

Proposed Regulations
NEW YORK STATE DEPARTMENT OF HEALTH
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Proposed Rule Making:

Addition of Part 300 to Title 10 NYCRR (Statewide Health Information Network for New York (SHIN-NY))

Publication Date: 11/04/2015

Comment Period Expiration: 12/21/2015

Proposed Text and Statements:

SUMMARY OF EXPRESS TERMS

Public Health Law § 206(18-a)(d) gives 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).

This regulation makes clear that, consistent with 42 USC § 17938, Qualified entities (QEs) may, without patient authorization, make patient information available among SHIN-NY participants or other entities otherwise serving the patient so long as the QEs enter into and adhere to participation agreements that comply with federal requirements under HIPAA and 42 CFR Part 2 for business associates and qualified service organizations. This regulation specifies consent requirements to access patient information made available through the QEs. This regulation incorporates legal requirements related to disclosure of patient information without consent, as well as laws that specifically authorize disclosure of patient information for health care purposes, including public health and health oversight purposes, without the type of written, signed authorization that contains all of the elements that would be required for a health care provider to get permission to disclose patient information to a third party for purposes other than health care.

In order to participate in the SHIN-NY, regional health information organizations will need to be certified as QEs by the Department and satisfy certification requirements on an ongoing basis under the procedures established by this regulation.

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), 2800, 2803, 2816, 3600, 3612, 4000, 4010, 4400, 4403, 4700 and 4712 of the Public Health Law, a new Part 300 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 300

Statewide Health Information Network for New York (SHIN-NY)

Sec.

300.1 Definitions

300.2 Establishing the SHIN-NY

300.3 Statewide collaboration process and SHIN-NY policy guidance

300.4 Qualified Entities

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§ 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 make possible the electronic exchange of clinical information among qualified entities and qualified entity 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.
- (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 participant” means any health care provider, health plan, governmental agency or other type of entity or person that has executed a participation agreement with a qualified entity, pursuant to which it has agreed to participate in the SHIN-NY.
- (d) “Health care provider” means a health care provider as defined in paragraph (b) of subdivision one of section 18 of the Public Health Law entitled “Access to patient information.”
- (e) “Statewide collaboration process” means an open, transparent process within which multiple SHIN-NY stakeholders contribute to recommendations for SHIN-NY policy guidance.
- (f) “SHIN-NY policy guidance” means the set of policies and procedures, including technical standards and SHIN-NY services and products that are approved by the New York State Department of Health.
- (g) “Patient information” means health information that is created or received by a qualified entity 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.
- (h) “Minor consent patient information” means patient information relating to health care of a patient under 18 years of age for which the patient provided his or her own consent as permitted by law, without a parent’s or guardian’s permission.
- (i) “Health oversight agency” means an agency or authority of the United States, or New York State, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws

for which health information is relevant.

(j) “Public health authority” means an agency or authority of the United States, the New York State Department of Health, a New York county health department or the New York City Department of Health and Mental Hygiene, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(k) “Written authorization” means a signed consent that complies with the requirements for written authorizations in this Part. A written authorization may be an electronic record with an electronic signature, as provided by State Technology Law Article 3 (Electronic Signatures and Records Act).

(l) “Law” means a federal, state or local constitution, statute, regulation, rule, common law, or other governmental action having the force and effect of law, including the charter, administrative code and rules of the city of New York. Required by law means a mandate contained in law that compels a person or entity to make a use or disclosure of patient information and that is enforceable in a court of law.

§ 300.2 Establishing the SHIN-NY. The New York State Department of Health may:

(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 participants.

(c) Administer the statewide collaboration process and facilitate the development, regular review and update of SHIN-NY policy guidance.

(d) Perform regular audits, either directly or through contract, of qualified entity functions and activities as necessary to ensure the quality, security and confidentiality of data in the SHIN-NY.

(e) Provide technical services, either directly or through contract, to ensure the quality, security and confidentiality of data in the SHIN-NY.

(f) Assess qualified entity participation in the SHIN-NY and, if necessary, suspend a qualified entity’s access to or use of the SHIN-NY, when it reasonably determines that the qualified entity 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) Publish reports on health care provider participation and usage, system performance, data quality, the qualified entity certification process, and SHIN-NY security.

(h) Take such other actions as may be needed to promote development of the SHIN-NY.

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

(a) SHIN-NY policy guidance. The New York State Department of Health may establish SHIN-NY policy guidance as set forth below:

(1) The New York State Department of Health shall establish or designate a policy committee 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 service requirements;
- (4) organizational characteristics of qualified entities; and
- (5) qualified entity certification.

