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 or residents 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 or residents 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.

SUMMARY OF THE ASSESSMENT OF PUBLIC COMMENT

The Department of Health ("the Department") received 43 comments about the proposed regulations, which implement section 2802-b of the Public Health Law (PHL) concerning the inclusion of a Health Equity Impact Assessment (HEIA) with certain certificate of need (CON) applications.

COMMENT: Many comments were received in support of the definitions within the regulations. In general, commenters were supportive of the requirement for independent entities to have experience and supportive of the prohibition on independent entities having a conflict of interest with the Article 28 facility for which they perform a HEIA. Multiple commenters voiced support of the definition of meaningful engagement, with some commenters requesting further clarification as to what constitutes "advance notice" and requiring more than one form of stakeholder engagement.

RESPONSE: The regulation allows independent entities to utilize their expertise to drive decisions about stakeholder engagement, based on the size and scope of a specific project as well as the medically underserved populations impacted by the project. No changes to the regulation were necessary as a result of these comments.

COMMENT: The Department received numerous comments expressing concern that further regulatory exemptions from the requirement to perform a HEIA might be added. Commenters were opposed to any future regulatory expansions that would limit either the types of Article 28 facilities or the types of CON projects that require a HEIA.

RESPONSE: No changes to the regulation were requested from these comments so no changes are necessary. The Department will keep these comments in mind for any future rulemaking.

COMMENT: There was widespread support amongst commenters for the 10 percent threshold for changes in beds or services resulting from establishment CON applications, that would trigger a HIEA. Commenters also requested that a similar 10 percent threshold be added to minor construction CON applications subject to only limited review.

RESPONSE: No changes to the regulation are being made at this time; however, the Department intends to clarify in future rulemaking that minor construction and equipment projects subject to only limited review will require a HEIA if they result in a 10 percent or greater elimination, reduction, expansion or addition of beds and services.

COMMENT: The Department received two comments requesting the regulation be amended to exempt safety-net hospitals from the HEIA requirement. Similarly, a handful of commenters representing nursing homes expressed concern that requiring a HEIA would impede projects aimed at patient safety and infection control.

RESPONSE: A legislative amendment to PHL § 2802-b would be required in order to amend the regulations as these commenters have requested. As such, no changes to the regulation were made as a result of these comments.

COMMENT: The Department received a wide range of comments requesting clarification of the logistics for finding and paying for an independent entity. Some commenters expressed concerns about who the independent entity may be and suggested the Department provide a vetted list of independent entities. Commenters also expressed concern about the cost of having a HEIA performed.

RESPONSE: Article 28 facilities should factor in the cost of contracting with an independent entity into the project budget if they determine that their project will require one, as defined

PHL § 2802-b and these regulations. The Department has issued a standard template with detailed instructions to ensure the process is as clear and narrow as possible for independent entities. No changes to the regulation were made as a result of these comments.

COMMENT: Many commenters pointed to hospital closures as a gap in the legislation and regulation. Commenters suggested that HEIAs should be conducted when facilities close, and that communities impacted by facility closures should be meaningfully engaged.

RESPONSE: Pursuant to PHL § 2802-b, a HEIA is required for applications made pursuant to Article 28 of the PHL and subject to review or approval by the PHHPC or the Commissioner. However, medical facilities seeking to discontinue operation or surrender their operating certificates do not apply to the Department pursuant to Article 28 but rather must provide 90 days' notice of their intent to close and have their closure plan approved by the Commissioner. In addition, section 2801-g of the PHL governs general hospital closure plans and requires the Commissioner to conduct an "after closure" review which is subject to public comment. The Department is committed to including the principles of a HEIA into the closure plan process. No amendments to the regulation were made as a result of these comments.

ASSESSMENT OF PUBLIC COMMENT

The NYS Department of Health (Department) received public comments from Greater New York Hospital Association, Healthcare Association of New York State, Community Voices for Health Systems Accountability, LeadingAge NY, a broad coalition of health care consumer advocates and many others. In all, 43 comments were received. These comments and the Department's responses are summarized below.

