New Jersey
Innovation Institute
An NJIT Corporation

Consent Standards and Interoperability Challenges*

An Informational Presentation to the Sequoia Project's Privacy & Consent Workgroup.

April 5, 2024

* **DISCLAIMER**: The information, views and any opinions expressed in this presentation do **NOT** represent an official view of the State of New Jersey, including the New Jersey Department of Health. The information presented here is for general informational purposes only. The information provided here does not constitute legal advice.

In 2008, the New Jersey Legislature Declared:

It is desirable to implement an electronic health information infrastructure in the context of a Statewide health information technology plan that includes standards and protocols designed to promote patient education, patient privacy, physician best practices, electronic connectivity to health care data, and generally a more efficient and less costly means of delivering quality health care in New Jersey, in order to provide for an interoperative environment among health care providers, health care payers, employers, and patients in New Jersey . . .

Phases of Consent Work: **The NJ-HITC (2008-2012)**

- New Jersey Health Information Technology Commission was established by State Legislative action as part of the New Jersey Dept. Health.
- Fourteen (14) Members met monthly over nearly four (4) years.
- Privacy & Security Committee (**2010**).
  - Chaired by Privacy Attorney, Helen Oscislawski.
  - **Representatives** from State Departments and other SMEs ***met weekly*** to discuss NJ's consent standards in the context of implementing networked HIE across the State.
  - **Special guests** who were SMEs in HIE were invited to educate the group.
  - Discussed **other consent work** (e.g., NCVHS (sensitive health information); GWU (data segmentation); ONC Privacy & Security Tiger Team Recommendations).
  - **Legal analysis was completed reviewing NJ'S consent exceptions & requirements.**
  - Report to the NJ-HITC was completed and submitted.
- "**Opt-Out**" approach approved by NJ-HITC and 2-layered HIPAA Notice of Privacy Practices + consent capture + opt-out was recommended for HIE participation.

Phases of Consent Work: **Regional HIEs (2010-20xx)**

- New Jersey receives ONC Funding to promote statewide electronic HIE under ARRA. Four (4) regional HIEs receive subgrant funds.
- **Use Case & Consent Development**
  - **Treatment & <u>Individual</u> Care Coordination**
    - ✓ General clinical information (e.g., physician practices, hospitals etc.)
    - ✓ Certain sensitive information (e.g., HIV/AIDS consent exception for Tx)
    - **X** 42 CFR Part 2; State-licensed Substance Abuse providers (i.e., Part 2); State-licensed/funded Behavioral Health providers.
  - **<u>Population</u>-based activities & Health Care Operations**
    - ✓ General clinical information (e.g., physician practices, hospitals etc.)
    - **X** HIV/AIDS
    - **X** 42 CFR Part 2; State-licensed Substance Abuse providers (i.e., Part 2); State-licensed/funded Behavioral Health providers.
  - **Other Consent-related Issues:** Public Health (not a "public health authority"); Research (IRB consensus & trust); Patient Portals (minors)

The Consent Conundrum **(*pre*-2024): Recipient Name**

Treatment, Population Health & HCO Uses & Disclosures

- **42 CFR Part 2/NJ Substance Abuse providers** and **Behavior Health (BH) providers** (which includes licensed units within hospitals & their affiliated facilities) require **specific consent** to disclose and use information originating from such sources for *even treatment*.
- **HIV/AIDS Information** has an exception for treatment, but not for population health and HCO-type activities, which requires a **specific consent** (follows 42 CFR 2.31)
- Specific consent requiring **identifying by name** the ***receiving party*** of such information.
- **THE CONSENT CONUNDRUM:** Even if compliant consents are initially captured from individuals, when the entities participating in an HIE expands (i.e., new participants are added) a previously captured consent that did not list the new parties by name would not meet the legal standard for specific consent. As a result, these categories of information could not be shared with the *new* HIE participants, even for treatment purposes (other than HIV/AIDS), *unless* updated consents are obtained from the individuals. *This was not manageable*. Therefore, data-contributing participants from New Jersey would attempt to **"filter"** out this ***type of data* by source**, if possible. However, this **is not always technologically possible** to achieve depending on: (1) the EHR and health IT used by the particular data source/participant and/or the HIE, and (2) if the data can be segmented by source (e.g., a BH unit) or otherwise can be identified by CPT code or discrete field for filtering.