§ 300.4 Qualified entities.

(a) Each qualified entity shall:

- (1) Maintain and operate a network of qualified entity participants seeking to securely exchange patient information.
- (2) Connect to the statewide infrastructure to allow qualified entity participants to exchange information with qualified entity participants of other qualified entities.
- (3) Submit to regular audits of qualified entity functions and activities by the New York State Department of Health as necessary to ensure the quality, security, and confidentiality of data in the SHIN-NY.
- (4) Ensure that data from qualified entity participants is only made available through the SHIN-NY in accordance with applicable law.
- (5) Enter into agreements with qualified entity 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 participant that supplies patient information and is a health care provider, and must be a qualified service organization of any qualified entity 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 participants, list the names of such qualified entity participants on its website, and make such information available at the request of patients.
- (7) 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) 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) Implement policies and procedures to provide patients with information identifying qualified entity 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 law regarding minor consent patient information;
- (2) to allow patients to deny access to specific qualified entity 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 core services to qualified entity participants:

- (1) Allow qualified entity participants to search existing patient records on the network.
- (2) Make available to qualified entity 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) Provide identity management services to authorize and authenticate users in a manner that ensures secure access.
- (7) Support public health reporting to public health authorities.
- (8) Deliver diagnostic results and reports to health care providers.

(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:

- (1) The qualified entity is capable of supporting and advancing the use of health information technology in the public interest and has a board of directors and officers with such character, experience, competence and standing as to give reasonable assurance of its abilities in this respect.
- (2) The qualified entity has the capability and infrastructure to operationalize the requirements in this section.
- (3) The qualified entity has technical infrastructure, privacy and security policies and processes in place to: manage patient consent for access to health information; support the authorization and authentication of users who access the system; audit system use; and implement remedies for breaches of patient information.

(e) The New York State Department of Health shall periodically require qualified entities to demonstrate continued compliance with the certification standards required pursuant to subdivision (d) of this section through a process of audit and re-certification by the New York State Department of Health or a certification body designated by the New York State Department of Health.

(f) The New York State Department of Health may, as it deems appropriate, audit qualified entities to ensure ongoing compliance with criteria and standards.

§ 300.5 Sharing of Patient Information.

(a) General standard. Qualified entity participants may only exchange patient information as authorized by law and consistent with their participation agreements with qualified entity participants. Under subdivision six of section 18 of the Public Health Law, individuals who work for a qualified entity are deemed personnel under contract with a health care provider

that is a qualified entity participant. As such, a qualified entity participant may disclose to such a qualified entity necessary patient information without a written authorization from the patient of the qualified entity participant. Qualified entity 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 subdivision (b)(2) or (c) of this section, a qualified entity shall only allow access to patient information by qualified entity 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.

(i) Patient information may not be disclosed to persons who, or entities that, become qualified entity 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 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 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.

(2) A minor's parent or legal guardian may authorize the disclosure of the minor's patient information, other than minor consent patient information.

(3) Minor consent patient information.

(i) In general, a minor's minor consent patient information may be disclosed to a qualified entity participant if the minor's parent or legal guardian has provided authorization for that qualified entity 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 participant disclose minor consent patient information to the minor's parent or guardian without the minor's authorization.

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

(i) treatment of such patient for sexually transmitted disease or the performance of an

abortion as provided in section 17 of the Public Health Law;

(ii) the diagnosis, treatment or prescription for a sexually transmitted disease as provided in section 2305 of the Public Health Law;

(iii) medical, dental, health and hospital services relating to prenatal care as provided in section 2504(3) of the Public Health Law;

(iv) an HIV test as provided in section 2781 of the Public Health Law;

(v) mental health services as provided in section 33.21 of the Mental Hygiene Law;

(vi) alcohol and substance abuse treatment as provided in section 22.11 of the Mental Hygiene Law;

(vii) any patient who is the parent of a child or has married as provided in section 2504 of the Public Health Law or an otherwise legally emancipated minor;

(viii) treatment that a minor has a Constitutional right to receive without a parent's or guardian's permission as determined by courts of competent jurisdiction;

(ix) Treatment for a minor who is a victim of sexual assault as provided in section 2805-i of the Public Health Law;

(x) Emergency care as provided in section 2504(4) of the Public Health Law.

(c) Access without written authorization. A qualified entity shall, where permitted by law, allow access to patient information without written authorization when:

(1) Prior consent has already been obtained for the disclosure as required by subdivision 23 of section 6530 of the Education Law, and no provision of law requires any additional written authorization.

