdivision. A proposal for the replacement of existing equipment, regardless of cost, which meets the criteria contained therein, shall not require an application but shall be processed pursuant to paragraph (6) of this subdivision.

(2) Certificate of Need applications shall be processed as follows:

(i) Applicants shall submit all such requests for approval of proposals described in this section through the electronic application submission process at the address posted on the department's website, including such information and documentation as the department requires to determine whether the proposal is acceptable to include the services to be provided and the facility areas to be utilized. If construction is required, the request should include the cost of such construction and information required by the State Department of Health Bureau of Architectural and Engineering Facility Planning under this Part.

(ii) A review shall be conducted of the proposal's compliance with applicable statutes, codes, rules, and regulations relating to the operation of the proposed facility as well as the structural, architectural, engineering, environmental, safety and sanitary requirement of licensed medical facilities as appropriate.

(iii) 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.

(iv) If the department determines that the proposal is not acceptable, the applicant shall be notified in writing of such determination and the bases thereof. For any application deemed unacceptable, 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.

(v) For any application for which the total basic cost of construction does not exceed \$30,000,000, as an alternative to the department's review of the architectural and engineering documentation required under this Part, the commissioner may accept a written self-certification by an architect or engineer licensed by the State of New York, that such project complies with applicable statutes, codes, rules, and regulation Parts 711 through 717 and 795 of this Title without exceptions or waivers. The self-certification shall be provided with the architectural and engineering documentation and will be made available for review at the onsite survey conducted by the department in accordance with article 28 of the Public Health Law. The costs of any subsequent corrections necessary to achieve compliance with the requirements when the prior work was not completed properly and was not accurately certified shall not be considered allowable costs for reimbursement under Part 86 of this Title. This clause does not waive any of the requirements of section 5-1.22 of this Title pertaining to any project interaction with public water systems.

(vi) Medical facilities undertaking programmatically related construction and/or acquisition projects during their fiscal year with an aggregate total cost that will exceed \$30,000,000 for general hospitals or \$8,000,00 for all other facilities shall submit a single application encompassing all such projects for review pursuant to the requirements of this

Part and article 28 of the Public Health Law. If a subsequent audit reveals that during any such period a medical facility has undertaken several projects or submitted several proposals or applications that are programmatically related and total more than \$30,000,000 in the aggregate for general hospitals or \$8,000,00 in the aggregate for all other facilities, the facility's reimbursement rate may be reduced to the extent it includes the cost of the related projects.

(3) Proposals requiring a Full Review, including a recommendation of the Public Health and Health Planning Council pursuant to the requirements of this Part and article 28 of the Public Health Law:

(i) any proposal involving total project cost in excess of \$60,000,000 for a general hospital or \$20,000,000 for all other facilities, except as otherwise provided under paragraph (4) of this subdivision;

(ii) the addition of beds totaling more than 10% of current beds or the conversion of more than 10% of current beds to a bed type of a higher level of care, regardless of cost;

(iii) any proposal for the addition or modification of the following services, or the initial acquisition of any equipment relating thereto, regardless of cost:

(a) adult or pediatric cardiac surgery; or

(b) kidney, heart, liver, and lung transplantation;

(iv) any proposal which would otherwise be eligible for Administrative Review, but which exceeds a facility's Administrative Review limitation; or

(v) any proposal which would otherwise be eligible for Administrative or Limited Review, but which is recommended for disapproval.

(4) Proposals eligible for Administrative Review.

(i) The commissioner may administratively approve applications submitted pursuant to article 28 of the Public Health Law and this Part without the recommendation of the Public Health and Health Planning Council where the total project cost does not exceed \$60,000,000 for a general hospital or \$20,000,000 for all other facilities. An application shall be eligible for Administrative Review even though total project costs exceed \$60,000,000 for a general hospital or \$20,000,000 for all other facilities, if:

(a) (1) total project costs do not exceed 10% of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application; and

(2) total project costs do not exceed \$150,000,000 for a general hospital or \$30,000,000 for all other facilities. Notwithstanding anything in this Part to the contrary, any cost increase of a project in excess of \$60,000,000 for general hospitals or \$20,000,000 for all other facilities that is administratively reviewed under this subparagraph, resulting in total project costs in excess of the \$150,000,000 for general hospitals or \$30,000,000 for all other facilities, or in excess of 10% of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application, shall subject the application to full review; or

(b) the project is funded primarily through awarded State grants.