The Consent Conundrum **(2024+): Recipient Name**

Treatment, Population Health & HCO Uses & Disclosures

- **42 CFR Part 2** and **NJ licensed Substance Abuse Providers:** Because of recent amendments to 42 CFR Part 2, in New Jersey Part 2 and licensed Substance Abuse Providers will no longer be required to identify the receiving party by name on a consent. **HOWEVER,** the new required **"redisclosure notice"** is going to present a new challenges with tagging in EHR systems until the technology supports it. Until notice tagging requirements can be met, the new more general recipient name standard cannot be used. *Would be interested in the group's thoughts on this.*

- **HIV/AIDS Information:** Since New Jersey's HIV law cites 42 CFR 2.31 for its consent standard, the requirements for this type of information also changed when Part 2 changed. So, the recipient name no longer has to be listed on consents for HIV/AIDS info. Notably, the New Jersey HIV law does not incorporate the redisclosure "notice" requirement from Part 2, and so avoids this issue.

- **Behavior Health (BH) Providers:** This currently remains unchanged in New Jersey. Consents that are captured would need to identify the recipient by name and so the challenge discussed on the previous slide remains. Data from sources that handle NJ-licensed BH Provider information would need to ***continue filtering this data out*** if participating in HIE activities as there would be no effective way to meet this consent standard on an ongoing basis going forward as recipients of such data through an HIE change.

The Consent Conundrum: **Expanding Use Cases**

- **42 CFR Part 2/NJ Substance Abuse Providers, BH Providers** and **HIV/AIDS information** all require that the consent **"describe <u>each</u> purpose"** of the use and disclosure of this type of information.
- Certainly, it would be in a data source's best interest to capture a consent that is worded as broadly as possible (e.g., "all purposes as described in the HIPAA NPP"). However, often **consent has already been captured** and data has been shared with an HIE based on limited use case (e.g., Treatment).
- **THE CONSENT CONUNDRUM:** This presents another consent conundrum because if the HIE decides to expand the uses of PHI that has been contributed to them in their HIPAA BAA capacity and can only be shared for treatment or other limited purposes as initially agreed and consented to, then use case purposes cannot be expanded beyond that unless consent is recaptured for the new expanded use case (which is often not manageable) **<u>OR</u>** there is an exception to consent that can be applied (e.g., NJ HIV/AIDS has an "anonymized" data and IRB approval exception for research). Otherwise, if consent cannot be recaptured and there is no applicable exception, then the data source and/or the HIE that is "storing" a data source's PHI on their behalf as a HIPAA BAA **would need to segment and filter these categories of information from being used and disclosed for such expanded other Use Cases.**

Data Segmentation

- For certain categories of data (i.e. data originating from New Jersey **licensed Behavioral Health Providers** (including facilities, units and programs)) which still requires ***recipients*** of such data to be **named specifically** in the consent form, consent management might not be enough of a solution. One question is whether the HL7 and FHIR consent management solutions being developed would efficiently and effectively allow names of new HIE recipients to be added to a consent form and presented to individuals for resigning? At scale (e.g., in the TEFCA environment) this does not seem possible.

- Discussion about **"data segmentation"** is needed:

    1. If an EHR can support segmenting off subsets of records from a health care system's Behavioral Health unit or affiliated BH facility, this is an option for New Jersey. However, **not all EHR vendors can support this technologically.**

    2. There are major EHR vendors that take a "one record" approach as their baseline. Thus, while they can *technically* support such segmentation, the **choose not to support it** as a favored position and often advocate against it.