(2) Disclosure to the individual entity accessing the patient information is:

(i) required by law; or

(ii) authorized by law:

(a) to a public health authority for public health activities;

(b) to a health oversight agency for health oversight activities; or

(c) to a federally designated organ procurement organization for purposes of facilitating organ, eye or tissue donation and transplantation.

(3) The health care provider treating the patient, a person acting at the direction of such health care provider, or other professional emergency personnel has documented that an emergency condition exists and the patient is in immediate need of medical attention, and an attempt to secure consent would result in delay of treatment which would increase the risk to the patient's life or health.

§ 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 care facilities as defined in paragraph (c) of subdivision one of section eighteen 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 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 participants authorized by law to access such patient information. Bi-directional access means that a qualified entity participant has the technical capacity to upload its patient information to the qualified entity so that it is accessible to other qualified entity participants authorized to access the patient information and that the qualified entity participant has the technical capacity to access the patient information of other qualified entity participants from the qualified entity when authorized to do so.

(b) The New York State Department of Health may waive the requirements of subdivision (a) 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.

SUMMARY OF THE REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law Section 206(18-a)(d) authorizes the Commissioner of Health to make rules and regulations to promote the development of a self-sufficient Statewide Health Information Network for NY (SHIN-NY) to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records (EHRs), personal health records (PHRs) and public health information systems while protecting patient privacy and ensuring data security. The Department of Health is exercising this authority in conjunction with its authority under Public Health Law Articles 28, 36, 40, 44 and 47 to regulate health care facilities as defined in Public Health Law section 18.

Purpose of Regulation:

This regulation will establish requirements for qualified entities and qualified entity participants in the SHIN-NY to allow them to securely exchange information across the state.

- Qualified Entities (QEs) (including RHIOs), through participation agreements with providers and patient consent, would implement a minimum set of core services. The QEs must also comply with federal and State laws, including laws regarding the confidentiality of alcohol and drug abuse treatment records under 42 CFR Part 2, confidential HIV-related information under PHL Article 27-F and mental health records under Mental Hygiene Law Article 33.
- The regulations would allow for the exchange of health information about minors of any age in a way that complies with current state and federal laws and regulations related to minor consented services.
- The department would create a certification process for QEs/RHIOs that ensures standard criteria are met for providing services to its members and that the number of QEs is sufficient to provide access to health information exchange services statewide.

Benefits of Regulation:

The regulation is intended to support the triple aim of improving the patient care experience (including quality and cost), improving the health of populations, and reducing the per capita cost of health care through the broad adoption of health information exchange by:

- increasing patient record availability to health care providers across the state;
- establishing the core set of health information exchange (HIE) services that provide clinical and administrative value to the healthcare system and are available to all providers and all patients in New York State; and
- reducing barriers for EHR integration with HIE services.

State and Local Cost:

To date, the development of the SHIN-NY and expansion of EHR adoption has been funded through a combination of federal and state funds distributed through grant programs, as well as private contributions from participating health plans, providers and other stakeholders. Currently, over 170 hospitals and over 8200 primary care providers qualify for “meaningful use” incentives under Medicaid and Medicare. In addition, through HEAL NY funding, it is expected that over 7800 primary and specialty care providers were supported to have adopted EHRs and be connected to the SHIN-NY by the end of 2013. Over 80% of hospitals and over 75% of Federally Qualified Health Centers (FQHCs) in New York State participate in RHIOs.

Investment in the operation of the SHIN-NY will also generate a substantial return through the elimination of wasted expenditures and promoting better quality health care at a lower cost. Three studies conducted in Rochester by the Health Information Technology Evaluation Collaborative (HITEC), an academic research consortium under contract with the State Department of Health to perform evaluation activities for the HEAL NY Program, identified improved quality and reduction in duplicative testing and in readmission rates for a two year study period for events in 2009-2010. Use of the Rochester RHIO by five Emergency Departments (EDs) resulted in 6 averted admissions per 100 patients who came to the ED, resulting in \$9 million projected savings annually across the adult community. Extrapolating the cost savings across the state would result in an annual savings of \$52 million. During the same study period, image exchange use through the Rochester RHIO within 90 days following an initial imaging procedure reduced the probability of repeat imaging by 35%. Finally, use of the Rochester RHIO after hospital discharge resulted in a 55% reduction in readmission within 30 days. These highly significant findings with important financial implications further demonstrate the value of the SHIN-NY.

