Statewide Collaboration Process

## Introduction

Effective as of July 10, 2024, New York State has promulgated amended regulations (10 NYCRR Part 300; the **SHIN-NY Regulations**) requiring that the New York State Department of Health (the Department) "establish a statewide collaboration process, which may include the designation of committees, representing qualified entities, SHIN-NY participants, relevant stakeholders, and health care consumers to make recommendations on SHIN-NY policy guidance and standards." This **Statewide Collaboration Process (SCP)** is administered jointly by the Department and its state-designated entity (SDE), the New York eHealth Collaborative (NYeC). In its role as SDE, NYeC facilitates an open and transparent SCP that is designed to ensure input from key stakeholders in the SHIN-NY in the development and implementation of SHIN-NY policy guidance and standards.

The SCP is the comprehensive, collaborative process through which SHIN-NY policies are developed, shared with stakeholders, and refined prior to consideration by the NYeC Board and the Department. Outputs of the SCP are formalized as SHIN-NY Standard Operating Procedures (SOPs), documents that each describe a specific area of SHIN-NY policy guidance. Through the SCP, standing and ad hoc committees and SHIN-NY work teams are designated to focus on priority areas of SHIN-NY policy, implementation and operations. Members of SCP committees are appointed to represent the diverse viewpoints of SHIN-NY Participants, Qualified Entities (QEs), state and local health authorities, patients, and other interested parties. Members of SHIN-NY work teams represent QEs, the SDE and the Department in performing their essential business and operational functions for the SHIN-NY.

## SOP Purpose, Scope, Limitations, and Intended Audience

### Purpose

The purpose of this SOP is to define and describe the SCP for the SHIN-NY. The SCP is an integral part of SHIN-NY governance and serves as a mechanism for developing and amending SHIN-NY policy guidance in the form of SHIN-NY SOPs.

### Scope

This SOP details the structure of the SCP, including SCP committee names and charters; their leadership, membership, and staffing models; scopes of responsibility for policy guidance and standards development; and the advisory and decision-making roles within the SCP framework. In addition, this SOP details the functions of the SCP, including the operating models for SCP committees; and processes for amending the Statewide Common Participation Agreement (SCPA) and other SHIN-NY SOPs.

#### Limitations

This SOP describes certain activities and procedures undertaken by the Department, NYeC and/or the NYeC Board of Directors in support of the SCP. However, these entities' roles in

<sup>&</sup>lt;sup>1</sup> N.Y. Comp. Codes R. & Regs. Tit. 10 § 300.3 - Statewide collaboration process and SHIN-NY policy guidance

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the SCP are not limited to these functions, nor shall this SOP in any way limit the powers and functions otherwise held by these entities.

#### Audience

The audience for this SOP includes QEs, required and voluntary SHIN-NY participants, New York state and local public health authorities, health care consumers, and all other stakeholders with an interest in the SHIN-NY.

### **Definitions**

**Statewide Common Participation Agreement (SCPA)** is defined as "...a common agreement, developed using a statewide collaboration process, consistent with any minimum standards set forth in the SHIN-NY policy guidance and approved by the New York State Department of Health, that is used statewide by each qualified entity or by SHIN-NY participants, allowing them to connect to the SHINY-NY statewide data infrastructure (SDI) either directly or through a contractor, and pursuant to which SHIN-NY participants agree to participate in the SHIN-NY and adhere to SHIN-NY policy guidance, including but not limited to causing patient data to be contributed to the SDI and authorizing the use of patient data for statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law."<sup>2</sup>

**Statewide Data Infrastructure (SDI)** is defined as "...the information technology infrastructure provided by the New York State Department of Health, either directly or through contract, to support the aggregation of data provided by qualified entities and SHIN-NY participants, statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law." The SDI includes a statewide data repository as well as centralized SHIN-NY systems operated or directed by NYeC.

## **Roles and Responsibilities**

**New York State Department of Health (the Department)** has decision-making authority for all SHIN-NY policy guidance and standards developed through the SCP. Through its public-private partnership with NYeC, the Department convenes the SCP committees to provide recommendations on potential changes to SHIN-NY policy guidance and standards, and may reconfigure, dissolve, or designate new committees at its discretion. The Department considers new or modified SHIN-NY policy guidance and standards at the request of the NYeC Board of Directors and responsible SCP committee Chair(s).

**NYeC Board of Directors (the Board)** reviews all recommendations on SHIN-NY policy guidance and standards changes made through the SCP, prior to the Department consideration. Members serve individually as Chairs for each SCP committee and bear responsibility for operating the committee in accordance with its charter and reporting on committee activities to fellow Board Members and/or the Department periodically, or upon

<sup>&</sup>lt;sup>2</sup> N.Y. Comp. Codes R. & Regs. Tit. 10 § 300.1 - Definitions

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request. Through its Nominating Committee, the Board considers nominations of and appoints members and Chairs of SCP committees.

**NYeC Staff** provide administrative coordination, support, and subject matter expertise to SCP committees. Staff support the SCP committee Chairs and facilitate the operations of each SCP committee in accordance with its charter. NYeC additionally serves as the convener of SHIN-NY standing and ad hoc work teams to support essential business and operational functions of the network.

**Qualified Entities (QEs)** participate through representatives as voting or ex officio members of SCP committees pursuant to the charters for those committees. QE representatives also participate in SHIN-NY standing and ad hoc work teams established by NYeC staff, including the SHIN-NY Leaders Group.

**SHIN-NY Participants** participate through representatives as voting or ex officio members of SCP committees pursuant to the charters for those committees. SHIN-NY Participants may also participate in SCP functions through guest attendance at meetings of SCP committees of which they are not members and the submission of public comments on, including suggested changes to, SHIN-NY SOPs and SHIN-NY proposals.

The **SHIN-NY Policy Committee (PC)** is an SCP standing committee with primary responsibility for the development and amendment of the Statewide Common Participation Agreement (SCPA), including the Election Process, and those SHIN-NY SOPs that address privacy and security policies, including patient consent.

The **Statewide Data Use Committee (SDUC)** is an SCP standing committee with responsibility for the development and amendment of SHIN-NY SOPs that address disclosures and uses of data contained in the SHIN-NY Statewide Data Infrastructure (SDI). The SDUC is additionally responsible for adjudication of SHIN-NY data use requests.

The **Technical Advisory Committee (TAC)** is an SCP standing committee with responsibility for the development and amendment of SHIN-NY SOPs that address technical data contribution standards for SHIN-NY Participants, including those involving core (required) data contributions and protocols for submissions directly to the Statewide Data Infrastructure; technical standards for services provided by QEs; and technical standards and requirements for interoperability among SHIN-NY participants.

The **SHIN-NY Leaders Group** is a standing SHIN-NY work team with responsibility for key business and operational decision-making related to cross-QE and SDE functions. NYeC convenes the group and determines its membership, which shall generally consist of executive-level leadership representing each QE, the SDE, and the Department.

## **Description of Standard Operating Procedures**

SHIN-NY SOP Procedures

1. Appointment to SCP Committees

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The NYeC Board shall appoint Chairs of and members to standing SCP committees from a slate submitted by the NYeC Nominating Committee. The Chairs of the PC, SDUC and TAC will seek candidates for recommendation to the NYeC Nominating Committee in accordance with their respective charters. NYeC staff shall also issue a public call for committee member nominations in advance of the NYeC Nominating Committee meeting; whenever practicable, a call will remain open for 30 days. Appointments to ad hoc SCP committees shall be managed on a case-by-case basis at the discretion of the NYeC Board and the Department, with support from NYeC staff.

## 2. Development of new SHIN-NY SOPs

The SHIN-NY Regulations require that recommendations on SHIN-NY policy guidance and standards be made through the SCP. The Department shall consider SHIN-NY policy guidance and standards recommendations made through the SCP and may accept or reject such recommendations at its sole discretion.

The SCPA incorporates the requirement that policy guidance and standards recommendations be made through the SCP, further clarifying the role of the SCP in the development and amendment of SHIN-NY standards and procedures known as "SHIN-NY SOPs." An initial set of SHIN-NY SOPs is listed in Exhibit B of the SCPA which includes both legacy (existing) SOPs carried forward from previously approved SHIN-NY policy guidance, and new SOPs which are needed to implement the terms of the SCPA. Legacy SOPs shall be carried forward as last amended and approved through the SHIN-NY Policy Committee (PC) process and/or through updates made by NYeC with QE input and approved by the Department. All subsequent amendments shall follow the procedure described below ("Review and amendment of existing SHIN-NY SOPs").

Table 1.1, below, lists the legacy and new SHIN-NY SOPs and indicates the entity principally responsible for each.

SHIN-NY SOP	Туре	Principally Responsible SCP Committee or Entity
State-Funded Participant Services Requirements for both QEs and NYeC (modification of existing Qualified Entity Minimum Technical Core Services Requirements)	Legacy	Technical Advisory Committee
QE Participant Member-Facing Services	Legacy	Technical Advisory Committee
Privacy and Security Policies and Procedures	Legacy	SHIN-NY Policy Committee
Election Process	New	SHIN-NY Policy Committee
Technical Standards for Interoperability and Data Sharing	New	Technical Advisory Committee

<sup>&</sup>lt;sup>3</sup> See https://www.health.ny.gov/technology/regulations/ for legacy SOP documents.

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SHIN-NY SOP	Туре	Principally Responsible SCP Committee or Entity
Contribution Requirements and Contribution Standards for Participants	New	Technical Advisory Committee
Platform Technical Specifications for both QEs and NYeC	New	Technical Advisory Committee
SDI Data Use Approval Process	New	Statewide Data Use Committee
Requirements for SDI Waiver Recipients Under 10 NYCRR §300.6	New	NYeC and/or the Department
Statewide Collaboration Process	New	NYeC and/or the Department
Oversight & Enforcement Policies and Procedures for QEs	Legacy	NYeC and/or the Department
Qualified Entity Organizational Characteristics Requirements	Legacy	NYeC and/or the Department

As indicated in Table 1.1, development of new SHIN-NY SOPs will be managed through SCP committees, and directed by the committee Chairs, or through NYeC and/or the Department. Each SCP committee or entity will develop the SOPs for which they are principally responsible, including by soliciting the advice, where needed, of other SCP committees, SHIN-NY standing or ad hoc work teams, SHIN-NY stakeholders, and subject matter experts. New SHIN-NY SOPs will be produced in a standard format using a template developed by NYeC.

For SHIN-NY SOPs managed through SCP committees, the Chair of the SCP committee that drafted a new SOP will present the draft to the NYeC Board for review and approval and will manage requested revisions. NYeC Board approval shall be documented in Board meeting minutes. Following NYeC Board approval, the new SOP will be shared with the Department for review and approval. Following the Department's approval, NYeC will post or otherwise make the new SOP available to the public.

From time to time, the development of additional SOPs not related to those listed in Table 1.1 may be required to provide guidance on emergent SHIN-NY policy issues, or otherwise serve the interests of the network. The creation of additional SOPs may be proposed by an SCP committee member or Chair, by NYeC, or by NYS DOH; SHIN-NY stakeholders may also propose a new SOP by submitting a request to the SHIN-NY PC Chair, in which case, the Chair will address such request through the Committee, or refer the request to the SDUC, TAC, NYeC and/or NYS DOH, as appropriate.

