

The SHIN-NY and Consent

Sequoia Project Interoperability Matters Privacy &
Consent Work Group | March 1, 2024

Agenda

15 minutes

The SHIN-NY 101

Cindy/Sam

New York: State of Consent

Laws, Regs, Policies and Procedures (P&Ps)

“Opt-in” Consent Limitations

SHIN-NY Statewide Community Consent Model

Framework, Form Choices, Registry

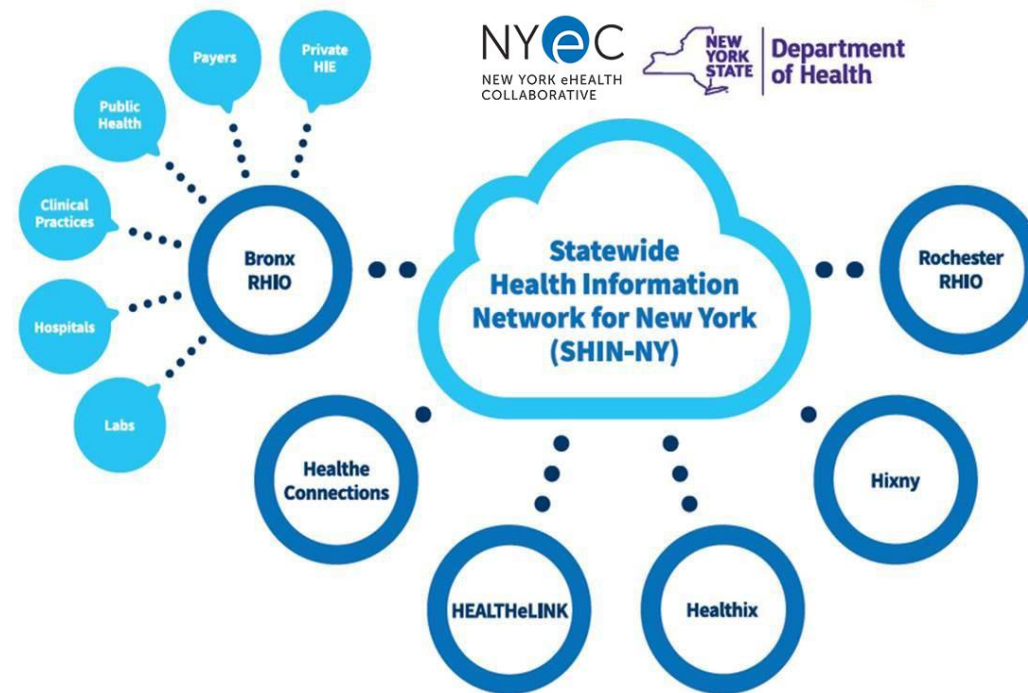
10 minutes

Q&A

SHIN-NY 101

The SHIN-NY in a Nutshell

- A secure network for sharing electronic clinical records
 - The SHIN-NY consists of regional RHIOs (also known as QEs) which are the backbone of the SHIN-NY, providing the services that make secure, vital access to a patient's health information possible statewide
- Records are accessed and exchanged securely between healthcare providers with appropriate consent
- Patients decide which entities can access or see their records



New York: State of Consent

Facts About New York Policy for Exchanging Health Records

- New York law is **stricter than HIPAA**.
- The law has generally been interpreted as requiring an “**opt-in**” (consent to access) rather than an “opt-out” consent, so even a clinician providing treatment needs a signed form before checking patient records.
- Consent exceptions are allowed in certain situations, including for public health, disaster tracking, and emergencies.

Laws and Regulations Permit Providers to Upload Data to the SHIN-NY Without Consent

- **HIPAA:** Allows disclosure of protected health information (PHI) to business associates holding PHI on behalf of the covered entity if the business associate enters into a business associate agreement and meets other HIPAA requirements.
- **42 C.F.R. Part 2** (SUD regulation): Permits providers to share patient information with qualified service organizations if they have a qualified service organization agreement (similar to a business associate agreement).
- **N.Y. PHL 18:** Restrictions on disclosure “shall not apply to disclosure to practitioners or other personnel employed by or under contract with the facility.”
- **SHIN-NY Regulation:** “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.”

...But Applicable Law Often Requires Consent for Disclosure

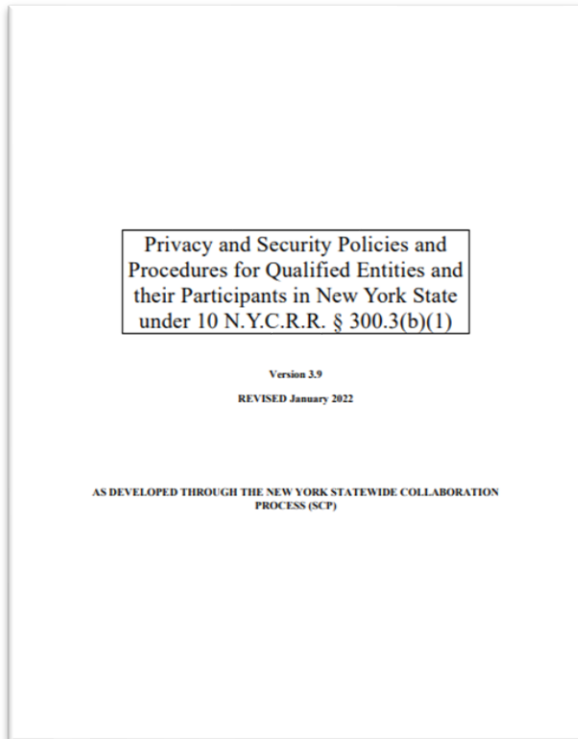
May Providers Disclose Health Information Without Patient Consent?

