

### Frequently Asked Questions: Guidance on the Health Equity Impact Assessment Requirement

New York State Public Health Law Section 2802-b requires a Health Equity Impact Assessment to be filed with a Certificate of Need application to the New York State Department of Health for the establishment, change in ownership, construction, renovation, and change in service of Article 28 health care facilities across the state. The purpose of the Health Equity Impact Assessment is to demonstrate how a facility's proposed project affects the accessibility and delivery of services and whether the project will enhance health and racial equity and contribute to mitigating health disparities in the project's service area, specifically for medically underserved groups. The requirement went into effect on June 22, 2023.

#### How to use this document:

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Questions not covered in this document can be directed to:

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### **Background and Legislative History**

The Health Equity Impact Assessment (HEIA) requirement was signed into law in December of 2021 and amended in February of 2022. The requirement went into effect with the law on June 22, 2023. Section 2802-b of the Public Health Law directs Article 28 facilities to file an HEIA with every Certificate of Need (CON) application for certain project applications requiring the New York State Public Health and Health Planning Council's or Commissioner of Health's approval.

The purpose of the HEIA is to:

- Demonstrate the health equity impacts of a proposed project by a health care facility;
- Identify how the project affects access to and delivery of health care services, as well as other aspects of health equity, specifically for medically underserved groups;
- Enhance health equity and contribute to mitigating health disparities in the facility's service area; and
- Ensure that stakeholder input and health equity impacts are considered when a CON
  application is being reviewed by the New York State Department of Health (NYSDOH).

The ultimate goal of the HEIA is to advance health and racial equity throughout New York State, particularly in medically underserved groups, by having health equity considerations become standard practice in the planning and execution of health care facility projects.

### <u>Acronyms</u>

ASC Ambulatory Surgery Center

CON Certificate of Need

D&TC Diagnostic and Treatment Center

HEIA Health Equity Impact Assessment

IE Independent Entity

NYSDOH New York State Department of Health

NYSE-CON New York State Electronic Certificate of Need

PHHPC Public Health and Health Planning Council

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### **Section 1: Requirement Criteria**

Article 28 facilities are responsible for completing the HEIA Requirement Criteria Form as part of the CON application. Use the <u>HEIA Requirement Criteria Form</u> to determine whether the facility will need to complete the HEIA for which the CON application is being prepared. All Article 28 facilities are subject to the HEIA requirement, including general hospitals, residential health care facilities (nursing homes), diagnostic and treatment centers (D&TCs), ambulatory surgery centers (ASCs), and midwifery birth centers.

### 1.1 Do I still need to submit the HEIA Requirement Criteria Form if all the answers are "NO"?

Yes. All Article 28 facilities that submit a CON application must complete the HEIA Requirement Criteria Form. If an applicant checks "NO" in both Sections A and B, the HEIA Requirement Criteria Form is the only HEIA-related document that the applicant would be required to submit in the New York State Electronic Certificate of Need (NYSE-CON) system to acknowledge that an HEIA is not required.

1.2 The HEIA requirement does not apply to D&TCs whose patient population is more than 50% combined patients enrolled in Medicaid or uninsured, unless the CON application includes a change in controlling person, principal stockholder, or principal member of the applicant. What documentation must be submitted to prove exemption from the HEIA requirement for qualified D&TCs?

Currently, there is no requirement to submit Medicaid and uninsured data with the HEIA Requirement Criteria Form. Facilities must review and complete both rows in Section A of the HEIA Requirement Criteria Form. If both rows are checked "NO", the completed HEIA Requirement Criteria Form is then submitted with the CON application. The Department will be able to review relevant parts of the CON application to confirm the Medicaid and uninsured data.

### 1.3 Is there a differentiation for administrative reviews compared to limited reviews? How should Section B/Table B be completed for administrative review projects?

Check "NO" in the first row of Table B for projects subject to administrative and full reviews, then review the rest of Table B with the CON project application to determine if the project matches any of the criteria listed in Table B. Note: The last row of Table B acts as a catch-all category for all review types.

