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 amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Paragraph (3) of subdivision (b) of section 710.1 is amended to read as follows:

(3) [Reserved.] <u>For purposes of this Part, "general hospital" means a general hospital as defined in subdivision 10 of section 2801 of the public health law.</u>

Subparagraph (iii) of paragraph (1) of subdivision (c) of section 710.1 is amended to read as follows:

(iii) the initial acquisition or addition of any equipment, regardless of cost, utilized in the provision of a service listed in paragraph (2) of this subdivision, other than the acquisition or addition of equipment subject to paragraph ([7]<u>6</u>) 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 [subparagraph]<u>paragraph (4)[(iii)]</u>of this subdivision;

Subparagraph (vi) of paragraph (1) of subdivision (c) of section 710.1 is amended to read as follows:

(vi) any other construction, addition or replacement proposal involving a total project cost in excess of $15,000,000 for a general hospital or $6,000,000 for all other facilities, except non-clinical and health information technology projects subject to paragraph [5](4) of this subdivision.

Subclause (3) of clause (b) of subparagraph (i) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(3) cardiac catheterization, including the relocation of any Cardiac Catheterization Laboratory Center service within a network or to another site in a multi-site facility, as defined in Section 401.1 of this Title, and the addition of a PCI Capable Cardiac Catheterization Laboratory Center at a facility that is not already approved to provide cardiac catheterization services; provided however that the addition of a PCI Capable Cardiac Catheterization Laboratory Center or Cardiac EP Laboratory Program at a facility approved to provide cardiac catheterization services shall be reviewed pursuant to paragraph (3) of this subdivision, and the addition of a Cardiac EP Laboratory Program services at a facility approved to provide cardiac surgery shall be reviewed pursuant to paragraph ([7]6) of this subdivision;

Clause (c) of subparagraph (i) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(c) any proposal involving total project cost in excess of $30,000,000 for a general hospital or $15,000,000 for all other facilities, except as otherwise provided under paragraph (3) of this subdivision;

Clause (a) of subparagraph (ii) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(a) The addition of equipment utilized in the provision of Cardiac Catheterization Laboratory Center services shall be eligible for limited review pursuant to paragraph ([7]6) of this subdivision, to the extent that it does not otherwise require an administrative or a full review under this Part;

The opening paragraph of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(i) [Except as otherwise stated in this paragraph, the]The commissioner may administratively approve applications submitted pursuant to Article 28 of the Public Health Law and this Part [but] without the recommendation of the [State Hospital Review]Public Health and Health

Planning Council[,] when an application has not been recommended for [approval]disapproval by the health systems agency having jurisdiction, and where the total project cost does not exceed $30,000,000 for a general hospital or $15,000,000 for all other facilities. An application shall be eligible for administrative review even though total project costs exceed $30,000,000 for a general hospital or $15,000,000 for all other facilities, if: (a) 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 (b) total project costs do not exceed [$50,000,000;]$100,000,000 for a general hospital [as defined in section 2801 of the Public Health Law]or $25,000,000 for all other facilities. Notwithstanding anything in this Part to the contrary, any cost increase of a project in excess of $30,000,000 for general hospitals or $15,000,000 for all other facilities that is administratively reviewed under the subparagraph, resulting in total project costs in excess of the [$50,000,000]$100,000,000 for general hospitals or $25,000,000 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. The following types of proposals are eligible for administrative review:

* * *

Clause (f) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(f) [in] the addition, updating or modification of equipment utilized in the provision of a service listed in paragraph (2) of this subdivision, by a medical facility already approved to provide such service, except for the addition of equipment utilized in cardiac catheterization laboratory center services by a facility already approved to provide such service, which shall be subject to limited review pursuant to paragraph ([7]6) of this subdivision;

Clause (q) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(q) [any proposal that relates to health information technology, provided that proposals with a total cost of up to $15 million may be reviewed under paragraph (5) of this subdivision]Reserved;

Subclause (7) of clause (w) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(7) neither the facility nor any part thereof, nor the project is currently or is proposed to be financed by bonds or other debt instruments insured, enhanced or guaranteed by any state or municipal agency or public benefit corporation. Notwithstanding anything in this Part to the contrary, any cost increase of a primary care services project resulting in total project costs in excess of the $30,000,000 threshold for general hospitals or the $15,000,000 threshold for all

other facilities shall subject the application or amendment, as the case may be, to full review.

Clause (e) of subparagraph (i) of paragraph (4) of subdivision (c) of section 710.1 is amended to read as follows:

(e) Subject to clause (d) of subparagraph (ii) of paragraph 5 of this subdivision, any proposal for a nonclinical infrastructure project with total project costs in excess of $6,000,000 [, 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.

A new clause (g) is added to subparagraph (i) of paragraph (4) of subdivision (c) of section 710.1 to read as follows:

(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.

A new subparagraph (ii) is added to paragraph (4) of subdivision (c) of section 710.1 to read as follows:

(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 $6,000,000, shall not require prior approval or written notice to the department under this Part, except as required by clause (d) of subparagraph (ii) of paragraph (5) of this subdivision.

The opening sentence of 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 $15,000,000 for a general hospital or $6,000,000 for all other facilities, 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.