An 18-month study in the Buffalo region looked at the number of multiple CT scans ordered for the same body part, for the same patient, over a six-month period. During the period, 2,763 CT scans were deemed to be potentially unnecessary, duplicative tests. 90% of the potentially duplicative tests were ordered by physicians who never or infrequently access the local health information exchange. By local calculations, that amounts to a potential additional cost of \$1.3 million over a six-month period for one test in one region of the state.

Costs to Regulated Entities:

The proposed regulation will require that health care facilities connect to the SHIN-NY. Average interface costs for hospitals are \$75,000 while interface costs for physician practices vary but generally average \$5,000 – 10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Some RHIOs have established this functionality for their participants, and therefore, there are reduced associated interface costs for their participants, which include physician practices. In some regions of the State, health plans have absorbed the interface costs for their network providers because they see the value of having their physicians connected to the SHIN-NY. Only health care providers, regulated by the Department of Health, using certified EHR technology need to comply with these requirements. Currently, adoption of certified EHR technology for health care facilities outside of hospitals and FQHCs is low because they are not eligible to receive meaningful use incentive payments.

Local Government Mandates:

The State Enterprise Health Information Exchange as part of the SHIN-NY is designed to streamline how providers interact with the many public health information systems that currently exist, to decrease reporting burdens, promote bidirectional information exchange, and advance public health priorities. Health care facilities operated by local governments will be required to comply with these regulations in the same manner as other health care facilities. Should local health departments need to make expenditures to comply with the regulatory requirements, they have opportunities to request funding through Article 6 Local Assistance Grant Program, and possibly other sources. Additionally, local agencies could seek a waiver to connect to their RHIO if funding is not available.

Paperwork:

Entities that wish to become QEs will need to submit an application for review by DOH to determine if the criteria outlined in the regulation have been met as well as meeting other criteria as may be required under the QE certification process.

Duplication:

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

Alternatives:

The Department established a statewide collaboration process to establish a governance and policy framework to allow health information sharing among disparate providers to improve quality, improve efficiency and reduce costs of health care on a statewide basis while ensuring the patient privacy and ensuring data security of patient information.

While other states have different models for health information exchange, and NY considered the approaches and models used in other states through its statewide collaborative process, based on the size, complexity and diversity of New York and the resources that were available, the State Department of Health determined that this model was the best approach to allow for statewide health information exchange.

Federal Standards:

This rule aligns with current federal laws and regulations governing the adoption of interoperable exchange of health information and meaningful use requirements under the HITECH provisions of ARRA, as well as federal standards regarding the exchange of certain alcohol and drug abuse patient records under 42 CFR Part 2.

Compliance Schedule:

Since RHIOs or QEs are largely operational in NYS and the majority of hospitals and federally qualified health centers are already participants, and the number of physicians practices participating continues to grow and the infrastructure for the SHIN-NY is already in development, the estimated time period needed for regulated persons or entities to achieve compliance with the rule is practicable.

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REGULATORY IMPACT STATEMENT**Statutory Authority:**

Public Health Law § 206(18-a)(d) authorizes the Commissioner to make such rules and regulations as may be necessary to implement federal policies and disburse funds as required by the American Recovery and Reinvestment Act of 2009 and to promote the development of a self-sufficient Statewide Health Information Network for New York (SHIN-NY) 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. Such rules and regulations shall include, but not be limited to requirements for organizations covered by 42 USC 17938 or any other organizations that exchange health information through the SHIN-NY.

Meaning of “implement federal policies”

The federal government, through the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS), has been promoting and subsidizing the adoption of health IT for many years. According to the ONC-Coordinated Federal Health IT Strategic Plan: 2008-2012 (June 3,

2008), upon publication of Executive Order 13335 on April 27, 2004, President George W. Bush set a target for the majority of Americans to have access to electronic health records (EHRs) by 2014. Under EO 13335 (3 CFR 13335), ONC is charged with directing “the nationwide implementation of interoperable health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.”

Meaning of “disburse funds as required by the American Recovery and Reinvestment Act of 2009”

The American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111-5) includes within it the Health Information Technology for Economic and Clinical Health (HITECH) Act (HITECH is ARRA Division A, Title XIII-Health Information Technology and ARRA Division B, Title IV-Medicare and Medicaid Health Information Technology).

