Oversight & Enforcement Policies and Procedures for HINs

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AS DEVELOPED THROUGH THE

STATEWIDE COLLABORATION PROCESS (SCP)

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Introduction

The New York State Department of Health (The Department) is responsible for the oversight and enforcement of the SHIN-NY Regulation and related SHIN-NY Policy Guidance. The purpose of this document is to provide a high-level description of the procedures by which the Department, or its designee, will perform basic oversight of Health Information Networks (HINs). This includes requirements and enforcement actions for HIN self-audits, complaints, external monitoring, audits, and investigations. Authority for oversight, monitoring and enforcement of HINs is outlined in Section 300.2 of the SHIN-NY Regulation § Part 300, Establishing the SHIN-NY.

Out of scope for this document are activities related to:

(a) responding to allegations of privacy breaches, which are to be handled in accordance with applicable law and the Privacy and Security Policies and Procedures,

(b) investigations in response to subpoenas from law enforcement and other government agencies; and

(c) responding to allegations of breach of the Qualified Entity Participation Agreement (QEPA) and the Statewide Common Participation Agreement (SCPA).

Alleged privacy breaches and investigations by government agencies are to be reported to the Oversight Entity and may result in the Oversight Entity initiating additional investigations and audits as it sees fit. Any additional investigations and audits would follow the procedures described in the external audit and/or investigation section of the policies and procedures described herein.

For a HIN to participate in the SHIN-NY, they must comply with applicable state, federal and local law as well as the SHIN-NY Assessment Requirements. The SHIN-NY Assessment Requirements are designed to protect and maintain the reliability, accuracy, and integrity of the SHIN-NY. The four categories of Certification Requirements (Organizational Characteristics, Operational Requirements, Policies and Procedures, and Technical Services) are described in the Organizational Characteristics Requirements, as amended periodically.

The Oversight and Enforcement Policies set forth mechanisms for ensuring that:

(a) HINs comply with applicable state, federal and local law and the SHIN-NY Assessment Requirements; and

(b) Appropriate action is taken to respond to and/or resolve non-compliance.

Definitions

All capitalized terms used and not defined herein shall have the respective meanings given to such terms in the *Privacy and Security Policies and Procedures*, as amended periodically.

Enforcement Actions – particular sanctions and/or corrective action plans that may be imposed by the Oversight Entity on a HIN found to be out of compliance with federal, state, or local law and the SHIN-NY Regulation and/or SHIN-NY Assessment Requirements and are based on the nature and severity of the non-compliance as determined by the Oversight Entity.

Grievance Process – is outlined in the SHIN-NY Assessment Process documents. The Oversight Entity will review any grievances and make a determination according to the evidence submitted by the HIN as well as the original findings for the non-compliance determination.

Non-Compliance – an occurrence in which a HIN or its Participant(s) fails to comply with applicable law, SHIN-NY Regulation, SHIN-NY Assessment Requirements, or the SCPA including failures attributable to Participant activities overseen by a HIN.

Oversight Entity – the New York State Department of Health (the Department) or a third-party designated by the Department to conduct monitoring, audits, investigations, monitoring, and enforcement activities related to HIN compliance with applicable law, SHIN-NY Regulations, and SHIN-NY Assessment Requirements.

SHIN-NY Assessment Process – the structured process by which compliance with SHIN-NY Policy Guidance and the SHIN-NY Control Standard is demonstrated, evaluated, and monitored (*unified Certification Process and SDE Assessment Process*).

SHIN-NY Assessment Requirements – the integrated set of regulatory, policy, and contractual requirements that define expectations of the HINs. This includes but is not limited to the SHIN-NY Regulations, SHIN-NY Policy Guidance, participation agreements, and Data Use Agreements (*unified QE Certification and SDE Requirements*).

SHIN-NY Control Standard – the unified set of policy adherence controls derived from SHIN-NY Regulations and Policy Guidance (*unified the Certification Standard and the SDE Standard)*.

SHIN-NY Health Information Network (HIN) – a health information network that has been contracted or subcontracted by the New York State Department of Health that facilitates and oversees the exchange of Protected Health Information within the

SHIN-NY and is a party to the SCPA. A HIN can be either an entity certified under 10 NYCRR § 300.4 or the State Designated Entity (SDE).

Stakeholder – includes, but may not be limited to, parties interested in providing to or obtaining information from the SHIN-NY including such groups as consumers/patients, caregivers, physicians and clinicians, hospitals, payers including Medicaid and Medicare, public health practitioners or advocates, care coordination organizations, or nursing homes.