New SOPs shall be discussed by the SHIN-NY Policy Committee, SDUC, or TAC, as appropriate, and considered for referral to the NYeC Board and the Department. The NYeC Board shall consider such referrals and make a recommendation to the Department for or against the creation of the additional SOP. Recommendations in favor shall include a recommended SCP committee or other entity (e.g., NYeC or a SHIN-NY work team) that shall

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be responsible for the new SOP. Final determinations on additional SOP proposals will be made by the Department in its sole discretion, and these determinations will be documented in the appropriate committee meeting materials in order to ensure public disclosure.

For SHIN-NY SOPs managed through NYeC and/or the Department new SOPs drafted by NYeC will be presented to the appropriate SCP committee and/or to the NYeC Board, as appropriate, for review and approval. Following NYeC Board approval, the new SOP will be shared with the Department for review and approval. Following the Department's approval, NYeC will post or otherwise make the new SOP available to the public.

## 3. Review and amendment of existing SHIN-NY SOPs

The amendment of SHIN-NY SOPs shall be the responsibility of the SCP committee or entity principally responsible for that SOP pursuant to the process outlined below ("Amendment Procedures"), unless otherwise specified in a specific SHIN-NY SOP. SHIN-NY SOPs shall be reviewed and evaluated by their responsible committee or entity at least once annually to ensure their terms remain consistent with applicable New York State laws and regulations, and appropriate for the needs of the SHIN-NY. Amendments to existing SHIN-NY SOPs may be proposed by an SCP committee member or Chair, by NYeC, or by the Department; SHIN-NY stakeholders may also propose amendments to existing SOPs by submitting a request to the responsible SCP committee's Chair or, for SOPs managed through NYeC and/or the Department to NYeC. The responsible SCP entity must consider all reasonable requests for SOP amendments, as determined by the committee Chair (or their designee) or the entity.

Upon determining that an amendment is needed, the responsible SCP entity shall work to develop a proposed revision to the SOP. The Chair of the responsible SCP committee will present the amendment to the NYeC Board for review and manage any revisions which the NYeC Board may request prior to approval. For SOPs for which NYeC and/or the Department are responsible, NYeC will present the amendment to the appropriate SCP committee and/or to the NYeC Board for approval. Following NYeC Board approval, the amendment will be shared with the Department for review and approval. Following the Department's approval, NYeC will update the SOP in the *Version History* section to document the changes, and post or otherwise make the amended SOP available to the public.

Legacy SOPs that govern QE oversight and enforcement and QE organizational characteristics requirements will be updated by NYeC with input from the QEs, from the SCP Committees, where appropriate, and with the Department's oversight and approval.

## SCP Standing Committee Procedures

## 4. Operating model of SHIN-NY Policy Committee

The SHIN-NY Policy Committee (PC) operates as a standing SCP committee and is an advisory body to the NYeC Board of Directors and the Department. The NYeC Board appoints the PC Chair and policy committee members from a slate submitted by the NYeC Nominating Committee.

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The PC is primarily responsible for the SHIN-NY SOP concerning Privacy and Security Policies and Procedures, as well as amendments to the Statewide Common Participation Agreement (SCPA) and the Election Process SOP. The PC will set and publish an Annual Policy Agenda at least once annually which describes its intended priorities for the following year. The PC shall operate consistent with its charter, as approved by the NYeC Board.

### 5. Establishment and operating model of Statewide Data Use Committee

The Statewide Data Use Committee (SDUC) shall be established at the direction of the NYeC Board of Directors and the Department to serve as one of their advisory bodies. The NYeC Board shall appoint the SDUC Chair and members from a slate submitted by the NYeC Nominating Committee. The SDUC Charter shall be drafted and approved by the NYeC Board prior to the establishment and first convening of the SDUC.

The SDUC will operate as a standing SCP committee and is principally responsible for the SHIN-NY SOP concerning the SDI Data Use Approval Process, as well as for adjudication of SHIN-NY data use requests pursuant to that SOP. The SDUC shall operate consistent with its charter, as approved by the NYeC Board.

## 6. Establishment and operating model of Technical Advisory Committee

The Technical Advisory Committee (TAC) shall be established at the direction of the NYeC Board of Directors and the Department to serve as one of their advisory bodies. The NYeC Board shall appoint the TAC Chair and members from a slate submitted by the NYeC Nominating Committee. The TAC Charter shall be drafted and approved by the NYeC Board prior to the establishment and first convening of the TAC.

The TAC will operate as a standing SCP committee and is principally responsible for the SHIN-NY SOPs concerning technical requirements for interoperability and data sharing among SHIN-NY participants. The TAC shall operate consistent with its charter, as approved by the NYeC Board.

### 7. Establishment of new SCP committees

The NYeC Board or the Department may elect to establish a new SCP standing or ad hoc committee to meet emergent needs of the SHIN-NY. The decision to establish such a new committee shall be made by mutual agreement of the NYeC Board and the Department. In the event a new committee is established, NYeC will provide staff support to facilitate its functioning. For new standing committees, the NYeC Board shall appoint committee Chairs and members from a slate submitted by the NYeC Nominating Committee. Charters for all new standing committees shall be drafted and approved by the NYeC Board prior to the establishment and first convening of the committee; ad hoc committees may be convened without a formal charter document. All documentation requirements described in this SOP shall apply to any new SCP committee unless otherwise specified in its charter.

### 8. Dissolution of an existing SCP committee

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The Department may, in its sole judgment, dissolve an existing SCP committee. The process for dissolution shall be determined by the Department as needed.

## 9. Governance of standing and ad hoc SHIN-NY work teams

NYeC, in its role as the SDE, shall convene standing and ad hoc SHIN-NY work teams, including the SHIN-NY Leaders Group, to assist in fulfilling the business and operational needs of the SHIN-NY. Membership of SHIN-NY work teams will be established by NYeC and will include staff and subject matter experts (SMEs) from NYeC, QEs, and the Department as appropriate. A member of NYeC leadership, or their designee, shall facilitate each SHIN-NY work team. These work teams can seek input and feedback from and provide input and feedback to the SCP committees, as needed.

SHIN-NY work teams support the implementation of SHIN-NY policy and standards developed through the SCP. SHIN-NY work teams are not primarily responsible for development or amendment of SHIN-NY SOPs; however, SCP committees may request feedback and input from or otherwise coordinate with a work team(s) when developing and/or amending such SOPs. SHIN-NY work teams may, at the direction of the NYeC Board or the Department, lead the development of proposals for new SHIN-NY SOPs.

### 10. Governance of SHIN-NY Leaders Group

The SHIN-NY Leaders Group is a standing SHIN-NY work team through which NYeC convenes the executive-level leadership of NYeC, each QE and representatives from the Department for key business and operational decision-making. This work team will perform functions previously managed through the SHIN-NY Business and Operations Committee (BOC), a legacy SCP committee. QE Leaders will report out relevant activities of the Group to the NYeC Board on a rotating basis.

#### **SCPA Procedures**

## 11. Implementation of the Statewide Common Participation Agreement

The implementation of the Statewide Common Participation Agreement (SCPA) by SHIN-NY participants and HINs, including NYeC and each QE, shall be the responsibility of NYeC, as the state designated entity and partner of the Department. NYeC is developing the SCPA in partnership with the SHIN-NY PC, the Department, SHIN-NY participants, QEs, and interested health care and social services stakeholders across New York State. NYeC has implemented an open and transparent process for input on and discussion of the SCPA by providing at least one public webinar session about the SCPA, sharing webinar materials and a recording via its website (<a href="www.nyehealth.org">www.nyehealth.org</a>), and administering a 30-day public comment period process on the SCPA. NYeC reviewed and analyzed all public comments received through this process and incorporated public comments into the SCPA as determined to be appropriate or necessary to implement the SHIN-NY regulations. The final SCPA was approved by the NYeC Board on February 28, 2025 and by the Department on April 2, 2025. The NYeC Board and the Department will monitor implementation of the SCPA based upon

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progress updates provided by NYeC staff and through feedback provided by SHIN-NY stakeholders.

12. Amendments to the Statewide Common Participation Agreement

The SHIN-NY Policy Committee (PC) shall be responsible for considering and developing amendments to the SCPA, as directed by the NYeC Board and the Department. Proposals for amendments to the SCPA may also be submitted to the PC by SHIN-NY stakeholders; such proposals will be reviewed and discussed by the PC at the discretion of the Chair. Any necessary clarification or addition to the SCPA that can, in the judgment of the NYeC Board and the Department, be accomplished without amendment and instead through development of a new or amended SHIN-NY SOP shall be managed accordingly. The PC Chair, with support from NYeC staff, shall be responsible for ensuring that meeting minutes accurately reflect any discussion of SCPA amendments which takes place during a PC meeting and that are posted on the NYeC website for public access.

### **Amendment Procedures**

This SCP SOP shall be reviewed and evaluated by NYeC staff at least once annually to ensure its terms remain consistent with applicable New York State laws and regulations, and appropriate for the needs of the SHIN-NY. SHIN-NY stakeholders may submit proposals to amend this SOP addressed to NYeC staff for consideration. Proposals to amend this SOP shall be considered by the NYeC Board and the Department. All amendments to this SOP shall be documented in the *Version History* section and published according to the practices described in *Section 2, Review and amendment of existing SHIN-NY SOPs*. NYeC will post or otherwise make the amended SOP available to the public.

## **Documentation Requirements**

NYeC, in coordination with each SCP committee, is responsible for the public disclosure of committee meeting agendas, meeting minutes, white papers, and recommendations.<sup>4</sup> NYeC, in coordination with each SCP committee Chair, shall ensure these documentation and disclosure requirements are met in a timely fashion (i.e., as soon as practicable prior to or after each meeting).

All documentation associated with SCP committee or entity work shall be made available on NYeC's website (<a href="www.nyehealth.org">www.nyehealth.org</a>).

SHIN-NY standing and ad hoc work teams may, but are not required to, make their work products available on a case-by-case basis at the discretion of NYeC and the Department. In these cases, such documentation will be made available on NYeC's website (<a href="www.nyehealth.org">www.nyehealth.org</a>).

<sup>&</sup>lt;sup>4</sup> N.Y. Comp. Codes R. & Regs. Tit. 10 § 300.3 - Statewide collaboration process and SHIN-NY policy guidance

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## **Attachments**

- SHIN-NY Policy Committee Charter as last amended and approved by the NYeC Board on February 4, 2025.
- Statewide Data Use Committee Charter (as approved by the NYeC Board on January 2, 2025)
- Technical Advisory Committee Charter (as approved by the NYeC Board on January 15, 2025)
- SHIN-NY SOP Template

## **Version History**

Version Number	Date Adopted	Summary of Action/Changes
1.0	4/01/25	Approved by NYeC Board
	4/02/25	Approved by NYS Department of Health

#### NEW YORK eHEALTH COLLABORATIVE, INC.

#### **Charter of the SHIN-NY Policy Committee**

#### As Amended and Adopted at the February, 4 2025 Board Meeting

#### Introduction

In 2024, amendments to the SHIN-NY Regulation 10 NYCRR § 300.3(a) and (b) acknowledged the need for a more comprehensive and transparent Statewide Collaboration Process (SCP). The updated regulation authorizes the establishment of other committees, in addition to the SHIN-NY Policy Committee, to provide governance for the development of technical standards for interoperability and data sharing as well as requirements and procedures for data use and disclosure using the statewide data infrastructure. In that context, two new SHIN-NY Governance Committees have been formed: a Technical Advisory Committee (TAC)and a Statewide Data Use Committee (SDUC). These three governance committees will make policy and standards recommendations to the NYeC Board of Directors for approval and submission to the New York State Department of Health for final review and approval.

