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IT Update:
The Statewide Health Information
Network for New York, RHIOs, QEs,
and Providers

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Background of Health Information Exchange

- The development of community-based regional health information exchange (“HIE”)
 - Improve health care / control costs
 - Regional Health Information Organizations (“RHIOs”) and Health Information Organizations (“HIOs”)
 - RHIO stakeholders, RHIO participants, authorized users

Background of Health Information Exchange

- Patient consent threshold:
 - New York regulatory authorities' interpretation of existing New York law has been that providers are not required to obtain patient consent to upload patient information to a RHIO, as long as the RHIO does not make the information accessible without patient consent (or accessible pursuant to an exception)

The New SHIN-NY Regulations

- Public Health Law § 206(18-a)(d) – gives NYS DOH authority to promulgate regulations that govern the SHIN-NY
- NYS DOH published regulations relating to the SHIN-NY in September 2014 (Part 300 to Title 10 NYCRR)
 - Comment period expired on October 20, 2014

Overview of the SHIN-NY

- The development of a statewide health information exchange – The Statewide Health Information Network for New York (“SHIN-NY”)
 - New York eHealth Collaborative (“NYeC”), NYS DOH
 - Standardization of health information exchange in New York State through stakeholder collaboration; development of policies, standards, protocols and operational guidance for health information exchange through the SHIN-NY

Overview of the Content of the SHIN-NY Regulations

The SHIN-NY regulations:

- 1) Establish structure for the SHIN-NY
- 2) Codify rules regarding patient consent
- 3) Set forth patient rights
- 4) Incorporate “SHIN-NY Policy Standards” (formerly known as “Statewide Policy Guidance”)

Content of SHIN-NY Regulations

Establish Structure for the SHIN-NY

- The NYS DOH will continue to partner with a State Designated Entity (i.e. NYeC), whose functions are set out in the regulations
- State Designated Entity will:
 - Oversee the implementation and ongoing operation of the SHIN-NY
 - Administer the statewide collaboration process
 - Develop and implement the process by which organizations (RHIOs) become certified and re-certified as Qualified Entities (“QEs”)

Content of SHIN-NY Regulations

Establish Structure for the SHIN-NY

- In order to participate in the SHIN-NY, RHIOs must be certified as QEs and satisfy certain requirements on an ongoing basis
- QE Certification requirements:
 - QE must have certain organizational characteristics
 - QE must have sufficient capability and infrastructure to operationalize all SHIN-NY requirements

Content of SHIN-NY Regulations

Establish Structure for the SHIN-NY

(QE Certification requirements continued...)

- QE must have privacy and security policies that comply with statewide policies regarding: patient consent, authorization and authentication of users, remedies for breaches of health information
- QE must require its QE Participants to comply with SHIN-NY policy standards
- QE will be each QE Participant's business associate

Content of SHIN-NY Regulations

Establish Structure for the SHIN-NY

- **Qualified Entity Participation Agreement (“QEPA”)** – Contract between State Designated Entity and QEs
- Regulations mandate that the contract (i.e. QEPA) contain provisions requiring QE to:
 - Act as intermediary between State Designated Entity and QE Participants
 - Build, maintain and operate a network of QE Participants seeking to exchange information
 - Adhere to minimum standards applicable to QEs (i.e. certification requirements)
 - Submit to regular audits
 - Ensure data from QE Participants is made available through the SHIN-NY
 - Participate in the statewide collaboration process
 - Provide explicit protections for patient rights
 - Enter into “QE Participation Agreements” with its QE Participants

Content of SHIN-NY Regulations

Establish Structure for the SHIN-NY

- **Participation Agreements (“PAs”)** – contracts between QEs and their QE Participants (contemplated, but not extensively covered in the regulations)
 - QEPA contractually requires QEs to have written PAs with their QE Participants
 - Mandatory PA provisions
 - Other PA provisions

Mandatory PA Provisions

(Participation Agreements continued...)

- QEPA sets forth certain mandatory content for PAs:
 - Obligation to indemnify QE for its negligent acts or omissions, subject to a cap of \$1,000,000
 - Minimum insurance requirements, as defined by QE for each QE Participant
 - Acknowledgement that data may be shared with other participants of QE as well as participants other QEs
 - Obligation to provide information and/or allow audit to the extent necessary for QE to fulfill its reporting, audit and investigation obligations under the QEPA and Statewide Policy Guidance

Other PA Provisions

(Participation Agreements continued...)

