Organizational Characteristics Requirements

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AS DEVELOPED THROUGH THE STATEWIDE COLLABORATION PROCESS

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Introduction

This document establishes the Organizational Characteristics required for Health Information Networks (HINs) to participate in the SHIN-NY. These requirements are evaluated through the SHIN-NY Assessments (*combined term for QE Certification and the SDE Assessment*) as applicable, in accordance with the SHIN-NY Regulations (10 NYCRR Part 300) and SHIN-NY Policy Guidance and applicable SOPs.

The SHIN-NY Assessment Requirements fall into the following four categories:

1. **Organizational Characteristics**, non-profit status, good standing in the State of New York, list of Participants, open board structure, necessary insurance. The Organizational Characteristics are outlined in this document.
2. **Operational Requirements,** infrastructure to operationalize the SHIN-NY requirements, including policies and practices for non-discriminatory exchange of data, system performance, SHIN-NY Participant Facing Services, business plans, audit procedures, participation in statewide policy development, and evaluation processes. These requirements are found in the Participant Member Facing Services Requirements as well as in sections of the Qualified Entity Participation Agreement (QEPA), as well as the Data Use and Contribution requirements outlined in the Statewide Common Participation Agreement (SCPA) as amended periodically.
3. **Policies and Procedures,** including adherence to the SHIN-NY Policy framework for consent, authorization, authentication, access, patient engagement and access, audit, breach, sanctions, and cybersecurity. These requirements are found in the 'Privacy and Security Policies and Procedures.
4. **Technical Services,** technical service requirements and interoperability (SHIN-NY statewide Patient Record Lookup (sPRL) technical specifications) that users of the SHIN-NY can expect to be available within any region of the State of New York. These requirements are found in the Required Participant Services Policy Guidance and the sPRL Technical Specifications SOP, as amended periodically.

In order to participate in the SHIN-NY as a HIN, pursuant to New York State regulations, an organization must satisfy the SHIN-NY Assessment Requirements. The New York State Department of Health (the Department) serves as the Oversight Entity to ensure the integrity of the SHIN-NY and maintain the public trust. In this role, the Department can assign a third-party that will be responsible for facilitating the SHIN-NY Assessment Process.

The Department can waive certain Organizational Characteristics as set forth in this document to enable other HINs in New York State to operate. This determination would require input from the State Designated Entity Board of Directors and would be based on an applicant's ability to meet the Operational, Policies and Procedures, and Technical requirements as outlined in this document.

HINs are required to actively participate in the SHIN-NY Assessment Process and engage in ongoing monitoring of their compliance with the SHIN-NY Assessment Requirements including the State Designated Entity's role (SDE) of operating the Statewide Data Infrastructure (SDI).

Definitions

All capitalized terms used and not defined in this document shall have the respective meanings given to such terms in the Privacy and Security and the Oversight and Enforcement Policy and Procedures as well as applicable SOPs.

Organizational Characteristics

In order to participate in the SHIN-NY as a HIN, an organization must comply with the SHIN-NY Assessment Requirements, which are designed to protect and maintain the reliability, accuracy, and integrity of the SHIN-NY. HIN requirements apply both to the Qualified Entities (QEs) and the State Designated Entity (SDE) unless otherwise specified.

The following "**Organizational Characteristics**" must be met as part of the SHIN-NY Assessment Requirements:

1. **Organizational Information**: (1) Corporate Name as set forth in the Certificate of Incorporation and Address, as well as the Name and Address of all facilities owned and operated by the corporation; (2) Names and Titles of senior leadership.

2. **Non-Profit Status:** Organized as a 501(c)3 in accordance with Article 13 of the Not-for-Profit Corporation Law, whose incorporation articles have been filed with the Division of Corporations of the New York State Department of State.

3. **Good Standing in New York State**: Applicable certificates in New York State including NY Charities Registration and NY Vendor Responsibility Registration that attest to an organization being current with filing requirements within their jurisdiction.

4. **Governance Structure:**

    1) Current Listing of Board members, their titles and organizational affiliation on the organization's website;
    2) Availability of organizational bylaws to the public, upon request;
    3) Public health and physician representation on the Board, to the extent possible;
    4) Inclusive decision-making process;
    5) Transparency;
    6) Policies and procedures that outline the organization's governance structure to include Board recruitment; meetings and meeting minutes; reporting; conflicts of interest policy; clearly defined organizational mission and strategic goals.

5. **Required Participant Services and SHIN-NY Participant Member Facing Services Availability to All Participants:** Provision of SHIN-NY Required Services (as such term is defined in the Technical Requirements policy guidance) and provision of SHIN-NY Participant Facing Services (as such term is defined in the SHIN-NY Participant Facing Services Requirements).

