

Qualified Entity (QE) Organizational Characteristics Requirements

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**AS DEVELOPED THROUGH THE NEW YORK STATEWIDE COLLABORATION
PROCESS (SCP)**

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Introduction

This document outlines the requirements for Organizational Characteristics, and sets forth the minimum requirements for participation in the Statewide Health Information Network of NY (SHIN-NY) and certification as a Qualified Entity (the “Certification Requirements”). 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 for QEs and their Participants in New York State* (as amended from time-to-time, the “Policies and Procedures”).

The Certification Requirements fall into the following four categories:

1. **Organizational Characteristics**, e.g., 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**, e.g., infrastructure to operationalize the SHIN-NY requirements, including policies and practices for non-discriminatory exchange of data, system performance, member-facing services, business plans, audit procedures, participation in statewide policy development, and evaluation processes. These requirements are found in the *Qualified Entity (QE) Member Facing Services Requirements* (as amended from time-to-time, the “Member Facing Services Requirements”) as well as in sections of the Qualified Entity Participation Agreement (QEPA), as amended from time-to-time.
3. **Policies and Procedures**, e.g., approach for consent, authorization, authentication, access, patient engagement, audit, breach and sanctions. These requirements are found in the Policies and Procedures that outlines the policy implementation specifications.
4. **Technical Services**, e.g., baseline technical capabilities (*i.e.*, Minimum Technical Requirements) and interoperability (*i.e.*, SHIN-NY 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 *Qualified Entity (QE) Minimum Technical Requirements* (as amended from time-to-time, the “Minimum Technical Requirements”).

In order to participate in the SHIN-NY and become certified as a QE, pursuant to New York State regulations applicable to the SHIN-NY, an entity must satisfy the Certification Requirements. As such, the New York State Department of Health (NYS DOH) serves as the certification and monitoring entity to ensure the integrity of the SHIN-NY and maintain the public trust. NYS DOH, in its role as the certification and monitoring entity, can assign these functions to an outside entity that will be responsible for carrying out the certification process. “Certification Process” means the process by which an organization becomes qualified and re-certified as a Qualified Entity for participation in the SHIN-NY by demonstrating compliance with the Certification Requirements. “Certification Body” means NYS DOH or the entity designated by NYS DOH to oversee the Certification Process.

The NYS DOH may at its discretion, with input from the State Designated Entity Board of Directors, and based on an applicant’s ability to demonstrate its ability to fill gaps in services whether by geography or types of population, make a determination to waive certain organizational characteristics of a QE, so long as that QE adheres to the Operational Requirements, Policies and Procedures and Technical Services listed above.

QEs will actively participate in the Certification Process as described herein and participate in ongoing monitoring of their compliance with the Certification Requirements in accordance with the policies and procedures set forth in the *Oversight & Enforcement Policies and Procedures for QEs* (as amended from time-to-time, the “Oversight and Enforcement Policies”).

During the Certification Process, QE may propose an alternative method for satisfying a Certification Requirement or demonstrate that satisfaction of a Certification Requirement would impose an undue hardship on QE. The Certification Body, in its sole discretion, may elect to excuse such QE from satisfaction of such Certification Requirement.

Organizational Characteristics

In order to participate in the SHIN-NY and become certified as a QE, an entity must comply with the Certification Requirements, which are designed to protect and maintain the reliability, accuracy, and integrity of the SHIN-NY.

“**Organizational Characteristics**” are the set of Certification Requirements set forth herein relating to the following:

1. **Organizational Information:** (1) Address for all facilities; (2) Name and title of senior leadership
2. **Non-Profit Status:** Organized as a 501(c)3, whose incorporation articles have been filed with State of New York
3. **Good Standing in New York State:** Applicable certificates in New York State
4. **Governance Structure:** (1) Listing of Board members and their organizational affiliation on the candidate’s website; (2) Provision of organizational bylaws to the public upon request; (3) Public Health and physician representation on the Board, if possible; (4) Inclusive decision-making process; (5) transparency
5. **Availability to All Participants:** Provision of Minimum services (as such term is defined in the Minimum Core Services Technical Requirements) in accordance with the Minimum Technical Requirements and Member Facing Services (as such term is defined in the Member Facing Services Requirements) in accordance with the Member Facing Services Requirements
6. **Comprehensive, Up-to-Date List of Participants:** If QE has executed Participant Agreements with Participants, a list of such Participants and identification of such Participants that are providing data
7. **Participant Flow-Down Requirements:** If QE has executed Participant Agreements with Participants, procedures to address Participant compliance with the Statewide Policy Guidance
8. **Insurance/Liability Coverage:** 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 executed by the State Designated Entity and QE.

1. Organizational Information

To satisfy the Certification Requirements for Organizational Information, a QE shall publicly provide:

- 1.1 Address for all of its facilities.
- 1.2 Chief Executive Officer, Executive Director and other senior executives.

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

- 1.3 Documentation of required organizational characteristics and attestation that the QE candidate will provide the Certification Body updated information as changes occur within 30 days of change.