(ii) The following types of proposals shall require an Administrative Review even if they meet the total project cost threshold for Limited Review under paragraph (5) of this subdivision:

(a) the addition or modification of a licensed service other than those set forth in paragraph (3) of this subdivision which require Full Review;

(b) the addition of beds totaling up to 10% of current beds or the conversion of up to 10% of current beds to a bed type of a higher level of care, regardless of cost;

(c) the conversion of beds other than a conversion which would establish a higher level of care, which proposal would require a full review, including a recommendation of the Public Health and Health Planning Council, and except as provided for in paragraph (5) of this subdivision;

(d) the temporary addition of beds to a facility's certified capacity, for a period of time not to exceed one year, required to address high priority health care needs for which there is a demonstrated severe shortage;

(e) the operation or relocation of an extension clinic as defined in section 401.1 of this Title, when such relocation is to a site outside of the current service area of the extension clinic, as defined in paragraph (5) of this subdivision;

(f) the addition of a methadone maintenance treatment program;

(g) an application for the relocation of long-term ventilator beds from one residential health care facility to another residential health care facility with common ownership.

Common ownership shall be found when the ownership in the operator of each

residential health care facility is the same, provided the percentage of ownership interest of each owner may vary between the two facilities but must meet the whole in common ownership; or

(h) the addition of chronic renal dialysis stations by a facility approved and operating dialysis stations. A facility approved to provide only chronic renal dialysis shall be deemed approved to provide:

(1) all modalities of chronic renal dialysis; and

(2) chronic renal dialysis services to patients at home, provided that a facility shall give the appropriate area office of the department at least 15 days' written notice prior to commencing or terminating the facility's program for the provision of chronic renal dialysis services to patients at home.

(5) Proposals eligible for Limited Review.

(i) Proposals where total project cost does not exceed \$30,000,000 for a general hospital or \$8,000,000 for all other facilities, and for which a higher level of review is not otherwise required under this Part, shall be eligible to be reviewed under this paragraph, except for proposals covered by paragraph (6) of this subdivision.

(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 computed tomography (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, except examination rooms which are covered under paragraph (6) of this subdivision.

(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, other than when routine maintenance and repairs are performed or for routine purchase of equipment.

(d) Heating, ventilating, air conditioning, plumbing, electrical, water supply, and fire protection 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.

(iii) The following proposals shall also be subject to Limited Review under this paragraph for programmatic and/or public need purposes:

(a) Any proposal to decertify a facility's beds, for which a higher level of review is not otherwise required under this Part. The applicant shall submit information indicating the

number of beds to be decertified, where the beds to be decertified are physically located in the facility and what, if any, alternate use will be made of the space.

(b) Any proposal solely to decertify services, other than those set forth in subparagraph (3)(iii) of this subdivision. The applicant shall submit information indicating the services to be decertified, where the services to be decertified are physically provided and what, if any, alternate use will be made of the space.

(c) Any proposal to add services, other than those set forth in subparagraphs (3)(iii) and (4)(i) of this subdivision, for which a higher level of review is not otherwise required under this Part. The applicant shall submit information indicating the services to be certified, the additional staffing requirement, if any, where the services to be certified are physically provided in the facility and what, if any, construction will be required in the facility.

(d) Any proposal to convert beds from one category to another in the categories listed in this clause and for which the acute care inpatient facility is already a certified provider. The applicant shall submit information indicating the number of beds to be converted and the categories from and to which the beds will be converted.

This clause applies to beds in the following categories:

(1) medical/surgical;

(2) intensive care;

(3) coronary care;

(4) pediatric;

(5) pediatric intensive care;

(6) neonatal intensive care;

(7) neonatal intermediate care;

(8) neonatal continuing care;

(9) maternity; and

(10) chemical dependence - detoxification.

(e) Any proposal to relocate an extension clinic within the same service area, defined as:

(1) one or more postal zip code areas in each of which 25% 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.

(f) Any proposal to operate, change services offered, change hours of operation, or relocate a part-time clinic site other than the discontinuance of service subject to clause 6(i)(d) of this subdivision. Requests for approval shall be consistent with the provisions of section 703.6(b) of this Title. If a proposal requests approval for an arrangement or services that are not permissible for a part-time clinic, the proposal will not be accepted for processing under this section.