Activities of the SHIN-NY Policy Committee will remain largely the same with some additional modifications as reflected in this Charter document. The New York State Department of Health shall consider SHIN-NY policy guidance recommendations made through the statewide collaboration process and may accept or reject SHIN-NY policy guidance recommendations at its sole discretion.

The New York eHealth Collaborative ("NYeC") works in partnership with the New York State Department of Health as the State Designated Entity (the "SDE") responsible for operating and maintaining the SHIN-NY and does so in collaboration with the regionally based QEs and their Participants. Together they are governed through the open and transparent *Statewide Collaboration Process* that is designed to ensure input from key stakeholders in the SHIN-NY in the development and implementation of SHIN-NY Policy Standards. These policy standards are designed to establish privacy and security policies that comport with existing laws. NYeC staff provide leadership to the work of the Committee and the development of the policies and procedures that serve as policy guidance to the SHIN-NY Regulation and are outlined in the *SHIN-NY Privacy and Security Policies and Procedures for Qualified Entities and their Participants*.

The policies and procedures are not a static document. As the SHIN-NY continues to mature, these Policy Standards are amended from time to time to reflect the benefit of implementation and operational experience, new technology developments, changes in federal and state laws and other considerations. The Committee is formally chartered to assist in this ongoing process.

#### I. PURPOSE

The development and maintenance of privacy and security policies for the SHIN-NY is designated to the Committee by the NY State Department of Health under the statewide collaboration process. The Committee is convened and managed for this purpose by NYeC in its role as the SDE.

#### II. COMMITTEE MEMBERSHIP

The Committee shall comprise at least thirteen (13) but no more than fifteen (15) members, including the Committee Chair. Members shall be appointed by the NYeC Board of Directors from a slate submitted by the NYeC Nominating Committee at any meeting of the NYeC Board of Directors.

Committee members shall be appointed by the NYeC Board of Directors from a slate submitted by the NYeC Nominating Committee. Committee members so appointed shall serve up to two (2) three (3) year terms, or until their earlier resignation or removal; provided, however, that the Chair of the Committee, in his or her discretion, may recommend to the Nominating Committee a one-time term extension for an individual Committee member for good cause.

To the extent possible, Committee membership shall be representative of the broader healthcare stakeholder community including but not limited to public health, hospitals, providers, health plans, attorneys, Qualified Entities, consumers and consumer advocates, state healthcare associations, security experts and health care policy experts. Membership should be representative and diverse in terms of geographic distribution, experience in policy and legislative areas, and should at a minimum include, if at all possible:

- A minimum of four (4) general hospitals or health care facilities which are required to contribute data to the SHIN-NY, or their representative(s), which may include state hospital associations
- A minimum of two (2) local health departments which utilize or intend to utilize QE or SHIN-NY data
- A minimum of one (1) community-based or human services organization which utilizes or intends to utilize QE or SHIN-NY data
- A minimum of one (1) health plan which utilizes or intends to utilize QE or SHIN-NY data
- At least one (1) member representing an entity coordinating health-related social need services pursuant to the State's Medicaid program
- A minimum of one (1) other provider organization of a type not otherwise represented above (e.g., primary care practice, LTC)
- A minimum of one (1) consumer and/or consumer advocate.
- A minimum of two (2) Qualified Entities (QEs)

The membership may also include ex officio non-voting members that include but are not limited to the following stakeholder groups: one (1) SHIN-NY QE Leadership Team representative, and a minimum of one (1) representative from each of the following stakeholder entities: NYS OMH, OASAS, OPWDD, NYDOHMH, and other relevant stakeholder entities.

Ex officio members of the Committee have input into policy discussions as part of the regular Policy Committee meetings. They do not have a vote on resolutions and recommendations from the Committee to the NYeC Board of Directors.

The Committee is Chaired by a member of the NYeC Board of Directors who is chosen from a slate submitted by the NYeC Nominating Committee at the Annual Meeting of the NYeC Board of Directors, and such chair shall serve a term(s) of three (3) years. The Chair shall preside at meetings of the Committee and shall have authority to convene meetings, set agendas for meetings and determine the Committee's information needs. In the absence of the Chair at a duly convened meeting, the Chair shall select a temporary substitute from among its members to serve as Chair of the Committee for such meeting.

Work of the SHIN-NY Policy Committee is staffed by NYeC.

#### III. COMMITTEE MEETINGS

The Committee shall meet on a regular basis and at least monthly or as circumstances dictate. Committee meetings may be held as conference call meetings via Teams or Zoom. A majority of the members of the Committee shall constitute a quorum for a meeting, and the affirmative vote of a majority of the members present at a meeting at which a quorum is present shall constitute the action of the Committee.

Work of the Committee will follow the general principles of the Statewide Collaboration Process that promotes an open and transparent process where decisions of the Committee will be guided by consensus of the members.

#### IV. KEY RESPONSIBILITIES

#### **Committee:**

- Ensure modernization of existing SHIN-NY Privacy and Security Policies and a framework for development of new policies consistent with federal and state regulations and/or legislation that support and increase access and usage.
- 2. Review and consider policy proposals submitted by SHIN-NY stakeholder groups.
- 3. Develop policy issue papers and FAQs on SHIN-NY policy guidance.
- 4. Propose an annual policy Agenda and scope of work for NYS DOH and NYeC Board of Directors approval.
- 5. Ensure public comments on major SHIN-NY policy changes as needed.
- 6. Ensure regular Committee activity updates to the NYeC Board of Directors.
- 7. Provide policy input as needed for the work of the Technical Advisory Committee (TAC) and the Statewide Data Use Committee (SDUC).

#### Chair:

- Provide leadership and direction to the work of the Committee.
- Convene and facilitate regularly scheduled meetings of the Committee.
- Foster a decision-making process that facilitates a full discussion of all views and builds toward consensus when possible.
- Refer SHIN-NY privacy and security policy recommendations to the NYeC Board of Directors for approval before forwarding to NYS DOH for final review and incorporation into SHIN-NY Policy Guidance.
- Establish ad hoc workgroups of the Committee with subject matter experts as needed.
- Provide regular updates on Committee work to the NYeC Board of Directors.
- Convene an annual SHIN-NY Policy Agenda planning process.

#### Members:

- Actively participate in regularly scheduled meetings of the Committee.
- Actively participate in ad hoc workgroups as needed.

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• Contribute knowledge and expertise that will further inform overall policy development and

implementation keeping the best interests of the SHIN-NY enterprise in mind and putting aside

#### NEW YORK eHEALTH COLLABORATIVE, INC.

#### Charter of the SHIN-NY Statewide Data Use Committee

### As Adopted on January 2, 2025

**Introduction:** Amendments to the SHIN-NY Regulations (10 NYCRR Part 300), effective July 10, 2024, require the establishment of "a statewide collaboration process, which may include the designation of committees representing qualified entities, SHIN-NY participants, relevant stakeholders, and healthcare consumers to make recommendations on SHIN-NY policy guidance and standards." The regulation also requires the creation of requirements and procedures for the disclosure of data using the statewide data infrastructure (SDI), to the New York State Department of Health (NYS DOH) or its designated contractor, and for the use and re-disclosure of such data to support statewide reporting and analytics for public health surveillance and Medicaid purposes. Such requirements and procedures will constitute new components of SHIN-NY policy guidance, which is the holistic set of policies and procedures developed through the statewide collaboration process which governs the SHIN-NY.

In 2024 and beyond, the SHIN-NY is continuing its ongoing transformation into a public health data utility suitable to support the "nation-leading monitoring and surveillance system to inform targeted and appropriate responses to public health crises and to drive broader health care insights" envisioned by Governor Hochul in her 2023 State of the State remarks. NYeC, as steward of the SHIN-NY, is responsible for supporting this transformation – including by administering requests for use of SHIN-NY data, managing the provision of SHIN-NY data outputs to requesters, and upholding a transparent and open governance model for data use. As the central functions of the SHIN-NY evolve towards public health and Medicaid, a centralized capability to evaluate and adjudicate data use requests is also necessary.

**Purpose:** NYeC will establish a Statewide Data Use Committee (SDUC) to apply the requirements and procedures for the disclosure of data using the statewide data infrastructure (SDI) defined in SHIN-NY policy guidance by reviewing and adjudicating data use requests. The SDUC will serve as subject matter experts on the contents of the SDI and the permitted purposes for which SDI data may be used, as well as prohibited uses of the same.

**Composition:** The SDUC will be composed of a cross-section of SHIN-NY stakeholders representing QEs, SHIN-NY participants, patient and consumer advocates, and subject matter experts in relevant areas of data use, patient privacy, and access. NYeC staff with relevant expertise will support the functions of the SDUC but will not hold voting seats.

Chair: The SDUC will be chaired by a NYeC Board member and selected by a vote of the NYeC Board based on the recommendation of the Board's Nominating Committee. The Chair will participate as a voting member of the SDUC. The SDUC Chair has the authority to convene meetings, set agendas for meetings, and determine the Committee's information needs. The Chair will be responsible for directing regular updates to the NYeC Board and NYS DOH on SDUC activities, with support from NYeC staff.

Membership: In addition to the SDUC Chair, the SDUC will have up to eight (8) voting members as below:

• Up to two (2) representatives of health care entities subject to SHIN-NY regulations, which may include state hospital associations

- Up to two (2) Qualified Entity (QE) representatives with data use and data privacy experience
- A minimum of one (1) representative from provider organizations such as primary care
  practices, adolescent and pediatric practices, health plans, mental health, substance use
  disorders, community-based/human services organizations
- Up to two (2) consumer or patient advocates
- A minimum of one (1) subject matter expert (state or national) focused on data use, patient privacy and access, and relevant NYS laws and regulations

All SDUC members shall disclose their conflicts of interest with relevance to SDUC activities. Members may be required, in their judgement or in the judgement of the Chair, to recuse themselves from particular data use case adjudication decisions.

SDUC members may be appointed to and serve on other Statewide Collaboration Process (SCP) committees simultaneously.

Member Selection and Terms: Inaugural members of the SDUC will be selected through the NYeC Board's Nominating Committee process. A call for inaugural member nominations will be broadly distributed to SHIN-NY participants and stakeholders which will be considered by the NYeC Nominating Committee when presenting a slate of candidates to the NYeC Board. In the future, a similar public call for committee member nominations will be issued by NYeC staff; wherever practicable, a call will remain open for 30 days. Nominations received through this call will be forwarded to the Nominating Committee for consideration. SDUC members may also be recommended to the Nominating Committee by the SDUC Chair in consultation with incumbent SDUC members and NYeC. Members will serve terms of three years each and may serve up to two successive terms with potential nomination for a third term if circumstances merit reappointment, at the discretion of the SDUC Chair.

**Meeting Cadence and Procedure:** The SDUC will meet at a frequency determined by the Chair, but no less than quarterly. SDUC members will participate in meeting pre-work and offline review of data use case requests between scheduled meetings as needed. NYeC staff will work with the Chair to establish a protocol for sharing data use request documentation with SDUC members promptly to support efficient adjudication during meetings.

Meetings of the SDUC will be hosted on a virtual conferencing platform, or hybrid in-person and virtually, and will generally be closed to the public, with exceptions made upon request and at the discretion of the Chair. Meeting details will be announced on the NYeC website at least five (5) business days prior to the meeting, or as soon as practicable for meetings scheduled with less advance notice. The SDUC will keep meeting minutes which will be made available to the public via the NYeC website following each meeting.

