Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new section 400.26, and amending sections 600.1 and 710.2, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new section 400.26 is added, to read as follows:

Section 400.26. Health Equity Impact Assessments.

(a) In accordance with Public Health Law § 2802-b, applications under Article 28, meeting the criteria set forth in this section, shall include a health equity impact assessment. The purpose of the health equity impact assessment is to demonstrate how a proposed project affects the accessibility and delivery of health care services to enhance health equity and contribute to mitigating health disparities in the facility's service area, specifically for medically underserved groups.

(b) Definitions. For the purposes of this section the following terms shall have the following meaning:

(1) "*Independent entity*" means individual or organization with demonstrated expertise and experience in the study of health equity, anti-racism, and community and stakeholder engagement, and with preferred expertise and experience in the study of health care access or delivery of health care services, able to produce an objective written assessment using a standard format of whether, and, if so, how, the facility's proposed project will impact access to and delivery of health care services, particularly for members of medically underserved groups.

(2) "*Conflict of Interest*" means having a financial interest in the approval of an application or assisting in drafting any part of the application on behalf of the facility, other than the health equity assessment.

(3) "*Stakeholders*" shall include individuals or organizations currently or anticipated to be served by the facility, employees of the facility including facility boards or committees, public health experts including local health departments, residents of the facility's service area and organizations representing those residents, patients of the facility, community-based organizations, and community leaders.

(4) "*Meaningful engagement*" shall mean providing advance notice to stakeholders and an opportunity for stakeholders to provide feedback concerning the facility's proposed project, including phone calls, community forums, surveys, and written statements. Meaningful engagement must be reasonable and culturally competent based on the type of stakeholder being engaged (for example, people with disabilities should be offered a range of audiovisual modalities to complete an electronic online survey).

(c) In accordance with Public Health Law 2802-b, applications for the construction, establishment, change in establishment, merger, acquisition, elimination or substantial reduction, expansion or addition of a hospital service or health-related service of a hospital that require review or approval by the public health and health planning council or the commissioner, shall include a health equity impact assessment; provided, however, that a health equity impact assessment shall not be required for the following:

(1) projects that do not require prior approval but instead only require a written notice to be submitted to the Department prior to commencement of a project pursuant to Part 710 of this Title;

(2) minor construction and equipment projects subject only to limited review pursuant to Part 710 of this Title, unless such project would result in the elimination, reduction, expansion or addition of beds or services;

(3) establishment (new or change in ownership) of an operator, including mergers and acquisitions, unless such establishment would result: (i) the elimination of a hospital service or health-related service; (ii) a 10 percent or greater reduction in the number of certified beds, certified services, or operating hours or (iii) a change of location of a hospital service or health-related service; and

(4) applications made by a diagnostic and treatment center whose patient population is over fifty percent combined patients enrolled in Medicaid or uninsured, unless the application includes a change in controlling person, principal stockholder, or principal member of the facility.

(d) A health equity impact assessment shall be performed by an independent entity without a conflict of interest, using a standard format provided by the Department, and shall include:

(1) meaningful engagement of stakeholders commensurate to the size, scope and complexity of the facility's proposed project and conducted throughout the process of developing the health equity impact assessment, to incorporate and reflect community voices;

(2) a description of the mechanisms used to conduct meaningful engagement;

(3) a documented summary of statements received from stakeholders through meaningful engagement as submitted to, or prepared by, the facility or independent entity. The Department reserves the right to request and review individual statements as submitted, or prepared by the facility or independent entity, while reviewing the health equity impact assessment.

(4) documentation of the contractual agreement between the independent entity and the facility;

(5) a signed attestation from the independent entity that there is no conflict of interest; and

(6) a description of the independent entity's qualifications.

(e) When submitting an application to the Department requiring a health equity impact assessment, the application must include:

(1) a full version of the application and a version with proposed redactions, if any, to be shared publicly; and

(2) a signed written acknowledgment that the health equity impact assessment was reviewed by the facility, including a narrative explaining how the facility has or will mitigate potential negative impacts to medically underserved groups identified in the health equity impact assessment. The narrative must also be made available to the public and posted conspicuously on the facility's website until a decision on the application is rendered by the public health and health planning council or the commissioner.

Paragraph (5) of subdivision (b) of section 600.1 is amended to read as follows:

(b) Applications to the council shall contain information and data with reference to: (5) the following documents shall be filed:

* * *

(5) the following documents shall be filed:

* * *

(iii) <u>a health equity impact assessment, if applicable, pursuant to section 2802-b of the Public Health Law and section 400.26 of this Title;</u>

(iv) such additional pertinent information or documents necessary for the council's consideration, as requested.

