

## **SUMMARY OF EXPRESS TERMS**

Public Health Law sections 206(18-a)(d) and 2816 give the Department broad authority to promulgate regulations, consistent with federal law and policies, that govern the Statewide Health Information Network for New York (SHIN-NY).

These amendments support the development of the statewide data infrastructure, thereby increasing interoperability and providing the flexibility necessary for the SHIN-NY to adapt in a constantly evolving technological environment. The goal of these amendments is to ensure consistency across the SHIN-NY in how SHIN-NY participants connect and exchange data, to support public health during emergencies and to assist with Medicaid reporting in support of the Medicaid program's Social Security Act section 1115 waiver (see 42 USC § 1315).

In order to promote efficiency through the development of network-wide policies, processes, and solutions, these amendments create a process to develop the statewide data infrastructure that will facilitate the exchange of data among SHIN-NY participants. Relevant activities required of the Department or its contracted vendor under the amendments include enhancement of the data matching process for patient demographic information submitted by SHIN-NY participants, creation of a statewide provider directory to serve as a standardized resource for resolving provider and facility identities, development of a statewide patient consent management system, and the aggregation of data from SHIN-NY participants in a secure statewide repository.

In addition, under these regulations, the Department will create a statewide common participation agreement to be used by each qualified entity and which will allow SHIN-NY participants to connect to the statewide data infrastructure by agreeing to participate in the SHIN-NY and adhering to SHIN-NY policy guidance. This will allow patient data to be

contributed to the statewide data infrastructure and used for statewide reporting and analytics for public health activities and Medicaid purposes, to the extent authorized by law. Any disclosure of data from the statewide data repository, a component of the statewide data infrastructure, will be in accordance with the SHIN-NY policy guidance reviewed and approved by relevant stakeholders through the statewide collaboration process.

This will further promote consistency and efficiency across the SHIN-NY by requiring the qualified entities to use and accept network-wide agreements and patient consent decisions. The statewide common participation agreement will eliminate the current variation in the terms and conditions applicable to participating in the SHIN-NY through one qualified entity versus another. The amendments also reduce ambiguity by requiring qualified entities to honor and implement patient consent decisions that authorize data access by treating providers across the network, regardless of which qualified entity such providers have contracted with, to participate in the SHIN-NY.

This amendment will further the Legislature's intent under chapter 54 of the Laws of 2023, which appropriated an additional \$2.5 million "for modernizing health reporting systems." By clarifying the data reporting and aggregation responsibilities applicable to the qualified entities, the proposed amendments will transform the SHIN-NY into a functional resource for the analysis and reporting of statewide health information for authorized public health and health oversight purposes.

Pursuant to the authority vested in the Commissioner of Health and the Public Health and Health Planning Council by sections 201, 206(1) and (18-a)(d), 2803, 2816, 3612, 4010, 4403, and 4712 of the Public Health Law, Part 300 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to read as follows:

Section 300.1 Definitions. For the purposes of this Part, these terms shall have the following meanings:

- (a) “*Statewide Health Information Network for New York*” or “*SHIN-NY*” means the technical infrastructure and the supportive policies and agreements that:
  - (i) make possible the electronic exchange of clinical information among [qualified entities and qualified entity] SHIN-NY participants for authorized purposes to improve the quality, coordination and efficiency of patient care, reduce medical errors and carry out public health and health oversight activities, while protecting patient privacy and ensuring data security; and
  - (ii) enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data, and public health information systems, while protecting patient privacy and ensuring data security.
- (b) “*Qualified entity*” means a not-for-profit regional health information organization or other entity that has been certified under section 300.4 of this Part.
- (c) “[*Qualified entity*] SHIN-NY participant” means any health care provider, health

plan, governmental agency or other type of entity or person that has executed a statewide common participation agreement with a qualified entity or with the entity that facilitates their connection to the SHIN-NY statewide data infrastructure, pursuant to which it has agreed to participate in the SHIN-NY.

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- (g) “*Patient information*” means health information that is created or received by a [qualified entity] SHIN-NY participant and relates to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual, and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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- (m) “*Statewide common participation agreement*” 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 SHIN-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.

- (n) “Statewide data infrastructure” 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.
- (o) “Public health activities” 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.
- (p) “Medicaid 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.

Section 300.2 Establishing the SHIN-NY. The New York State Department of Health shall:

- (a) oversee the implementation and ongoing operation of the SHIN-NY;
- (b) implement the infrastructure and services to support the private and secure exchange of health information among [qualified entities and qualified entity] SHIN-NY participants;
- (c) provide, either directly or through contract, statewide data infrastructure and any other SHIN-NY services that the New York State Department of Health deems necessary to effectuate the purposes of this Part;
- (d) administer the statewide collaboration process and facilitate the development, regular review and [update] amendment of SHIN-NY policy guidance;

[(d)](e) perform regular audits, either directly or through contract, of qualified entity and SHIN-NY participant functions and activities as necessary to ensure the quality, security and confidentiality of data in the SHIN-NY;

[(e)](f) provide [technical services], either directly or through contract, [to ensure the quality, security and confidentiality of data in the SHIN-NY;] strategic leadership on the use of the statewide data infrastructure to ensure health information exchange services are efficiently deployed in the SHIN-NY to support:

- (1) the exchange of data among SHIN-NY participants;
- (2) the matching of patient demographic information submitted by SHIN-NY participants;
- (3) a statewide provider directory;
- (4) a statewide consent management system; and
- (5) aggregation of data from SHIN-NY participants in a statewide repository;

[(f)](g) assess qualified entity and SHIN-NY participant participation in the SHIN-NY and, if necessary, suspend a qualified [entity's] entity or SHIN-NY participant's access to or use of the SHIN-NY, as provided in the statewide common participation agreement, or when it reasonably determines that the qualified entity or SHIN-NY participant has created, or is likely to create, an immediate threat of irreparable harm to the SHIN-NY, to any person accessing or using the SHIN-NY, or to any person whose information is accessed or transmitted through the SHIN-NY;

[(g)](h) publish reports on health care provider participation and usage, system performance, data quality, the qualified entity certification process, and SHIN-NY security;

[(h)](i) take such other actions, including but not limited to the convening of appropriate advisory and stakeholder workgroups, as may be needed to promote development of the SHIN-NY;

(j) approve the statewide common participation agreement under which SHIN-NY participants supply patient information to the SHIN-NY using qualified entities or the entity that facilitates their connection to the statewide data infrastructure, and qualified entities supply patient information using the statewide data infrastructure. Any such qualified entity or third-party entity that facilitates a SHIN-NY participant's connection must be the "business associate," as defined in 42 USC § 17921, of any SHIN-NY participant that supplies patient information and is a health care provider, and must be a qualified service organization of any SHIN-NY participant that supplies patient information and is an alcohol or drug abuse program required to comply with federal regulations regarding the confidentiality of alcohol and substance abuse patient records. 42 USC § 17921, effective February 17, 2009, which has been incorporated by reference in this Part, has been filed in the Office of the Secretary of State of the State of New York. The section of the United States Code incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Office of the Law Revision Counsel of the United States House of Representatives.

Section 300.3 Statewide collaboration process and SHIN-NY policy guidance.