If the project matches any of the criteria listed in Table B, the applicable row should be marked "YES." If any row is marked "YES", an HEIA is needed and all required HEIA documents must be completed and submitted with the CON application. If none of the criteria are applicable to the proposed project and all of the rows are marked "NO", the project is exempt from the HEIA requirement. However, a HEIA Requirement Criteria Form must still be submitted with the CON application to acknowledge that an HEIA is not needed.

#### 1.4 Are Ambulatory Surgery Centers (ASCs) considered D&TCs or general hospitals?



ASCs are categorized as D&TCs in the CON process. Since ASC facility projects are considered D&TCs, ASCs should complete Table A of the HEIA Requirement Criteria Form.

### 1.5 If a facility is moving to a new location within the same service area or zip code, is an HEIA still required?

Based on the information provided, the change in location would trigger an HEIA even if it is in the same service area or zip code. A "change in location of services or care" accounts for any move of a facility's physical address, regardless of the proximity to the existing service area.

## 1.6 Is an HEIA required if we are relocating two existing extension clinics to another location within the same service area? The move will also reduce the number of total dialysis stations from 58 to 53 stations.

The reduction in dialysis stations from 58 to 53 results in a percentage change of 9%, which does not trigger an HEIA. However, the change in location to a new address does meet the criteria described in the last row of Table B. In this particular scenario, the change in location would require an HEIA to be filed with a CON application.

### 1.7 Is an HEIA required if an applicant is relocating an existing clinic to an extension clinic at a different address?

Depending on the cost of the proposed project, this would likely require a limited review application for minor construction to be submitted for renovations done at the extension clinic. The applicant should refer to the first row in Table B of the HEIA Requirement Criteria Form to determine whether the relocation of the existing clinic will lead to the elimination, reduction, or expansion in the number of certified beds, certified services or care, and/or operating hours. If the project requires an administrative review, the applicant should review the last row of Table B. Relocating an existing clinic to a building located at a different address qualifies as a "change in location of services or care."

### 1.8 As a new Article 28 midwifery birth center, do we need to conduct an HEIA if we estimate a payor mix of at least 75% Medicaid in the first year of operation?

Currently, the HEIA exemption is only pertinent to D&TCs under the statute. Other facility types with high Medicaid patient populations do not qualify for an exemption from the HEIA.

### 1.9 What timeframe should a D&TC use to calculate the combined total percentage of uninsured patients and patients enrolled in Medicaid?

For an existing D&TC, you should refer to the most recent annual budget statistics to calculate whether the facility has a 50% or greater combined Medicaid and uninsured patient mix. For example, the D&TC should examine data from September 2022 through August 2023 (fiscal year) to determine whether the facility is subject to the HEIA requirement. For a new D&TC, the facility should use proposed budget projections due to the lack of historical data.

#### 1.10 Do Medicare patients count toward the 50% carve-out number?

No. Medicare patients do not count toward the 50%. The D&TC carve-out is for centers whose patient population is more than 50% combined patients enrolled in Medicaid or uninsured, unless the CON application includes a change in controlling person, principal stockholder, or principal member of the applicant.



## 1.11 Are the Statewide Health Care Facility Transformation Program based projects required to complete the HEIA Requirement Criteria Form? Is there an exception for such projects?

At this time, projects under the Statewide Health Care Facility Transformation Program that meet the eligibility criteria, as outlined in regulation, are subject to the HEIA requirement.

### 1.12 Are birthing centers required to complete Section A or Section B of the HEIA Requirement Criteria Form?

Midwifery birth centers are not considered to be D&TCs and therefore, must complete Section B of the HEIA Requirement Criteria Form. Section A of the HEIA Requirement Criteria Form should be completed by Article 28 D&TCs that are certified to provide birthing services to low-risk patients during pregnancy, labor, and delivery, and those who require a stay of less than 24 hours after birth.

### 1.13 If an applicant has multiple projects scheduled for this year, does an HEIA need to be completed for each project?

The applicant will need to use the HEIA Requirement Criteria Form to determine whether an HEIA will be needed for every CON application submitted. One HEIA cannot be used for multiple CON projects. Each HEIA should be comparable with the size, scope, and nature of the CON project.