    3. If final changes to the HIPAA Privacy Rule will incorporate treating **"reproductive health data" (RHD)** differently from other PHI, then the "tagging" and "segmentation" of such data within the larger EHR data set will likely face challenges like we saw with Part 2 and HIV/AIDS in New Jersey. Specifically, RHD would have to be identified by CPT code or some other identifier in order to be "sequestered" from sharing AND if it is not contained in a discrete data field (e.g., pdf document) it can get missed up and slips through.

Select Federal and New Jersey Consent Requirements

CONSENT ELEMENT ↓	42 CFR Part 2	HIV/AIDS (NJ) (follows 42 CFR §2.31)	HIPAA	Community Mental Health Services Act (NJ)	Part 2 & HIV/AIDS (NJ) (Intermediaries)	Venereal Diseases (NJ) Tuberculosis (NJ) Genetic Information (NJ) Most Licensed Professionals (NJ)
Name of Person	Identify name of patient	Identify name of patient	Identify name of patient	Identify name of patient	Identify name of patient	*Can Follow HIPAA*
Description of the Information to be disclosed and/or used	A description of the information to be used or disclosed that identifies the information in a "*specific* and *meaningful* fashion"	A description of the information to be used or disclosed that identifies the information in a "*specific* and *meaningful* fashion"	The information must be described in a "*specific* and *meaningful* fashion"	*Silent. Can Follow HIPAA.*	A description of the information to be used or disclosed that identifies the information in a "*specific* and *meaningful* fashion"	*Can Follow HIPAA*
Purpose of the disclosure and/or use of the Info	Must describe ***each purpose***. The statement "at the request of the patient" is a sufficient description of the purpose when a patient initiates the consent and does not, or elects not to, provide a statement of the purpose. The statement, "for treatment, payment, and health care operations" is a sufficient description of the purpose when a patient provides consent once for all such future uses or disclosures for those purposes. ***NOTE!*** *Part 2* ***REQUIRES*** *signed consent even for* ***Treatment*** *disclosures.* ***HOWEVER,*** for a single consent for all future uses and disclosures for treatment, payment, and health care operations, the Recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.	Must describe ***each purpose***. The statement "at the request of the patient" is a sufficient description of the purpose when a patient initiates the consent and does not, or elects not to, provide a statement of the purpose. ***NOTE!*** *HIV/AIDS Law does* ***NOT*** *require signed consent for* ***Treatment*** *disclosures nor contain the same Part 2 requirement of obtaining consent once for future treatment, payment and health care operations.*	Must describe ***each purpose***.	Describe the ***purpose*** and "predictable outcome"	Must describe ***each purpose***. ***NOTE!*** *Part 2* ***REQUIRES*** *signed consent even for* ***Treatment*** *disclosures.* ***HOWEVER,*** for a single consent for all future uses and disclosures for treatment, payment, and health care operations, the Recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.	*Can Follow HIPAA*
Person/Entity **Disclosing**	Specific Name of person(s) OR class of person(s) authorized to make the requested use or disclosure	Specific Name of person(s) OR class of person(s) authorized to make the requested use or disclosure	Identifies the specific person OR ***class of persons*** making disclosure	***Name*** or Title of the Person or ***Entity*** making disclosure	Specific Name of person(s) OR class of person(s) authorized to make the requested use or disclosure	*Can Follow HIPAA*

