

## **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 surveillance and Medicaid purposes, to the extent authorized by law.

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 surveillance and Medicaid purposes, in accordance with SHIN-NY policy guidance.

- (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 surveillance and Medicaid purposes, consistent with applicable law.

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 SHINY-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 SHINY-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 designated contractor 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 surveillance 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 surveillance 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 surveillance 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:

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(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 surveillance and Medicaid purposes, in accordance with SHIN-NY policy guidance.

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 its Medicaid 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 further support such direct connection to the statewide data infrastructure, 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.