The tasks to be performed by the Certification Body in the Certification Process include:

- 1.4 Verification of the QE candidate's listing of facilities and leadership.
- 1.5 Verification of the QE candidate's attestation to provide updated information as changes in the organization occur.
- 1.6 Performance of audits that confirms the QE Organization Information meets the Certification Requirements.
- 1.7 Acceptance and recording of all changes as submitted by QE to the Certification Body related to Organization Information.
- 1.8 **Standard for QE to meet Certification Requirements**: Documentation contains all required information.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 1.9 Self-audits that will identify any organizational changes.
- 1.10 Reporting any changes to the Certification Body as required within 30 days.

2. Non-Profit Status

To satisfy the Certification Requirements for Non-Profit Status, a QE shall:

2.1 Be a non-profit organization incorporated in New York State with federal tax-exempt status.

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

2.2 New York Certificate of incorporation pursuant to Section 402 of the Not-for-Profit Corporation Law.

The tasks to be performed by the Certification Body in the Certification Process include:

2.3 Verification of the QE candidate's New York Certificate of Incorporation.

2.4 Notation of reports from the QE of any change in non-profit status.

2.5 Confirmation of QE non-profit status as part of its audit process.

2.6 **Standard for QE to meet Certification Requirements:** Documentation meets New York State incorporation requirements.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

2.7 Self-audits that will identify any non-profit status changes.

2.8 Reporting mechanism for all changes as required to the Certification Body.

3. Good Standing in New York State

To satisfy the Certification Requirements for Good Standing in New York State, a QE shall:

- 3.1 Have in place the New York Charities Registration from the Attorney General.
- 3.2 Have in place the New York Vendor Responsibility Registration from the Office of the State Comptroller.

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

- 3.3 Evidence of all applicable New York State certificates.

The tasks to be performed by the Certification Body in the Certification Process include:

- 3.4 Verification of all applicable New York State certificates supplied by the QE.
- 3.5 Notation and recording of all reports from the QE related to any changes in standing in New York State.
- 3.6 Certification Body's audit confirms and validates QE's status in Good Standing in New York State.
- 3.7 **Standard for QE to meet Certification Requirements:** QE documentation related to New York State registrations meets New York State standards and is up to date.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 3.8 Self-audits that regularly review QE's New York State registrations to ensure they are up to date.
- 3.9 Notification to Certification Body of change of status related to New York State required non-profit registrations within 30 days.

4. Governance Structure

To satisfy the Certification Requirements for Governance Structure, the QE shall:

- 4.1 Maintain an up to date list of Board members and their organizational affiliation on the QE candidate's website.
- 4.2 Make the organization bylaws available to the public upon request.
- 4.3 If possible, include Public Health and physician representation on the Board.
- 4.4 Provide an inclusive decision-making process characterized by multi-stakeholder participation that includes stakeholder representatives that reflect the QE 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 abuse 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.
- 4.5 Provide regular opportunities for public attendance, comments and feedback at meetings of its board of directors, and publish minutes of meetings

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

- 4.6 Up to date list of Board members with evidence of its presence on the QE website. Documentation of QE Bylaws with evidence that supports availability to the public upon request.
- 4.7 Documentation substantiating the multi-stakeholder inclusivity requirements.

The tasks to be performed by the Certification Body in the Certification Process include:

- 4.8 Review and verification that the QE candidate's description of its governance structure, website, and availability of bylaws to the public meet the Governance Structure requirements in 4.1, 4.2, 4.3, and 4.4.
- 4.9 Notation and recording of and changes and or non-conformance to the QE governance structure as reported by the QE.
- 4.10 Confirmation of QE conformance with governance structure requirements as part of its audit process.
- 4.11 **Standard for QE to meet Certification Requirements:** QE governance structure documentation and website postings meets the Certification Requirements for governance structure.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 4.12 Self-audits that monitor and report changes in governance structure or participation.

5. Availability to All Participants

To satisfy the Certification Requirements for Availability for All Participants, the QE shall:

- 5.1 Provide the Minimum Technical Requirements in accordance with the Dial Tone Service Requirements and the Member Facing Services in accordance with the Member Facing Service Requirements to Participants who enter into a Participant Agreement with QE. The QE must enter into Participation Agreements with all willing Practitioners, Provider Organizations, health homes and Payers (as such terms are defined in the Policies and Procedures) within the geographic or functional service area of the QE that commit to meet the QE's reasonable terms for participation, and specifically cannot make a pre-requisite for participation that the Participant have a contractual relationship with any other Participant in the QE. Allied Individuals and Organizations will have limited agreements with QEs for receipt of alerts.

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

- 5.2 Attestation through the signed QEPA that the QE will provide the Minimum Technical Requirements and Member Facing Services to Participants who enter into a Participant Agreement with QE.