CONSENT ELEMENT ↓	42 CFR Part 2	HIV/AIDS (NJ) (follows 42 CFR §2.31)	HIPAA	Community Mental Health Services Act (NJ)	Part 2 & HIV/AIDS (NJ) (Intermediaries)	Venereal Diseases (NJ) Tuberculosis (NJ) Genetic Information (NJ) Most Licensed Professionals (NJ)
Person/Entity **Receiving**	The name(s) of the person(s), or class of persons, to which a disclosure is to be made ("recipient(s)"). For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the Recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.	The name(s) of the person(s), or class of persons, to which a disclosure is to be made ("recipient(s)"). For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the Recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.	Identifies the specific person OR ***class of persons*** to whom a disclosure is to be made	Name or Title of the ***Person*** or ***Organization*** to whom a disclosure is to be made	Specific Name of "intermediary(ies) + Name of member participants of the intermediary(ies) **OR** A general designation of a participant(s) or class of participants, which must be limited to a participant(s) who has **a treating provider relationship** with the patient whose information is being used or disclosed. **INTERMEDIARY MUST** provide **List of Disclosures** upon request (see below).	*Can Follow HIPAA*
Redisclosure Notice	Must contain a **specific Notice to Recipient**. Two options: Long Form or **Short Form** (new). "42 CFR Part 2 prohibits unauthorized use or disclosure of these records." **NOTE**: If Part 2 Info is disclosed/ accessed electronically through HIE/EMR and without the signed consent attached, then the **Notice to Recipient MUST be provided to the Recipient electronically through the HIE/EMR.**	**No notice requirement for HIV/AIDS Law.** Although HIV/AIDS Law requires the form of consent set forth at 42 CFR Part 2.31, the notice requirement is set forth at 42 CFR Part 2.32 and is not required by the HIV/AIDS Law.	Must contain statement in the Consent that the information disclosed may be subject to redisclosure by the recipient and NOT protected by HIPAA	Must contain a **specific Notice to Recipient** of Mental Health Records: **"Disclosure without the authorization of the person who is the subject of the records, or as otherwise provided by law, is prohibited."**	**For Part 2 Only:** Must contain a **specific Notice to Recipient**. Two options: Long Form or **Short Form** (new). "42 CFR Part 2 prohibits unauthorized use or disclosure of these records." **NOTE**: If Part 2 Info is disclosed/ accessed electronically through HIE/EMR and without the signed consent attached, then the **Notice to Recipient MUST be provided to the Recipient electronically through the HIE/EMR.** **No notice requirement for HIV/AIDS Law.**	For **Genetic Information:** Consent should contain a statement that the Consent serves as notice of receipt of the test results or records, results or findings of genetic testing by the intended recipients. *For all others, can Follow HIPAA*

Phases of Consent Work: **NJHIN (2014…)**

- **New Jersey Health Information Network (NJHIN)** launched in 2014.
- State-wide interoperability working with all hospitals, long-term, post acute, assisted living, substance use providers, etc.
- Funded by the New Jersey Department of Health (NJDOH) and New Jersey Department of Human Services (NJDHS).
- The only NJ network authorized to connect to public health registries.
- NJHIN Core Use Cases
  - Event notifications – ADT/CCDA
  - Master Person Index (MPI)

Phases of Consent Work: **NJII (2015 . . .)**

- **New Jersey Innovation Institute (NJII)** is the State Designated Entity (SDE) partnered with NJDOH to advance interoperable HIT services to support NJHIN.
- Trusted Data Sharing Organizations (TDSOs) sign a DURSA.
- Use Case Development
- Consent Pilots
- Electronic Consent Management (njii.com)

Electronic Case Reporting (eCR)

Electronic Consent Management Registry (eConsent)

Birth/Fetal Death Registry (BFD)

Emergency Medical Services Registry (EMS)

Consumer Access

Electronic Practitioner Orders for Life-Sustaining Treatment (emPOLST)

Perinatal Risk Assessment (PRA)

Active Care Relationship Service (ACRS)

Consolidated Clinical Data Architecture (CCDA)

Admission, Discharge, Transfer Notifications (ADT)

Master Person Index (MPI)

NJHIN

Use Case Exhibit (UCE)

A **Use Case Exhibit (UCE)** is a data sharing scenario with a specific purpose, type of data exchange, and description of interactions between people and systems.

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Thank You

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