(a) SHIN-NY policy guidance. The New York State Department of Health shall

establish SHIN-NY policy guidance as set forth below:

- (1) The New York State Department of Health shall establish [or designate a policy committee] 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.
  - (2) Policy committee agendas, meeting minutes, white papers and recommendations shall be made publicly available.
  - (3) 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.
- (b) Minimum contents of SHIN-NY policy guidance. SHIN-NY policy guidance standards shall include, but not be limited to policies and procedures on:
- (1) privacy and security;
  - (2) monitoring and enforcement;
  - (3) [minimum] core service requirements;
  - (4) organizational characteristics of qualified entities; [and]
  - (5) qualified entity certification;
  - (6) technical standards for interoperability and data sharing among SHIN-NY participants, qualified entities, and the New York State Department of Health or its designated contractor; and
  - (7) requirements and procedures for the disclosure of data, using the statewide



data infrastructure, to the New York State Department of Health or its designated contractor, and for the use and re-disclosure of such data to support statewide reporting and analytics for public health activities and Medicaid purposes.

Section 300.4 Qualified entities.

(a) Each qualified entity shall:

- (1) maintain and operate a network of [qualified entity] SHIN-NY participants seeking to securely exchange patient information;
- (2) connect to the statewide data infrastructure to allow [qualified entity] SHIN-NY participants to exchange information with [qualified entity] SHIN-NY participants of other qualified entities and with the New York State Department of Health or its designated contractor to support statewide reporting and analytics for public health activities and Medicaid purposes;
- (3) submit to regular audits of qualified entity functions and activities by the New York State Department of Health or its designated contractor as necessary to ensure the quality, security, and confidentiality of data in the SHIN-NY;
- (4) ensure that data from [qualified entity] SHIN-NY participants is only made available through the SHIN-NY in accordance with applicable law;
- (5) enter into agreements, including the statewide common participation agreement, with [qualified entity] SHIN-NY participants that supply patient information to, or access patient information from, the qualified entity. A

qualified entity must be the “business associate,” as defined in 42 USC § 17921, of any [qualified entity] SHIN-NY participant that supplies patient information and is a health care provider, and must be a qualified service organization of any [qualified entity] SHIN-NY participant that supplies patient information and is an alcohol or drug abuse program required to comply with Federal regulations regarding the confidentiality of alcohol and substance abuse patient records;

- (6) allow participation of all health care providers in the geographical area served by the qualified entity that are seeking to become [qualified entity] SHIN-NY participants, list the names of such [qualified entity] SHIN-NY participants on its website, and make such information available at the request of patients;
- (7) submit data, including patient information, using the statewide data infrastructure, to the New York State Department of Health or its designated contractor, according to specifications provided by the New York State Department of Health;
- (8) submit reports on health care provider participation and usage, system performance and data quality, in a format determined by the New York State Department of Health;
- ~~[(8)]~~(9) adopt policies and procedures to provide patients with access to their own patient information that is accessible directly from the qualified entity, except as prohibited by law;
- ~~[(9)]~~(10) implement policies and procedures to provide patients with information

identifying [qualified entity] SHIN-NY participants that have obtained access to their patient information using the qualified entity, except as otherwise prohibited by law.

- (b) Each qualified entity shall have procedures and technology:
- (1) to exchange patient information for patients of any age, consistent with all applicable laws regarding minor consent patient information;
  - (2) to allow patients to approve and deny access to [specific qualified entity] SHIN-NY participants; and
  - (3) to honor a minor's consent or revocation of consent to access minor consent patient information.
- (c) Each qualified entity shall provide [the following minimum set of] such core services to [qualified entity] SHIN-NY participants as required by the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part. Such core services shall include, but not be limited to:
- (1) allow [qualified entity] SHIN-NY participants to search existing patient records on the network;
  - (2) make available to [qualified entity] SHIN-NY participants and public health authorities a clinical viewer to securely access patient information;
  - (3) [permit secure messaging among health care providers;
  - (4)] provide tracking of patient consent;
  - [(5) provide notification services to establish subscriptions to pre-defined events and receive notifications when those events occur;
  - (6)](4) provide identity management services to authorize and authenticate users in a

manner that ensures secure access;

(5) submit data using the statewide data infrastructure, to the New York State Department of Health or its designated contractor, to support the aggregation of data, statewide reporting and analytics for public health activities and Medicaid, consistent with applicable law;

[(7)](6) support Medicaid and public health reporting to public health authorities;

[(8) deliver diagnostic results and reports to health care providers.]

(7) provide SHIN-NY participants with appropriate access to data using the statewide data infrastructure.

(d) The New York State Department of Health shall certify qualified entities that demonstrate that they meet the requirements of this section to the satisfaction of the New York State Department of Health. The New York State Department of Health may, in its sole discretion, select a certification body to review applications and make recommendations to the New York State Department of Health regarding certification. The New York State Department of Health shall solely determine whether to certify qualified entities. To be certified, a qualified entity must demonstrate that it meets the following requirements:

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(3) The qualified entity has technical infrastructure, privacy and security policies and processes in place to: manage patient consent for access to health information consistent with section 300.5 of this Part and the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part; support the authorization and authentication of users who access the

system; audit system use; and implement remedies for breaches of patient information.

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Section 300.5 Sharing of Patient Information.

(a) General standard. [Qualified entity] SHIN-NY participants may only exchange patient information as authorized by law and consistent with their statewide common participation agreements [with qualified entity participants]. Under section 18(6) of the Public Health Law, individuals who work for a qualified entity or the entity that facilitates SHIN-NY participants' connection to the statewide data infrastructure are deemed personnel under contract with a health care provider that is a [qualified entity] SHIN-NY participant. As such, a [qualified entity] SHIN-NY participant may disclose to such a qualified entity necessary patient information without a written authorization from the patient of the [qualified entity] SHIN-NY participant. [Qualified entity] SHIN-NY participants may, but shall not be required to, provide patients the option to withhold patient information, including minor consent patient information, from the SHIN-NY. Except as set forth in paragraph (b)(2) or subdivision (c) of this section, a qualified entity shall only allow access to patient information by [qualified entity] SHIN-NY participants with a written authorization from:

- (1) the patient; or
- (2) when the patient lacks capacity to consent, from:
  - (i) another qualified person under section 18 of the Public Health Law;

- (ii) a person with power of attorney whom the patient has authorized to access records relating to the provision of health care under General Obligations Law article 5, title 15; or
  - (iii) a person authorized pursuant to law to consent to health care for the individual.
- (b) Written authorization.
  - (1) Written authorizations must [specify to whom disclosure is authorized] be obtained using a statewide form of consent, approved by the New York State Department of Health, that allows patients to approve and deny access to information in the SHIN-NY by SHIN-NY participants.
    - (i) Patient information may not be disclosed to persons who, or entities that, become [qualified entity] SHIN-NY participants subsequent to the execution of a written authorization unless:
      - (a) the name or title of the individual or the name of the organization are specified in a new written authorization; or
      - (b) the patient's written authorization specifies that disclosure is authorized to persons or entities becoming [qualified entity] SHIN-NY participants subsequent to the execution of the written authorization and the qualified entity has documented that it has notified the patient, or the patient has declined the opportunity to receive notice, of the persons or entities becoming [qualified entity] SHIN-NY participants subsequent to the execution of the written authorization.

- (ii) Any written authorization shall remain in effect until it is revoked in writing or explicitly superseded by a subsequent written authorization. A patient may revoke a written authorization in writing at any time by following procedures established by the qualified entity consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.
- (2) Qualified entities shall permit access to all of a patient's information by all persons or entities authorized to access information in the SHIN-NY, or any other general designation of who may access such information, after consent is obtained.
- (3) A minor's parent or legal guardian may authorize the disclosure of the minor's patient information, other than minor consent patient information.
- ~~[(3)]~~(4) Minor consent patient information.
  - (i) In general, a minor's minor consent patient information may be disclosed to a [qualified entity] SHIN-NY participant if the minor's parent or legal guardian has provided authorization for that [qualified entity] SHIN-NY participant to access the minor's patient information through the SHIN-NY. Such access shall be deemed necessary to provide appropriate care or treatment to the minor. However, if federal law or regulation requires the minor's authorization for disclosure of minor consent patient information or if the minor is the parent of a child, has married or is otherwise emancipated, the disclosure may not be made without the minor's

authorization.