A majority of the members of the SDUC shall constitute a quorum for a meeting, and the affirmative vote of a majority of members present at a meeting at which a quorum is present shall constitute the action of the Committee. The Committee may also act by unanimous written consent of its members (including by e-mail), or in such other manner as may be prescribed in the applicable SHIN-NY standard operating procedures (SOPs).

**Committee Functions:** The SDUC will have a combination of advisory and decision-making roles, including:

- 1) Periodically review and assess the adequacy of this Charter and recommend revisions to the NYeC Board, per the process described in SOPs;
- 2) Develop and amend SOPs for the review and adjudication of data use requests which require use, disclosure, or re-disclosure of data from the SDI, including amending the list of SDI Permitted Purposes, subject to approval by the NYeC Board and NYS DOH; and
- 3) Adjudicate data use requests consistent with the SHIN-NY SOPs.

Upon formation, the SDUC will establish a workplan for delivering on items (1) and (2), which will include pathways for different types of use case requests (e.g., limited datasets, identifiable datasets, emergency use) and specify authorized requester types.

Until the Statewide Common Participation Agreement (SCPA) becomes effective, data use case requests will continue to be decided following the legacy approach used by NYeC and the Qualified Entities (QEs) pursuant to the Data Use and Contribution Agreement (DUCA). Under the DUCA framework, NYeC will consult with the SDUC regarding data use requests from designated NYS DOH staff that are submitted to the QEs for approval.

When the SCPA becomes effective, the SDUC will adjudicate data use requests as specified in the SOPs developed and approved per item (2). The SDUC may make one of three determinations with respect to a data use request: approve, revise and resubmit, or reject. Approved data use case requests will be operationalized by NYeC, with the SDUC and the SHIN-NY Policy and Technical Advisory Committees providing advice upon request.

**Committee Scope:** The scope of the SDUC includes all data use requests fulfilled by the SDI, or by QEs using centralized SHIN-NY infrastructure, with two exceptions:

- (1) Data requests that are submitted and processed pursuant to the DUCA prior to the effective date of the SCPA; and
- (2) Data requests otherwise required by NYS law or NYS DOH policy (e.g., supplying data to the HERO, supplying Health Related Social Needs (HRSN) screenings and referral data to NYS DOH for NYHER 1115 waiver support).

Oversight and Appeals: Oversight of SDUC and SDI adherence to the SOPs and SDI operationalization of approved data use cases will be provided through regular monitoring and periodic audits of approved use cases by an independent third-party auditor engaged by NYeC ("the auditor"). Determinations or reports made by the auditor will be subject to approval by the Audit & Compliance Committee of the NYeC Board. Determinations or reports made by the auditor and approved by the Audit & Compliance Committee will be binding on NYeC. The SDUC Chair, with support from NYeC staff, will be responsible for regularly briefing the Audit Committee and the NYeC Board on the SDUC's progress in developing SHIN-NY SOPs. The Chair will also brief the Audit & Compliance Committee and NYeC Board intermittently on the data use request pipeline, including average initial response and adjudication times.

SDUC approvals and denials of data use case requests are subject to a 10-business day appeals period, starting immediately upon public posting of the summary decision memo. Any SHIN-NY participant (defined as an individual or entity which participates in the SHIN-NY by contributing and/or accessing SHIN-NY data) may submit an appeal of the SDUC's use case summary memo approving or rejecting a use case. In the event of an appeal, the SDUC will refer the matter to the auditor for review.

The auditor will consider appeals of SDUC decisions to approve or reject a data use case request, pursuant to the SHIN-NY SOPs governing such decisions.

During the pendency of any appeal, NYeC may begin work to design specifications and conduct testing with regard to the use case, provided that, except in the case of a state or local public health emergency or state disaster emergency, the use case shall not be fulfilled from the SDI and no data shall be provided to the requester from the SDI unless and until such appeal is resolved and approval of the use case is affirmed.

The outcome of an appeal will be posted publicly as an addendum to the summary decision memo for the use case in question. The SDUC, with support from NYeC staff, is responsible for communicating the appeal outcome with the SHIN-NY stakeholder who submitted the appeal.

#### NEW YORK eHEALTH COLLABORATIVE, INC.

### **Charter of the SHIN-NY Technical Advisory Committee**

#### As Adopted on January 15, 2025

**Introduction:** Amendments to the SHIN-NY Regulations (10 NYCRR Part 300), effective July 10, 2024, require the establishment of "a statewide collaboration process, which may include the designation of committees representing qualified entities, SHIN-NY participants, relevant stakeholders, and healthcare consumers to make recommendations on SHIN-NY policy guidance and standards." The regulation also requires that such policy guidance and standards include technical standards for interoperability and data sharing among SHIN-NY participants, Qualified Entities (QEs), and the New York State Department of Health (NYS DOH) or its designated contractor. Such requirements and procedures will constitute new components of SHIN-NY policy guidance, which is the holistic set of policies and procedures developed through the statewide collaboration process which governs the SHIN-NY.

Consistent technical standards for interoperability and data sharing will provide benefit to QEs and SHIN-NY Participants in their use of health information exchange. Moreover, in 2024 and beyond, the SHIN-NY is continuing its ongoing transformation into a public health data utility suitable to support the "nation-leading monitoring and surveillance system to inform targeted and appropriate responses to public health crises and to drive broader health care insights" envisioned by Governor Hochul in her 2023 State of the State remarks. Consistent technical standards for the SHIN-NY are also necessary as the central functions of the SHIN-NY evolve towards public health and Medicaid.

**Purpose:** NYeC will establish a SHIN-NY Technical Advisory Committee (TAC) to provide advice and recommendations on technical standards for interoperability and data sharing within the SHIN-NY.

In providing advice and recommendations, the SHIN-NY TAC will seek to leverage national HIE standards and to harmonize with evolving federal program requirements to the extent possible, aiming to limit the burden of adoption on New York participants.

**Composition:** The SHIN-NY TAC will comprise up to 11 members, including the Chair, with HIE and health information technology (HIT) expertise who are willing and able to represent the broad and diverse interests of New York State's health care community. NYeC staff with relevant expertise will support the functions of the TAC but will not hold voting seats.

Chair: The TAC will be chaired by a NYeC Board member and selected by a vote of the NYeC Board based on the recommendation of the Board's Nominating Committee. The Chair shall serve a term(s) of three (3) years and shall participate as a voting member of the TAC. The TAC Chair has the authority to convene meetings, set agendas for meetings, and determine the Committee's information needs. The Chair will be responsible for directing regular updates to the NYeC Board and NYS DOH on TAC activities, with support from NYeC staff.

Membership: In addition to the TAC Chair, the TAC will have up to ten (10) voting members as below:

• <u>Up to four (4)</u> representatives of health care entities which are required to contribute data to the SHIN-NY, or their representative(s), which may include state hospital associations

- Up to two (2) representatives of health care entities not directly subject to SHIN-NY regulations, but which are impacted by statewide health care reforms and reliant on effective functioning of the SHIN-NY
- A minimum of two (2) representatives from the QEs with technology and interoperability experience
- A minimum of one (1) subject matter expert (state or national) who specializes in federal data collection and interoperability standards
- A minimum of one (1) subject matter expert (state or national) focused on patient privacy and access

In addition, membership will include up to <u>four</u> ex officio non-voting members representative of state and local public health and Medicaid interests, including: NYS DOH's Office of Public Health and Office of Health Insurance Programs; New York City's Department of Health and Mental Hygiene (DOHMH); and county health departments.

All TAC members are expected to disclose their conflicts of interest with relevance to TAC activities.

TAC members may be appointed to and serve on other Statewide Collaboration Process (SCP) committees simultaneously.

Member Selection and Terms: Inaugural members of the TAC will be selected through the NYeC Board's Nominating Committee process. A call for inaugural member nominations will be broadly distributed to SHIN-NY participants and stakeholders which will be considered by the NYeC Nominating Committee when presenting a slate of candidates to the NYeC Board. In the future, a similar public call for committee member nominations will be issued by NYeC staff; wherever practicable, a call will remain open for 30 days. Nominations received through this call will be forwarded to the Nominating Committee for consideration. TAC members may also be recommended to the Nominating Committee by the TAC Chair in consultation with incumbent TAC members and NYeC. Members will serve terms of three years each and may serve up to two successive terms with potential nomination for a third term if circumstances merit reappointment, at the discretion of the TAC Chair.

**Meeting Cadence and Procedure:** The TAC will meet at a frequency determined by the Chair, but no less than quarterly. TAC members will participate in meeting pre-work and offline review of materials between scheduled meetings as needed. The Chair shall be responsible for convening and facilitating TAC meetings with support from NYeC staff.

Meetings of the TAC will be hosted on a virtual conferencing platform, or hybrid in-person and virtually, and will generally allow public participation, at the discretion of the Chair. Meeting details will be announced on the NYeC website at least five (5) business days prior to the meeting, or as soon as practicable for meetings scheduled with less advance notice. The TAC will keep meeting minutes which will be made available to the public via the NYeC website following each meeting.

A majority of the members of the TAC shall constitute a quorum for a meeting, and the affirmative vote of a majority of members present at a meeting at which a quorum is present shall constitute the action of the Committee. The Committee may also act by unanimous written consent of its members (including by e-mail), or in such other manner as may be prescribed in the applicable SHIN-NY SOPs.

**Committee Functions:** The TAC will provide advice and recommendations on technical standards for interoperability and data sharing within the SHIN-NY. The Committee will provide input and recommendations on topics including, but not limited to:

- Potential SHIN-NY data collection and transmission standards to promote standardization, quality, interoperability, and use;
- Technical requirements to fulfill statewide use cases or as required to support New York State public health activities and population health objectives (e.g., Medicaid 1115 Waiver);
- New federal or state legal requirements and their implications for the SHIN-NY; and
- Direct data contribution standards to the statewide data infrastructure (SDI).

SOP Template
Insert SOP Title Here

## Introduction

Provides background context on origin of SOP.

## SOP Purpose, Scope, Limitations, and Intended Audience

Describes what the SOP includes and its intended audience, as well as any limitations to its authority (e.g., deference to another SOP on a specific issue); references applicable section(s) of the Statewide Common Participation Agreement.

### **Definitions**

Includes definitions of key terms used in this SOP.

## **Roles and Responsibilities**

Includes relevant organization types/individuals (i.e., QEs, SHIN-NY Participants, NYeC, NYS DOH, patients).

## **Description of Standard Operating Procedures**

Includes substance of the SOP.

### **Amendment Procedures**

Includes procedure for amendments to this SOP.

## **Documentation Requirements**

Includes approach to producing public-facing documentation or updates related to the SOP.

### **Attachments**

• List of attachments to this SOP.

## **Version History**

Version Number	Date Adopted	Summary of Changes



### SHIN-NY PARTICIPANT ELECTION SCHEDULE SOP

### Introduction

Pursuant to the <u>Statewide Common Participation Agreement (SCPA)</u>, each <u>SHIN-NY Participant</u> must select a <u>Designated HIN</u> and may also select one or more <u>Additional HIN(s)</u> or <u>Value-Added Services HIN(s)</u> (or <u>VAS HIN)</u> on the <u>Election Schedule</u> in accordance with this Standard Operating Procedure.

## Purpose, Scope and Intended Audience

This SHIN-NY SOP identifies the process and timeframe by which SHIN-NY Participants will make HIN selections, or changes to such selections, on the Election Schedule.