Comment: One commenter suggested that an Article 28 facility's internal staff, such as a population health department, could be qualified to complete the facility's own Health Equity Impact Assessments (HEIA).

Response: Pursuant to Public Health Law (PHL) § 2802-b, HEIAs are required to be performed by an independent entity. The regulation goes on to further define what an independent entity means and to require that the independent entity performing a HEIA not have a conflict of interest. No changes to the proposed rulemaking were made as a result of this comment.

Comment: A few commenters suggested that the Department compile a list of independent entities that meet the qualifications to conduct a HEIA. Applicants would choose from this vetted list of independent entities, and the Department would be responsible for ensuring independent entities' quality of work.

Response: The Department will not be issuing a list of independent entities at this time. The purpose of not creating a list of independent entities is to ensure that the Department does not

inadvertently limit the pool of qualifying individuals or organizations that could conduct HEIAs. No changes to the proposed rulemaking are necessary as a result of this comment.

Comment: One commenter desired clarity on who would meet the criteria for independent entities outlined in the regulations, stating that there may not be any one type of organization or entity with access to the needed data as well as the interest and experience to undertake such work.

Response: The proposed regulation broadly states that independent entities must have expertise and experience in the areas of health equity, anti-racism, and community and stakeholder engagement, with preferred expertise and experience in health care access or delivery of health care services. Facilities can enlist one independent entity that possesses the mandatory areas of expertise, but that independent entity may require a subcontract with another individual or organization in order to "supplement" the expertise, experience, and/or function needed to ensure a comprehensive HEIA. No changes to the proposed rulemaking are necessary as a result of this comment.

Comment: One commenter noted that the consultants that are typically hired to develop certificate of need applications on behalf of facilities may not be the right ones to conduct HEIAs.

Response: The proposed regulation broadly states the qualifications of an independent entity. Individuals and organizations that meet the Department's qualifications (including having no conflict of interest) may or may not be the same as those that currently assist with certificate of

need applications. No changes to the proposed rulemaking are necessary as a result of this comment.

Comment: One commenter recommended that "expertise and experience in the study of health care access or delivery of health care services" be a requirement of the independent entity, instead of a preferred qualification, as outlined in the proposed regulations.

Response: PHL § 2802-b(1)(c) defines "health equity impact assessment" as an assessment of "whether, and if so how, a project will improve access to hospital services and health care," and the law therefore anticipates that independent entities that are responsible for assisting facilities with conducting HEIAs be able to conduct a thorough assessment that speaks to health care access and delivery of health care service impacts. No changes to the proposed rulemaking were made as a result of this comment.

Comment: One commenter desired clarity on the qualifications of the independent entity by trying to understand whether the independent entity must have a professional certification from a certain organization or institution to qualify.

Response: The regulation does not require a specified certificate or certification for the independent entity, but rather lay out minimum requirements on expertise and experience. This does not preclude individuals intending to work as, or for, an independent entity from seeking professional certification, designation, training, or education that would help them gain expertise.

Comment: One commenter asked that the Department consider alternate methods for an individual or organization to demonstrate their efforts related to health equity, such as including a carve out for organizations with certifications or designations related to health equity.

Response: The parameters of an independent entity are broadly stated, limited only to showing evidence of no conflict of interest and a 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. Organizations with certifications or designations related to health equity that meet the stated parameters are eligible to conduct an independent HEIA.

Comment: One commenter stated that the regulations should specify that the HEIA must indicate both pros and cons of a facility project and incorporate the more neutral language utilized in the statute. Specifically, the commentor suggested that the regulations be amended to include that the HEIA is "to demonstrate whether, and if so, how a proposed project affects the accessibility and delivery of health care services to enhance or hinder health equity and contribute to mitigating health disparities in the facility's service area, specifically for medically underserved groups."

Response: The regulation elaborates upon, but does not deviate from, the statute. Program documents and guidance articulate the Department's expectation for HEIAs to provide a comprehensive set of findings (both positive and negative). No changes were made to the regulation; however, the Department will consider making these amendments in future rulemaking.

Comment: One commenter stated that the independent entity must have no conflict of interest, and that this requirement be vigorously enforced.