- (ii) In no event may a [qualified entity] SHIN-NY participant disclose minor consent patient information to the minor's parent or guardian without the minor's authorization.

[(4)](5) Minor consent patient information includes, but is not limited to, patient information concerning:

\* \* \*

- (x) emergency care as provided in section 2504(4) of the Public Health Law[.];

- (xi) treatment provided with the consent of no person other than the minor patient, where the patient is a homeless youth as defined in section 532-A of the executive law, or receives services at an approved runaway and homeless youth crisis services program or transitional independent living support program as defined in section 532-A of the executive law.

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Section 300.6 Participation of health care facilities.

- (a) [One year from the effective date of this regulation, general hospitals as defined in subdivision ten of section two thousand eight hundred one of the Public Health Law, and two years from the effective date of this regulation, all health] Health care facilities as defined in section 18(c)(1) of the Public Health Law, including those who hold themselves out as urgent care providers[, utilizing certified electronic health record technology under the federal Health Information Technology for



Economic and Clinical Health Act (HITECH),] must become [qualified entity] SHIN-NY participants in order to connect to the SHIN-NY through a qualified entity, and must allow private and secure bi-directional access to patient information by other [qualified entity] SHIN-NY participants authorized by law to access such patient information. [Bi-directional] As used in this subdivision, bi-directional access means that a [qualified entity] SHIN-NY participant has the technical capacity to upload its patient information to the qualified entity so that it is accessible to other [qualified entity] SHIN-NY participants authorized to access the patient information and that the [qualified entity] SHIN-NY participant has the technical capacity to access the patient information of other [qualified entity] SHIN-NY participants from the qualified entity when authorized to do so, consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.

(b) All health care facilities required to become SHIN-NY participants pursuant to subdivision (a) of this section must supply patient information to the statewide data infrastructure.

(c) The New York State Department of Health may waive the requirements of [subdivision] subdivisions (a) or (b) of this section for health care facilities that demonstrate, to the satisfaction of the New York State Department of Health:

- (1) economic hardship;
- (2) technological limitations or practical limitations to the full use of certified electronic health record technology that are not reasonably within control of the health care provider; [or]
- (3) other exceptional circumstances demonstrated by the health care provider to

the New York State Department of Health as the Commissioner may deem appropriate; or

- (4) the facility has the technical capacity for private and secure bi-directional access, executes a statewide common participation agreement, connects to the SHIN-NY and supplies patient information to the statewide data infrastructure in accordance with this Part and the SHIN-NY policy guidance. As used in this paragraph, bi-directional access means that a SHIN-NY participant has the technical capacity to upload its patient information to the SHIN-NY so that it is accessible to other SHIN-NY participants authorized to access the patient information and that the SHIN-NY participant has the technical capacity to access the patient information of other SHIN-NY participants when authorized to do so, consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (PHL) § 206(18-a)(d) authorizes the Commissioner to make such rules and regulations as may be necessary to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data and public health information systems, while protecting patient privacy and ensuring data security. In addition, PHL sections 201, 206(1), 2803, 2816, 3612, 4010, 4403, and 4712 authorize the Commissioner to make such rules and regulations as may be necessary to effectuate the provisions and purposes of PHL Articles 28 (hospitals), 36 (home care services), 40 (hospice), 44 (health maintenance organizations) and 47 (shared health facilities) and provide additional authority for the Commissioner to create and make use of the Statewide Health Information Network for New York (SHIN-NY).

### **Legislative Objectives:**

The explicit legislative objective of PHL § 206(18-a) is the promotion of widespread, non-duplicative interoperability among disparate health information systems and data types, including electronic health records, personal health records, health care claims, payment and other administrative data and public health information systems, while protecting patient privacy and ensuring data security. Such interoperability is intended to improve patient outcomes, minimize unnecessary service utilization, and reduce health care costs by fostering efficiency and supporting care coordination.

Existing regulations at 10 NYCRR Part 300 advanced these legislative objectives by establishing requirements for the regional health information organizations (RHIOs) that

were created as health information exchanges in New York State. Under the provisions of Part 300, the RHIOs became the qualified entities (QEs) that facilitate the exchange of health information in the SHIN-NY. These regulatory amendments will further the legislative intent by making it easier for health care providers, health plans, and governmental agencies to become SHIN-NY participants and access the SHIN-NY through the use of a statewide common participation agreement, while ensuring patient privacy and data security.

**Needs and Benefits:**

Pursuant to the current regulation, responsibility for the development and maintenance of SHIN-NY policies and technical infrastructure is divided between the QEs and the Department. In practice, this division of oversight and operational responsibilities has resulted in the deployment of disparate forms, processes, and technology solutions across the network. The proposed amendments are necessary to support the development of the statewide data infrastructure, thereby increasing interoperability and providing the flexibility necessary for the SHIN-NY to adapt in a constantly evolving technological environment. The goal of these amendments is to ensure consistency across the SHIN-NY in how SHIN-NY participants connect and exchange data, and to support the sharing of information for public health purposes, such as the Medicaid program's Social Security Act section 1115 waiver (see 42 USC § 1315).

In order to promote efficiency through the development of network-wide policies, processes, and solutions, these amendments create a process to develop the statewide data infrastructure that will facilitate the exchange of data among SHIN-NY participants by enhancing the matching of patient demographic information submitted by SHIN-NY

participants, with a statewide provider directory, and statewide consent management system.

In addition, under these regulations, the Department will create a statewide common participation agreement to be used statewide by each qualified entity whether the participant connects through a qualified entity or directly through the statewide infrastructure. This will enable SHIN-NY participants to connect with the statewide data infrastructure and contribute patient data. Furthermore, the statewide common participation agreement will allow the use of such data for statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law. The regulations define the terms “public health activities” and “Medicaid purposes” and the [SHIN-NY policy guidance](#) sets forth the instances in which a participant may disclose protected health information to the Department, without affirmative consent of the patient.

The regulations will further promote consistency and efficiency across the SHIN-NY by requiring the QEs to use and accept network-wide agreements and patient consent decisions. The statewide common participation agreement will eliminate the current variation in the terms and conditions applicable to participating in the network through one QE versus another. The regulatory amendments will also reduce ambiguity by requiring QEs to honor and implement patient consent decisions that authorize data access by treating providers across the network, regardless of which QE such providers have contracted with to participate in the SHIN-NY.

These amendments will also further the Legislature’s intent under chapter 54 of the Laws of 2023, which appropriated an additional \$2.5 million “for modernizing health reporting systems.” As the COVID-19 and requirement to use the Hospital Emergency

Reporting Data System (HERDS) for crucial public health reporting pandemic demonstrated, the current framework for SHIN-NY data collection and reporting is insufficient to enable timely analysis and decision making in situations involving an emergent public health concern. By providing for a statewide data infrastructure and explicitly requiring all SHIN-NY participants to submit data for aggregation, these amendments will ensure that facilities and the Department are not required to navigate and implement an ad-hoc or emergency data collection procedure during future public health scenarios of urgent concern. Additionally, it will enable more efficient reporting for healthcare facilities.

Moreover, interoperability and analytics based on data from the SHIN-NY will be a key component of the Department's mandatory reporting in relation to the Medicaid program's Social Security Act section 1115 demonstration project and associated waiver. Whereas the current regulation merely authorizes the QEs to disclose patient information without written consent to a public health authority or health oversight agency, the proposed amendments will require the QEs and SHIN-NY participants to submit data using the statewide data infrastructure, both on a regular basis and in response to ad-hoc requests from the Department or its designated contractor. By clarifying the data reporting and aggregation responsibilities applicable to the QEs and the permissible uses of such data by the Department or its designated contractor, the proposed amendments will transform the SHIN-NY into a functional resource for the analysis and reporting of statewide health information for authorized public health and health oversight purposes.