## **Definitions**

All <u>underlined</u> terms in this SHIN-NY SOP are defined in the SCPA and SHIN-NY SOPs Glossary, which is available here: <u>SCPA and SHIN-NY SOPs Glossary</u>.

### **Procedures**

Each SHIN-NY Participant must select one Designated HIN. The Designated HIN is the HIN to which Participant will <u>Contribute Core SHIN-NY Data</u> and the HIN that is required to provide or arrange for the provision of <u>Required Participant Services</u> to Participant free of charge. Participant may change its Designated HIN in accordance with this SOP.

Each SHIN-NY Participant may also select one or more Additional HIN(s). An Additional HIN could be selected if the Participant would like to receive Required Participant Services from any HIN other than the Designated HIN. Any selected Additional HINs are not required to provide services to a Participant unless the Participant separately reaches agreement on any fees that may be required for such services.<sup>1</sup> Participant may change its Additional HIN(s) in accordance with this SOP.

Each SHIN-NY Participant may also select one or more VAS HIN(s). A VAS HIN could be selected if the Participant would like to receive Value-Added Services from that HIN. Any selected VAS HINs are not required to provide Value-Added Services to Participant unless the Participant separately reaches agreement on any fees that may be required for such services and agrees on the scope of such services.<sup>2</sup> NYeC may be selected as a VAS HIN only by Eligible NYeC Participants. Participant may change its VAS HIN(s) in accordance with this SOP.

The process for making initial selections and subsequent changes to such elections on the Election Schedule will include the following:

<sup>&</sup>lt;sup>1</sup> Additional HINs may, but are not required to, charge for services provided to SHIN-NY Participants.

<sup>&</sup>lt;sup>2</sup> Value-Added Services HINs may, but are not required to, charge for Value-Added Services provided to SHIN-NY Participants



### SHIN-NY PARTICIPANT ELECTION SCHEDULE SOP

- 1. **Election Schedule Distribution & Access:** Beginning in April 2025, NYeC will distribute the SCPA (including the Election Schedule to all SHIN-NY Participants via DocuSign<sup>3</sup> for their review, execution, and initial HIN election ("Initial Election"). During its Initial Election, a SHIN-NY Participant is required to select its Designated HIN. Selection of Additional HIN(s) and VAS HIN(s) during the Initial Election process is optional. After its Initial Election, a SHIN-NY Participant can add an Additional HIN(s) or a VAS HIN(s) or change its prior selection of its Designated HIN, Additional HIN(s) or VAS HIN(s) in accordance with Section 5 of this SOP.
- 2. **Election Schedule:** The Election Schedule will collect the following information:
  - a. Required: Indicate Participant type and category (Regulated Participant (e.g., Article 28 Hospital) or Voluntary Participant (e.g., physician practice, IPA))
  - b. Required: Identify any other individuals or entities to be included as a SHIN-NY Participant with signing Participant (e.g., affiliated entities, subsidiaries, "child entities" within a health system)
  - c. Required: Select Designated HIN
  - d. Optional: Select Additional HIN(s)
  - e. Optional: Select Value-Added Services HIN(s)

### 3. Initial Election Process:

- A. When a SHIN-NY Participant makes its Initial Election, a notice of such election ("Initial Election Request") will be sent to the prospective HIN(s) and to NYeC. If Participant does not select its current HIN as its Designated HIN, the Initial Election Request will also be sent to Participant's current HIN.
- B. To the extent necessary to Contribute data to or to access or use the prospective HIN's SHIN-NY Platform or to receive Required Participant Services (or Value-Added Services, if applicable), and to the extent requested by a prospective HIN, Participant shall register with the prospective HIN in accordance with the following:
  - i. Participant will provide the prospective HIN with any documents and information requested by the prospective HIN (provided that such request cannot conflict with the SHIN-NY SOPs or the SCPA).
  - ii. Participant will register as either a <u>Data Provider</u> or a <u>Data Recipient</u>, or as both, and may only participate in the SHIN-NY in accordance with such registration.

<sup>3</sup> This SOP describes the initial distribution, execution and HIN selection process for the SCPA. This process may be replaced, and this SOP may be amended, later in 2025 to include a portal-like functionality that SHIN-NY Participants will be able to access to execute the SCPA and make or change their HIN selection(s).



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- iii. The prospective HIN may decline to accept Participant's selection for cause, including for following reasons:
  - 1. Participant's failure to provide adequate documentation and information as requested by prospective HIN
  - 2. Participant does not meet particular conditions that are needed to connect to prospective HIN, but are not required by the SCPA or the SHIN-NY SOPs (e.g., security requirements)
- iv. The prospective HIN shall reject Participant's selection if:
  - Participant fails to meet standards applicable to SHIN-NY Participants as set forth in the SHIN-NY SOPs
  - 2. Participant has been excluded from participation in federally funded health care programs such as Medicare or Medicaid (HHS OIG Exclusion List)
- v. If applicable, during the prospective HIN's registration process, Participant will continue to contribute Core SHIN-NY Data to and/or receive Required Participant Services (or Value-Added Services, if applicable) from the current HIN.
- C. At the conclusion of a prospective HIN's registration process:
  - i. If the prospective HIN declines to register Participant, (i) the prospective HIN shall notify Participant and all HINs (including NYeC) within 5 business days of such determination and such notice shall include the rationale for such determination; (ii) Participant's Initial Election of such prospective HIN shall be null and void; (iii) Participant may select another prospective HIN in accordance with this SOP; and (iv) if applicable, Participant will continue to contribute Core SHIN-NY Data to and/or receive Required Participant Services (or Value-Added Services, if applicable) from the current HIN until another prospective HIN has accepted Participant's registration.
  - ii. If the prospective HIN accepts Participant's registration, the prospective HIN shall notify Participant, the current HIN (if applicable) and NYeC within 5 business days of such determination that it has accepted the Initial Election and the effective date thereof.
- D. Participant and the prospective HIN(s), and the current HIN (if applicable), shall cooperate to effectuate Participant's Initial Election in accordance with this SOP.
- E. Promptly upon the effective date of the Initial Election of a Designated HIN, Participant who is a Data Provider will Contribute SHIN-NY Data to the new Designated HIN in accordance with the SCPA. The history of prior Contributed data may remain with the former HIN and requested via Other Approved



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<u>Network</u> query (if applicable), or transferred to the newly-Designated HIN through an approach acceptable to both HINs.

#### 4. Initial Election Deadlines:

- A. Regulated Participants may execute the SCPA and select a Designated HIN on the Election Schedule at any time after the Election Schedule is provided to them (beginning on or about April 1, 2025), but all Regulated Participants must do so on or before **September 30, 2025**.
- B. Voluntary Participants may execute the SCPA and select a Designated HIN (and Additional HIN(s) and Value-Added Services HIN(s)) on the Election Schedule at any time after the Election Schedule is provided to them (beginning in April 2025). There will be a longer period of time for Voluntary Participants to transition to the SCPA and the Election Schedule. This SOP will be updated to provide additional information on this transition process and timeline during 2025.

## 5. Changes to the Election Schedule:

- A. Participants may, but are not required to, change their HIN selections or make new or additional HIN selections on the Election Schedule in accordance with the following:
  - i. A Participant that wishes to change its selection of a Designated HIN on the Election Schedule may do so at any time after January 1, 2026. A Participant that wishes to change its selection of an Additional HIN(s) or a VAS HIN(s) or make a new selection of an Additional HIN(s) or a VAS HIN(s) may do so at any time.
  - ii. A notice of the request to change selection(s) ("Change Request") will be sent to the current and prospective HINs and to NYeC.
  - iii. To the extent necessary to Contribute data to or to access or use the prospective HIN's SHIN-NY Platform or to receive Required Participant Services (or Value-Added Services, if applicable), and to the extent requested by a prospective HIN, Participant shall register with the prospective HIN in accordance with the following:
    - Participant will provide the prospective HIN with any documents and information requested by the prospective HIN (provided that such request cannot conflict with the SHIN-NY SOPs or the SCPA).
    - 2. Participant will register as either a <u>Data Provider</u> or a <u>Data Recipient</u>, or as both, and may only participate in the SHIN-NY in accordance with such registration.



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- 3. The prospective HIN may decline to accept Participant's selection for cause, including the for following reasons:
  - a. Participant's failure to provide adequate documentation and information as requested by prospective HIN
  - Participant does not meet particular conditions that are needed to connect to prospective HIN, but are not required by the SCPA or the SHIN-NY SOPs (e.g., security requirements)
- The prospective HIN shall decline to accept Participant's selection if:
  - a. Participant fails to meet standards applicable to SHIN-NY Participants as set forth in the SHIN-NY SOPs
  - b. Participant has been excluded from participation in federally funded health care programs such as Medicare or Medicaid (HHS OIG Exclusion List)
- 5. During the prospective HIN's registration process, Participant will continue to contribute Core SHIN-NY Data to and/or receive Required Participant Services (or Value-Added Services, if applicable) from the current HIN.
- iv. At the conclusion of a prospective HIN's registration process:
  - 1. If the prospective HIN declines to register Participant, (i) the prospective HIN shall notify Participant and all HINs (including NYeC) within 5 business days of such determination and such notice shall include the rationale for such rejection; (ii) Participant's selection shall be null and void; (iii) Participant may select another prospective HIN in accordance with this SOP; and (iv) Participant will continue to contribute Core SHIN-NY Data to and/or receive Required Participant Services (or Value-Added Services, if applicable) from the current HIN until another prospective HIN has accepted Participant's registration.
  - 2. If the prospective HIN accepts Participant's registration, (i) the prospective HIN shall notify Participant, the current HIN and NYeC within 5 business days of such determination that it has accepted the selection and the effective date thereof.
- v. Both the current and prospective HINs and Participant shall cooperate to effectuate Participant's change of HIN in accordance with this SOP.
- vi. Promptly upon the effective date of the selection change of a Designated HIN, Participant who is a Data Provider will Contribute SHIN-NY Data to the new Designated HIN in accordance with the SCPA. The



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history of prior Contributed data may remain with the former selected HIN and requested via <u>Other Approved Network</u> query (if applicable), or transferred to the newly-Designated HIN through an approach acceptable to both HINs.

### **Amendment Procedures**

This SOP shall be reviewed and evaluated by NYeC staff and the SHIN-NY Policy Committee at least once annually beginning with the date on which this SOP was initially approved, to ensure its terms remain consistent with applicable New York State laws and regulations, and appropriate for the needs of the SHIN-NY. SHIN-NY stakeholders may submit proposals to amend this SOP addressed to NYeC staff for consideration. Proposals to amend this SOP shall be considered by SHIN-NY Policy Committee for recommendation to the NYeC Board and NYS DOH. All amendments to this SOP shall be documented in the *Version History* section. NYeC will post or otherwise make the amended SOP available to the public.

## **Version History**

Version Number	Date Adopted	Summary of Action/Changes
1.0	3/24/25	Approved by Policy Committee
	4/01/25	Approved by NYeC Board
	4/02/25	Approved by NYS Department of Health



REQUIRED CORE SHIN-NY DATA CONTRIBUTIONS FOR DATA PROVIDERS

#### Introduction

In accordance with the <u>Statewide Common Participation Agreement (SCPA)</u>, each <u>SHIN-NY Participant</u> that is a <u>Data Provider</u> must <u>Contribute Core SHIN-NY Data</u> to its <u>Designated Health Information Network's (HIN's) SHIN-NY Platform</u> in accordance with this Standard Operating Procedure. "Data Provider" means a SHIN-NY Participant only if such Participant Contributes data to a SHIN NY Platform. All <u>Regulated Participants</u>, including <u>SDI Waiver Participants</u>, shall be Data Providers, and <u>Voluntary Participants</u> may also be required to be Data Providers under the SHIN-NY SOPs. A SHIN-NY Participant can be both a Data Provider and a Data Recipient.