Response: The Department has issued a conflict-of-interest attestation form that both the Article 28 facility and the independent entity must sign and submit with the facility's HEIA and other required HEIA documents.

Comment: One commenter stated that the definitions of "stakeholders" and "meaningful engagement" are overly broad and goes beyond the intent of statute by listing additional stakeholders that must be consulted. The comment is tied to the concern over cost of hiring an independent entity that will be responsible for meaningfully reaching a broad range of stakeholders, and that independent entities should have the flexibility to identify the stakeholders and means of engagement that make sense given the unique characteristics of the community being assessed.

Response: The definition of "stakeholders" in the regulation is framed to ensure a comprehensive and inclusive approach. In accordance with the statute, the Department was intentional in outlining a broad definition to allow the expertise of independent entities in determining the key stakeholders that should be consulted for a facility's HEIA. The stakeholders identified in the regulation are not an exhaustive list but instead include groups of individuals that align with the law as written. "Meaningful engagement" as defined in regulation also aligns with the law and ensures that the community has a voice in the HEIA. No changes to the regulation were necessary as a result of this comment.

Comment: One commenter requested that the definition of "stakeholder" include a reiteration of the medically underserved groups that are outlined in the law, noting that they are priority communities to engage with, even if a specific medically underserved group is not part of the defined "service area." The commenter stated that the independent entity must specifically reach out for input from medically underserved groups.

Response: The statutory list of medically underserved groups is included in program and guidance documents, and the Department does not believe they need to be renamed in the regulation. The Department is asking that the "service area" defined by the HEIA and CON application for the project remain the same and therefore, those in the service area must be included. The expertise of the independent entity will guide the meaningful engagement of the medically underserved groups. No changes to the regulation were made as a result of this comment.

Comment: While several commenters supported the proposed regulations' elaboration of different types of meaningful engagement, they suggested that the Department require multiple forms of engagement. Commenters suggested that the Department specify that meaningful engagement requires more than one method/form of engagement, while one commenter asked that the Department prohibit the use of only one form of engagement.

Response: The proposed regulation states that the degree of meaningful engagement must be commensurate to the size, scope, duration, and complexity of the facility project. It is the Department's expectation that upon evaluating the certificate of need application, the independent entity will consider, identify, and offer multiple forms of meaningful engagement to

ensure maximal depth and reach across a wide breadth of stakeholders. Program and guidance documents will reiterate that independent entities deploy a range of methods/forms of meaningful engagement. No changes to the regulation were made as a result of these comments.

Comment: Commenters supported the inclusion of cultural competence in the definition of meaningful engagement and agreed with the importance of the independent entity deploying culturally competent methods of engagement.

Response: The Department appreciates these comments in support of the regulation. Program and guidance documents will reiterate the Department's expectations on methods of meaningful engagement and resources to ensure cultural competence.

Comment: One commenter expressed concern that elderly people and their loved ones are not included as "stakeholders" and are often left out of decision-making processes. The commenter referenced the Department's Master Plan for Aging to ensure these populations are being represented.

Response: PHL § 2802-b defines "medically underserved group" to include "older adults." This means that HEIAs must identify the extent to which older adults within an applicant's service area will be impacted. In addition, throughout the process of developing the regulation and program documents, the Department's Office of Health Equity and Human Rights (OHEHR) has been working with the Office of Aging and Long-term Care (OALTC) as well as advocates representing aging communities to ensure this population is being included. No changes to the regulation are necessary as a result of this comment.

Comment: Several commenters suggested that the language in Section 400.26(c)(3) of the regulations, that exempts certain establishment certificate of need applications from having to submit a HEIA, should include a guarantee or moratorium that the applicant will not make subsequent changes that might eliminate, reduce or change certified services or care provided by the facility following approval of a merger or acquisition. The commenters suggested that the Department consider a similar process to "limited life" certificate of need applications currently in place for ambulatory surgery centers.

Response: Any subsequent changes to beds or services by an applicant would require approval by the Department through the certificate of need application process, which would then trigger the requirement for a HEIA. As such, no changes to the proposed regulation are necessary as a result of this comment.