The tasks to be performed by the Certification Body in the Certification Process include:

- 5.3 Verification of the signed QEPA by the QE candidate.
- 5.4 Verification of the signed Participant Agreement between the QE and the Participant.
- 5.5 Notation and recording of any rejections of Participants as reported to the Certification Body by the QE.
- 5.6 Audit that monitors policies and procedures of a random selection as determined by the Certification Body of applicable Participants.
- 5.7 Event audits that are triggered by rejection complaints.
- 5.8 **Standard for QE to meet Certification Requirements:** Attestation through the QEPA that commits the QE to providing Minimum Technical Requirements and Member Facing Services to Participants who enter into a Participant Agreement with QE.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 5.9 Self-audits that track and report changes in policy related to participation in QE's network by Participants to the Certification Body.
- 5.10 Process for justification and reporting of participation rejections to Certification Body.

6. Comprehensive, Up-to-Date List of Participants

To satisfy the Certification Requirements for managing the Comprehensive, Up-to-Date List of Participants, the QE shall:

- 6.1 Comprise a list of all Participants and identify such Participants that are providing data as required in the Policies and Procedures.
- 6.2 At a minimum, update the list quarterly.
- 6.3 Publish the list on the QE's website.

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

- 6.4 Evidence of the process for comprising and maintaining updated lists of Participants.
- 6.5 Website screenshots that evidence the existence of the complete list on the site.
- 6.6 Evidence that the list includes designations for those Participants that are supplying data.

The tasks to be performed by the Certification Body in the Certification Process include:

- 6.7 Review and verification that a significant sample of Participants as supplied by the QE candidate is complete, up to date, and indicates those Participants that supply data.
- 6.8 Notations and recording of any changes to the list of Participants as reported by the QE.
- 6.9 Confirmation during the audit that the contact information corresponding to the list of Participants is accurate, up to date, and is posted on the QE website.
- 6.10 **Standard for QE to meet Certification Requirements**: The list of Participants contains the accurate legal or trade name of the Participant and a designation as to whether or not they are supplying data.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 6.11 Self-audits that ensure tracking and correction of the list of Participants as changes occur.
- 6.12 Notification related to changes to the list of Participants through website posting of corrected and/or updated list.

7. Participant Flow-Down Requirements

To satisfy the Certification Requirements for managing Participant Flow-Down Requirements, the QE shall:

- 7.1 Establish monitoring and enforcement policies and procedures for compliance by Participants, with all applicable Statewide Policy Guidance.
- 7.2 Inform all Participants about the monitoring and enforcement policies.

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

- 7.3 Copy of the QE monitoring and enforcement policies and procedures.
- 7.4 Copy of the Participant Agreement between the QE and the Participant that includes the flow-down requirements for adhering to the Statewide Policy Guidance as set forth in the Statewide Policy Guidance.

The tasks to be performed by the Certification Body in the Certification Process include:

- 7.5 Review and verification that the Participant Agreements between the QE and the Participant contain flow-down requirements for adhering to the Statewide Policy Guidance as set forth in the Statewide Policy Guidance.
- 7.6 Review of QE monitoring and enforcement policies.
- 7.7 Verification of QE's notification regarding the QE monitoring and enforcement policies to all Participants.
- 7.8 Review and confirmation that the Participant Agreements between the QE and the Participant contain all of the flow-down requirements for adhering to the Statewide Policy Guidance as set forth in the Statewide Policy Guidance during the audit process.

7.9 Standard for QE to meet Certification Requirements:

- 7.9.1 QE has monitoring and enforcement policies to promote compliance by Participants with Statewide Policy Guidance.
- 7.9.2 QE contractual arrangements meets requirements for Participant Agreements set forth in applicable law, the Statewide Policy Guidance and the QE Participation Agreement (QEPA).
- 7.9.3 Agreements contain flow-down requirements for adhering to Statewide Policy Guidance as set forth in the Statewide Policy Guidance.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 7.10 Self-audits that identify gaps in application of monitoring and enforcement policies and procedures.
- 7.11 Notification to the Certification Body of changes in QE monitoring and enforcement policies and procedures that impact the flow-down requirements for Participants within 30 days.

8. Insurance/Liability Coverage

To satisfy the Certification Requirements for Insurance/Liability Coverage, the QE shall:

- 8.1 Secure insurance liability coverage as outlined and agreed to in the QEPA so as to reduce the risk of exposure as a result of the exchange of individually identifiable health information.

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

- 8.2 Copy of the QE's certificate of insurance and other relevant supporting documentation, including copies of insurance policies, if appropriate.

The tasks to be performed by the Certification Body in the Certification Process include:

- 8.3 Review of and verification that the QE's certificate of insurance and other relevant supporting documentation meets the requirements as outlined in the signed QEPA.
- 8.4 Notation and recording of any changes to the levels of insurance coverage as reported by the QE.
- 8.5 Confirmation of validity of QE's certificate of insurance and other relevant supporting documentation as part of the review process.
- 8.6 **Standard for QE to meet Certification Requirements:** QE documentation of insurance coverage meets the agreed upon levels as outlined in the QEPA.

In addition to QE's obligations under or in accordance with the Oversight and Monitoring Policies, QEs shall ensure that an ongoing monitoring process includes:

- 8.7 Self-audits that ensure the appropriate coverage level is maintained.
- 8.8 Notification of any QE insurance coverage levels to the Certification Body.