Clause (g) of subparagraph (iv) of paragraph (5) of subdivision (c) of section 710.1 is amended to read as follows:

[(g) Any proposal to acquire, install or modify health information technology; provided that, notwithstanding any inconsistent provision in this paragraph, the cost of the proposal does not exceed $15 million. The applicant shall submit information, as requested by the department, including information concerning 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]Reserved.

Clause (b) of subparagraph (ii) of paragraph (6) of subdivision (c) of section 710.1 is amended to read as follows:

(b) Requests for approval of proposals described in this subparagraph shall be made [directly to the Director of the Division of Health Facility Planning. The applicant shall submit three (3)

copies of such request] through the electronic application submission process at the address posted on the department's website or any other means approved by the department, including information indicating the services to be provided, the facility areas to be utilized, and such other information as the Department may require. If construction is required, the request should include the cost of such construction and other information required by the Bureau of Architectural and Engineering Facility Planning under this Part. If the proposal involves the addition of Cardiac EP Laboratory Program Services, the applicant shall also submit a copy to the local health systems agency (HSA) having jurisdiction, if any. The HSA shall have 10 days to make a recommendation to the department.

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]ospital 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 (CON) 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 establishment 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, non-clinical 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 CON 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, *et seq.*, defines three levels of review for construction projects. Construction projects of greater complexity and higher costs undergo full review, requiring submission of a CON 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 CON application including forms and schedules which are less detailed than those needed for full review, and involves review for financial feasibility and public need. Limited review requires a narrative describing the construction activity to be undertaken, the cost of the construction and where applicable, architecture/engineering drawings or certification and does not include review for financial feasibility or public need.

Section 710.1(c)(1) specifies that CON applications are necessary for certain types of construction projects, generally including the addition, modification or decertification of licensed services, changes in the method of delivery of a licensed service, regardless of cost, or the acquisition 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 $15 million. Section 710.1(c)(3) provides that projects eligible for "administrative review" generally include those with a total project cost that does not exceed $15 million. However, an application shall be eligible for administrative review even though total project costs exceed $15 million, if: (a) total project costs do not exceed 10 percent of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application; and (b) total project costs do not

exceed $50 million for a general hospital or $25 million for all other facilities. Further, under section 710.1(c)(3)(i)(q), administrative review also applies to proposals related to health information technology (HIT) with a total cost above $15 million.

Section 710.1(c)(5) identifies construction projects subject to "limited review," which generally includes projects with costs that do not exceed $6 million. 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(5)(iv)(g) further provides for limited review of any proposal to acquire, install or modify HIT that does not cost more than $15 million.

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 last several years, the Department has refined the CON 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.

This proposal represents the next phase of CON streamlining measures and will: (1) raise the monetary thresholds impacting the level of review for "general hospital" construction projects; (2) eliminate the requirement that notice be provided for non-clinical infrastructure

projects that do not exceed $6 million; (3) eliminate the requirement for Department approval of HIT projects, instead requiring notice which, for HIT projects impacting patient care, will include certification as to interoperability and compliance with other applicable requirements; (4) update language to require that construction applications be submitted electronically; and (5) correct several erroneous references within the regulation. The proposal does not modify the level of review required to add, reduce or decertify medical services in a community.

Section 710.1(c)(2)(i)(c) will be amended to subject "general hospital" construction projects to full review if they exceed $30 million. Section 710.1(c)(3)(i) will be amended to require administrative review if costs are not more than $30 million for "general hospitals" or, if in excess of $30 million, no more than 10 percent of operating costs and no more than $100 million. Section 710.1(c)(1)(vi) will be amended to raise the threshold for limited review of a general hospital construction project to $15 million.

These increases recognize the overall upward movement in construction costs for large-scale projects undertaken by "general hospitals". The relative size of operating budgets and accumulated financial resources of applicants other than "general hospitals" make the current dollar thresholds still appropriate for those facilities.

In addition, section 710.1(c)(4)(i)(e) will be amended to apply the notice requirement to non-clinical infrastructure projects costing over $6 million. A new section 710.1(c)(4)(ii) will reflect that neither review nor notice is required for non-clinical infrastructure projects that do not exceed $6 million. Both provisions will reflect, however, that non-clinical projects impacting clinical spaces, services or equipment will continue to be subject to limited review under section 710.1(c)(5)(ii)(d).

Section 710.1(c)(3)(i)(q), which subjects HIT projects to administrative review if they are over $15 million, and section 710.1(c)(5)(iv)(g), which subjects HIT projects to limited review if they are no more than $15 million, will be repealed. A new section 710.1(c)(4)(i)(g) will provide that Department review of HIT projects is not required, but a facility will be required to provide notice to the Department that it is undertaking such a project. For HIT projects involving systems that impact patient care, the notice will have to include certification as to the system's interoperability and conformance with state and federal guidelines governing the use and exchange of information.

Finally, this proposal will amend section 710.1(c)(6)(ii)(b), related to limited review cardiac catheterization proposals, to update language and clarify that applications must be submitted electronically, consistent with Department practice.

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. Further, these changes are consistent with a broader effort being undertaken by the Department, in consultation with stakeholders, to fundamentally restructure health care statutes, regulations and policies to better align with changes in the health care system, affording opportunities to streamline 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 CON application or would need to prepare a less complex application, meaning that they will pay less in application fees, 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 general 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 fiscal impact on the Department.

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 CON application.

Duplication:

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

Alternatives:

The Department considered higher increases of the 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 CON 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.