(g) The relocation of an extension clinic within the same service area, defined as:

Notwithstanding anything in this Title to the contrary, any proposal for the reallocation, relocation, or redistribution of acute care beds from one general hospital to another general hospital within the same established article 28 network. The applicant shall

submit information indicating the current and proposed certified bed capacity for each service and facility for which the reallocation, relocation or redistribution of beds is proposed.

(h) Any proposal to operate a mobile van extension clinic.

(6) 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.

(b) 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 a medical facility's inventory control functions, provided that for proposals under this clause with a total cost of up to \$12,000,000, including separate proposals which are programmatically related, no written notice shall be required. This subparagraph shall not apply to activities requiring a Limited Review under paragraph (5) of this subdivision.

(c) Any proposal for the addition or renovation of examination rooms within or adjacent to previously certified space.

(d) 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.

(e) Any proposal for the replacement of existing equipment, 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. 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 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. 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.

(f) Subject to clause (5)(ii)(d) of this subdivision, any proposal for a nonclinical infrastructure project with total project costs in excess of \$12,000,000, 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.

(g) Any proposal that relates to health information technology regardless of cost. For health information technology proposals involving the implementation of clinical information systems, electronic medical records, computerized physician order entry, radiology systems, lab ordering systems or other health information systems impacting patient care, the facility's written notice to the department shall include a certification of the technology's interoperability with other systems and conformance with State and Federal guidelines and regulations governing the use and exchange of information, including privacy and security, that is acceptable to the department.

(h) Any project eligible for review under paragraph 5 of this subdivision that does not impact the applicant's operating certificate and for which the applicant has submitted a written self certification by an architect or engineer licensed by the State of New York as delineated under subparagraph (2)(v) of this subdivision.

(ii) Proposals for a nonclinical infrastructure project, 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, where total project costs do not exceed \$12,000,000, shall not require prior approval or written notice to the department under this Part, except as required by clause (5)(ii)(d) of this subdivision.

(iii) 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.

(d) Medical facilities shall maintain a record of all additions to property, plant and equipment made during the appropriate 12-month period reflected in their capital budget. Each addition, which is subject to paragraph (1) of subdivision (c) of this section, must be supported by an application approved pursuant to article 28 of the Public Health Law and this Part. Each medical facility shall, as a matter of routine, submit with the annual certified cost reimbursement reporting forms required by the department, identification of

its annual capital expenditures, as provided for in the section entitled “Changes in financial positions,” indicating separately the total amounts thereof involving projects in the following categories: below \$8 million and over \$8 million, which have received appropriate approvals pursuant to this Part, and the nature of each approval. The facilities shall also provide to the department annually, on forms provided by the department, a list of projects between \$1 million and \$8 million, which have been undertaken by the facility, although such projects do not require certificate of need approval.

(e) All drawings and specifications shall bear the seal and signature of an architect or engineer licensed to practice in New York State. The commissioner, at his discretion, may waive the above requirement when the construction is less than \$10,000 in value, unless otherwise provided for in this Part.

(f) All construction in or of a medical facility shall have competent and adequate architectural and/or engineering inspection at the construction site to ensure that the completed work conforms with the approved plans and specifications.

(g) As a part of the application required for approval of the project, the applicant shall give the following assurances:

(1) that the applicant has or will have a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way sufficient to assure use and possession for the purpose of the construction and operation of the facility;

(2) that the applicant will obtain the approval of the commissioner of all required submissions, which shall conform to the standards of construction and equipment of this Subchapter;

(3) that the applicant will submit to the commissioner final working drawings and specifications, which shall conform to the standards of construction and equipment of this Subchapter, prior to contracting for construction, unless otherwise provided for in section 710.7 of this Part;

(4) that the applicant will cause the project to be completed in accordance with the application and approved plans and specifications;

(5) that the applicant will provide and maintain competent and adequate architectural and/or engineering inspection at the construction site to insure that the completed work conforms with the approved plans and specifications;

(6) that if the project is an addition to a facility already in existence, upon completion of construction all patients shall be removed from areas of the facility which are not in compliance with sections 711.4 through 711.8 of this Title, or other pertinent provisions of this Subchapter, unless a waiver is granted to specific provisions by the commissioner, under section 711.9 of this Title;

(7) that the facility will be operated and maintained in accordance with the standards prescribed by law; and

(8) that the applicant will comply with the provisions of the Public Health Law and the applicable provisions of this Title with respect to the operation of all established, existing medical facilities in which the applicant has a controlling interest.