	General Health Information			Sensitive Health Information		
	HIPAA	NY Educ. Law	SHIN-NY Regulation	42 CFR Part 2 (SUD)	NY Mental Hygiene Law	NY HIV Law
Disclosures to covered entities for treatment, payment, or health care operations	Typically yes	DOH has interpreted law as requiring consent	Typically no	No	Typically no	Typically yes
Disclosures to CBOs	Sometimes	See above	Typically no	No	Typically no	Typically no

Key New York State Requirements on Consent

- **Education Law 6530(23):** Health professionals engage in unprofessional conduct when disclosing patient information without consent, except as authorized or required by law. State has interpreted this to mean that “health care providers need consent to disclose clinical data to third parties under the basic ethical rule of provider-patient confidentiality.”
- **Mental Hygiene Law 33.13:** Typically requires consent for disclosures, but exceptions for disclosures to (1) insurers for payment purposes, and (2) managed care plans and health homes for purposes of care coordination.
- **Public Health Law 2782** (HIV confidentiality): Permits disclosures for treatment and payment purposes without consent, but no provision allows for disclosures to CBOs or for quality improvement purposes without consent.
- **SHIN-NY Regulation (10 NYCRR Part 300):** Generally requires written authorization for disclosures, but consent exceptions include disclosures for emergency treatment, disclosures to public health agencies, and those required by law.

SHIN-NY Policies and Procedures ("SHIN-NY P&Ps")



P&Ps Sections

Consent

Authorization

Authentication

Access

Patient Education,
Engagement, and
Access

Audit

Breach

Compliance

Sanctions

Cybersecurity

Consent Levels: 1 and 2

Treatment

Quality
Improvement

Care
Management

Insurance
Coverage
Reviews

These are considered **Level 1 uses**. They are permitted from the most common form of consent.

Level 2 uses require additional consent components and include but are not limited to:

- Payment
- Research; and
- Marketing.

Consent Exceptions

One-to-One
Exchange

Public Health
Reporting and
Access

Disaster /
Emergency
Tracking

“Break the Glass”
Emergency
Disclosures

QE Operations

De-Identified Data

Organ
Procurement

Patient Care Alerts

Disclosures to
Payers for Quality
Measures

Death Notifications
/ Disclosures to
Death Investigators

Telehealth

Consent and CBOs

CBOs That Are HIPAA Covered Entities

- May receive data under the same circumstances as health care providers.
- This means that these CBOs may receive alerts without consent for individuals under their care.
- These CBOs may also receive PHI without written consent when providers make referrals to these CBOs under the "one-to-one" exchange exception.

CBOs That Are Not HIPAA Covered Entities

- Under current SHIN-NY rules, may only receive data with written consent.
- Reflects HIPAA, which has more significant restrictions on when data can be sent to non covered entities.

Limitations to NY Consent Model

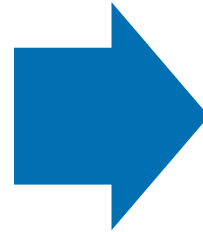
- Inability for NY HIE to participate (e.g., reciprocate) in National Networks
- Difficult to share data with organizations that do not collect consent such as CBOs, payers, etc.
- Patient Burden: patients must opt-in at every facility/ provider / point-of-care
- Provider Burden: providers must collect consent prior to accessing patient records (with some exceptions, such as emergency “break the glass” access)
- Six separate consent HIEs across the SHIN-NY

SHIN-NY Statewide Community Consent Model

SHIN-NY Consent Model Coming Change

Opt-In, Single Provider Consent to Access [current]

- Patients Consent to Access at each healthcare organization they visit
- Every provider collects consent
- Regional registries hold patient consent forms



Statewide Consent to Access [transition begins in 2024]

- Patients consent "One and Done" for all connected healthcare organizations
- Aligns with national networks so the SHIN-NY HIEs can participate
- A single statewide registry holds patient consent forms

Model Form Choices

YES

I GIVE CONSENT

- for all my current and future treating providers, my health insurer, and social service organizations providing services to me to access my health information for the purposes described on this form.

NO

EXCEPT IN AN EMERGENCY

- I DENY consent except in the case where a health care provider seeks to access my health information to treat me during a medical emergency.

NO

I DENY CONSENT

- for anyone to access my health information through the SHIN-NY.

Statewide Consent Registry

NYeC

- Service for QEs to submit consent values
- Ability for QEs to query consent value for given patient
- Service to distribute consent values to QE
- Capability to link to national networks

QEs

- Ability to query shared consent registry
- Ability to receive and use patient consent values from the single shared consent registry along with local consent
- Transmit consent values for patients to the shared consent registry

Master Opt-Out List

- (consent verification)

Questions?



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