Third-Party Assessor – the entity designated by the New York State Department of Health to conduct SHIN-NY Assessments, monitoring, and control validation activities (*unified Certification Body and Independent Assessor*).

1. Oversight

This section sets forth the process for monitoring a HIN's compliance with applicable state, federal and local law and the SHIN-NY Assessment Requirements (*unified QE Certification and SDE Assessment Requirements*) and describes the mechanisms for investigating potential non-compliance. All Non-Compliance, regardless of the method of detection, will be addressed by the Oversight Entity who will gather the information necessary for determining what, if any, corrective actions are appropriate. Oversight of Participants shall be conducted through the HIN responsible for such Participants, except where the Department determines direct oversight is required.

The mechanisms for detection by the Oversight Entity of Non-Compliance include:

(a) a HIN's obligation to report Non-Compliance, whether discovered in connection with a self-audit or otherwise;

(b) a complaints process through which stakeholders in the SHIN-NY, including Participants, can file complaints and/or reports of Non-Compliance;

(c) an external audit and internal audit process through which the Oversight Entity monitors and audits a HIN's compliance with applicable state, federal and local law and the SHIN-NY Assessment Requirements; and

(d) other monitoring activities conducted by the Oversight Entity

The following outlines the policies and procedures for (i) The Complaints Process, (ii) Internal Investigation and Reporting, (iii) External Investigation and Reporting, (iv) Audits, and (v) Record Retention.

1.1 Complaints Process

1.1.1 Each HIN shall develop and implement policies and procedures for receiving, investigating and responding to complaints from stakeholders of the SHIN-NY, including Participants. Such policies should include both Non-Compliance complaints as well as general complaints.

1.1.2 Any stakeholder in the SHIN-NY, including any Participant, may file a complaint of any suspected Non-Compliance with the HIN or the Oversight Entity. The complaint (the "Non- Compliance Complaint") must be in writing and must include the following information if known:

(a) the suspected Non-Compliance,

(b) the acts or omissions believed to constitute Non-Compliance;

(c) the name of the HIN involved;

(d) the name of the Participant involved, if any;

(e) all dates related to the suspected Non-Compliance;

(f) all locations related to the suspected Non-Compliance, if any.

1.1.3 A Non-Compliance complaint related to HIN or Participant must be filed within 180 days from the date the complainant knew or should have known that non-compliance occurred for the Non-Compliance complaint to be subject to investigation under this Policy.

1.1.4 If a Non-Compliance complaint related to HIN or Participant is filed with the HIN, the HIN shall conduct an internal investigation in accordance with Section 1.2: Internal Investigations and Reporting of these procedures. If a Non-Compliance complaint is filed with the Oversight Entity, the Oversight Entity shall follow the procedures set forth in either Section 1.2: Internal Investigations and Reporting or Section 1.3: External Investigation and Reporting outlined in these procedures.

1.2 Internal Investigation and Reporting

1.2.1 If a HIN becomes aware of potential Non-Compliance or receives notice of a Non-Compliance complaint (as defined above), the HIN shall conduct an internal investigation of such complaint to determine whether Non-Compliance has occurred.

1.2.2 The HIN shall begin the internal investigation within 30 days after becoming aware of potential Non-Compliance or receiving notice of a Non-Compliance complaint.

1.2.3 The HIN shall complete the internal investigation as soon as reasonably practicable but, no later than 60 days after becoming aware of potential Non-Compliance or receiving notice of a Non-Compliance complaint. Following an internal investigation conducted pursuant to Section 1.2.1 each HIN shall report to the Oversight Entity in writing the existence of any Non-Compliance immediately after the HIN determines that Non-Compliance has occurred. The report (the “Non-Compliance Report”) shall describe the Non-Compliance and any harmful effects known to the HIN, the SHIN-NY enterprise, and/or any Participants that may have been harmed resulting from the Non-Compliance.

1.2.4 If the Oversight Entity directs the HIN to perform an internal investigation based on a suspected non-compliance issue reported to the Oversight Entity, the HIN shall report the results of such investigation to the Oversight Entity upon completion of the internal investigation. If the HIN did not detect Non-Compliance as a result of

such internal investigation, the HIN shall provide to the Oversight Entity a written statement that no Non-Compliance was detected, and a summary of the internal investigation conducted outlining the investigation findings.