Subdivision (b) of section 710.2 is amended to read as follows:

(b) The application setting forth the scope and concept of the project shall include the following if applicable:

* * *

(11) a health equity impact assessment, if applicable, pursuant to section 2802-b of the Public Health Law and section 400.26 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803(2)(a) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to effectuate the provisions and purposes of Article 28 of the PHL. Chapter 766 of the Laws of 2021 and Chapter 137 of the Laws of 2022 amended Article 28 of the PHL by adding a new Section 2802-b, requiring health equity impact assessments to be submitted to the Department of Health (Department) for certain applications requiring review or approval by PHHPC or the Commissioner.

Legislative Objectives:

The legislative objective of PHL § 2802-b is to ensure the establishment, ownership, construction, renovation, and change in service of health care facilities defined in Article 28 (including general hospitals, nursing homes, diagnostic and treatment centers, and midwifery birth centers) do not adversely impact the public health of, service delivery to, or access to hospital and health-related services for medically underserved groups. Applications for select projects will be required to include a health equity impact assessment as part of the application process. The purpose of the assessment is to ensure community members, including members of medically underserved groups, are meaningfully engaged and considered in the development of proposed facility projects, encourage facilities to understand the health equity impacts of proposed projects and mitigate potential negative impacts from proposed projects, and allow the Department and PHHPC to consider how proposed projects will impact medically underserved groups when approving or denying applications. The intended impact of this legislation is to embed equity into structural decision-making processes, which will help New York's health care facilities stay accountable to enhancing health equity in their communities.

Needs and Benefits:

These regulations are necessary to implement PHL § 2802-b. Specifically, the regulations set forth criteria that: (1) qualifies an independent entity to conduct an objective health equity impact assessment; (2) defines a conflict of interest such that it would prevent an otherwise independent entity from performing an objective health equity impact assessment; (3) specifies requirements for meaningful engagement with stakeholders as part of the health equity impact assessment; (4) defines the type of applications for which a health equity impact assessment is and is not required; and (5) clarifies standards for completion of the health equity impact assessment, including the use of a template issued by the Department and inclusion of a narrative statement from the facility in response to the findings of the assessment.

In addition, the regulations require facilities to integrate health equity into their decision making and planning processes to promote the maximum utilization of resources and ensure that medically underserved groups are not negatively impacted by proposed establishment, ownership, construction, renovation, and/or change in service applications. Requiring a demonstration of meaningful engagement with stakeholders will ensure that the people whom the health care facilities serve have a voice in proposed projects. This assessment is critical for Article 28 facilities to consider when making changes to their services, facilities and ownership. The regulations ensure that a facility reviews the findings of the health equity impact assessment and develops a narrative statement for how it will mitigate potential for exacerbating health inequities in underserved communities.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The proposed regulation will require a health equity impact assessment to be completed with the submission of certain applications and will therefore require health care facilities to pay for such an assessment to be performed. Facilities are required to utilize an independent entity without a conflict of interest to complete the health equity impact assessment. The projected costs associated with performing such an assessment are not easily identifiable, as they will vary greatly depending on the size, scope and complexity of a facility's proposed project. However, the Department anticipates these costs could range anywhere from $500 to upwards of $30,000. These costs are unavoidable in the regulations, as PHL § 2802-b requires health equity impact assessments to be performed by independent entities.

Costs to State and Local Governments:

There is no impact on costs to state and local governments associated with this regulation unless they operate an Article 28 health care facility, in which case they may be required to submit a health equity impact assessment pursuant to the proposed regulations. The proposed regulations also define "stakeholders" to include local health departments, so local health departments may be asked to comment as part of a facilities' meaningful engagement of stakeholders. In this instance, local health departments may bear minimal costs associated with staff time but there are no major operational costs to local governments.

Costs to the Department of Health:

This regulation will result in an operational cost to the Department of Health due to the hiring of staff responsible for reviewing and analyzing data from health equity impact assessments submitted to the Department.

Local Government Mandates:

There is no impact on local government mandates associated with this regulation.

Paperwork:

This regulation will require Article 28 health care facilities to conduct a health equity impact assessment as part of their application. These facilities will need to contract with an independent entity to conduct a health equity impact assessment and document such agreement in appropriate records. Facilities also must submit documentation of their agreements with independent entities conducting health equity impact assessments.

In addition, the proposed regulation will require facilities to review their health equity impact assessments and develop a narrative on how they intend to mitigate potential harms to medically underserved groups. Facilities must submit this narrative along with their health equity impact assessments as part of the application.