Beyond supporting interoperability and consistency across the network for QEs and SHIN-NY participants and clarifying the data reporting obligations of both, these

regulations also address the need to allow for providers to connect directly to the statewide data infrastructure and participate in SHIN-NY data exchange and data reporting without a qualified entity acting as intermediary. To that end, the definition of “qualified entity participant” has been changed to refer to “SHIN-NY participants,” which will account for the possibility that provider organizations may participate in the SHIN-NY without contracting with one of the qualified entities. In such circumstances, the provider organization would enter into the statewide common participation agreement with the Department or its designated contractor, under which the organization would agree to adhere to applicable SHIN-NY policies and provide data to other SHIN-NY participants and the Department for data reporting and aggregation. To create an option for such direct connection to the statewide data infrastructure as an alternative to connecting through one of the qualified entities, subdivision 300.6(c)(4) is amended to exempt a health care facility that demonstrates “the technical capacity for private and secure bi-directional access, executes a statewide common participation agreement, and connects to the SHIN-NY using the statewide data infrastructure” from the requirement to enter into a participation agreement with a qualified entity. These changes reflect the fact that health information technology has rapidly advanced since the inception of the SHIN-NY, to the point where most larger health systems now possess the technical capacity to connect to and retrieve data from a statewide network without the assistance of a dedicated health information exchange partner or may exchange through electronic health record networks established at the national level.

These regulations account for the possibility that the Department, its designated contractor, and/or other types of health care organizations or other national networks might

provide data and/or services through the SHIN-NY in the future. Data and services may be provided through the SHIN-NY by the Department, by its designated contractor, or by other SHIN-NY participants that meet the minimum technical, security, privacy, organizational and other requirements set forth by the Department. Along with the provisions that authorize providers to connect directly to the SHIN-NY, this change will support the shift to an ecosystem model for New York's health information system in favor of the current system under which participation is restricted to those organizations that contract and follow the policies of the certified QEs.

Finally, these amendments will promote the development of a statewide provider directory and consent management system, both of which have been longstanding goals for the Department and will contribute substantially to the modernization of New York's health reporting system once implemented.

## **COSTS**

### **Costs to Private Regulated Parties:**

The private parties subject to the proposed amendments are the QEs and SHIN-NY participants. To the extent that any expenditures are necessary by QEs in order to comply with these amendments, such expenditures are expected to continue to be reimbursed using money appropriated to the Department's designated contractor. It is not anticipated that SHIN-NY participants will incur any costs as a result of these amendments. Most regulated facilities are currently connected to the SHIN-NY via a qualified entity. The amendments are also intended to allow the alignment of SHIN-NY interoperability requirements with interoperability requirements from the federal Department of Health and Human Services. By aligning with federal interoperability requirements, this should create more efficiency



by leveraging interoperability standards currently built into electronic health records.

**Costs to Local Government:**

This proposal will not impact local governments unless they operate a health care facility, in which case the impact would be the same as outlined above for private parties.

**Costs to the Department of Health:**

While there will be costs to build the statewide data infrastructure initially, those costs have already been budgeted. It is anticipated there will be greater efficiency in how technology is deployed in the SHIN-NY. Initial outlays will be funded through a \$2.5million increase in the budget appropriation that occurred in the SFY 2023-2024 budget.

**Costs to Other State Agencies:**

The proposed regulatory changes will not result in any additional costs to other State agencies.

**Local Government Mandates:**

Health facilities operated by local governments will be required to comply with these amendments in the same manner as other facilities. The regulation is not anticipated to impose any direct costs on SHIN-NY participants, including local health departments.

**Paperwork:**

No new paperwork requirements would be imposed under the proposed amendments. Any consent forms that are developed will replace current consent forms and deployed can be done electronically. Additionally, there will be less variation in consent forms because of a consistent consent form developed by the Department.

**Duplication:**

This regulation will not conflict with any state or federal rules.

**Alternatives:**

An alternative to the proposed regulation would be not to make any amendments to 10 NYCRR Part 300 regulations. However, these amendments are necessary to fulfill the legislature's objective of creating an efficient statewide health information network that serves as a resource for patients, providers, and public health officials across the State. These regulations are essential to improve the long-term efficacy of the SHIN-NY and therefore the alternative of not making any amendments to the regulation was not considered viable.

**Federal Standards:**

The proposed amendments do not duplicate or conflict with any federal regulations. These amendments will complement the Office of the National Coordinator for Health Information Technology (ONC) Final Rule implementing certain provisions of the 21st Century Cures Act (85 Fed. Reg. 25642, May 1, 2020), which requires patient information to be accessible under application programming interface (API) requirements and prohibits actions that constitute information blocking. See 42 USC § 300jj-11 et seq.

**Compliance Schedule:**

The amendments will be effective upon publication of a Notice of Adoption in the New York State Register.

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## **STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments. By having a standard participation agreement across the state, SHIN-NY participants will have a consistent participation agreements that will not vary by region. This should result lower costs compared to current variation across the state.

## **STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for this amendment is not being submitted because the amendment will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. By having a standard participation agreement across the state, SHIN-NY participants will have a consistent participation agreements that will not vary by region. This should result lower costs compared to current variation across the state. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for the proposed regulatory amendments is not being submitted because it is apparent from the nature and purposes of the amendment that it will not have a substantial adverse impact on jobs and/or employment opportunities.

## SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The Department received comments from Statewide Health Information Network for New York (SHIN-NY) qualified entities, associations representing health care providers, hospitals, and federally qualified health centers, a non-profit organization, and a government agency. Several comments were supportive of the regulation and of the intent to modernize the SHIN-NY. Several commenters also requested clarification regarding the Medicaid reporting use cases and public health activities that would permit the Department to access data in the statewide data infrastructure and statewide data repository. The Department emphasizes that any such access will be made in accordance with applicable federal and state law, and pursuant to a review and approval process to be established in consultation with stakeholders through the statewide collaboration process. The Department also received questions regarding the ability of SHIN-NY participants to connect to the network directly, and suggestions regarding the composition of SHIN-NY committees and workgroups.

In response to public comments, references to “public health surveillance” have been changed to “public health activities,” the term that is used in the federal Health Insurance Portability and Accountability Act (HIPAA) standards. Also, definitions of “public health activities” and “Medicaid purposes” have been added to the definitions in section 300.1 of the regulation. The Department also updated the Regulatory Impact Statement to indicate that the regulation will “create an option” for providers to connect directly to the SHIN-NY “as an alternative to connecting through” one of the qualified entities. In addition, the word “specific” was removed from paragraph 300.4(b)(2) to make

clear that community-wide consents, which are already approved by the Department, will continue to be permitted under the regulation. In subdivision 300.1(m), the phrase “in accordance with SHIN-NY policy guidance” has been replaced with the phrase “consistent with applicable law.” Finally, language in subdivision 300.2(j) has been amended to make clear that the reference is to a qualified entity or third-party entity that facilitates a SHIN-NY participant’s connection, not to the Department’s “designated contractor,” which is the New York eHealth Collaborative (NYeC).



## ASSESSMENT OF PUBLIC COMMENT

The Department received comments from Statewide Health Information Network for New York (SHIN-NY) qualified entities, associations representing health care providers, hospitals, and federally qualified health centers, a non-profit organization, and a government agency. Several comments were supportive of the regulation and of the intent to modernize the SHIN-NY. Several commenters also requested clarification regarding the Medicaid reporting use cases and public health activities that would permit the Department to access data in the statewide data infrastructure and statewide data repository. The Department emphasizes that any such access will be made in accordance with applicable federal and state law, and pursuant to a review and approval process to be established in consultation with stakeholders through the statewide collaboration process.