#### 1.14 Do closure plans submitted to the NYSDOH require an HEIA?

The Department's closure plan process is not subject to the statutory HEIA requirement. Medical facilities seeking to discontinue operation or surrender their operating certificates do not apply to the Department pursuant to Article 28 of the Public Health Law (which articulates the HEIA requirement) but rather must provide 90 days' notice of their intent to close and have their closure plan approved by the Commissioner. Closure plans for service categories or bed reduction are part of the Department's CON process and therefore an HEIA may be applicable depending upon the proposed project.

## 1.15 Once a project is determined to require an HEIA, are you expecting the applicant to submit the HEIA with the CON application on the date of CON submission? Or just the HEIA Requirement Criteria Form and then later the HEIA?

The Department will not acknowledge and review a CON application until it is considered complete. If the project does not require an HEIA, the CON application must include a completed HEIA Requirement Criteria Form. If the project does require an HEIA, the CON application must include a completed HEIA Requirement Criteria Form and the required HEIA program documents. The HEIA must be filed together with the CON application and HEIA Requirement Criteria Form for the Department to consider the CON application complete.

1.16 Does a primary care practice require a CON and HEIA? The practice intends to provide standard primary care services, including but not limited to general check-ups, preventive care, and non-specialized treatment for common illnesses and conditions.

Refer to the NYSDOH's website to review the types of facilities subject to the CON process: <a href="https://www.health.ny.gov/facilities/cons/more">https://www.health.ny.gov/facilities/cons/more</a> information/.



### 1.17 In an instance where a residential health care facility would like to add an in-facility dialysis service that is subject to a limited review CON, is an HEIA required?

The facility may be required to complete the HEIA. Refer to the first row of Table B (construction or equipment) on the HEIA Requirement Criteria Form. If there will be a 10% or more expansion of certified services or operating hours, then an HEIA is required. Calculate the percentage change from the number of certified/authorized services (as indicated on the facility's operating certificate) specific to the category of service. For example, if a nursing home adds two ventilator-dependent beds and the facility had none previously, this would exceed the 10% threshold. If another nursing home has 3 services on their operating certificate (baseline, adult day health care, and respiratory), and wants to add dialysis services, that will exceed the 10% threshold.

#### 1.18 Is every administrative or full review subject to an HEIA as a blanket rule?

In accordance with Public Health Law 2802-b, limited, administrative, and full review CON applications are subject to the HEIA requirement unless a project meets the exemption criteria outlined in regulation and statute. For example, the regulation notes that projects that require only written notification to the Department are not subject to an HEIA.

### **Section 2: Independent Entity**

An independent entity (IE) is an 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. The IE must be able to produce an objective, written assessment using a standard format of whether, and if so how, the facility's proposed project will impact the access and delivery of health care services, particularly for members of medically underserved groups. To determine eligibility, the applicant needs to complete the <a href="HEIA Conflict-of-Interest Form">HEIA Conflict-of-Interest Form</a> to demonstrate that the IE is qualified and independent.

#### 2.1 Is there a pre-approved list of independent entities that the NYSDOH can share?

No. The Department is not issuing a list of pre-approved independent entities. The parameters of IE are broadly stated yet provide enough specificity to ensure independent entities possess a baseline level of expertise and have no conflict-of-interest as required by law. 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.

#### 2.2 How do we find an IE?

Look within your existing networks, including in health care, universities, and public health spaces to help identify a qualified individual or organization. If a candidate is unfamiliar with the HEIA requirement, we suggest directing them to the <u>HEIA website</u> to review the regulation and program documents. Use the <u>HEIA Conflict-of-Interest Form</u> to help confirm that the IE is indeed qualified and independent.

### 2.3 Does the IE need to have a certification or complete specific educational courses to qualify?



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

## 2.4 Can our facility utilize a population health/public health department university program that is a separate branch of the overall parent organization but knows our healthcare facility and patient population?

