

Qualified Entity (QE) Organizational Characteristics Requirements

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STATEWIDE COLLABORATION PROCESS (SCP)**

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Introduction

This document outlines the requirements for Qualified Entity (QE) Organizational Characteristics and sets forth the minimum requirements for participation and certification to operate as a QE in the Statewide Health Information Network for New York (SHIN-NY). 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 periodically, the "Policies and Procedures").

The Certification 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, QE Participant member-facing services, business plans, audit procedures, participation in statewide policy development, and evaluation processes. These requirements are found in the *Qualified Entity (QE) Participant Member Facing Services Requirements* (as amended periodically, the "Member Facing Services Requirements") as well as in sections of the Qualified Entity Participation Agreement (QEPA), as well as the Data Use and Contribution Agreement (DUCA) as amended periodically.
3. **Policies and Procedures**, 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 for QEs and their Participants.
4. **Technical Services**, technical service requirements (*i.e.*, Minimum Core Services Technical Requirements) and interoperability (SHIN-NY 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 *Qualified Entity (QE) Minimum Core Services Technical Requirements* (as amended periodically, the "Minimum Technical Requirements") and the sPRL Technical Specifications (as amended periodically).

In order to participate in the SHIN-NY as a certified Qualified Entity (QE) pursuant to New York State regulations, an entity must satisfy the SHIN-NY Policy Adherence Certification Requirements. The New York State Department of Health (NYS DOH) serves as the oversight, monitoring, and certification entity to ensure the integrity of the SHIN-NY and maintain the public trust. In this role, NYS DOH can assign an outside entity that will be responsible for facilitating the certification process.

"Certification Process" means the activities by which an organization becomes qualified and re-certified to operate as a Qualified Entity in the SHIN-NY by demonstrating compliance with the Certification Requirements. "Certification Body" means NYS DOH or an entity designated by NYS DOH to oversee the Certification Process. Should NYS DOH designate an entity to manage the Certification Process, this State Designated Entity will work collaboratively with NYS DOH. In this situation the State Designated Entity would serve as the manager of the Certification Process and NYS DOH would function as the overall authority.

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

QEs are required to actively participate in the Certification Process and engage in ongoing monitoring of their compliance with the Certification Requirements as set forth in the QE Certification Process and Procedures document as amended periodically.

Organizational Characteristics

In order to participate in the SHIN-NY as a certified 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.

The following “**Organizational Characteristics**” must be met as part of the Certification 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 State of New York Division of Corporations.
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 corporation 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 QE governance structure to include Board recruitment; meetings and meeting minutes; reporting; conflicts of interest policy; clearly defined organizational mission and strategic goals.
5. **SHIN-NY Core Services and QE Participant Member Facing Services Availability to All QE Participants:** Provision of SHIN-NY minimum core services (as such term is defined in the Minimum Core Services Technical Requirements) and provision of QE Participant Member Facing Services (as such term is defined in the QE Participant Member Facing Services Requirements).
6. **Management of QE Participants:** QE has executed Participant Agreements 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 providing data on the QE’s website.
7. **Participant Flow-Down Requirements:** QE has executed Participant Agreements that include procedures to address Participant compliance with the Statewide Policy Guidance clearly outlined with all Participants.
8. **Insurance/Liability Coverage:** QE 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) executed by the State Designated Entity and QE.

1. Organizational Information Requirements for QE Certification

A QE shall publicly provide:

- (i) QE 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 QE Certification Requirements

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

- (i) Documentation of the QE corporate name, address, and a complete listing of any owned and operated facilities of the QE with the full name of the facility and address.
- (ii) Attestation that the QE information is current and that notification of changes in any organizational information will be provided to the NYS DOH and the State Designated Entity 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 NYS DOH and State Designated Entity as required within 30 days.

2. Non-Profit Status Requirements for QE Certification

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

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

- (i) Documentation in the form of a current New York Certificate of Incorporation that is complete and meets New York State incorporation requirements.

2.2 QE Monitoring and Self-Audit

QEs 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 NYS DOH and the State Designated Entity.