The Department also received questions regarding the ability of SHIN-NY participants to connect to the network directly, and suggestions regarding the composition of SHIN-NY committees and workgroups. Minor clarifications to the regulation, including definitions of the terms “public health activities” and “Medicaid purposes” have been made in response to the comments received.

**Comment:** One commenter suggested the formation of an advisory committee supporting the modernization and innovation of a comprehensive, affordable New York Statewide Health Information Exchange.

**Response:** Under the existing regulation, there are several active committees and workgroups that are committed to promoting innovation, collaboration, and the

modernization of SHIN-NY policies, practices, and technologies. Additionally, the amended text of paragraph 300.3(a)(1) will require the Department to establish a process, including “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.” All stakeholders are encouraged to participate in the development of the SHIN-NY by joining or attending the meetings of relevant committees and workgroups. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested several changes involving qualified entity network infrastructure, electronic health record (EHR) data integration, and data organization.

**Response:** The proposed amendments are intended to modernize the SHIN-NY and to promote interoperability, consistency, and data liquidity across the network. To accomplish these aims, the regulation requires the Department or its designated contractor to develop and implement a statewide data infrastructure that will complement the existing infrastructure maintained by qualified entities and will support: (1) the exchange of data between qualified entity participants, (2) the development and deployment of a statewide provider directory, and (3) the maintenance of a statewide consent management system.

The regulation also requires SHIN-NY participants to use the statewide common participation agreement, which will establish a set of common policies and technical requirements applicable to all qualified entities and participants across the network.

Additionally, the regulation will give SHIN-NY participants the option to directly connect to, and exchange, data through the statewide data infrastructure without contracting with a

qualified entity to facilitate the network connection. In addition to promoting efficiency and interoperability, these changes will provide SHIN-NY participants with a new level of flexibility to seek out the data-sharing arrangement and partner(s) that best match their operational needs. These changes will also enable standardization and alignment with federal interoperability requirements. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the Department wait to amend the regulation in light of ongoing federal health information exchange (HIE) initiatives. Another commenter suggested that the goals presented by the Department could be achieved without significant changes to the existing regulation.

**Response:** These amendments are necessary to modernize the SHIN-NY, promote interoperability, consistency, and data liquidity across the network, and allow the Department and health care providers to fulfill reporting obligations. The Department will work with stakeholders through the statewide collaboration process to ensure consistency with evolving federal and regional initiatives as the policies and procedures required to support these amendments are developed. In the event that federal or other initiatives substantially alter the operational landscape for health information exchange, the Department will respond to such developments through the statewide collaboration process or, if necessary, by amending the regulation as appropriate. No changes have been made to the regulation in response to this comment.

**Comment:** Several commenters suggested that the regulation should define the scope of the

public health activities and Medicaid purposes that would permit the Department to access patient data in the SHIN-NY.

**Response:** Any Department request for data from the statewide data infrastructure will be made consistent with applicable federal and state laws, regulations, and policies. In order to provide clarification on this point, references to “public health surveillance” have been changed to “public health activities,” the term that is used in the federal Health Insurance Portability and Accountability Act (HIPAA) standards. Also, definitions of “public health activities” and “Medicaid purposes” have been added to the definitions in section 300.1 of the regulation.

Subdivision 300.1(o) defines “public health activities” as “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.” This new definition is consistent with the rules for Public Health Reporting and Access that are already in effect under Section 1.2.2 of the SHIN-NY policy guidance available at:

[https://www.health.ny.gov/technology/regulations/shin-ny/docs/privacy\\_and\\_security\\_policies.pdf](https://www.health.ny.gov/technology/regulations/shin-ny/docs/privacy_and_security_policies.pdf).

Subdivision 300.1(p) defines “Medicaid purposes” as “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.”

As is already the case under existing federal and state law and regulations, any disclosure of data from the statewide data repository, a component of the statewide data infrastructure,

will be in accordance with the SHIN-NY policy guidance, reviewed and approved by relevant stakeholders through the statewide collaboration process.

**Comment:** One commenter suggested that the Department assess whether joining the Office of the National Coordinator's (ONC) Trusted Exchange Framework and Common Agreement (TEFCA) would be a viable alternative to the changes planned at the NYS level.

**Response:** The proposed amendments are intended to complement the exchange capabilities enabled by TEFCA and to avoid redundancy. As the capabilities regarding public health are developed within TEFCA, the Department will continue to review and plan for efficiencies. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested deferring any changes to the regulation until an overall public health data collection strategy has been developed.

**Response:** These amendments are necessary to modernize the SHIN-NY, promote interoperability, consistency, and data liquidity across the network, and allow the Department and health care providers to fulfill reporting obligations. Access to data from the statewide data infrastructure and statewide data repository for public health activities will be consistent with applicable laws, regulations and current SHIN-NY policy and practice, which aligns with HIPAA regulations. The SHIN-NY Policies and Procedures further describe the public health purposes for which patient information may be reported to the Department without affirmative consent. No changes have been made to the regulation in response to this comment.

**Comment:** One commenter suggested there be more robust hospital representation on the SHIN-NY Policy Committee, the committee that meets under the statewide collaboration process to discuss the Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State under 10 NYCRR § 300.3(b)(1).

**Response:** Hospitals and health systems are well-represented under the existing regulation, and all stakeholders are encouraged to monitor and participate in meetings of the SHIN-NY Policy Committee as appropriate. In addition to the SHIN-NY Policy Committee, which is comprised of stakeholders representing policy makers, consumers, providers, and health systems, the amended text of paragraph 300.3(a)(1) will require the Department to establish a process, including “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.” No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the statewide collaboration process be updated and that the details of such process be made more readily available to the public.

**Response:** The SHIN-NY Policy Committee meets regularly to discuss topics from its annual policy agenda and solicits public comments on key policy issues. The SHIN-NY Policy Committee’s annual agenda, meeting schedule, and meeting notes are publicly posted on the website of the Department’s designated contractor, New York eHealth Collaborative (NYeC): <https://www.nyehealth.org/shin-ny/shin-ny-governance/>. It is anticipated that any additional advisory committees formed pursuant to paragraph 300.3(a)(1) will also make meeting information and materials available to the public. No

changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested clarifying that healthcare facilities may seek a waiver from connectivity requirements if they are effectively making patient records available to a patient's other healthcare providers, such as through participation in national health information exchange, and are causing patient data to be contributed to the statewide data infrastructure for public health surveillance and Medicaid purposes.

**Response:** Guidance for health care facilities seeking a waiver of the requirement to connect to the SHIN-NY will be developed through the statewide collaboration process following adoption of these regulatory amendments. Such guidance will include information about the procedures to be used to establish and demonstrate secure bi-directional access to patient data by facilities seeking a waiver of the requirement to connect to the network by contracting with a qualified entity. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested clarifying the text of proposed paragraph 300.4(c)(7), which requires qualified entities to provide SHIN-NY participants with appropriate access to data using the statewide data infrastructure, to make clear that this provision does not require qualified entities to provide SHIN-NY participants with direct, unlimited access to the statewide data infrastructure.

**Response:** The text of paragraph 300.4(c)(7) is intended to require qualified entities to provide participants with *appropriate* access to data from the statewide data infrastructure. It is not intended to modify the procedures used by qualified entities to ensure that SHIN-

NY participants are legally authorized to access data before providing data to participants, nor to require that qualified entities provide participants with a direct connection to the statewide data infrastructure. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the language in the Regulatory Impact Statement be updated to clarify that a direct connection to the statewide data infrastructure is an alternative method of connection and is not being promoted as a better option than connecting through a qualified entity.