Comment: Many commenters stated opposition to the Department including any further exemptions to the types of project applications for which a HEIA will be required.

Response: Pursuant to PHL § 2802-b, applications submitted to the Department for the construction, change in establishment, merger, acquisition, elimination or substantial reduction, expansion or addition of a hospital service or health-related service of a hospital, require a HEIA. The regulation is consistent with the statute and the exemptions in the regulation simply set forth the situations in which an application pursuant to Article 28 of the PHL is not required or where the project applications are of such a nature that they would not be considered "substantial" pursuant to the statute. No amendments to the regulation are necessary as a result of these comments; however, the Department will keep these comments in mind for future rulemaking.

Comment: One commenter suggested that the HEIA only be required for certificate of need applications subject to full review.

Response: The proposed regulation is consistent with the statute and the exemptions in the regulation simply set forth the situations where the project applications are of such a nature that they would not be considered "substantial" pursuant to the statute. There are projects determined "substantial" by the Department that span across all types of review. No changes to the proposed regulation were made as a result of this comment.

Comment: One commenter recommended that the Department consider exempting specific limited review nursing home facility projects from the HEIA requirement, even if they involve decertifying beds or expanding or reducing service or care, specifically:

1. Projects that involve upgrading, reconfiguring, or expanding space to improve the quality or safety of care, infection prevention and control, or quality of life of nursing home residents.
2. Projects that would decertify nursing home beds or services if the Department's need methodology for nursing home beds in the county reflects a determination that there is no public need for the beds; or the number of beds to be decertified represents 25 percent or less of the facility's certified beds; or the resulting space will be used to provide housing or community-based services for older adults or people with disabilities.
3. Projects that add services that will support the health care or social care needs of older adults or people with disabilities.

4. Projects that involve the establishment of a not-for-profit parent and the expansions of services for older adults or the reduction, elimination or relocation of a duplicative service in the same service area.

Response: The proposed regulation is consistent with the statute and the exemptions in the regulation simply set forth the situations where the project applications are of such a nature that they would not be considered "substantial" pursuant to the statute. Further, the statute applies to Article 28 licensed facilities broadly and therefore does not allow the Department to make exemptions specific to facility type. The Department intends to monitor the first year of implementation of this new requirement to better understand the types of projects that require a HEIA. No amendments to the regulation were made as a result of these comments.

Comment: Several commenters supported the Department's proposed definition of "substantial" as 10 percent or greater, as outlined in the regulations. Some commenters suggested this percentage be further defined to clarify 10 percent of services and beds within a specified category of care, and not calculated against all beds in the facility.

Response: The Department's intent for defining "substantial" as 10 percent or greater is that 10 percent will apply to a specific category of service (not all services) and, similarly, 10 percent of the specific bed type, not all beds. Program documents and guidance issued by the Department clarify this expectation. No changes to the regulation are necessary as a result of these comments.

Comment: One commenter suggested certificate of need applications that do not result in either the elimination of a hospital or health-related service or a substantial reduction, expansion, or addition of beds or services should be exempt from the HEIA requirement.

Response: The proposed regulation is consistent with the statute and the exemption in the regulation simply sets forth the situations where the project applications are of such a nature that they would not be considered "substantial" pursuant to the statute. No changes to the proposed regulation were made as a result of this comment.

Comment: A few commenters suggested that a HEIA should only be required for projects that result in changes to an operating certificate for an Article 28 health care facility.

Response: Although statute includes the term "substantial," the Department does not agree that only those projects with changes to the operating certificates are "substantial." All exemptions have been carefully considered and defined in regulation according to the intent of the original legislation. No changes were made to the regulation as a result of these comments.

Comment: One commenter requested that the HEIA requirement not apply to projects that require only written notification to the Department and that the exemption for minor construction and equipment projects subject only to limited review be expanded to all such projects, even if they would result in the elimination, reduction, expansion or addition of beds or services.