Under HITECH, HHS has provided and is continuing to provide billions of dollars for:

- Medicare and Medicaid incentive payments to health care providers that adopt “meaningful use” of certified electronic health record (EHR) technology. 42 USC §§ 299b-31, 299b-33, 1395w-4, 1395w-23, 1395ww, 1396b; 42 CFR Part 495.
- Grants to states to promote health IT. New York State received a federal grant to prepare and submit to the federal government a statewide health IT plan to develop health information exchange across health care systems and to move New York State toward the meaningful use of certified EHR technology. 42 USC § 300jj-33. These regulations implement that plan.
- The creation and funding of health IT Regional Extension Centers (RECs) to assist health care providers in the selection, acquisition, implementation and meaningful use of certified EHR technology to improve health care quality and outcomes. Two RECs in New York have received federal grants. 42 USC § 300jj-32.

Meaning of “the development of a self-sufficient statewide health information network for New York (SHIN-NY)”

On the State level, New York is creating a Statewide Health Information Network for New York (SHIN-NY). Under the Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) Capital Grant Program (PHL § 2818) Phases 1, 5, 10, 17 and 22, New York promoted broad adoption of EHRs and other health IT tools and is subsidizing the operations of Regional Health Information Organizations (RHIOs) that facilitate health information exchange between disparate providers and health systems. The creation of the SHIN-NY and the expenditure of federal and State funds for health IT is being coordinated by DOH’s Office of Quality and Patient Safety (OQPS). The Legislature established the OQPS Bureau of Health Information Exchange (referred to in the law as “the office of Health e-Links New York”) “to enhance the adoption of an interoperable regional health information exchange and technology infrastructure that will improve quality, reduce the cost of health care, ensure patient privacy and security, enhance public health reporting including bioterrorism surveillance and facilitate health care research in the state of New York” (L. 2006, ch. 57, Part G, § 1), and the Legislature has since then appropriated money in the Chapter 54 budget

appropriation laws to fund the office of Health e-Links (or “health e-link”). In the 2014-2015 budget, the Legislature appropriated \$55 million for the SHIN-NY (L. 2014, ch. 54), and in the 2015-2016 budget, the Legislature appropriated \$45 million for the SHIN-NY.

Meaning of “organizations covered by 42 USC 17938”

Federal regulations implementing the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 are in 45 CFR Parts 160 and 164, and HITECH made a number of amendments to those federal regulations. One such amendment is a section of HITECH codified in 42 USC § 17938 (“Business associate contracts required for certain entities”). Under 42 USC § 17938: “Each organization, with respect to a [HIPAA-]covered entity, that provides data transmission of protected health information to such entity (or its business associate) and that requires access on a routine basis to such protected health information, such as a Health Information Exchange Organization, Regional Health Information Organization, E-prescribing Gateway, or each vendor that contracts with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section 164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this title [enacted Feb. 17, 2009].”

Prior to the enactment of HITECH, on December 15, 2008, ONC had already published a guidance document called “The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment.” That guidance made clear the federal government’s view that under HIPAA, RHIO participants may disclose health information to RHIOs without any authorization from patients provided that the RHIOs enter into appropriate “business associate” agreements with the RHIO participants.

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/>;

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/introduction.pdf>; 45

CFR § 164.502(e). 42 USC § 17938 codified this guidance into law.

In 2010, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) likewise issued guidance (which was supplemented on December 8, 2011) explaining that under 42 CFR Part 2, RHIO participants may disclose alcohol and substance abuse patient records to RHIOs without patient consent provided that the RHIOs enter into appropriate Qualified Service Organization agreements with the RHIO participants.

<http://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>; December 8, 2011, FAQs (available upon request); 2 CFR § 2.12(c)(4).

This regulation implements federal policies, including the federal policies effected by the HITECH provisions of ARRA to enable widespread interoperability among disparate health information systems, while protecting patient privacy and ensuring data security. These regulations include the requirements for organizations such as RHIOs, which under 42 USC § 17938 make it possible, without patient authorization, to exchange patient information among disparate health care providers so long as those organizations comply with federal

requirements for business associates and qualified service organizations.

Public Health Law Sections 201, 206(1), 2800, 2803, 2816, 3600, 3612, 4000, 4010, 4400, 4403, 4700 and 4712 authorize the Commissioner to make such rules and regulations as may be necessary to effectuate the provisions and purposes of Public Health Law Articles 28, 36, 40, 44 and 47 and provide additional authority for the Commissioner to create and make use of the SHIN-NY.

Legislative Objectives:

This regulation will establish formal requirements for operation of the SHIN-NY in order to advance health information technology adoption and use statewide for the public good. The Department would regulate people and entities in New York that exchange health information using the SHIN-NY, including Regional Health Information Organizations (RHIOs) and other such health IT entities.