**Response:** The Department acknowledges the potential for misunderstanding based on the previous wording and has updated the Regulatory Impact Statement to indicate that the regulation will “create an option” for providers to connect directly to the SHIN-NY “as an alternative to connecting through” one of the qualified entities.

**Comment:** One commenter suggested updating paragraph 300.4(b)(2) to remove the requirement that the qualified entities allow patients to approve and deny access to “specific” SHIN-NY participants. The commenter contended that the reference to a “specific” participant conflicted with the statewide form of consent, approved by the Department, that allows patients to approve or deny access by a general designation of participants, also known as a “community-wide” or “All-In” consent.

**Response:** While it is anticipated that patients will have the ability to approve and deny access to specific SHIN-NY participants under the statewide consent model once a robust statewide provider directory has been developed, the technological solution is not yet in



place to allow this. As a result of this comment, the word “specific” was removed from paragraph 300.4(b)(2) to make clear that community-wide consents, which are already approved by the Department, will continue to be permitted under the regulation.

**Comment:** One commenter raised concerns that the proposed regulation changes lack the detail necessary to ensure smooth implementation.

**Response:** These regulations are and have always been considered the framework for the SHIN-NY. The details of policy and implementation are established through the statewide collaboration process and described in SHIN-NY policy guidance. As is reflected in the amended text of paragraphs (6) and (7) of subdivision 300.3(b), the Department will be required to use the statewide collaboration process to develop and issue new SHIN-NY policy guidance regarding the exchange and disclosure of patient data provided for in the amended regulation. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that a statewide consent framework should be established to further enhance patient privacy and potentially reduce the burden on patients and providers.

**Response:** The proposed regulation will establish a statewide consent framework by requiring that all written authorizations be obtained using a single statewide patient consent form. The regulation will also require the Department to provide strategic leadership to support a statewide consent management system. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that additional statewide core services be added based on requests from the health care community.

**Response:** These amendments are necessary to modernize the SHIN-NY, promote interoperability, consistency, and data liquidity across the network, and allow the Department and health care providers to fulfill reporting obligations and respond to emerging public health issues. As the impact of value-added care becomes apparent over time, the Department will work with stakeholders through the statewide collaboration process to address any required changes to SHIN-NY policies and procedures, or, if necessary, to the regulation. No changes to the regulation have been made in response to this comment.

**Comment:** Two commenters raised concerns that allowing participants to connect directly to the statewide data infrastructure would create two tiers of participants and would endanger the privacy and security of the protected health information within the SHIN-NY.

**Response:** These amendments will promote consistency across the state and foster the expansion of the SHIN-NY in accordance with legislative objectives by allowing health care providers and other organizations to connect to the network and exchange data, provided they are able to demonstrate the technical, security, and operational capabilities required to safeguard patient information. As described in section 300.6, all health care facilities that connect to the statewide data infrastructure will be required to demonstrate the technical capacity for secure bi-directional access to patient data consistent with the SHIN-NY policy guidance developed through the statewide collaboration process. Such policy

guidance is anticipated to include procedures that will allow the Department or its designated contractor to confirm that a SHIN-NY participant has demonstrated this capability, including verification of applicable data security protocols. Whereas an organization seeking to perform the functions of a regional health information organization as part of the SHIN-NY would be subject to the established qualified entity certification requirements, the regulations provides the Department with the flexibility to establish appropriate technical and security policies for the entity or entities that facilitate direct connection to the statewide data infrastructure through the statewide collaboration process, with the benefit of stakeholder input. In so doing, the regulation accounts for the fact that such entities, while serving an essential role in the expansion of the statewide network, will not have the same obligation to manage patient data, patient consent decisions, and provider access issues across dozens or hundreds of health care providers as that faced by current or future qualified entities. No changes to the regulation have been made in response to this comment.

**Comment:** Two commenters noted that there was not enough detail provided about the content of the statewide common participation agreement. This made it difficult for the commenters to assess the impact this statewide participation agreement would have and raised concerns that the final agreement would be restrictive and negatively impact overall SHIN-NY participation.

**Response:** As indicated in the proposed amendments, the statewide common participation agreement will be developed through the statewide collaboration process. This process is anticipated to involve substantial participation from qualified entity representatives and

other relevant stakeholders to ensure that the statewide participation agreement includes the necessary and appropriate terms to establish a participation framework that meets the needs of qualified entities, SHIN-NY participants, and the Department. No changes to the regulation have been made in response to these comments.

**Comment:** Two commenters raised concerns about the resources, time and effort it would take to implement a statewide common participation agreement.

**Response:** The Department is cognizant of the resources and time that will be required to successfully implement the statewide common participation agreement, and will support qualified entities and SHIN-NY participants through the statewide collaboration process and dedicated guidance on the use of the statewide common participation agreement. No changes to the regulation have been made in response to these comments.

**Comment:** Two commenters raised concerns that DOH will have too much involvement in the structure and technology of the SHIN-NY with these changes.

**Response:** Since they were initially promulgated, these regulations have placed responsibility for oversight and management of the SHIN-NY on the Department as the agency which administers and funds the network. The proposed amendments are necessary to fulfill the SHIN-NY's intended purpose to function as a truly statewide network of health care providers that can facilitate the efficient exchange of health care information, consistent with patient consent. No changes to the regulation have been made in response to these comments.

**Comment:** Two commenters raised concerns that the statewide data infrastructure will contain information that is not currently allowable under existing public health regulations.

**Response:** All personal health information contained in the SHIN-NY is stored, accessed, and transmitted pursuant to applicable federal and state laws, regulations, and policies, including but not limited to those governing the use of specific sensitive data subject to enhanced confidentiality protections. The Department will continue to strictly comply with applicable laws, regulations, and policies in its collection, use, and disclosure of patient data. No changes to the regulation have been made in response to these comments.

**Comment:** Two commenters raised concerns that the changes proposed in the regulation do not sufficiently leverage previous investments made by New York State into the current SHIN-NY infrastructure.

**Response:** It is only through the previous investments made that the Department is able to move to this next evolution of the SHIN-NY. The existing infrastructure, relationships, policies, and lessons learned will be retained as the Department works with stakeholders to implement these changes and modernize the SHIN-NY to better serve the needs of qualified entities, SHIN-NY participants, and patients. No changes to the regulation have been made in response to these comments.

**Comment:** Two commenters stated that the proposed changes are not consistent with the New York Health Equity Reform (NYHER) 1115 Waiver, TEFCA, or federated models adopted by other states.

**Response:** These amendments are intended to provide the Department and the SHIN-NY

with the flexibility to develop solutions and services that maximize efficiency and consistency with existing regional and national health information exchange initiatives. The amendments are consistent with the Social Security Act section 1115 waiver and TEFCA designs which allow for access to information for activities in regional areas using interoperable data standards and also statewide information. No changes to the regulation have been made in response to these comments.

**Comment:** One commenter raised concerns that the process to disclose data from the statewide data repository would be duplicative of the established Statewide Planning and Research Cooperative System (SPARCS) and the Public Health and Health Planning Council (PHHPC) processes.

**Response:** Pursuant to the regulations at 10 NYCRR section 400.18, data from the Statewide Planning and Research Cooperative System (SPARCS) is only disclosed for research purposes upon approval of a data request by the SPARCS Data Governance Committee. Any disclosure of data from the statewide data repository to the Department will be made in accordance with applicable law for Medicaid purposes and/or public health activities only, and pursuant to a review and approval process to be established through the statewide collaboration process. As a result, such disclosures would not be duplicative of existing processes. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter raised concerns that the statewide data repository would create a target for hackers.