Duplication:

This regulation does not have any duplications in state or federal law. There is some overlap between the health equity impact assessment and some of the required content for the certificate of need (CON) process. Specifically, Schedules 16-24 of the CON [excluding Schedule 23] application include questions for facilities to answer regarding the community need and impact on certain populations for changes in health care facilities. However, these questions are minimal and do not require "meaningful community engagement" to complete. This regulation is a means of ensuring "meaningful community engagement" and a full impact assessment focused on health equity for facilities participating in the certificate of need process.

Alternatives:

One alternative to the proposed regulation the Department considered was requiring all CON applications under Article 28 of the Public Health Law to be subject to the health equity

impact assessment requirement. However, this alternative was ultimately not incorporated into the regulation because the Department decided to focus on the potential health equity impacts of proposed projects that involve access to or delivery of health services, and to exempt proposed projects such as routine repairs or maintenance. Another alternative the Department considered was to articulate more stringent requirements on the types of individuals or organizations that qualify to serve as independent entities for purposes of conducting health equity impact assessments. However, this alternative was not incorporated into the proposed regulation because the Department did not want to limit the types of individuals or organizations with expertise and qualification that may prove to offer invaluable insight through their assessments.

Federal Standards:

There are no federal statutes or standards with respect to health equity impact assessments as a component of the CON process for facilities.

Compliance Schedule:

This regulation will become effective after publication of Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments and small businesses will not be affected by this rule, unless they operate a general hospital. Where a local government or small business operates a general hospital, they will be similarly affected as any other regulated entity under the rule. There are over 150 Article 28 health care facilities owned by municipalities and local governments in the State. The Department does not anticipate a change in establishment applications by such applicants as a result of the proposed regulation.

Compliance Requirements:

Pursuant to Public Health Law (PHL) § 2802-b, health care facilities regulated under Article 28 of the PHL will be required to have a health equity impact assessment performed by an independent entity when submitting certain applications to the Department for approval by the Public Health and Health Planning Council (PHHPC) or the Commissioner of Health (Commissioner). The regulations will help to further define what an independent entity is for purposes of performing a health equity impact assessment, the types of applications requiring such an impact assessment and the documentation required to be submitted to the Department.

Professional Services:

The regulations require a health equity impact assessment to be performed by an independent entity without a conflict of interest.

Compliance Costs:

The proposed regulation will require a health equity impact assessment to be completed with the submission of certain applications and will therefore require local governments and

small businesses operating health care facilities regulated under Article 28 of the PHL to pay for such an assessment to be performed. Facilities are required to utilize an independent entity without a conflict of interest to complete the health equity impact assessment. The projected costs associated with performing such an assessment are not easily identifiable, as they will vary greatly depending on the size, scope and complexity of a facility's proposed project. However, the Department anticipates these costs could range anywhere from $500 to upwards of $30,000. These costs are unavoidable in the regulations, as PHL § 2802-b requires health equity impact assessments to be performed by independent entities.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not require any special technology and does not impose an unreasonable financial burden on anyone.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since these new requirements are statutory and apply to all Article 28 of the PHL health care facility operators.

Small Business and Local Government Participation:

The Department has taken steps to notify stakeholders about the effects of this regulation and has provided the opportunity for them to comment on the proposed regulations. In addition, the regulation will be presented to PHHPC on March 30, 2023, where there will be an opportunity for public comment prior to being published in the State Register and subject to a 60-day public comment period.

RURAL AREA FLEXIBLITY ANALYSIS

Type and Number of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein."

The following 44 counties have an estimated population of less than 200,000 based upon the 2020 United States Census:

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County

Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

Reporting, recordkeeping, and other compliance requirements; and professional services:

Pursuant to Public Health Law (PHL) § 2802-b, health care facilities regulated under Article 28 of the PHL will be required to have a health equity impact assessment performed by an independent entity when submitting certain applications to the Department for approval by the Public Health and Health Planning Council (PHHPC) or the Commissioner of Health (Commissioner).

Compliance Costs:

Per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not require any special technology and does not impose an unreasonable financial burden in rural areas.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since these new requirements are statutory and apply to all Article 28 of the PHL health care facility operators.

Rural Area Participation:

The Department has taken steps to notify stakeholders on the effects of this regulation and has provided the opportunity for them to comment on the proposed regulations. In addition, the regulation will be presented to PHHPC on March 30, 2023, where there will be an opportunity for public comment prior to being published in the State Register and subject to a 60-day public comment period.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these proposed regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs or employment opportunities.