Response: The proposed regulation already sets forth that projects that require only written notification to the Department are not subject to a HEIA. With respect to minor construction and equipment projects subject only to limited review, PHL § 2802-b requires all applications to

include a HEIA, but limits the definition of “application” to only “substantial” reductions, expansions or additions. As such, the regulation specifies that if a limited review minor construction or equipment project also results in the elimination, reduction, expansion or addition of beds or services, a HEIA will be required. No changes to the regulation are being made at this time; however, the Department intends to clarify in future rulemaking that minor construction and equipment projects subject to only limited review will require a HEIA if they result in a 10 percent or greater elimination, reduction, expansion or addition of beds and services.

Comment: Several commenters stated opposition to the regulations exempting limited review applications for “minor construction and equipment projects.” These commenters recommended that the Department further narrow “minor” to limit the number of limited review applications that would be exempt from including a HEIA. Commenters suggested that the Department include “relocation of beds and services” to the list of minor construction projects subject only to limited review but that still require a HEIA.

Response: Pursuant to PHL § 2802-b, the exemptions outlined in the regulation are the projects the Department has determined as not constituting substantial changes, and therefore exempt from the HEIA requirement. That said, the Department agrees with the commentors that minor construction projects subject only to limited review that would result in a change in location of beds and services, are substantial changes and therefore should be subject to a HEIA. No changes to the regulation are being made at this time; however, the Department intends to make this amendment in future rulemaking.

Comment: One commenter suggested that the Department consider exempting projects awarded through the Statewide Health Care Facility Transformation Program (SHCFTP) from the HEIA requirement. Given the purpose of such grants and rigor by the State in identifying areas of highest need, the commenter noted the HEIA would be a duplicative, costly addition to a state-directed, state-funded project.

Response: Pursuant to PHL § 2802-b, applications submitted to the Department for the construction, change in establishment, merger, acquisition, elimination or substantial reduction, expansion or addition of a hospital service or health-related service of a hospital, require a HEIA. The regulation is consistent with the statute and the exemption in the regulation simply sets forth the situations in which an application pursuant to Article 28 of the PHL is not required or where the project applications are of such a nature that they would not be considered "substantial" pursuant to the statute. No amendments to the regulation are necessary as a result of these comments.

Comment: One commenter stated that certain hospital networks that have safety-net provider status should be exempt from having to submit a HEIA. This commenter pointed to the exemption for diagnostic and treatment centers with patient populations over 50 percent Medicaid or uninsured (combined) and stated that the hospital network they represented also satisfied this requirement and should therefore be exempt. In contrast, several commenters voiced support that safety-net hospitals are subject to the HEIA requirement and emphasized that they should not be exempt.

Response: Pursuant to PHL § 2802-b applications submitted to the Department for the construction, change in establishment, merger, acquisition, elimination or substantial reduction,

expansion or addition of a hospital service or health-related service of a hospital, require a HEIA. The proposed regulation is consistent with the statute and the exemption in the regulation for diagnostic and treatment centers whose patient population is over 50 percent combined patients enrolled in Medicaid or uninsured, comes directly from PHL § 2802-b(2)(a)(ii). No amendments to the regulation were made as a result of these comments.

Comment: One commenter noted that while most Federally Qualified Health Centers fall under the legislative carveout for diagnostic and treatment centers, some Federally Qualified Health Centers would be required to submit a HEIA. The commenter states examples where specific diagnostic and treatment centers will not meet the 50 percent combined Medicaid or uninsured.

Response: PHL § 2802-b(2)(a)(ii) exempts diagnostic and treatment centers that have a patient makeup of 50 percent or more Medicaid or uninsured (combined) unless the certificate of need application includes a change in controlling person, principal stockholder, or principal member of the facility. When submitting a certificate of need application, facilities should accurately attest to their patient insurance mix as requested within the New York State Electronic Certificate of Need (NYSE-CON) application system. For those providers that do not meet the 50 percent threshold, and are submitting a certificate of need application for a substantial change, a HEIA must be completed. No amendments to the regulation were made as a result of this comment.

Comment: One commenter stated that the HEIA requirement should not apply to residential health care facilities (nursing homes). They described how the proposed regulations will impede

intended goals as applied to nursing home projects, that the unique circumstances of nursing homes and the interests of the residents they serve are not reflected in statute, and that since the vast majority of nursing home residents on any given day are Medicaid beneficiaries, nursing homes should also be exempt from the HEIA requirement.