**Response:** Data in the statewide data repository will be stored, accessed, and transmitted in accordance with applicable law and industry best practices, including but not limited to HITRUST and national standards such as those promulgated by the National Institute of Standards and Technology (NIST). These are the same standards applicable to patient data maintained by qualified entities. No changes to the regulation have been made in response to these comments.

**Comment:** One commenter suggested that instead of the changes made by the regulation, DOH could invest in existing qualified entities to create an infrastructure to meet its needs.

**Response:** These amendments are necessary to promote interoperability, consistency, and data liquidity across the SHIN-NY. Although the Department will continue to rely on the expertise its qualified entity partners have developed since the SHIN-NY was established, the disparate technical infrastructure, policies, and practices between the various qualified entities would unduly complicate the process of establishing a truly statewide network as set forth in the regulation. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked for clarification on the definition of the statewide common participation agreement, provided in subdivision 300.1(m). The commenter requested that the Department clarify who was being referenced by the word “them,” and to clarify who the contractor is. Additionally, the commenter asked to clarify if the statewide reporting and analytics referenced are limited to public health surveillance. The commenter also asked if data can be used for any Medicaid purpose or if it is limited to statewide

reporting and analytics.

**Response:** The word “them” in subdivision (m) of section 300.1 refers to SHIN-NY participants who will connect to the statewide data infrastructure either directly or through a contractor. With respect to the use of data from the statewide data repository, the commenter is directed to the response above regarding the inclusion of definitions of “public health activities” and “Medicaid purposes” at subdivisions (o) and (p) of section 300.1, respectively, as well as the fact that any such disclosure will be made pursuant to a review and approval process involving relevant stakeholders to be developed through the statewide collaboration process.

**Comment:** One commenter requested that the following terms be defined: “statewide reporting,” “statewide analytics,” “public health surveillance,” “strategic leadership,” and “Medicaid purposes.”

**Response:** The commenter is directed to the responses above regarding the Department’s access to and use of data from the statewide data infrastructure for Medicaid purposes and public health activities. Specific details regarding the statewide reporting and statewide analytics that will support Medicaid and public health activities will be developed in conjunction with stakeholders through the statewide collaboration process. The term “strategic leadership” means the Department’s guidance regarding the overall strategic vision and plan for the SHIN-NY as well as consultation and decision-making authority on specific operational and policy details to be developed through the statewide collaboration process. No further changes to the regulation have been made in response to this comment.



**Comment:** One commenter recommended using the phrase “consistent with applicable law” in the definition of “Statewide common participation agreement” in subdivision 300.1(m) in order to make this definition more consistent with the definition of “Statewide data infrastructure” in subdivision 300.1(n).

**Response:** The Department agrees that the regulation reads better with the same phrase used in both definitions. The phrase “in accordance with SHIN-NY policy guidance” has been replaced with the phrase “consistent with applicable law” in subdivision 300.1(m).

**Comment:** One commenter asserted that the description of the statewide common participation agreement does not address the exchange of data.

**Response:** The definition of “Statewide common participation agreement” indicates that it will be the agreement “pursuant to which SHIN-NY participants agree to participate in the SHIN-NY and adhere to SHIN-NY policy guidance.” Since participation in the network necessarily implies the exchange of patient data, no changes to the regulation have been made in response to this comment.

**Comment:** One commenter stated that the definition of statewide data infrastructure provided in subdivision 300.1(n) only addresses the Department of Health’s use of the infrastructure and does not mention that it will be used to support the exchange of data among SHIN-NY participants or that SHIN-NY participants will be allowed to access it.

**Response:** Under these amendments, the primary purpose of the statewide data infrastructure is to complement the networks currently maintained by the qualified entities by allowing SHIN-NY participants to connect to and exchange data over a network that

reaches providers and health care facilities across the state. In addition to facilitating data exchange among participants, the statewide data infrastructure will also include the statewide data repository as a component that will enable the secure collection and aggregation of patient data. This repository is anticipated to serve as a valuable source of reporting and statistics for the Department and SHIN-NY participants alike. Accordingly, amended subdivision 300.2(f) requires the Department or its designated contractor to provide strategic leadership on the use of the statewide data infrastructure to support activities including “the exchange of data among SHIN-NY participants” and the “aggregation of data from SHIN-NY participants in a statewide repository.” Additional guidance on the data that will be sent to the statewide data repository and how it will be made available to participants, the Department, and other appropriate stakeholders will be developed through the statewide collaboration process. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter stated that the Department of Health needed to take a more involved role in the statewide data infrastructure and should not be allowed to subcontract the creation of this infrastructure.

**Response:** Nothing in these amendments should be construed to limit the Department’s ongoing oversight and administrative responsibilities with respect to the SHIN-NY, consistent with the regulation and with current practice. Subdivision 300.2(f) is intended to provide the Department with the flexibility needed to oversee the efficient development and deployment of health information exchange services that will support the transition to a more consistent and interoperable statewide network and to allocate resources appropriately

for that purpose. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the term statewide repository be defined within the regulation.

**Response:** As indicated in amended paragraph 300.2(f)(5), the statewide data repository will be a component of the statewide data infrastructure that will be developed to enable the secure collection and aggregation of data from SHIN-NY participants. As a part of the SHIN-NY, the statewide data repository will be developed and implemented with the same focus on patient privacy and data security that underpins the regulation and the network as whole. This fundamental focus is reflected in paragraphs 300.1(a)(i) and (ii), which define the SHIN-NY as the technical and legal infrastructure that enables interoperability and the exchange of patient information “while protecting patient privacy and ensuring data security.” Similarly, paragraph 300.3(b)(1) requires SHIN-NY policy guidance to include policies and procedures on privacy and security, and it is anticipated that the policy guidance will be updated through the statewide collaboration process to include data access, security, and confidentiality policies specific to the statewide data repository during development of the technical solution. No changes were made to the regulation in response to this comment.

**Comment:** Two commenters stated that the requirements and procedures for the statewide data infrastructure should be included in the regulations.

**Response:** Consistent with the existing regulations and current practice, these amendments

are intended to provide as much information as is currently possible about the requirements applicable to various components of the SHIN-NY, while retaining appropriate flexibility and mandating stakeholder collaboration in the development of more specific policies and procedures. Moreover, as a practical matter, the regulatory authority to develop this new technical solution and the development phase itself are both necessary pre-requisites to defining specific rules applicable to the data that will be stored, transmitted, and accessed through the statewide data infrastructure. Correspondingly, new paragraph 300.3(b)(7) mandates the development of SHIN-NY policy guidance on “requirements and procedures for the disclosure of data, using the statewide data infrastructure, to the New York State Department of Health or its designated contractor.” No changes were made to the regulation in response to these comments.

**Comment:** One commenter suggested that the term “designated contractor” in subdivision 300.2(j) in reference to third-party contractors of SHIN-NY participants be changed, since the term “designated contractor” is used in these regulations to refer to the New York eHealth Collaborative (NYeC).

**Response:** The Department agrees with this suggestion and the language in subdivision 300.2(j) has been changed to make clear that the reference is to a qualified entity or third-party entity that facilitates a SHIN-NY participant’s connection, not to the Department’s “designated contractor,” which is NYeC.

**Comment:** One commenter stated that the term “specifications” used in paragraph 300.4(a)(7) is too broad of a term.

**Response:** As used in paragraph 300.4(a)(7), the word “specifications” means the technical and operational specifications provided by the Department to the qualified entities regarding the submission of data to the Department through the statewide data infrastructure. Any use of such data by the Department will be in accordance with applicable state and Federal laws, regulations, and policies. No further changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked for clarification on the requirement outlined in paragraph 300.4(c)(6) for qualified entities to support Medicaid. Specifically, they asked if this support was limited to Medicaid reporting to public health authorities.