Needs and Benefits:

This regulation facilitates the operation of a statewide interoperable health information infrastructure that will provide clinicians and consumers with access to health information in a timely, secure, efficient, and effective way.

Benefits of consistent policy implementation:

As the use of health information technology expands, the regulation will formalize a common policy framework across the entire health care system to maximize the use and benefits of the SHIN-NY. The SHIN-NY enables delivery of appropriate care at the appropriate time in a coordinated, patient-centered manner. RHIOs and QEs facilitate access to the SHIN-NY through participation agreements and technical services to connect health care providers to the network. A certification process has been established by the State Department of Health for QE designation. In order to qualify to become a QE, a set of minimum criteria must be met. Consistent implementation of statewide policies through the regulatory process leads to a common approach to education and training of providers and consumers and can lead to reduction in costs and creation of efficiencies across the state. The regulation will further promote adoption, usage and sustainability of health information exchange organizations and the SHIN-NY by:

- Increasing patient record availability on a statewide basis
- Establishing the core set of HIE services that provide clinical and administrative value to the healthcare system
- Reducing barriers for EHR integration with HIE services
- Increasing participation of all stakeholders including payers
- Creating opportunities for emerging health care payment, delivery and access reforms through new models of care such as health homes, patient centered medical homes and Accountable Care Organizations, among others.

In addition, HITECH established a program for incentive payments to Medicaid providers

who demonstrate “meaningful use” of certified EHR technology with the ultimate goal of promoting health care quality and care coordination through state health information exchange (HIE) activities. Providers that achieve NCQA Patient Centered Medical Home designation qualify for meaningful use incentive payments. This regulation will expand access to and use of the SHIN-NY to additional segments of the broader health care system (e.g., mental health, alcohol and substance abuse and social services agencies) to improve health, improve health care and reduce costs. The Department of Health needs clear regulatory authority to apply these policies more broadly.

State and Local Cost:

To date, the development of the SHIN-NY and expansion of EHR adoption has been funded through a combination of federal and state funds distributed through grant programs, as well as private contributions from participating health plans, providers and other stakeholders. Currently, over 170 hospitals and over 8200 primary care providers qualify for “meaningful use” incentives under Medicaid and Medicare. In addition, through HEAL NY funding, it is expected that over 7800 primary and specialty care providers were supported to have adopted EHRs and be connected to the SHIN-NY by the end of 2013. Over 80% of hospitals and over 75% of Federally Qualified Health Centers (FQHCs) in New York State participate in RHIOs.

Investment in the operation of the SHIN-NY will generate a substantial return through the elimination of wasted expenditures and promoting better quality health care at a lower cost. Three studies conducted in Rochester by the Health Information Technology Evaluation Collaborative (HITEC), an academic research consortium under contract with the State Department of Health to perform evaluation activities for the HEAL NY Program, identified improved quality and reduction in duplicative testing and in readmission rates for a two year study period for events in 2009-2010. Use of the Rochester RHIO by five Emergency Departments (EDs) resulted in 6 averted admissions per 100 patients who came to the ED, resulting in \$9 million projected savings annually across the adult community. Extrapolating the cost savings across the state would result in an annual savings of \$52 million. During the same study period, image exchange use through the Rochester RHIO within 90 days following an initial imaging procedure reduced the probability of repeat imaging by 35%. Finally, use of the Rochester RHIO after hospital discharge resulted in a 55% reduction in readmission within 30 days. These highly significant findings with important financial implications further demonstrate the value of the SHIN-NY.

An 18-month study in the Buffalo region looked at the number of multiple CT scans ordered for the same body part, for the same patient, over a six-month period. During the period, 2,763 CT scans were deemed to be potentially unnecessary, duplicative tests. 90% of the potentially duplicative tests were ordered by physicians who never or infrequently access the local health information exchange. By local calculations, that amounts to a potential additional cost of \$1.3 million over a six-month period for one test in one region of the state. Across the country, states have used similar studies to project the value of statewide HIE. Based on estimates of 85% provider and patient participation in its statewide HIE, Rhode

Island forecasted an annual savings of \$95 per person. Boston Consulting Group. *Rhode Island Quality Institute Business case for Health Information Exchange*. December 5, 2009. In a similar study of fully operational statewide HIE in Maine that factored in the total operational costs, researchers projected significant, but more modest net savings of \$35 per person per year. Center for Health Policy and Research. *The Impact of Electronic Health Information Exchange (HIE) Services in Maine: Avoidable Service and Productivity Savings Estimates Related to HealthInfoNet Services*. November 2008.