Response: Pursuant to PHL § 2802-b, residential health care facilities are licensed under Article 28 of the PHL and therefore subject to the HEIA requirement. The statute only exempts diagnostic and treatment centers whose patient population is over 50 percent or more Medicaid or uninsured patients (combined) and does not exempt residential health care facilities. The regulation, along with guidance and documents issued by the Department, was developed to apply universally to the various types of Article 28 facilities subject to the HEIA requirement. No changes to the regulation were made as a result of these comments.

Comment: One commenter stated that Continuing Care Retirement Communities (CCRCs) should be exempt from the HEIA requirement given the unique operational setup of CCRCs.

Response: Residential health care facilities within Continuing Care Retirement Communities are licensed under Article 28 of the PHL and projects conducted by residential health care facilities are subject to review through the certificate of need application process. Therefore, the HEIA requirement would only apply to those aspects of a CCRC that are licensed under Article 28 of the PHL, whereas other facilities located within a CCRC and licensed under Articles 7 of the Social Services Law and 46 of the PHL would not be subject to the HEIA. No changes to the regulation were made as a result of these comments.

Comment: One commenter noted that any certificate of need applications to sell or privatize nursing homes are required to complete a HEIA.

Response: The regulation reiterates the statutory requirement that any application for establishment (new or change in ownership) of an operator that results in a substantial change to hospital service or health-related service, will be required to include a HEIA. No changes to the regulation are necessary as a result of this comment.

Comment: One commenter noted the need for a clear, standardized process with program documents and a timeline that correlates to timely review of the overall certificate of need application.

Response: This comment is outside the scope of the proposed regulation; however, the Department has issued and distributed standardized program documents. No changes to the regulation are necessary as a result of this comment.

Comment: One commenter suggested a broad advisory committee should be formed to make recommendations about the regulations that move toward equity.

Response: This comment is outside the scope of the proposed regulation; however, the Department met with various stakeholders representing medically underserved communities, consumer advocates, representatives of facilities, hospital associations, and more at various points throughout the development of the regulation and in the program planning and implementation process. The goal of conducting multiple meetings with these stakeholders is to ensure the Department had a comprehensive understanding of stakeholders' recommendations

and could prioritize equity. No changes to the regulation are necessary as a result of this comment.

Comment: A few commenters suggested that reports such as hospitals' community health needs assessment or community service plans and other similar reports that are related to health equity be considered in the HEIA review process.

Response: Community health needs assessments (CHNAs), community needs assessments (CNAs), and community service plans (CSPs) are not the same thing as a HEIA. The legislative intent was not to utilize the CHNAs/CNAs/CSPs in place of HEIAs. PHL § 2802-b makes clear that the purpose of a HEIA is to understand the impacts of a specific facility project and how the project will improve access to services and care, improve health equity, and reduce health disparities, whereas CHNAs, CNAs, and CSPs capture the landscape of a facility's services and community needs. The Department conducted an extensive comparison analysis to review the required documents that facilities are currently required to complete under the certificate of need process to ensure the information collected through the HEIA was distinct and not redundant. While reports containing relevant information may be shared with the independent entity to be considered for a specific project's HEIA, the Department will only review information submitted through the approved HEIA template to ensure a standardized review process. No changes to the regulation are necessary as a result of these comments.

Comment: One commenter named a few ways that the general public should be involved in the HEIA process, including the opportunity to give testimony on the proposed regulations, to be

notified about upcoming certificate of need applications, that the certificate of need application be made publicly available as well as a summary sheet, and that a member of the public be able to request a hearing to include additional information on the application.

Response: Meetings of the Public Health and Health Planning Council (PHHPC), where certificate of need applications are reviewed and discussed, are open to the general public. Meeting materials are made available in advance of each meeting. Members of the general public gave public comment and testimony at the March 30, 2023 PHHPC meeting when the Department presented the proposed regulation for discussion. The proposed regulation was also subject to a 60-day public comment period and presented again to PHHPC on June 15, 2023, at which time the general public were able to provide comments. The regulation requires 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 HEIA, to incorporate and reflect community voices. Moreover, as required by law all HEIAs will be made publicly available on the Department's website along with a redacted version of the certificate of need application which they accompany. As such, the general public has been involved in the development of the regulation and will continue to be involved in the HEIA process. No changes to the regulation are necessary as a result of this comment.