The population health/public health department at an affiliated university or college must be financially independent and cannot have a financial outcome tied to the project outcome. Facility leadership (CEO/COO) is encouraged to take a close read of both the HEIA Conflict-of-Interest Form and the attestation at the end of the HEIA Template to review the factors that constitute a conflict-of-interest. Facility leadership should feel confident that they and their candidate for IE can attest to independence and required expertise.

### 2.5 Is the IE expected to have experience in the geographic region or service area of the proposed facility project?

Ideally, the IE would have a link to the local community, but the NYSDOH does not want to be prescriptive about the geographic specialty area of the IE to prevent limiting options. Under the experience and expertise of the IE, the HEIA should be able to speak to the potential impacts in the geographic region or service area of the proposed facility project.

### 2.6 Would employees of a health care facility (under which the project is being filed) fall under bullet point #2 of the HEIA Conflict-of-Interest Form?

To determine whether an employee at a health care facility may qualify as an IE, we recommend that facility leadership take a close look at the HEIA Conflict-of-Interest Form to clarify whether the employee will truly not benefit financially from the proposed project. The employee also may not assist in writing any part of the CON application.

### 2.7 Can an IE be rejected upon review of an HEIA that has been completed and paid for in good faith?

The Department developed the HEIA Conflict-of-Interest Form to help applicants determine whether an individual or organization is qualified to be an IE. In the rare case that an IE does not complete the HEIA to the standards stipulated by regulation, statute, and DOH HEIA documents, the Department will communicate next steps with the applicant in the NYSE-CON system.

### Section 3: Contracting with an Independent Entity

#### 3.1 Are there any caps on costs for contracting an IE?

Article 28 facilities should factor the cost of contracting with an IE into the project budget if they determine that their project will require an HEIA. The NYSDOH is monitoring the first year of implementation of this new HEIA requirement to determine the average costs associated with conducting an HEIA.



#### 3.2 Is there a required or preferred process for payment?

There is not a required or preferred process for contracting and payment. These are legal business transactions that should occur in consultation with the facility and IE's legal counsel.

#### 3.3 What financial assistance exists for the IE to conduct the assessment for our project?

At this time, there is no financial assistance from the Department being offered to offset facilities' cost of conducting HEIAs. Article 28 facilities should factor in the cost of contracting with an IE into the project budget if they determine that their project will require an HEIA.

### 3.4 What guidance does the NYSDOH give in terms of how to complete the contract between the facility and the IE?

The Department is not providing guidelines for completing the agreement between the facility and the IE. These are business transactions that should occur in consultation with the facility and the IE's legal counsel.

### **Section 4: HEIA Template and Data Tables**

The HEIA Template and Data Tables are the foundation of the HEIA. The HEIA Template is an evidence-based, five-step approach to conducting an HEIA, and includes steps for scoping, potential impacts, mitigation, monitoring, and dissemination. The Data Tables collect stakeholder contacts, engagement methods, stakeholder views, and statements provided directly by stakeholders, and review the demographics of the service area. Please note that the service area is the geographical region where the applicant's facility is located and the regions where populations that use the facility are located. The service area in the HEIA should match the service area in the accompanying CON application.

#### 4.1 How will the IE obtain the information required for the HEIA?

The IE can refer to the HEIA Template Instructions to find a list of sources to use to complete the HEIA. These sources include:

- Stakeholder interviews
- Using publicly available sources, such as U.S. Census Bureau data, the Community Health and Community Service Needs Assessments, medical literature, or grey literature
- Collaborating and sharing data between the IE and applicant

Since the HEIA is a new statutory requirement effective June 22, 2023, the IE will have the option to share if any data required by the HEIA Template was difficult to find. The Department plans to use this information to help refine the documents and program guidance moving forward.

#### 4.2 Where can I find the "Meaningful Engagement" tab in the Data Tables workbook?

The "Meaningful Engagement" tab is the first tab in the Data Tables workbook. In some browsers, you may need to view the document in full screen or use the "scroll to see all sheets" arrow to view this tab. You can also click on the three dots to the left of the "Scoping Sheet 1" tab to access the "Meaningful Engagement" tab.