6. **Management of Participants**: The organization has executed Statewide Common Participation Agreement (SCPA) and other Data Use Agreements (DUA) as applicable with all Participants that are up to date based on any statewide policy changes; Maintains an up-to-date list of such Participants; and Identifies Participants that are contributing data on the HIN's website.

7. **Participant Flow-Down Requirements**: The organization has an executed a SCPA that includes procedures to address Participant compliance with the SCPA, Statewide Policy Guidance, and applicable SOPs clearly outlined for all Participants.

8. **Insurance/Liability Coverage:** The organization maintains liability coverage relevant to the exchange of individually identifiable health information in accordance with such standards as may be required by regulation, Statewide Policy Guidance, or the Qualified Entity Participation Agreement (QEPA) by the State Designated Entity and QE.

1. Organizational Information Requirements for SHIN-NY Assessments

A HIN shall publicly provide:

(i) HIN Corporate Name and Address and Address for all facilities owned and operated by the corporation.

(ii) Chief Executive Officer, Executive Director and other senior executive names and titles that may include Chief Operating Officer (COO), Chief Financial Officer (CFO) and/or their equivalents, if applicable.

1.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of SHIN-NY Assessments:

(i) Documentation verifying the HIN corporate name, address, and a complete listing of any owned and operated facilities of the HIN with the full name of the facility and address.

(ii) Attestation that the HIN information is current and that notification of changes in any organizational information are provided to the Department (and the State Designated Entity, if applicable) within 30 days of the change.

1.2 QE Monitoring and Self-Audit Requirements

QEs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring that identifies any organizational changes.

(ii) Notification of any changes to the Department and State Designated Entity as required within 30 days.

2. Non-Profit Status Requirements for SHIN-NY Assessments

To satisfy the assessment requirements for Non-Profit Status, a HIN shall:

(i) Be a non-profit organization incorporated in New York State with federal tax-exempt status and hold a New York Certificate of Incorporation pursuant to Section 402 of the NY State Not-for-Profit Corporation Law.

2.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of SHIN-NY Assessment:

(i) Documentation to verify a current New York Certificate of Incorporation that is complete and meets New York State incorporation requirements.

2.2 Monitoring and Self-Audit

HINs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring that identifies any non-profit status changes.

(ii) Notification of all non-profit status changes as required to the Department (and the State Designated Entity, if applicable).

3. New York State ‘Good Standing’ Requirements for SHIN-NY Assessment

To satisfy the SHIN-NY Assessment Requirements for New York State ‘Good Standing’, a HIN must:

(i) Have in place the New York Charities Registration certificate from the NY State Attorney General Charities Bureau.

(ii) Have in place the New York Vendor Responsibility Registration certificate issued within one year of the certification of the Vendor Responsibility Questionnaire from the Office of the State Comptroller.

3.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of assessment:

(i) New York Charities Registration Information that is complete and up to date.

(ii) New York Vendor Responsibility Registration Information that is complete and up to date.

3.2 Monitoring and Self-Audit

HINs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring to regularly review the New York State registrations to ensure they are up to date.

(ii) Notification to the Department (and the State Designated Entity, if applicable) of change of status related to New York State required non-profit registrations within 30 days.

4. Governance Structure Requirements for SHIN-NY Assessment

To satisfy the SHIN-NY Assessment Requirements for Governance Structure, the HIN must:

(i) Maintain an up-to-date list of Board members, their titles and organizational affiliation on the HIN website.

(ii) Make the organization's bylaws available to the public upon request.

(iii) If possible, include public health and physician representation on the Board.

(iv) Provide an inclusive decision-making process characterized by multi-stakeholder participation that includes stakeholder representatives that reflect the QE general service area. Examples of such stakeholder representatives may include but are not limited to:

(a) physician groups,
(b) sole practitioners and small ambulatory physician offices (i.e., between 1-5 physicians),
(c) diagnostic and treatment centers and licensed clinicians providing mental health and substance use disorder services,
(d) community health centers or federally qualified health centers (FQHCs),
(e) a county or municipal Public Health Department,
(f) general hospitals,
(g) long-term care providers, including long-term Home Health Care providers,
(h) data suppliers, including pharmacies, laboratories and imaging centers,
(i) insurers and purchasers (e.g., employers),
(j) rural health networks and
(k) New Yorkers as patient/consumer representatives.

(v) Provide regular opportunities for public attendance, comments, and feedback at meetings of its board of directors and publish minutes of meetings on the HIN website.

(vi) Have policies and procedures that outline the governance structure to include: Board recruitment; meetings and meeting minutes; reporting; conflicts of interest policy; clearly defined organizational mission and strategic goals.