1.3 External Investigation and Reporting Process

1.3.1 Upon receipt of a Non-Compliance complaint by the Oversight Entity, the Oversight Entity will either

(a) conduct an investigation (an "External Investigation") of such Non-Compliance complaint or

(b) refer such Non-Compliance complaint to the applicable HIN if the Oversight Entity determines, based on a preliminary review of the facts, that an internal investigation by the HIN is necessary or appropriate.

If the Oversight Entity refers the Non-Compliance complaint to the HIN, the HIN shall conduct an internal investigation pursuant to Section 1.2.1: Internal Investigations and Reporting and provide any reports or notices required by that Section.

1.3.2 If the Oversight Entity determines that it will conduct an external investigation, the Oversight Entity will begin the external investigation within 30 days after receipt of a Non-Compliance Report or a Non-Compliance complaint. To begin the external investigation, the Oversight Entity will notify

(a) in the case of a Non-Compliance Report, the HIN who filed the Non-Compliance Report or

(b) in the case of a Non-Compliance complaint, the complainant and the HIN named in the Non-Compliance complaint.

The notice ("Investigation Notice") will include a summary of the intended external investigation, including any requests for additional information from the HIN, the Participant and/or the complainant.

1.3.3 Each HIN will require its Participants to cooperate with the Oversight Entity in connection with any external investigation, including by providing to the Oversight Entity the information requested in the investigation notice and access to its books, records, accounts, and other sources of information related to the scope of the external investigation.

1.3.4 The Oversight Entity will document its findings ("Report of Findings") in response to the receipt of a Non-Compliance complaint. If the investigation is conducted on behalf of the Oversight Entity by a third-party assessor, a report of findings will be submitted to the Oversight

Entity upon completion of the investigation. In either case the report of findings will be shared with the applicable HIN. Such report of findings will include, at a minimum, the following:

(a) the alleged non-compliance as related to applicable state, federal and local law and/or the SHIN-NY Assessment Requirements,

(b) events giving rise to the alleged non-compliance,

(c) method of discovery of the non-compliance, i.e., self-audit, complaint, etc.

(d) summary of the external investigation or an explanation if one was not conducted, if applicable, and

(e) a summary of the findings and recommendations for corrective action if required.

1.3.5 The Oversight Entity will finalize the report of findings as soon as reasonably practicable after the receipt of a Non-Compliance report or a Non-Compliance complaint.

NOTE: The factors to be considered by the Oversight Entity when determining whether an external investigation or an internal investigation by the HIN is necessary or appropriate include, but are not limited to, the following: nature of the Non-Compliance complaint, or history of complaints similar to the Non- Compliance complaint with respect to the applicable HIN(s).

1.4 Audits

1.4.1 External Audits at the Discretion of the Oversight Entity

1.4.1.1 The Oversight Entity may, in conjunction with its ongoing monitoring, conduct periodic assessments of compliance with specific state, federal and local law and SHIN-NY Assessment Requirements. In circumstances where the audit assessment is performed by a third-party designee of the Oversight Entity, the third-party will submit a report of findings and recommendations for potential follow up actions to the Oversight Entity.

1.4.1.2 Typically, external Audits will be performed during regular business hours upon reasonable notice to the HIN. However, the Oversight Entity may, at its discretion, perform an audit with no advance notice to the HIN. External audits may be performed no more than once per year per HIN, unless there is reason to believe that the HIN is in Non-Compliance with applicable state, federal and local law or one or more of the SHIN-NY Assessment Requirements.

1.4.1.3 The HIN shall require its Participants to cooperate with the Oversight Entity in connection with any external audit, including by

providing the Oversight Entity access to records, and other sources of information related to the scope of the external audit.

1.4.1.4 The results of any external audit will be documented in a written report (External Audit Report) by the Oversight Entity or its designee and shared with the applicable HIN. Such external audit report will include, at a minimum, the following:

(a) scope of the external audit performed,

(b) a summary of the findings including any Non-Compliance related to applicable state, federal and local law or the SHIN-NY Assessment Requirements and the events giving rise to non-compliance if applicable,

(c) the method of discovery of non-compliance

(d) a root cause analysis if non-compliance occurred

(e) and recommendations for corrective action if required.

1.4.1.5 The Oversight Entity will finalize the external audit report as soon as reasonably practicable after providing notice to the HIN of its intention to perform an external audit.

1.4.1.6 The Oversight Entity retains discretion to conduct audits with or without prior notice where there is reasonable suspicion of Non-Compliance.

1.4.2 HIN Audits, Self-Monitoring and Reporting.

1.4.2.1 Each HIN shall perform a self-audit in order to verify its compliance with applicable state, federal and local law and the SHIN-NY Assessment Requirements at least once per year, as required by the Oversight Entity as part of the SHIN-NY Assessment Process.