## Purpose, Scope and Intended Audience

This SHIN-NY SOP identifies the Core SHIN-NY Data that Data Providers must Contribute to the SHIN-NY, as well as requirements by which such data must be contributed. Core SHIN-NY Data means <u>Core QE Data</u> and/or <u>Core Statewide Data Infrastructure (SDI) Data</u>.

This SOP sets forth the minimum required data that Data Providers must Contribute. Data Providers may Contribute other types of data to HINs (e.g., <u>Additional Data</u>), and HINs may receive such other types of data, in accordance with the terms of the SCPA.

### **Definitions**

All <u>underlined</u> terms in this SHIN-NY SOP are defined in the SCPA and SHIN-NY SOPs Glossary, which is available here: <u>SCPA and SHIN-NY SOPs Glossary</u>.

## **Procedures**

Each Data Provider must Contribute Core SHIN-NY Data to its Designated HIN's SHIN-NY Platform for all of its patients, members, enrollees or clients, as applicable. A Data Provider shall not withhold or otherwise prevent Contribution of any Core SHIN-NY Data unless the Data Provider has obtained a waiver under Section 4.2(a) of the SCPA, an individual objects in writing to the Contribution of their data, or the SHIN-NY SOPs or applicable law exempt such Core SHIN-NY Data from the requirement to Contribute.

To the extent applicable, and as specified in the SHIN-NY SOPs, Data Providers shall, working as necessary with Designated HIN and/or <u>Additional HIN</u>, if applicable, appropriately and adequately identify, label, or tag any of its SHIN-NY Data that is (i) subject to <u>Part 2</u>; (ii) subject



REQUIRED CORE SHIN-NY DATA CONTRIBUTIONS FOR DATA PROVIDERS

to New York Mental Hygiene Law § 33.13; or (iii) is otherwise defined in the SHIN-NY SOPs as <u>Sensitive Data</u> that requires such identification, labeling, or tagging where technically feasible or required by applicable law. To the extent permitted by applicable law and the SHIN-NY SOPs, Data Providers may provide such identification one time, rather than on a continuous basis, provided that in all cases such identification is made prior to, or simultaneously with, Contribution of the applicable data.

Such Contributions shall be made in accordance with the following:

- **1. Core QE Data.** If a Data Provider chooses a QE as its Designated HIN on the <u>Election Schedule</u>, the Data Provider must Contribute the following data to the <u>QE Platform</u>:
  - a. USCDI Data Elements. Data Providers must, and Voluntary Participants are encouraged to, Contribute United States Core Data for Interoperability (USCDI) v1 (or later versions) data elements as published by the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator (ONC). See <a href="https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi">https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi</a>
  - b. **Encounter/Event Notification Data.** Encounter/Event Notification Data is both Core QE Data and Core SDI Data (see section 2[b]). Data Providers that are Regulated Participants shall Contribute near real-time Admission, Discharge, Transfer (ADT) data for all clinical encounters in support of the Statewide Encounter Gateway, and in alignment with the ADT data specification defined in the SHIN-NY ADT Data Contribution Specification in Appendix A. Voluntary Participants are encouraged to submit data representing an encounter/event for clinical encounters regardless of standard used to communicate the encounter (e.g. ADT, CCD).
- **2. Core SDI Data.** The following data must be Contributed to the <u>Statewide Data Infrastructure (SDI)</u>, either directly by SDI Waiver Participants<sup>1</sup> or by QEs that receive such data from their Data Providers:
  - a. **Patient Identity Data.** For QEs in which multiple sources are contributing data such that a Master Patient Index (MPI) is required to manage identities, the full MPI must be

<sup>&</sup>lt;sup>1</sup> The process for approval of SDI Waiver Participants is currently under development and is not expected to be available until later in 2025, at the earliest. Updates to the SHIN-NY SOPs and/or additional SHIN-NY SOPs will be released to address SDI Waiver Participation prior to that time.



REQUIRED CORE SHIN-NY DATA CONTRIBUTIONS FOR DATA PROVIDERS

Contributed to the SDI. At minimum, a full extract must be submitted daily, however, other methods for the SDI to access the data (e.g., via API) may be supported.

- b. **Encounter/Event Notification Data.** Encounter/Event Notification Data is both Core QE Data and Core SDI Data (see section 1[b]). SDI Waiver Participants and QEs shall Contribute data representing an encounter/event from all clinical encounters regardless of standard used to communicate the encounter (e.g. ADT, CCD). QEs shall Contribute near real-time ADT data for all clinical encounters in support of the Statewide Encounter Gateway, and in alignment with the ADT data specification defined in the SHIN-NY ADT Data Contribution Specification in Appendix A.
- c. **Patient Clinical Observations and Vitals Data.** SDI Waiver Participants and QEs shall Contribute clinical observations, including laboratory tests and results, and vital sign data to the SDI. The required data elements and details for converting the data from their native format to the required standards for the SDI are outlined in the SHIN-NY Clinical FHIR Implementation Guide (https://shinny.org/).
- d. **1115 Waiver Data.** QEs shall Contribute <u>1115 Waiver</u> Data to the SDI as it is received by QEs. 1115 Waiver Data includes <u>Screenings</u>, <u>Eligibility Assessments</u>, and closed loop <u>Referrals</u>. 1115 Waiver Data must comply with and be validated against the 1115 Waiver FHIR Implementation Guide upon submission to the SDI (<a href="https://shinny.org/us/ny/hrsn/index.html#health-related-social-needs-hrsn">https://shinny.org/us/ny/hrsn/index.html#health-related-social-needs-hrsn</a>).
- 3. Change of Designated HIN. If a Data Provider changes its Designated HIN through an update to its Election Schedule (in accordance with the SHIN-NY Participant Election Schedule SOP), the Data Provider will Contribute its Core SHIN-NY Data to the newly-Designated HIN upon the effective date of such change. The history of prior Contributed data may remain with the former Designated HIN and requested via Other Network query (if applicable), or transferred to the newly-Designated HIN through an approach that is acceptable to both HINs.

## **Amendment Procedures**

As technology standards and data needs evolve, the SHIN-NY Technical Advisory Committee will identify needs for updates and modifications to requirements for Core SHIN-NY Data Contributions. Any revisions to this SOP will be made in accordance with the Statewide Collaboration Process SOP.



# REQUIRED CORE SHIN-NY DATA CONTRIBUTIONS FOR DATA PROVIDERS

## **Version History**

Version Number	Date Adopted	Summary of Changes
1.0	3/28/25	Approved by Technical Advisory Committee
	4/01/25	Approved by NYeC Board
	4/02/25	Approved by NYS Department of Health

Appendix A

[See Attached]



SHIN-NY TECHNICAL STANDARDS FOR INTEROPERABILITY & DATA SHARING

#### Introduction

In accordance with the <u>Statewide Common Participation Agreement (SCPA)</u>, each <u>SHIN-NY Participant</u> that is a <u>Data Provider</u> must <u>Contribute Core SHIN-NY Data</u> to its <u>Designated Health Information Network's (HIN's) SHIN-NY Platform</u> in accordance with the Required Core SHIN-NY Data Contributions for Data Providers SOP. This SHIN-NY Technical Standards for Interoperability and Data Sharing SOP defines the means and methods by which Data Providers and QEs are to securely transmit Core SHIN-NY Data to the applicable SHIN-NY Platforms.

## Purpose, Scope, and Intended Audience

This SOP sets forth a minimum set of interoperability and data sharing guidelines to govern how Data Providers and QEs Contribute Core SHIN-NY Data to the applicable SHIN-NY Platform (QE Platform and/or Statewide Data Infrastructure (SDI)).

Nothing in this SOP alters or limits the obligations of a SHIN-NY Participant regarding public health reporting, technical standards for public health reporting, or other requirements for public health reporting as specified by Applicable Law.

### **Definitions**

All <u>underlined</u> terms in this SHIN-NY SOP are defined in the *SCPA and SHIN-NY SOPs Glossary*, which is available here: <u>SCPA and SHIN-NY SOPs Glossary</u>.

#### **Procedures**

Each Data Provider and QE must Contribute Core SHIN-NY Data, as defined in the Required Core SHIN-NY Data Contributions for Data Providers SOP, to the applicable SHIN-NY Platform via the methods described below:

- 1. **Core QE Data.** Data Providers must Contribute Core QE Data to their Designated HIN's QE Platform using the means and methods described below:
  - a. Data Providers are to Contribute United States Core Data for Interoperability (USCDI) v1 (or later versions) data elements as published by the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator (ONC). Although a specific data transport mechanism is not defined, Data Providers must Contribute Core QE Data using methods that are compliant with the SHIN-NY Privacy and Security SOPs and supported by the Designated HIN's QE Platform.



#### SHIN-NY TECHNICAL STANDARDS FOR INTEROPERABILITY & DATA SHARING

- b. Data Providers are required to Contribute Admit, Discharge & Transfer (ADT) data to QE Platforms in near real-time via HL7 v2 (or later versions).
- c. SHIN-NY Participants that make requests for Encounter Alerts from their Designated HIN based on ADT events must securely submit a patient roster to their Designated HIN identifying the individuals for whom Encounter Alerts of ADT events are requested. Participants must submit the patient rosters using any open technical standard that is compliant with the SHIN-NY Privacy and Security SOPs and supported by both the Participant and Designated HIN.
- d. Data Providers are encouraged to support delivery using HL7 Fast Healthcare Interoperability Resources (FHIR) Release 4 conforming to the US Core Implementation Guide for Information Delivery if possible. Note that this delivery standard may be required in future revisions of this SOP. See <a href="https://hl7.org/fhir/R4/">https://hl7.org/fhir/R4/</a>
- e. Data Providers using interfaces for Core QE Data Contribution are encouraged to use HL7 v2 (or later versions), but may use any open technical standard that is compliant with the SHIN-NY Privacy and Security SOPs and supported by both the Participant and HIN. For example, formats including HL7 v2 (or later versions) and Secure File Transport Protocol (SFTP) are permissible. See <a href="https://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=185">https://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=185</a>
- f. A SHIN-NY Participant may use Direct Secure Messaging for Core QE Data Contribution if supported by the HIN. See <a href="https://www.healthit.gov/sites/default/files/page/2020-07/0720\_Direct%20Secure%20Messaging%20Basics.pdf">https://www.healthit.gov/sites/default/files/page/2020-07/0720\_Direct%20Secure%20Messaging%20Basics.pdf</a>
- 2. **Core SDI Data.** QEs and SDI Waiver Participants must contribute Core SDI Data, as defined in the Required Core SHIN-NY Data Contributions for Data Providers SOP, to the SDI using the means and methods described below:
  - a. With exception of Patient Identity Data, QEs and SDI Waiver Participants are required to support delivery of Core SDI Data using HL7 Fast Healthcare Interoperability Resources (FHIR) Release 4 conforming to the US Core Implementation Guide for Information Delivery if possible. Note that this delivery standard may be required in future revisions of this SOP. See <a href="https://hl7.org/fhir/R4/">https://hl7.org/fhir/R4/</a>



#### SHIN-NY TECHNICAL STANDARDS FOR INTEROPERABILITY & DATA SHARING

- b. Patient Identity Data must be Contributed to the SDI. Acceptable methods for submission may be using SFTP, HL7 v2 (or later versions), API, or other direct connections (e.g. database-to-database), pending approval by NYeC.
- c. QEs are to Contribute Admit, Discharge & Transfer (ADT) data to the SDI Encounter Hub in near real-time via HL7 v2 (or later versions)).
- 3. **Data Contribution via an Intermediary.** A Data Provider that uses an <u>Intermediary</u> to Contribute Core SHIN-NY Data may use any open technical standard compliant with the SHIN-NY Privacy and Security SOPs and supported by both the Data Provider and the Intermediary.