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### 4.3 In the HEIA Template, do we have to break out the populations to discuss potential impacts if the impacts are the same?

The statute mandates careful consideration of each medically underserved group impacted by the CON project. Therefore, it is important to consider the demographics of the service area and identify each medically underserved group impacted by the project in step 1, question 2. In subsequent answers, you need to identify the groups that experience specific impacts. However, if the impacts are truly the same for several different groups, it is not necessary to break out the groups in each answer.

4.4 How is the State defining "service area" for the Data Tables? Should service area zip codes be interpreted as the zip codes currently surrounding the facility or do these zip codes pertain to the zip codes of residence for new potential patients because of the CON application?

The service area is the geographical region where the applicant's facility is located as well as the geographical regions where populations that use the facility are located. The service area in the HEIA should match the service area defined in the corresponding CON application.

4.5 Please confirm if civil rights complaints should include complaints made by employees. The requirement doesn't specify.

In step 1, question 10 of the HEIA Template, the IE must provide a summary of civil rights access complaints against the applicant, if applicable. This includes all complaints filed with the New York State Division of Human Rights, the U.S. Department of Health and Human Services Office of Civil Rights, or any other federal, state, or local agency within the last ten years, including civil rights complaints filed with these entities by employees of the applicant. The IE should contact the applicant to obtain and review any civil rights access complaints filed against the facility. The facility should have access to copies of any complaint(s) and any corrective action that was taken or plans to be taken.

4.6 Please clarify the intent/scope of the requirement and intended sources for step 1, question 8, of the HEIA Template, which reads: Summarize the performance of the applicant in meeting its obligations requiring the provision of uncompensated care, community services, and/or access by minorities and people with disabilities to programs receiving federal financial assistance. Will these obligations be affected by the implementation of the project?

The IE should provide insight on the current and anticipated performance of the applicant in meeting its obligations, if any, as outlined under Public Health Law Section 2807-K, General Hospital Indigent Care Pool, and federal regulations requiring the provision of uncompensated care, community services, and/or access by minorities and people with disabilities to programs receiving federal financial assistance. Examples of community services include programs that directly benefit the community (i.e. grants or resources offered to partners that will benefit the general public) or partnerships with community-based organizations (i.e. working with neighboring providers to meet the social service needs of patients or residents). Possible sources for a facility's community service/community benefit information include the facility's website, Community Health Needs Assessment, Community Service Plan, IRS form 990, or information supplied directly by the facility to the IE.



## 4.7 Will the HEIA be revised to include the recent amendment to Section 2802-b of the Public Health Law which requires consideration of reproductive health services and maternal health care?

Section 2802-b of the Public Health Law was amended by Chapter 702 of the Laws of 2023 on December 8, 2023, taking effect retroactively on June 22, 2023. With a new paragraph (j) to subdivision 3 of Section 2802-b, the amendment expands the scope of the HEIA to include impacts to reproductive health services and maternal health care. The HEIA program documents have been updated as of December 13, 2023, to reflect this amendment. Applicants will be required to demonstrate how proposed projects will impact the availability, provision, and delivery of reproductive health services and/or maternal health care in the applicant's facility and service area.

#### 4.8 Clarify the types of meaningful engagement required for smaller CON projects.

The degree of meaningful engagement must be commensurate to the size, scope, duration, and complexity of the facility project. Meaningful engagement must also be reasonable based on the type of stakeholder being engaged. It is the Department's expectation that upon evaluating the CON application, the IE will consider, identify, and offer multiple forums through which stakeholders can provide feedback to ensure maximal depth and reach across a wide breadth of stakeholders. The IE should deploy a range of culturally competent methods of engagement.

### **Section 5: Public Posting of Documents**

When an HEIA is filed with a CON application, the applicant must provide a full version of the application and a version with proposed redactions. The applicant is required to post the redacted CON application and the HEIA on its website within one week of acknowledgement by the NYSDOH, and until a decision on the application is rendered by the Public Health and Health Planning Council (PHHPC) or the Commissioner of NYSDOH. The Department will also publicly post the redacted CON application and the HEIA on the NYSE-CON system within one week of the filing.