(h) The applicant shall be required to adequately equip the facility to assure its proper operation.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2)(a) provides that the Public Health and Health Planning Council (PHHPC) shall adopt rules and regulations, subject to the approval of the Commissioner of Health, to effectuate the purposes of PHL Article 28 with respect to hospitals.

Legislative Objectives:

PHL section 2800 declares that “[h]ospitals and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health” and bestows upon the Department of Health the “central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services.” The review of applications for hospital establishment and construction is referred to as the Certificate of Need process, the objectives of which are to align health care resources with community health needs, preserve and promote access to high quality health care, and control utilization to promote cost-effective health care.

PHL section 2801-a provides that hospitals, defined in PHL section 2801 to mean “general hospitals”, nursing homes and diagnostic and treatment centers, may not be established except as approved by PHHPC. PHHPC may not approve the establishment of hospitals unless it is satisfied as to the public need for and financial feasibility of the proposed project, the character and competence of the proposed owners and operators, and such other matters as it deems pertinent. The construction of a hospital, defined by PHL section 2801 to mean the erection, building, or substantial acquisition, alteration,

reconstruction, improvement, extension, or modification of a hospital, including its equipment, requires the prior approval of the Commissioner under PHL section 2802. The Commissioner may approve a construction application only after affording PHHPC an opportunity to make a recommendation, except where regulations adopted by PHHPC and approved by the Commissioner provide that PHHPC review is not necessary, and only if the Commissioner is satisfied as to public need, financial feasibility and character and competence. PHL section 2802 details procedures for approval of hospital construction projects and provides that certain types of hospital construction projects require written notice to the Department but not prior approval. These include the acquisition of minor equipment, nonclinical infrastructure projects (such as replacement of heating, ventilating and air conditioning systems, parking lots and elevators), the replacement of existing equipment, and other projects set forth in regulation.

Current Requirements:

Consistent with these provisions, Department regulations establish the parameters of the Certificate of Need process for establishment and construction projects. Part 600, et seq., of Title 10 of the Official Compilation of New York Codes, Rules, and Regulations (NYCRR) pertains to establishment and 10 NYCRR Part 710, et seq., relates to construction projects.

Part 710 of 10 NYCRR defines three levels of review for construction projects, (i) Full Review, (ii) Administrative Review or (iii) Limited Review.

Construction projects of greater complexity and higher costs undergo Full Review, requiring submission of a Certificate of Need application that includes a series of forms and schedules and a detailed review for financial feasibility and public need. PHHPC

must be afforded an opportunity to make a recommendation on full review construction projects, while the ultimate determination of whether to approve such projects lies with the Commissioner.

Applications that undergo Administrative or Limited Review may be approved by the Commissioner without the recommendation of PHHPC. Administrative Review requires a Certificate of Need application including the same forms and schedules used for Full Review, including those for a financial review. Limited Review uses abbreviated schedules including a narrative describing the construction activity to be undertaken, the cost of the construction, and where applicable, architecture/engineering drawings or certification. Limited review generally does not include a review for financial feasibility.

Section 710.1(c)(1) specifies that Certificate of Need applications are necessary for certain types of construction projects, including the addition, modification, or decertification of licensed services, changes in the method of delivery of a licensed service, regardless of cost, or certain acquisitions or addition of equipment. Subsequent paragraphs delineate the criteria by which projects are assigned an appropriate level of review based on the type of action, the services, and specific circumstances of a project as well as the project cost.

Section 710.1(c)(2) provides that “Full Review” is required for construction applications that involve the addition of beds, the addition or modification of a change in delivery for certain services, and proposals involving total project costs in excess of \$30 million for general hospitals or \$15 million for all other facilities.

Section 710.1(c)(3) provides that projects eligible for “Administrative Review” generally.

include those with a total project cost that does not exceed \$30 million. However, an application shall be eligible for Administrative Review even though total project costs exceed \$30 million, if: (a) total project costs do not exceed 10 percent of the total operating costs of the facility for the year ended two years prior to the submission of the application; and (b) total project costs do not exceed \$100 million for a general hospital or \$25 million for all other facilities.

Section 710.1(c)(5) identifies construction projects subject to “Limited Review,” which generally include projects with costs that do not exceed \$15 million for a general hospital and \$6 million for all other facilities. Pursuant to section 710.1(c)(5)(ii), Limited Review also applies to non-clinical projects involving heating, ventilating, air conditioning, plumbing, electrical, water supply and fire protection systems where such projects involve the modification or alteration of clinical space, services, or equipment.