## **Amendment Procedures**

As technology standards and data needs evolve, the SHIN-NY Technical Advisory Committee will identify needs for updates and modifications to requirements technical standards for interoperability and data sharing in the SHIN-NY. Any revisions to this SOP will be made in accordance with the Statewide Collaboration Process SOP.

## **Version History**

Version Number	Date Adopted	Summary of Action/Changes
1.0	3/28/25	Approved by Technical Advisory Committee
	4/01/25	Approved by NYeC Board
	4/02/25	Approved by NYS Department of Health



Statewide Data Infrastructure (SDI) Data Use Approval Process

### Introduction

Effective as of July 10, 2024, New York State has promulgated regulations (the SHIN-NY Regulations) requiring that the New York State Department of Health (the Department) "provide, either directly or through contract, [the Statewide Data Infrastructure (the SDI)] and any other SHIN-NY services that the [the Department] deems necessary to effectuate the purposes of [the SHIN-NY Regulations]." The SDI, which includes a secure statewide data repository as well as centralized systems operated or directed by New York eHealth Collaborative (NYeC), will support increased interoperability, provide flexibility for the SHIN-NY to adapt in a constantly evolving technological environment, and facilitate the exchange of data among SHIN-NY participants, including the Department.

SHIN-NY participants that have received a waiver from the Department under 10 N.Y.C.R.R. § 300.6(b)(4) will connect to the SDI, cause patient data to be contributed to the SDI and authorize the use of patient data for statewide reporting and analytics for public health surveillance and Medicaid purposes, in accordance with the SHIN-NY SOPs.

NYeC, as the State Designated Entity (SDE) for the SHIN-NY, will maintain the technical and administrative resources which comprise the SDI. The Statewide Data Use Committee (SDUC), a standing committee of the SHIN-NY statewide collaboration process (SCP), will provide stakeholder engagement and governance support for the SDI. In these roles, NYeC and the SDUC will administer requests for use of SDI Data (as defined below), manage the provision of SDI Data to requesters, and uphold a transparent and open governance model for data use, in each case in accordance with and pursuant to this SOP.

## SOP Purpose, Scope, Limitations, and Audience

### **Purpose**

Scope

The purpose of this SOP is to set forth requirements and procedures for the use, disclosure, and re-disclosure of SDI Data, including disclosure to the Department and the use and re-disclosure of SDI Data to support statewide reporting and analytics for public health activities and Medicaid purposes. This SOP sets forth procedures to ensure that SDI Data is used, disclosed and re-disclosed only for the SDI Permitted Purposes (as defined below).

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<sup>1</sup> 10 N.Y.C	.R.R. § 3	00.2(c).	



Statewide Data Infrastructure (SDI) Data Use Approval Process

This SOP details the requirements and procedures for the use, disclosure, and re-disclosure of SDI Data for the Public Health Permitted Purposes, Medicaid Permitted Purposes (each, as defined below), and, subject to the limitations set forth below, such other SDI Permitted Purposes as may be identified from time to time as described under "Additional SDI Permitted Purposes" below.

All actions of the SDUC described here (including without limitation any approval or denial of any Data Use Request) shall be exercised in accordance with the SDUC Charter.

### Limitations

This SOP does not apply to, and no additional approval is required for use, disclosure or redisclosure of SDI Data for any SDI Permitted Purposes which are required to meet the maintenance and operational needs of the SHIN-NY, specifically:

- Maintaining and operating the Statewide Master Patient Index (sMPI) and the Statewide Patient Record Lookup (sPRL);
- Facilitating the exchange of data by and among the SHIN-NY Qualified Entities (QEs);
- Facilitating the exchange of data by and among the SHIN-NY Qualified Entities (QEs);
- Facilitating the tracking and monitoring and exchange of data related to patient consents, including without limitation maintaining and operating a statewide consent management system; and
- Operating the SDI, including but not limited to (A) collecting, aggregating, and
  performing quality assurance on data contributed to or held or maintained in or
  transmitted through the SDI; (B) conducting inquiries and performing discovery with
  respect to Core SDI Data (as defined in the SCPA) to assess the scope of Core SDI Data
  and/or whether it is feasible to fulfill a potential data use request; and (C) analyzing
  Core SDI Data to assess the feasibility of developing new Required Participant Services
  (as defined in the SCPA) or other types of services to be provided through the SHIN-NY.
- This SOP does not apply to use, disclosure or re-disclosure of data from QE Platforms. However, additional SOP(s) may be developed in accordance with the Statewide Collaboration Process to address the use, disclosure and re-disclosure of data in QE Platforms for the QE Permitted Purposes (as such term is defined in the SCPA). Further, this SOP applies to data originally maintained in QE Platforms but later contributed, shared, disclosed, transferred or otherwise made available to the SDI, including as further described in the definition of SDI Data.

#### Audience

The audience for this SOP includes QEs, required and voluntary SHIN-NY participants, New York state and local public health authorities, health care consumers, and all other stakeholders with an interest in the SHIN-NY and the SDI.



Statewide Data Infrastructure (SDI) Data Use Approval Process

### **Definitions**

**Authorized Requester** means designated staff of QEs, NYeC, or the Department and designated staff of such other entities as may be approved by the SDUC.

**Data Lake** means a secure data repository that is part of the SDI.

**Data Use and Contribution Agreement (DUCA)** means the agreement between a QE and NYeC regarding such QE's contribution of data to the Data Lake and QE's and NYeC's use and disclosure of such data.

Data Use Requests means requests for use, disclosure and re-disclosure of Core SDI Data for Public Health Permitted Purposes, Medicaid Permitted Purposes, as well as any future SDI Permitted Purposes that the SDUC may review and approve. Each Data Use Request shall include a detailed explanation of the intended use, disclosure or re-disclosure of Core SDI Data, and the basis on which the intended use, disclosure or re-disclosure is for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations). All Data Use Requests shall be produced in a standard format using the form included as <a href="Attachment A">Attachment A</a> to this SOP, as such form may be amended, modified or replaced from time to time by the SDUC.

**De-identified Data** has the meaning set forth in the Privacy and Security SHIN-NY SOPs. As of the date hereof, De-identified Data is defined in the Privacy and Security SHIN-NY SOPs to mean data that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Data may be considered de-identified only if it satisfies the requirements of 45 C.F.R. § 164.514(b).

**Limited Data Set** has the meaning set forth in the Privacy and Security SHIN-NY SOPs. As of the date hereof, Limited Data Set is defined in the Privacy and Security SHIN-NY SOPs to mean Protected Health Information (as defined therein) that excludes the 16 direct identifiers set forth at 45 C.F.R. § 164.514(e)(2) of an individual and the relatives, employers or household members of such individual.

Narrow Data Use Request means a Data Use Request for data consisting solely of a Limited Data Set, De-Identified Data, and/or aggregate data (*i.e.*, non-individual level statistics). For example, a Data Use Request for a de-identified flat file containing all calendar year 2023 patient encounters in New York State with CPT code 33418, for patients who live in New York State, including patient's county of residence only, is a Narrow Data Use Request. The SDUC may establish additional criteria that must be satisfied in order to constitute a Narrow Data Use Request.



Statewide Data Infrastructure (SDI) Data Use Approval Process

**Medicaid Permitted Purposes** means "purposes related to the administration of the Medicaid program, including but not limited to reporting to support any Social Security Act section 1115 waiver approved by the Centers for Medicare and Medicaid Services."<sup>2</sup>

**Public Health Permitted Purposes** means "purposes for which a SHIN-NY participant is permitted to disclose protected health information to a public health authority without an authorization or opportunity to agree or object under federal standards for uses and disclosures for public health activities," which purposes are further defined in the Privacy and Security SHIN-NY SOPs.

**QE Platform** means the platform by which a QE maintains data contributed, shared, disclosed transferred or otherwise made available by SHIN-NY participants in accordance with the SCPA.

**Qualified Entity Participation Agreement (QEPA)** means the agreement or set of agreements between NYeC and each QE pursuant to which such QE participates in the SHIN-NY, as such agreements may be amended, modified or replaced from time to time.

**SDI Data** means all data maintained in the SDI, including but not limited to Core SDI Data (as defined in the SCPA). SDI Data includes data contributed, shared, disclosed, transferred or otherwise made available to NYeC by SHIN-NY participants or the Department pursuant to and in accordance with the SCPA, by QEs pursuant to the QEPA, or by the Department pursuant to DUA. SDI Data shall include data contributed, shared, disclosed, transferred or otherwise made available to NYeC by QE or SHIN-NY participants, where applicable, specifically in fulfillment of a Data Use Request approved pursuant to this SHIN-NY SOP, whether contributed, shared, disclosed, transferred or otherwise made available to NYeC before or after such approval. For example, upon approval of a Data Use Request and in order to operationalize such approved Data Use Request, NYeC may request from QEs certain data maintained in the QE Platforms. QE shall provide such data to NYeC pursuant to and in accordance with the QEPA, at which point such data shall become SDI Data and may be shared subject to and in accordance with such approved Data Use Request.

**SDI Permitted Purposes** means the purposes for which SDI Data may be used or disclosed. The SDI Permitted Purposes shall include, at a minimum:

- i. Public Health Permitted Purposes;
- ii. Medicaid Permitted Purposes;
- iii. Maintaining and operating the "Statewide Master Patient Index" and the "Statewide Patient Record Lookup" each as defined by or described in the SHIN-NY SOPs;

<sup>&</sup>lt;sup>2</sup> 10 N.Y.C.R.R. § 300.1(p).

<sup>&</sup>lt;sup>3</sup> 10 N.Y.C.R.R. § 300.1(o).



Statewide Data Infrastructure (SDI) Data Use Approval Process

- Facilitating the tracking, monitoring, and exchange of data related to patient consents, including without limitation maintaining and operating a statewide consent management system;
- v. Fulfilling NYeC's obligations related to the SHIN-NY and the SCPA, including but not limited to facilitating the exchange of data by and among the QEs; and
- vi. Operating the SDI, including but not limited to (A) collecting, aggregating, and performing quality assurance on data contributed to or held or maintained in or transmitted through the SDI; (B) conducting inquiries and performing discovery with respect to Core SDI Data to assess the scope of Core SDI Data and/or whether it is feasible to fulfill a potential data use request; and (C) analyzing Core SDI Data to assess the feasibility of developing new State-Funded Participant Services or other types of services to be provided through the SHIN-NY.

Other permitted purposes may be added to or removed from this list pursuant to the Statewide Collaboration Process.