Comment: A few commenters stated that the regulations should state the statutory requirement that the assessments be posted within one week of filing, for clarity and to provide opportunity for public comment.

Response: Pursuant to PHL 2802-b(5), the Department must publicly post all applications and the corresponding HEIA on the Department's website within one week of the filing. Since this is

a statutory requirement with the onus on the Department and not regulated entities, the Department did not feel it was necessary to include in the regulation. No changes to the regulation were made as a result of these comments.

Comment: Several commenters noted support for the use of an independent entity, a standard conflict of interest form, and the list of qualifications of the independent entity outlined in the proposed regulations in order to ensure an “objective written assessment.”

Response: The Department appreciates these comments in support of the regulation. No changes to the regulation are necessary as a result of these comments.

Comment: One commenter stated that the proposed regulations do not mention the statute’s detail of the scope and contents of the HEIA.

Response: PHL § 2802-b(3) sets forth detailed requirements for the scope and contents of a HEIA. In developing the HEIA template and other related program documents, the Department included these requirements. The Department did not feel it was necessary to include all of these requirements in the regulation. No changes are being made to the regulation as a result of this comment; however, the Department will consider making this amendment in future rulemaking.

Comment: A few commenters expressed concerns over the cost incurred by facilities to get HEIAs together as well as potential delays to the projects themselves and the Department’s review of the certificate of need application. Commenters expressed concerns that the high price

of an independent entity to conduct a thorough HEIA will dissuade projects aimed at innovation, improving care, and quality of life.

Response: If an application requires a HEIA pursuant to PHL § 2802-b and the regulation, Article 28 facilities should factor in the cost of having a HEIA performed into the project budget. The Department has done its best to standardize the process of completing a HEIA, with detailed instructions and a template form, to ensure the process is as clear and narrow as possible for independent entities to complete. In addition, HEIA-dedicated Department staff are available to answer questions that applicants or independent entities may have. No changes to the regulation were made as a result of these comments.

Comment: One commenter suggested that applicants should be able to consult with the Department about the need for inclusion of a HEIA with a particular certificate of need application.

Response: As part of the required program documents, the Department has created clear criteria about which projects are subject to the HEIA requirement. Introducing an additional consultation step for each individual assessment would introduce unnecessary delays. No changes were made to the regulation as a result of this comment.

Comment: Two commenters suggested an abbreviated/shorter version of the standard form the Department will issue for independent entities to complete.

Response: There is flexibility built into the HEIA template that the Department has issued, with the ability of the independent entity to explain if certain questions are not applicable based on the

project or relevance to the facility. No changes to the regulation are necessary as a result of these comments.

Comment: One commenter asked that independent entities include evidence that health care facilities are holding themselves accountable for progress in developing strategies to address social drivers of health for all people.

Response: The HEIA template includes areas for the independent entities to collect data on how a facility plans for health equity sustainability. The facility itself must review the HEIA and describe their own plans to ensure positive equity outcomes and mitigation plans to address any potential negative impacts to medically underserved populations as a result of the project. No changes to the regulation are necessary as a result of this comment.

Comment: A commenter sought clarification about what happens after a CON with an HEIA is submitted, including timelines for DOH evaluation of the HEIA.

Response: The Department is hiring a dedicated unit to review and evaluate the HEIAs that are received. The intention is that the HEIA will be reviewed in tandem with other parts of the CON application to mitigate delays to final decisions rendered by the Department. This will allow the Department to follow the already existing quality metrics for reviewing CON applications to ensure they are not sitting with the Department for an extended period of time.

Comment: Another commenter stated that they were concerned that the submission of the HEIA with the CON will increase the time it takes to prepare CON applications and the commenter requested to see the regulations amended to allow HEIAs to be submitted after submission of a CON application.