3. New York State ‘Good Standing’ Requirements for QE Certification

To satisfy the Certification Requirements for New York State ‘Good Standing’ a QE 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 QE Certification Requirements

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

- (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 QE Monitoring and Self-Audit

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

- (i) Ongoing monitoring to regularly review QE’s New York State registrations to ensure they are up to date.
- (ii) Notification to NYS DOH and the State Designated Entity of change of status related to New York State required non-profit registrations within 30 days.

4. Governance Structure Requirements for QE Certification

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

- (i) Maintain an up-to-date list of Board members, their titles and organizational affiliation on the QE's website.
- (ii) Make the organization 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 QE website.
- (vi) Have policies and procedures that outline the QE governance structure to include: Board recruitment; meetings and meeting minutes; reporting; conflicts of interest policy; clearly defined organizational mission and strategic goals.

4.1 QE Certification Requirements

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

- (i) An up-to-date list of Board members.
- (ii) Documentation of QE 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 QE Monitoring and Self-Audit

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

- (i) Ongoing monitoring and notification of any changes in QE governance structure or participation to NYS DOH and the State Designated Entity as required.

5. SHIN-NY Core Services and QE Participant Member Facing Services Availability to All Participants Requirements for QE Certification

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

- (i) Provide the SHIN-NY Minimum Core Services in accordance with the SHIN-NY Minimum Core Services Technical Requirements and the QE Participant Member Facing Services in accordance with the QE Participant Member Facing Services policy guidance to Participants who enter into a Participant Agreement with the QE. The QE must enter into Participant Agreements with all willing Practitioners, Provider Organizations, Health Homes, Payers, and other Participants as such terms are defined and outlined in the Policies and Procedures that commit to meet the QE's 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.

5.1 QE Certification Requirements

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

- (i) A fully executed QEPA that commits the QE to providing the SHIN-NY Minimum Core Services and QE Participant Member Facing Services to Participants who enter into a Participant Agreement with the QE.
- (ii) Signed and dated Participant Agreements between the QE and all of 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 QE may delay Participant onboarding based on technical and/or security issues identified in the onboarding process.

5.2 QE Monitoring and Self-Audit

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

- (i) Ongoing monitoring that tracks and notifies NYS DOH and the State Designated Entity of any changes in policy related to participation in the QE by Participants.

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 QE Certification

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

- (i) Incorporate all applicable SHIN-NY Privacy and Security Policies and Procedures flow down requirements into the QE Participant Agreement either in the body of the Agreement and/or as an Addendum to the Agreement that may be updated from time to time as changes in policy and flow down requirement occur.
- (ii) Establish monitoring and enforcement policies and procedures for compliance by QE Participants with all applicable Statewide Policy Guidance flow down requirements.
- (iii) Provide all QE Participants with information about the monitoring and enforcement policies.

7.1 QE Certification Requirements

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

- (i) Documented QE monitoring and enforcement policies to ensure compliance by QE Participants with Statewide Policy Guidance flow-down requirements. Policies should include the process for sharing the monitoring and enforcement policies with the QE Participants.
- (ii) Documented QE contractual arrangements that meet the requirements for QE Participant Agreements set forth in applicable law, the Statewide Policy Guidance, and the QE Participation Agreement (QEPA) including all flow-down requirements.

7.2 QE Monitoring and Self-Audit

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

- (i) Ongoing monitoring that identifies gaps in application of monitoring and enforcement policies and procedures.
- (ii) Notification to the NYS DOH and the State Designated Entity of changes in QE monitoring and enforcement policies and procedures that impact the flow-down requirements for Participants within 30 days of planned changes.

8. QE Insurance/Liability Coverage Requirements for QE Certification

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

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

8.1 QE Certification Requirements

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

- (i) QE documentation of insurance coverage that meets, at a minimum, the agreed upon levels as outlined in the QEPA.

8.2 QE Monitoring and Self-Audit

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

- (i) Ongoing monitoring of insurance coverage levels to ensure compliance with QEPA requirements.
- (ii) Notification of any QE insurance coverage level changes to the NYS DOH and the State Designated Entity.