Section 710.1(c)(4) provides that certain construction projects do not require review but require written notice to the Department. Such projects include non-clinical infrastructure projects (other than projects affecting clinical space, which would require limited review as noted above).

Needs and Benefits:

Over the years, the Department has periodically refined the Certificate of Need process to ensure that it continues to advance its objectives, is responsive to a changing health care environment, focuses Department and PHHPC resources on issues and projects with the

greatest impact, and is as streamlined and expeditious as possible within the parameters of the statutory authority.

In furtherance of these goals, Governor Hochul recognized in her 2024 State of the State that health care providers face administrative barriers when seeking to modernize and invest in their facilities, including specifically the Certificate of Need process. Governor Hochul thus directed the Department to review and amend the Certificate of Need process, including raising the cost thresholds for projects, stating that such reforms will reduce red tape and approval times for more rapid modernization of the State's health care infrastructure.

This proposal will raise monetary thresholds determining the level of review for clinical projects as well as the threshold for when certain projects require written notice. The proposal also focuses on specific services and projects and the level of review required by current regulations, with the goal of avoiding, among things, subjecting certain services and projects to unnecessary levels of review.

Project costs thresholds for certificate of need applications will shift from over \$15 million for a general hospital and \$6 million for all other facilities to over \$30 million for a general hospital and \$8 million for all other facilities.

Project cost thresholds were last raised in 2017; construction costs have more recently increased substantially. The amounts included in the proposal reflect an appropriate balance between the increased construction costs for large-scale projects and the desire to maintain sufficient oversight while reducing administrative barriers.

Certain review levels for some previously identified types of services and projects have been eliminated as they no longer require special consideration due to medical advancements. These projects will now be reviewed according to dollar cost thresholds and general provisions regarding impact on a facility's operating certificate.

The measures included in this streamlining initiative will continue to reflect the overall objective of the statutory and regulatory framework, as set forth in 10 NYCRR section 710.1(a), to help ensure that medical facilities are planned to achieve efficiency and economy of operation and care of high quality. At the same time, it will help support regulated providers in meeting heightened demands to be increasingly agile given ongoing health system reform and evolving trends in medicine. requirements and promote flexibility that supports efficiency and innovation.

COSTS:

Costs to Private Regulated Parties:

The proposed amendments will not increase costs for private entities subject to the requirements of PHL Article 28 and in fact are expected to have a favorable fiscal impact. Some applicants either would no longer need to submit a Certificate of Need application or would need to prepare a less complex application, meaning that they will pay less in construction fees associated with an application, which are required in higher amounts for applications requiring higher levels of review. These changes also should expedite the time for approval of projects and therefore minimize costs related to construction delays.

Costs to Local Government:

This proposal will not impact local governments unless they operate a hospital, in

which case they are likely to experience decreases in costs as noted above with respect to private entities.

Costs to the Department of Health:

This proposal is not anticipated to have a major fiscal impact on the Department. The annual impact on Certificate of Need construction fee revenues is entirely dependent on the total project costs and types of projects submitted and how many of them might fall within the narrow bands of cost threshold changes and programmatic changes proposed. As such, the impact would vary from year to year. Based on experience, the Department estimates the potential impact of this proposal to be in the range of \$200,000 to \$450,000 in reduced fee revenue out of \$8 million to \$12 million in total fees annually.

Costs to Other State Agencies:

The proposed regulatory changes will not result in additional costs to other State agencies.

Local Government Mandates:

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

Paperwork:

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

paperwork. The amendments will reduce paperwork by shifting projects to lower levels of review or removing the requirement for the filing of a Certificate of Need application with respect to certain projects.

Duplication:

This rule does not duplicate any other law, rule, or regulation.

Alternatives:

The Department considered other monetary thresholds but ultimately determined that the amounts included in the proposal reflect an appropriate balance between the recognition of increased construction costs for large-scale projects and the desire to maintain sufficient oversight for purposes of promoting high quality services aligned with community need.

Federal Standards:

The proposed amendments do not exceed any minimum standards of the Federal government. There are no Federal rules currently addressing the Certificate of Need process.

Compliance Schedule:

These regulations will be effective upon publication of a Notice of Adoption in the New York State Register and would apply to all construction applications submitted thereafter. Consequently, regulated parties should be able to comply with the proposed regulation as of its effective date.

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

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed rule will not have a substantial adverse impact on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of this proposed regulation.