Response: Pursuant to PHL § 2802-b(2)(i) HEIAs "shall be filed together with the application, and the application shall not be complete without the impact statement." As such, the regulation cannot be amended to allow HEIAs to be submitted after submission of a CON application.

Comment: Three commenters expressly suggested a delay in the effective date of the HEIA requirement.

Response: The regulation implements PHL§ 2802-b, which went into effect on June 22, 2023. A legislative amendment would have been required to delay implementation of the statute. No changes to the regulation were made as a result of these comments.

Comment: One commenter suggested that during the initial period following the statutory requirement going into effect, the Department allow certificate of need applications to be filed and acknowledged, and for the review process to begin while the HEIA is concurrently being completed. Another commenter offered an alternative in the first months following the effective date of the HEIA requirement, which is submission of their 2023 Community Health Needs Assessment.

Response: Pursuant to PHL § 2802-b(2)(i) HEIAs "shall be filed together with the application, and the application shall not be complete without the impact statement." As such, the regulation

cannot be amended to allow a CON application to be accepted and acknowledged by the Department without the submission of a required HEIA. The Department will not accept a Community Health Needs Assessment in place of a HEIA for reasons noted in a previous comment.

Comment: Multiple commenters stated that neither the statute nor the regulation describes what consideration the HEIA will entail or how it will influence certificate of need application decisions, with one commenter suggesting that the regulations must make mention of the law's expectation for the Commissioner of Health (Commissioner) and the PHHPC to consider the HEIA.

Response: Pursuant to PHL § 2802-b(b), when considering whether and on what terms to approve an application, the commissioner and the PHHPC must take the HEIA into consideration. The Department did not feel it was necessary to restate this statutory requirement on the commissioner and the PHHPC in the regulation. Similar to how the Department assesses certificate of need applications on financial feasibility, public need, and character and competence, the Department will now consider HEIA findings as another component that factors into the overall review and recommendation of certificate of need applications. No changes to the regulation were made as a result of these comments.

Comment: Four comments expressing concerns and opposition to the Ellis Hospital and St. Peter's Hospital/Trinity Health merger were received, citing loss of secular health care access for the affected region. The comments voiced support for the HEIA regulations and noted that they

would provide the opportunity for needed community engagement on mergers of other health care entities.

Response: Comments regarding particular health care transactions are outside the scope of the HEIA regulation and the Assessment of Public Comment. No changes to the regulation are required as a result of these comments.

Comment: One commenter noted that the regulations require a written acknowledgement and mitigation plan in the HEIA. The commenter was concerned that this requirement goes above and beyond the statute and may lead independent entities to go above and beyond the applicant facility's mission and service delivery capacities. The commenter recommended the Department clarify the role of the independent entity when conducting a HEIA for an applicant.

Response: Mitigation and monitoring are critical, evidence-based components of the stepwise structure of health impact assessments and HEIAs at large. The intent of the Department's requirement for a written acknowledgement and mitigation plan is to ensure that, at minimum, the facility has reviewed the HEIA findings and responded to the identified negative findings, with the expertise of the independent entity. The facility is not expected to remain contracted with the independent entity for services related to monitoring. The independent entity can offer perspective on ways the facility can establish monitoring "best practices" on their own. No changes to the regulation were necessary as a result of this comment.

Comment: Several commenters noted that hospital closures are not subject to the HEIA requirement despite their significant impact on communities. Commenters suggested that HEIAs should be conducted when facilities close, and that communities impacted by facility closures

should be meaningfully engaged.

Response: Pursuant to PHL § 2802-b, a HEIA is required for applications made pursuant to Article 28 of the PHL and subject to review or approval by the PHHPC or the Commissioner. However, medical facilities seeking to discontinue operation or surrender their operating certificates do not apply to the Department pursuant to Article 28 but rather must provide 90 days' notice of their intent to close and have their closure plan approved by the Commissioner. In addition, section 2801-g of the PHL governs general hospital closure plans and requires the Commissioner to conduct an "after closure" review which is subject to public comment. Finally, the Department is committed to including the principles of a HEIA into the closure plan process. No amendments to the regulation were made as a result of these comments.