4.1 SHIN-NY Assessment Requirements

The HIN must have governance structure documentation and a website that include:

(i) An up-to-date list of Board members.

(ii) Documentation of bylaws and process for making the bylaws available to the public upon request.

(iii) Process for making Board minutes available to the public upon request. Policies and procedures that govern overall Board management and governance structure as per § 4.vi, above.

4.2 Monitoring and Self-Audit

HINs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring and notification of any changes in governance structure or participation to the Department (and the State Designated Entity, as required).

5. Required Participant Services and SHIN-NY Participant Facing Services Availability to All Participants Requirements for SHIN-NY Assessment

To satisfy the SHIN-NY Assessment Requirements for Service Availability for all Participants, the HIN must:

(i) Provide the Required Participant Services in accordance with the SHIN-NY Regulation, SCPA, and the SHIN-NY SOPs including Technical Requirements and the SHIN-NY Participant Facing Services to Participants who select the HIN on the SCPA Election Form. The HIN must provide Required Participant Services to all Participants who select the HIN as a Designated HIN on the SCPAs Election Form.

5.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of assessment:

(i) A fully executed QEPA that commits the QE to providing the Required Participant Services and SHIN-NY Participant Facing Services to Participants who select the HIN on the SCPA Election Form.

(ii) Signed and dated Statewide Common Participant Agreements with their active Participants.

(iii) Policies and procedures that outline the process for Participant engagement and onboarding that may include the circumstances and process under which a HIN may delay Participant onboarding based on technical and/or security issues identified in the onboarding process.

6. Management of QE Participant Requirements for QE Certification

To satisfy the Certification Requirements for managing the QE Participants, the QE must:

(i) Comprise and maintain a full and comprehensive list of all QE Participants and identify those Participants that are data suppliers as per requirements in the Policies and Procedures.

(ii) At a minimum, update the list quarterly. Updates to the list shall be indicated by including a ‘last modified date’ clearly visible in the document.

(iii) Publish the list and a ‘last modified date’ on the QE’s website.

6.1 QE Certification Requirements

The QE shall supply the following evidence for purposes of certification:

(i) A list of the QE’s Participants containing the accurate legal or trade name of the Participant and a designation as to their status as a data supplier. This list should also be posted on the QE website.

(ii) A documented process for comprising and maintaining lists of QE Participants.

6.2 QE Monitoring and Self-Audit

QEs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring to track, update and correct the QE Participant list as changes occur.

(ii) Notification related to changes to the list of QE Participants through website posting of a corrected and/or updated list.

7. Participant Flow-Down Requirements for SHIN-NY Assessment

To satisfy the assessment requirements for managing Participant Flow-Down Requirements, the HINs must:

(i) Ensure adherence to all applicable SHIN-NY Privacy and Security flow down requirements for Participants that may be updated when changes in policy and flow down requirements occur.

(ii) Establish monitoring and enforcement policies and procedures for compliance by Participants with all applicable SCPA, Policy Guidance, and applicable SOP flow down requirements.

(iii) Provide all Participants with information about the Monitoring and Enforcement policies.

7.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of assessment:

(i) Documented HIN monitoring and enforcement policies to ensure compliance by Participants with SCPA, Policy Guidance, and applicable SOP flow-down requirements. Policies should include the process for sharing the monitoring and enforcement policies with the Participants.

7.2 Monitoring and Self-Audit

HINs shall ensure that a Monitoring and Self-Audit process is in place and includes:

(i) Ongoing monitoring that identifies gaps in application of monitoring and enforcement policies and procedures.

(ii) Notification to the Department (and the State Designated Entity, if applicable) of changes in monitoring and enforcement policies and procedures that impact the flow-down requirements for Participants within 30 days of planned changes.

8. Insurance/Liability Coverage Requirements for SHIN-NY Assessment

To satisfy the assessment requirements for Insurance/Liability Coverage, the HIN must:

(i) Maintain insurance liability coverage consistent with requirements established in the QEPA, SCPA, SHIN-NY Policy Guidance and applicable SOPs.

8.1 SHIN-NY Assessment Requirements

The HIN shall supply the following evidence for purposes of SHIN-NY Assessment:

(i) HIN documentation of insurance coverage that meets, at a minimum, the levels required as in the QEPA, SCPA, SHIN-NY Policy Guidance, SOPs, and applicable law.

8.2 Monitoring and Self-Audit

HINs shall ensure that a Monitoring and Self-Audit process includes:

(i) Ongoing monitoring of insurance coverage levels to ensure compliance with insurance requirements.

(ii) Notification of any HIN insurance coverage level changes to the Department (and the State Designated Entity, if applicable).