1.4.2.2 As stated in the Privacy & Security Policies and Procedures Section 6: Audit: Sub-section 6.2, a HIN shall conduct or shall require each of its Participants to conduct, periodic audits to monitor use of the SHIN-NY by Participants and their Authorized Users and ensure compliance with applicable state, federal and local law and the SHIN-NY Assessment Requirements. HINs shall have policies and procedures in place for this monitoring process to be checked as part of the SHIN-NY Assessment Process.

1.5 Record Retention

1.5.1 Each HIN shall retain records relating to this Section (including the results of all self-audits and all Non-Compliance Reports) for a period of at least six (6) years.

1.5.2 The Oversight Entity will retain records relating to this Section (including all investigation notices, reports of findings, external audit reports, Non-Compliance reports, Non-Compliance complaints) for a period of at least six (6) years.

2. Enforcement

The New York State Department of Health (the Department) as the Oversight Entity has authority to impose Enforcement Actions that may include particular sanctions and/or corrective action plans on a HIN or HINs who have been found to be out of compliance with federal, state, and local law or the SHIN-NY Regulation and SHIN-NY Assessment Requirements. The Enforcement Actions imposed on a HIN will be based on the nature and severity of Non-Compliance as determined by the Oversight Entity.

2.1 Types of Enforcement Actions

2.1.1 Enforcement Action Resolutions imposed by the Oversight Entity may include, but are not limited to:

(a) a written warning setting forth non-compliance related to applicable state, federal and local law or the SHIN-NY Assessment Requirement(s),

(b) corrective action requiring the HIN to take affirmative steps to resolve the Non-Compliance with milestones and dates by which each milestone must be completed,

(c) monitoring, requiring the HIN to undergo a period of monitoring to assure continued compliance with specific state, federal and local law and/or SHIN-NY Assessment Requirements,

(d) temporary restriction of QE participation in the SHIN-NY,

(e) permanent restriction of QE participation in the SHIN-NY, or

(f) imposition of withholding of State funding allocations in instances in which one or more of the above remedies has previously been imposed and there is clear need for additional remedies beyond (a) through (e) above that fit the severity of non-compliance.

2.2 Determining Applicable Enforcement Action

2.2.1 The Oversight Entity will consider the following factors in determining the appropriate Enforcement Action to be applied:

(a) Nature and extent of Non-Compliance and the extent of actual or potential harm to any stakeholder in the SHIN-NY and/or the SHIN-NY enterprise resulting from Non-Compliance.

(b) HIN's level of responsibility, (i.e., was the nature of the circumstances leading to or causing Non-Compliance inadvertent, negligent, reckless, or intentional).

(c) Any corrective action or other steps taken by the HIN to respond to the events leading up to or constituting Non-Compliance, including performance of an internal investigation by the HIN, the HIN's cooperation in the external investigation or external audit, as applicable.

(d) HIN's history of prior Non-Compliance.

(e) Consideration of the possible impact the Resolution may have on the SHIN-NY Participants.

(f) Such other factors as the Oversight Entity may deem appropriate.

2.3 Application of Enforcement Actions

2.3.1 Upon review of the Report of Findings or External Audit Report, as applicable, the Oversight Entity will determine the applicable Enforcement Action to be imposed on the HIN in accordance with the guidelines set forth in this Section 2.2.

2.3.2 The Oversight Entity will maintain documentation of the process that was used for determining the applicable Enforcement Action including documentation of all factors considered.

2.3.3 The Oversight Entity will provide written notice of the Enforcement Action to the HIN that will include

(a) reference to the applicable Report of Findings or External Audit Report,
(b) the Resolution
(c) any applicable timeframes,
(d) the factors considered when determining the Resolution; and
(e) the process for submitting a grievance to the determination.

2.4 Grievance

2.4.1 The HIN has the right to submit a grievance in writing to the Oversight Entity's imposition of a Non-Compliance Enforcement Action and Resolution no later than 60 days after receipt by the HIN of notification of such Enforcement Action. The grievance will follow the SHIN-NY

Assessment grievance process as outlined in the SHIN-NY Assessment Process guidance document.

2.4.2 The Oversight Entity will inform the HIN in writing of its decision regarding the imposed Enforcement Action.

2.5 Documentation

2.5.1 The Oversight Entity will retain records relating to this Section (including all Enforcement Action Notices and all documentation relating to determination of Enforcement Resolutions for at least six (6) years after a final determination is made with respect to each Resolution.