- Rights and obligations of RHIO (i.e. QE)
- Rights and obligations of Data Providers
 - Ownership of data / license to use
 - Limitations on use
- Rights and obligations of Data Recipients
 - Permitted uses
 - Prohibited uses
- Disclaimers and exclusion of warranties

Content of SHIN-NY Regulations

Codify rules regarding patient consent

- Regulations clarify that QEs may make it possible, without patient authorization, to make patient information available among disparate health care providers so long as the QEs enter into and adhere to participation agreements with their QE participants that comply with HIPAA
- Written authorization required for access to patient information made available through QEs
 - Exceptions – e.g., “Break the Glass”
 - Patient information may not be disclosed to entities becoming QE Participants subsequent to the execution of a written authorization unless and until such entities are specified in a new authorization

Content of SHIN-NY Regulations

Set forth patient rights

- Patient rights under the regulations include:
 - No entities other than the NYS DOH, State Designated Entity, QE and QE Participants shall have access to patient information through the SHIN-NY
 - Patient may determine which QE Participants may access that patient's information through the SHIN-NY
 - Patient shall have access to his/her own patient information
 - Patient shall have access to information identifying who has obtained access to his/her patient information through the SHIN-NY and under what authority the disclosure was made
 - Patient shall have the right to revoke access of any QE Participant to his/her patient information

Content of SHIN-NY Regulations

Incorporate “SHIN-NY Policy Standards” (formerly known as “Statewide Policy Guidance”)

- **Statewide Policy Standards:** The set of policies and procedures, including technical standards, that are developed through the statewide collaboration process
 - Incorporated by reference into the regulations
- Regulations require QEs, QE Participants and the State Designated Entity to comply with the current Statewide Policy Standards

SHIN-NY Policy Standards

- **“Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State” – Version 3.1 (as of June 2014)**
 - Sets forth the privacy and security-related policies governing interoperable health information exchange through the SHIN-NY
 - Aims to ensure trusted health information exchange through the SHIN-NY that will improve health care delivery and health outcomes for New Yorkers

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

- Contains provisions governing:
 - (1) **Patient consent** – Requirement to obtain affirmative consent to exchange health information via the SHIN-NY
 - Exceptions:
 - » One-to-One
 - » Public Health
 - » Breaking the Glass
 - » Converting Data
 - » Evaluating & Improving QE
 - » De-Identified Data
 - » Organ Procurement

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

(continued...)

- (2) Authorization** – sets forth requirements regarding the process of determining whether a particular individual within a QE Participant has the right to access protected health information via the SHIN-NY
- (3) Authentication** – sets forth requirements regarding the process of verifying that an individual who is authorized and is seeking to access information via the SHIN-NY is who he or she claims to be by providing proof of identity

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

(continued...)

- (4) Access** – sets forth minimum controls that QEs must implement to ensure that: (a) only Authorized Users access information via the SHIN-NY, and (b) they do so only in accordance with patient consent and with other requirements limiting access to specified information (e.g., that which is relevant to a patient’s treatment)
- (5) Patient engagement and access** – sets forth minimum requirements that QEs and QE Participants must follow to ensure that patients are able to understand what information exists about them, how the information is used, and how they can access such information

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

(continued...)

- (6) Audits** – sets forth minimum requirements that QEs must follow when logging and auditing access to Protected Health Information
 - QE access to audit information
 - Patient access to audit information
- (7) Breach** – sets forth minimum standards that QEs and QE Participants must follow in the event of a breach; designed to hold violators accountable and mitigate any harm that privacy violations may cause

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

(continued...)

- (8) HIPAA Compliance** – ensures that entities accessing Protected Health Information through a QE abide by the same applicable HIPAA requirements as Covered Entities even if they are not otherwise legally obligated to do so
- (9) Sanctions** – provides guidelines for the imposition of sanctions by QEs and QE Participants
 - Leaves flexibility to determine appropriate sanctions on a case-by-case basis

SHIN-NY Policy Standards

Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State – Version 3.1

- Other provisions:
 - Incorporates Model Consent Forms
 - Model Level 1 Consent
 - Model Level 2 Consent

SHIN-NY Policy Standards

- Other documents that comprise the SHIN-NY Policy Standards:
 - “Oversight & Enforcement Policies and Procedures for QEs”
 - “Qualified Entity (QE) Minimum Technical Requirements”
 - “Qualified Entity (QE) Member Facing Services Requirements”
 - “Qualified Entity (QE) Organizational Characteristics Requirements”

SHIN-NY Policy Standards

- QE Minimum Technical Requirements
“the essential capabilities...that each QE must be capable of providing...”
 - Patient Record Lookup
 - Secure Messaging
 - Consent Management
 - Notifications (Alerts)
 - Identity Management and Security
 - Provider & Public Health Clinical Viewer
 - Public Health Integration
 - Results Delivery

Comments, Questions & Answers

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