#### 5.1 What should be redacted from the CON application?

The redacted CON application is for the purpose of public viewing. The redactions may include any sensitive or private information for the applicant, and any confidential financial information that is exempt from public disclosure pursuant to Article 6 of the Public Officers Law. NYSDOH reserves the right to validate and ensure that any redactions made are appropriate and may change any of the redactions as necessary.

#### 5.2 Can an HEIA be requested as part of a Freedom of Information (FOIL) request?

The HEIA is required to be publicly posted on the applicant's website and <u>NYSE-CON</u>. The HEIA can also be accessed by submitting a FOIL request.

#### 5.3 Can the price of the contract between the IE and applicant be redacted?

No. 10 NYCRR § 400.26 provides for a redacted version of the CON application, but it does not provide for redactions in the HEIA. Per subdivision (d) of § 400.26, the HEIA must include documentation of the agreement between the IE and the facility. Per subdivision (e) of § 400.26,



applications that require an HEIA must include a full version of the application and a version with proposed redactions, if any, to be shared publicly.

### 5.4 If a new operator does not have a website, how can they comply with the requirement to publicly post the HEIA and redacted CON application?

The regulation requires that the HEIA and redacted CON application be posted on the facility's website. If a new operator submits a CON application to open a facility that is not yet operating and does not have a website, no action is required. If a website is created during the review of the CON application and HEIA, the operator is required to post the HEIA and redacted CON application on the applicant's website until a decision has been made.

### **Section 6: Submission and Review Timelines**

### 6.1 Is the IE required to submit the HEIA in the NYSE-CON system or should the applicant submit the HEIA?

The IE should provide the completed HEIA to the applicant and then the applicant should submit all materials into NYSE-CON.

#### 6.2 What time frame does an IE have to complete an HEIA?

The IE should complete the assessment in an efficient and reasonable time frame. This will depend on the size, scope, and complexity of the affiliated CON project and the duration of meaningful engagement with identified medically underserved groups and stakeholders. We recommend identifying an IE early in the project planning process to help ensure the timely completion of the HEIA. The HEIA does not have to be conducted after the CON application is finished.

#### 6.3 How long will the Department take to review HEIAs? How will the HEIA be assessed?

A dedicated unit has been established within the Department to review and evaluate HEIAs. The HEIA will be assessed based on the validity, strength, and value of the information presented and will be reviewed in tandem with other parts of the CON application to mitigate delays. For full review applications, the Department is prepared to offer a comprehensive perspective of HEIA findings to the PHHPC to be taken into consideration with the other sections of the CON application.

# 6.4 Can the findings from this assessment change a proposed project? For instance, if a hospital is losing money and plans to cut a service to survive, can the findings from an HEIA prevent a hospital from doing so? If so, will the hospital be given resources to maintain a losing service line?

The findings of an HEIA may include recommendations to modify a project to help minimize potentially negative impacts to the service area and community. The IE is required to identify mechanisms for mitigation and monitoring in Steps 3 and 4 of the HEIA Template. Mitigation and monitoring are critical, evidence-based components of the stepwise structure of health impact assessments and HEIAs at large. The purpose of the written acknowledgement and mitigation plan is to ensure that, at a minimum, the facility has reviewed the HEIA findings and responded to the identified negative findings. The independent entity can offer perspective on



ways the facility can establish monitoring "best practices" on their own. Suggested changes listed in the HEIA Template are not required to be implemented by the facility but are strongly recommended. As indicated at the end of the HEIA Template, the mitigation plan along with the rest of the HEIA must be made available to the public and posted conspicuously on the applicant's website until a decision on the CON application has been made.

### 6.5 For limited and administrative reviews, what are my options if the NYSDOH does not approve my CON application based on the HEIA findings?

If the Department determines that the proposal is not acceptable, the applicant will be notified in writing of such determination and the bases thereof. If the applicant disagrees with the Department's determination, the applicant may submit a CON application to be processed for full review in accordance with 10 NYCRR 710.1(c)(5)(d). A full review would require the application to be sent to the PHHPC.