Statewide Common Participation Agreement (SCPA) means "...a common agreement, developed using a statewide collaboration process, consistent with any minimum standards set forth in the SHIN-NY policy guidance and approved by the New York State Department of Health, that is used statewide by each qualified entity or by SHIN-NY participants, allowing them to connect to the SHINY-NY statewide data infrastructure either directly or through a contractor, and pursuant to which SHIN-NY participants agree to participate in the SHIN-NY and adhere to SHIN-NY policy guidance, including but not limited to causing patient data to be contributed to the statewide data infrastructure and authorizing the use of patient data for statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law."<sup>4</sup>

**Statewide Data Infrastructure (SDI)** means "...the information technology infrastructure provided by the New York State Department of Health, either directly or through contract, to support the aggregation of data provided by qualified entities and SHIN-NY participants, statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law." The SDI includes centralized SHIN-NY systems operated or directed by NYeC which serve to aggregate, store, and distribute or otherwise grant access to authorized users of SHIN-NY data.

**Statewide Data Use Committee (SDUC)** is defined as a committee of the Statewide Collaboration Process designated by the Department with responsibility for the development and amendment of SHIN-NY SOPs (or sections of SOPs) concerning disclosures and uses of data

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<sup>&</sup>lt;sup>4</sup> 10 N.Y.C.R.R. § 300.1(m).

<sup>&</sup>lt;sup>5</sup> 10 N.Y.C.R.R. § 300.1(n).



Statewide Data Infrastructure (SDI) Data Use Approval Process

contained in the SDI. The SDUC is additionally responsible for adjudication of SHIN-NY Data Use Requests in accordance with this SOP.

**Summary Decision Memo** is defined as a memo provided by NYeC to the SDUC and made public as set forth herein, which memo sets forth an analysis of whether a Data Use Request is for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations) or, if applicable, a Narrow Data Use Request or a Data Use Request for Urgent Public Health Surveillance. All Summary Decision Memos shall be in accordance with the form, if any, and otherwise satisfy any requirements established by the SDUC from time to time. All Summary Decision Memos shall be produced in a standard format using the form included as Attachment B to this SOP.

**Urgent Public Health Surveillance** is defined as a public health authority's surveillance of a communicable disease that the Department has determined represents a significant risk to public health. For instance, a declared public health emergency may trigger Urgent Public Health Surveillance but is not required. It is also possible that Urgent Public Health Surveillance may be required to determine whether a public health emergency should or should not be declared. The SDUC may establish additional criteria for determining Urgent Public Health Surveillance.

## **Description of Standard Operating Procedures**

## **Standard Review Process**

Except with respect to Narrow Data Use Requests (as defined above) or Data Use Request for Urgent Public Health Surveillance, which shall be reviewed as set forth below, all Data Use Requests shall be reviewed in accordance with the following procedure:

- 1. An Authorized Requester submits to NYeC a Data Use Request that meets the requirements described in the definition of "Data Use Request".
- 2. NYeC will evaluate the following:
  - a. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is for a Public Health Permitted Purpose or a Medicaid Permitted Purpose; and
  - b. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations).
  - c. In connection with NYeC's review, NYeC will make any initial clarifications with the requester.



Statewide Data Infrastructure (SDI) Data Use Approval Process

- 3. NYeC shall use commercially reasonable efforts to complete its review of the Data Use Request as soon as reasonably practicable, but in any event shall endeavor to complete its review within ten (10) business days after receipt by NYeC of the Data Use Request.
- 4. If the Data Use Request is determined by NYeC to be other than for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and/or other than in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations), NYeC shall provide notice of denial of the Data Use Request to the requester (including reasons for the denial) and shall so inform the SDUC.
- 5. If the Data Use Request is recommended by NYeC as for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations), NYeC shall document such recommendation in a draft Summary Decision Memo, shall refer the Data Use Request to the SDUC, and shall so inform the requester.
- 6. Upon referral to the SDUC by NYeC, the SDUC shall review the Data Use Request and the draft Summary Decision Memo, conduct any additional due diligence the SDUC deems necessary and appropriate (including without limitation discussions with the requester), and make a final determination on approval or denial of the Data Use Request.
- 7. The SDUC shall use commercially reasonable efforts to approve or deny the Data Use Request as soon as reasonably practicable, but in any event shall endeavor to approve or deny the Data Use Request within fifteen (15) business days after receipt by the SDUC of the Data Use Request and draft Summary Decision Memo. The vote of the SDUC will be conducted in accordance with the SDUC Charter.
- 8. As soon as reasonably practicable, but in any event within three (3) business days after the SDUC's decision, NYeC shall finalize the Summary Decision Memo and provide notice of the SDUC's decision to the requester.
- 9. NYeC shall be responsible for making the final Summary Decision Memo publicly available online at <a href="www.nyehealth.org">www.nyehealth.org</a>. NYeC shall endeavor to make such Summary Decision Memo publicly available concurrently with the provision of notice of the SDUC's decision to the requester, but in any event as soon as practicable after such notice is given.

**Expedited Review Process: Narrow Data Use Requests** 



Statewide Data Infrastructure (SDI) Data Use Approval Process

All Narrow Data Use Requests (as defined above) shall be reviewed in accordance with the following procedure:

- 1. An Authorized Requester submits to NYeC a Data Use Request that meets the requirements described in the definition of "Data Use Request" and that indicates that the Data Use Request is a Narrow Data Use Request.
- 2. NYeC will evaluate the following:
  - a. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is for a Public Health Permitted Purpose or a Medicaid Permitted Purpose;
  - b. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations). NYeC will make any initial clarifications with the requester; and
  - c. whether the Data Use Request is a Narrow Data Use Request.
  - d. In connection with NYeC's review, NYeC will make any initial clarifications with the requester.
- 3. NYeC shall use commercially reasonable efforts to make a determination regarding the Data Use Request as soon as reasonably practicable, but in any event shall endeavor to make a determination within five (5) business days after receipt by NYeC of the Data Use Request.
- 4. If the Data Use Request is determined by NYeC to be other than a Narrow Data Use Request, the Data Use Request will be reviewed in accordance with the Standard Review Process described above, commencing with step 2.
- 5. If the Data Use Request is determined by NYeC to be a Narrow Data Use Request, but other than for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and/or other than in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations), NYeC shall provide notice of denial of the Data Use Request to the requester (including reasons for the denial) and shall so notify the SDUC.
- 6. If the Data Use Request is determined by NYeC to be a Narrow Data Use Request and for a Public Health Permitted Purpose or a Medicaid Permitted Purpose and otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations), the Data Use Request shall be deemed approved and NYeC shall document the determination in a Summary Decision Memo. NYeC shall share the Summary Decision Memo with the SDUC for awareness and provide notice of approval of the Data Use Request to the requester.
- 7. NYeC shall be responsible for making the final Summary Decision Memo publicly available online at <a href="https://www.nyehealth.org">www.nyehealth.org</a>. NYeC shall endeavor to make such Summary Decision Memo publicly available concurrently with the provision of notice of the



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SDUC's decision to the requester, but in any event as soon as practicable after such notice is given.

## Expedited Review Process: Urgent Public Health Surveillance

All Data Use Requests related to Urgent Public Health Surveillance (e.g., a request for identifiable data on all Emergency Department encounters beginning 6/1/24 with symptoms consistent with H5N1) shall be reviewed in accordance with the following procedure:

- 1. An Authorized Requester submits to NYeC a Data Use Request that meets the requirements described in the definition of "Data Use Request" and that indicates that the Data Use Request is related to Urgent Public Health Surveillance.
- 2. NYeC will evaluate the following:
  - a. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is for a Public Health Permitted Purpose;
  - b. whether the use, disclosure and/or re-disclosure as described in the Data Use Request is otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations); and whether the Data Use Request is related to Urgent Public Health Surveillance.
  - c. In connection with NYeC's review, NYeC will make any initial clarifications with the requester.
- 3. NYeC shall use commercially reasonable efforts to make a determination regarding the Data Use Request as soon as reasonably practicable, but in any event shall endeavor to make a determination within three (3) business days after receipt by NYeC of the Data Use Request.
- 4. If the Data Use Request is determined by NYeC to be other than related to Urgent Public Health Surveillance, the Data Use Request will be reviewed in accordance with the Standard Review Process described above, commencing with step 2.
- 5. If the Data Use Request is determined by NYeC to be related to Urgent Public Health Surveillance and for a Public Health Permitted Purpose and otherwise in compliance with the SCPA, the SHIN-NY SOPs and applicable law (including the SHIN-NY Regulations), the Data Use Request shall be deemed approved and NYeC shall document the determination in a Summary Decision Memo. NYeC shall share the Summary Decision Memo with the SDUC for awareness and provide notice of approval of the Data Use Request to the requester.
- 6. NYeC shall be responsible for making the final Summary Decision Memo publicly available online at <a href="www.nyehealth.org">www.nyehealth.org</a>. NYeC shall endeavor to make such Summary Decision Memo publicly available concurrently with the provision of notice of the SDUC's decision to the requester, but in any event as soon as practicable after such notice is given.



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### Approved Data Use Requests

Approved Data Use Requests will be operationalized by NYeC, with the SDUC and the SHIN-NY Policy and Technical Advisory Committees providing advice upon request.

All Summary Decision Memos will be posted publicly on the NYeC website.

### Oversight and Appeals

Oversight and appeals of SDUC decisions will be conducted pursuant to the SDUC Charter. From and after receipt by NYeC of any successful appeal of previously approved Data Use Request (i.e., a previously approved Data Use Request is deemed to be denied), (a) NYeC shall not access, use or disclose SDI Data for the purposes described in the applicable Data Use Request; and (b) NYeC shall provide notice to the applicable requester of the successful appeal and shall request that the requester cease access, use or disclosure of SDI Data for the purposes described in the applicable Data Use Request; provided, however, that except as set forth herein, NYeC shall have no responsibility for any access, use or disclosure of SDI Data by the applicable requester from and after any successful appeal of any previously approved Data Use Request.

### Additional SDI Permitted Purposes

In the event that additions are made to the list of the SDI Permitted Purposes, the SDUC shall establish a process, if any, for addressing data use requests related to such additional purpose(s) and amend this SOP accordingly. For the avoidance of doubt, no additional approval process shall be required for use, disclosure or re-disclosure of SDI Data for any SDI Permitted Purposes which are required to meet the maintenance and operational needs of the SHIN-NY, as further described under "Limitations" above.

#### Records

NYeC shall maintain a record of all written documentation related to all Data Use Requests (including, but not limited to, all Data Use Requests, all notices to requesters in connection with Data Use Requests, all Summary Decision Memos, and all documentation in connection with the oversight and appeals process) in accordance with NYeC's data retention policies in effect from time to time, or such other policies as may be adopted by the SDUC in accordance with the Statewide Collaboration Process and the SDUC Charter.

### **Amendment Procedures**

Proposals to amend this SOP, including without limitation to reflect amendments or modifications to the definition of SDI Permitted Purposes approved pursuant to the Statewide



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Collaboration Process, shall be considered, approved and implemented by the SDUC in accordance with the Statewide Collaboration Process and the SDUC Charter. SHIN-NY stakeholders may submit proposals to amend this SOP to the SDUC (or to NYeC staff to provide to the SDUC) for the SDUC's consideration. All amendments to this SOP shall be documented in the Version History section and published in accordance with the Statewide Collaboration Process.

#### **Attachments**

- Form of Data Use Approval Request
- Form of Summary Decision Memo

## **Version History**

Version Number	Date Adopted	Summary of Action/Changes
1.0	3/17/25	Approved by Statewide Data Use Committee
	4/01/25	Approved by NYeC Board
	4/02/25	Approved by NYS Department of Health

Form of Data Use Approval Request

[Attached]

**Form of Summary Decision Memo** 

[Attached]