In addition to savings associated with reduction in unnecessary and duplicative testing, readmissions, and adverse drug events, participation in the SHIN-NY will also generate savings by minimizing the number of interfaces health care organizations need to access data. Currently, physician practices, hospitals, laboratories, public health agencies, and others must create and maintain costly and complex interfaces with every organization they wish to exchange data. In this point-to-point data exchange environment, a typical hospital with 10 interfaces can spend as much as \$200,000 in one-time development fees, and \$40,000 per year in maintenance fees. Delaware Health Information Network. *Final Report: Delaware Health Information Network Evaluation Analysis*. August 2011. The SHIN-NY and its QEs, serving as utilities and consolidating services and interfaces, have been and will continue to reduce the per unit connectivity cost for all participants.

The proposed regulation will require that health care facilities defined in PHL Section 18 that utilize certified EHRs, connect to the SHIN-NY through a QE and allow private and secure bi-directional access to patient information by other QE participants authorized by law to access such patient information.

Costs for facilities operated by State and local governments will be equivalent to costs for other regulated facilities.

Costs to Regulated Entities:

The proposed regulation will require that health care facilities defined in PHL Section 18 that utilize certified EHRs, including urgent care centers, connect to the SHIN-NY through a QE and allow private and secure bi-directional access to patient information by other QE participants authorized by law to access such patient information.

Average interface costs for hospitals are \$75,000 while interface costs for physician practices vary but generally average \$5000 – \$10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Some RHIOs have established this functionality for their participants, thereby reducing associated interface costs for their participants, which include physician practices. In some regions of the State, health plans have absorbed the interface costs for their network providers because they see the value of having their physicians connected to the SHIN-NY. Only health care providers using certified EHR technology need to comply with these requirements. Currently, adoption of certified EHR technology for health care facilities outside of hospitals and FQHCs is low because they are not eligible to receive meaningful use incentive payments.

This requirement, to connect a certified EHR to the SHIN-NY, may be waived for health care

facilities that meet criteria established by the commissioner, such as economic hardship, technological limitations that are not reasonably in the control of the provider or other exceptional circumstances demonstrated by the provider to the department.

The Department will develop a fair process for health care providers to demonstrate that they meet waiver criteria and for the Department to give such providers a waiver or extension of time to connect to the SHIN-NY.

The regulation is being put forth as a “public good” model. That is, a certain set of baseline services, both technical and administrative, will be made available to all providers within New York State, at no charge. The basic technical services will include: patient record look-up; provider and public health clinical viewer; secure messaging; consent management; notifications and alerts; identity management and security; public health reporting integration; and results delivery.

Local Government Mandates:

Health facilities operated by local governments will be required to comply with these regulations in the same manner as other facilities. Should local health departments need to make expenditures to comply with the regulatory requirements, they have opportunities to request funding through the Public Health Law Article 6 Local Assistance Grant Program, and possibly other sources.

Only health care providers using certified EHR technology need to comply with these requirements. This requirement, to connect a certified EHR to the SHIN-NY, may be waived for health care facilities that meet certain criteria, such as economic hardship, technological limitations that are not reasonably in the control of the provider or other exceptional circumstances demonstrated by the provider to the department.

Paperwork:

Entities that wish to become QEs will need to submit an application for review by DOH to determine if the criteria outlined in the regulation have been met as well as meeting other criteria as may be required under the QE certification process.

Any entity seeking certification as a QE, regardless the entity’s organizational structure, origin or type, will be subject to the full certification process. This certification process incorporates criteria that fall into four broad categories including: organizational characteristics; operational requirements; policies and procedures; and technical requirements. QEs would be subject to recertification and would also be subject to ongoing monitoring and enforcement activities between full certifications. This will ensure that patient information is made available to all providers participating in a patient’s care in a secure and confidential manner.

Duplication:

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

Alternatives:

The Department used the statewide collaborative process to solicit comments from a variety

of stakeholders to develop recommendations on regulations and its policy guidance. A series of summits and input opportunities were incorporated into the development process. In January of 2013 a summit of stakeholders, which included RHIO Executive Directors, Members of RHIO Board of Directors, the Board of Directors of the New York eHealth Collaborative, representatives for NYS DOH, NYC DOHMH and other stakeholders was conducted. The goal of the session was to establish the roles and responsibilities of Qualified Entities. Subsequent to the summit, a series of workgroups were launched to further define requirements and responsibilities.