**Response:** As is reflected in the Summary of Express Terms and the Regulatory Impact Statement, qualified entity support for Medicaid is currently only anticipated to include reporting to support the Medicaid program’s Social Security Act section 1115 waiver. Pursuant to paragraph 300.3(b)(7), further information regarding the Department’s use of the data to support statewide reporting and analytics will be formulated through the statewide collaboration process and formalized as new SHIN-NY policies and procedures. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that access to the statewide data repository be added to the requirement in paragraph 300.4(c)(7).

**Response:** Additional guidance on the data that will be sent to the statewide data repository and how it will be made available to participants, the Department, and other appropriate stakeholders will be developed through the statewide collaboration process. No changes to

the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the phrase “after consent is obtained” in paragraph 300.5(b)(2) be changed to “in accordance with the consent granted” for clarity.

**Response:** The proposed regulation, including section 300.5, makes clear that any access to patient data in the SHIN-NY must be in accordance with patient consent, if consent has been granted. As a result, the phrase “after consent is obtained” implies that such consent will determine which SHIN-NY participants, if any, are authorized to access a patient’s information. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked for clarification on whether subdivision 300.6(a) means that only Qualified Entities can connect to the statewide data infrastructure.

**Response:** As described in paragraph 300.6(c)(4), SHIN-NY participants can connect directly to the statewide data infrastructure. This process is anticipated to involve technical and/or operational support provided by a third-party entity selected by the Department or its designated contractor to facilitate connections to the statewide data infrastructure for SHIN-NY participants who do not contract with a qualified entity. Pursuant to paragraph 300.3(b)(6), technical standards for interoperability and data sharing among SHIN-NY participants, including participants who connect to the network directly, will be a required component of the SHIN-NY policy guidance developed through the statewide collaboration process. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked whether paragraph 300.6(c)(4) correctly described the

circumstances under which a facility may receive a waiver.

**Response:** Paragraph 300.6(c)(4) clarifies that participants do not need to connect to the SHIN-NY through a qualified entity (as set forth in subdivision 300.6[a]). The paragraph clarifies that participants connected to the SHIN-NY without a qualified entity must still provide data to the SHIN-NY and participate in bi-directional exchange. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter raised concerns about the SHIN-NY infrastructure being used to provide sensitive health data (e.g., abortion). They also suggested that the Department consider segregation or adopting an additional opt-in policy for sensitive data.

**Response:** Data in the statewide data repository will be stored, accessed, and transmitted in accordance with applicable law and industry best practices, including but not limited to HITRUST and national standards such as those promulgated by the National Institute of Standards and Technology (NIST). Additionally, both the patient consent forms currently in use and the pending statewide common participation agreement contain extensive guidance for patients regarding the effect of giving their affirmative consent for their information to be shared and accessed in the SHIN-NY. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter raised concerns that some providers may not have the technical capability to connect to the SHIN-NY based on their current electronic health record (EHR). Additionally, they stated that the cost and time to update to a compliant EHR would be prohibitive. As a result of these points, the commenter suggested that the previous

language be reinstated which only required providers with Office of the Nation Coordinator Certified EHR Technology (CEHRT) to connect.

**Response:** The Department is cognizant of the possibility that some providers may not yet have the technical capacity to connect to the SHIN-NY. Those providers are welcome to submit a waiver from connection as outlined in subdivision 300.6(c). However, the removal of the requirement for CEHRT from the regulation is necessary to begin the conversation with those providers who are not yet at a technical level for connection to understand remaining barriers. Use of the SHIN-NY has been shown to lead to better care coordination and a reduction in unnecessary tests. It is ultimately in the interest of patients, providers, health systems and the Department to have as many providers as possible across the state exchanging high-quality, secure health information through the SHIN-NY. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter sought clarification that the SHIN-NY is not intended to replace the methods or mechanisms used by other health agencies for disease or other reporting.

**Response:** None of the provisions in these regulations should be construed to alter or supplant any existing or future data reporting providers and health systems are obligated to perform pursuant to applicable law. No changes to the regulation have been made in response to these comments.

**Comment:** One commenter suggested stronger language be added to the regulations to ensure the SHIN-NY has appropriate technical, administrative, and physical safeguards to



protect the privacy and security of patient information in accordance with HIPAA and other applicable laws.

**Response:** Data in the statewide data infrastructure will be stored, accessed, and transmitted in accordance with applicable law and industry best practices, including but not limited to HITRUST and national standards such as those promulgated by the National Institute of Standards and Technology (NIST). No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that language in subdivision 300.2(i) specifically including local health departments as participants in advisory and stakeholder workgroups.

**Response:** While the Department acknowledges the important work of local health departments, these regulations do not require any specific workgroup composition in order to maintain the flexibility to assemble groups with varied membership and specific focus areas as needed. Local health departments are welcome to participate in SHIN-NY workgroups and the Department encourages their attendance and input. To request attendance to a specific workgroup, local health departments are asked to email [SHIN-NY@health.ny.gov](mailto:SHIN-NY@health.ny.gov) to coordinate. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the term “strategic leadership” in subdivision 300.2(f) be defined.

**Response:** The term “strategic leadership” means the Department’s guidance regarding the overall strategic vision and plan for the SHIN-NY as well as consultation and decision-

making authority on specific operational and policy details to be developed through the statewide collaboration process. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked that the criteria or conditions be defined which would meet the threshold to be considered irreparable harm as used in section 300.2(g).

**Response:** Since they were first promulgated, the regulations have left the determination of what would constitute “irreparable harm” to the SHIN-NY, to the Department as the agency responsible for oversight and administration of the network. Since providing a specific definition of “irreparable harm” would unnecessarily restrict the Department’s ability to assess and respond to threats to the integrity of the SHIN-NY, that phrase will not be further defined in the regulation. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter asked that the stakeholder and advisory groups mentioned in subdivision 300.2(i) include providers of diverse patient populations such as federally qualified health centers.

**Response:** The amended text of paragraph 300.3(a)(1) will require the Department to establish a process, including “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.” Providers are also encouraged to participate in SHIN-NY workgroups even if they are not permanent members of an advisory committee. To request attendance to a specific workgroup, please email

[SHIN-NY@health.ny.gov](mailto:SHIN-NY@health.ny.gov) to coordinate. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested enhanced data matching processes be implemented consistent with the Office of the National Coordinator's HTI-1 final rule and industry best practices.

**Response:** Policies and procedures regarding the implementation of a statewide provider directory will be developed through the statewide collaboration process. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter requested that the statewide consent management system be interoperable with electronic health records (EHR) and easily navigated by SHIN-NY participants.

**Response:** Policies and procedures regarding the implementation of a statewide consent management system will be developed through the statewide collaboration process. All stakeholders are encouraged to participate in the development of the SHIN-NY by joining or attending the meetings of relevant committees and workgroups. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the SHIN-NY change from an opt-in to an opt-out consent model for sharing patient data.

**Response:** The Department is not currently considering any change to the SHIN-NY's opt-in consent model. Changes to the SHIN-NY consent model may be considered following

implementation of the statewide common participation agreement and development of the statewide consent management system. No changes to the regulation have been made in response to this comment.

**Comment:** One commenter suggested that the language used in the common participation agreement be simple and easy to understand.

**Response:** Consistent with state policy, the Department will make every effort to ensure the language used in the common participation agreement is simple and easy to understand. No changes to the regulation have been made in response to this comment.