While other states have different models for health information exchange, and NY considered the approaches and models used in other states through its statewide collaborative process, based on the size, complexity and diversity of New York and the resources that were available, the State Department of Health determined that the current model was the best approach. The State Department of Health has convened and considered the recommendations of the workgroup established by Public Health Law § 206(18-a)(b), including the workgroup's interim report under § 206(18-a)(b)(iii). To date, the State Department of Health has acted in a manner that is consistent with the recommendations of the workgroup; however, in the event that the Department acts in a manner inconsistent with the recommendations of the workgroup, it shall provide the reasons therefor, as required by § 206(18-a)(d).

Federal Standards:

This rule aligns with current federal laws and regulations governing the adoption of interoperable exchange of health information and meaningful use requirements under the HITECH provisions of ARRA including the Electronic Health Record Incentive program. This rule also aligns with the SAMHSA federal standards regarding the exchange of certain alcohol and drug abuse patient records under 42 CFR Part 2.

Compliance Schedule:

Two years from the effective date of this regulation (or one year for general hospitals), health care facilities utilizing certified electronic health record technology under HITECH must become qualified entity participants in order to connect to the SHIN-NY through a qualified entity. Since RHIOs or QEs are largely operational in NYS and the majority of hospitals and federally qualified health centers are already participants, and the number of physician practices participating continues to grow and the infrastructure for the SHIN-NY is already in development, the estimated time period needed for regulated persons or entities to achieve compliance with the rule is two years (one year for general hospitals) from the time the rule becomes effective. Two years from the time the rule becomes effective (one year for general hospitals), health care facilities utilizing certified health record technology under HITECH must allow private and secure bi-directional access to patient information by other QE Participants authorized by law to access such patient information.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

The proposed rule will not have a substantial adverse impact on small businesses or local governments. Small businesses such as physician practices, that are not regulated by the Department, that adopt certified electronic record technology in order to qualify for meaningful use incentives, would not be required to exchange patient health information among disparate providers to facilitate care coordination and appropriate follow up. Although this exchange is encouraged, it is strictly optional for these practitioners in private practice. Local health departments that operate health facilities including Article 28 facilities, including outpatient departments of hospitals, diagnostic and treatment centers, free-standing ambulatory surgery centers and nursing homes, as well as home care services agencies, hospices and health maintenance organizations would be required to connect to the SHIN-NY would be impacted by the regulation if those facilities use certified electronic health record technology. Average interface costs for hospitals are \$75,000 while interface costs for physician practices vary but generally average \$5000 – \$10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Costs of connecting the SHIN-NY could be offset by funds from the meaningful use incentive program. A connection to the SHIN-NY satisfies one requirement of the meaningful use incentive program and will allow providers at these facilities to access Medicaid or Medicare Meaningful Use incentive payments. The meaningful use incentive program allows all individual eligible professionals who meet meaningful use requirements to apply for incentive payments of up to \$43,720 over a five year period. The Department of Health, with the New York eHealth Collaborative, has implemented an additional incentive program, with support from the Centers for Medicare and Medicaid Services (CMS), to allow meaningful use providers to receive an additional incentive payment of up to \$30,000 to help defray the cost of connecting to the SHIN-NY. It is anticipated that the incentive program will continue with additional funding from CMS. Additionally, any facility that is required to connect to the SHIN-NY under this regulation may request that this requirement be waived for its facilities based on economic or technical constraints. Accessing the SHIN-NY to perform required local health department surveillance and case

investigation activities has actually been documented to result in increased efficiency and decreased costs for the local health department. Through the statewide collaboration process, local governments have the opportunity to participate in SHIN-NY policy development including providing input on draft regulations. The SHIN-NY policy committee includes representatives from the local public health agencies.

Ensuring that clinical data are available in safe, secure way supports the goals of increasing the quality of care, increasing population health and reducing healthcare costs. Hospitals that connect to the SHIN-NY have been show to decrease the number of tests and imaging studies thus reducing costs.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

The proposed rule will not have a direct adverse impact on rural areas. Operation of the SHIN-NY and expanded use of certified EHR technology should improve health care, increase efficiency, reduce duplicative testing and reduce overall costs for underserved populations in the state, including rural areas.

JOB IMPACT STATEMENT

The proposed rule should not have any adverse impact on jobs and employment opportunities, but may increase the number of health IT jobs available in the state. The development and operation of the SHIN-NY will most likely result in opportunities for the development of new applications of health IT tools and services and may result in new health IT jobs in New York State. It has been estimated that the SHIN-NY, and related initiatives that use the data from the SHIN-NY has the potential to create 1,500 health technology jobs across New York State over the next five years.