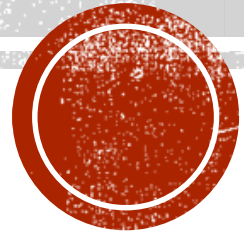
LAYING THE GROUNDWORK FOR ELECTRONIC CONSENTS TO RELEASE INFORMATION:



Progress towards national standards and technology solutions

OUTLINE

- Welcome
- Consent, Consent Directive
- National Standards
- Information Sharing and Interoperability
- Technology solutions

CONSENT

- Consent Definition:

in law, Consent is voluntary agreement with an action proposed by another.

- *Consent is an act of reason; the person giving consent must be of sufficient mental capacity and be in possession of all essential information in order to give valid consent.*
- *A person who is an infant, is mentally incompetent, or is under the influence of drugs is incapable of giving consent.*
- *Consent must also be free of coercion or fraud.*

SIGNED CONSENTS - PAPER TO DIGITAL

Issue for Signed Consents

- Wet signatures
  - Interoperability of wet signatures
- Electronic signatures
  - SAMHSA finalized its proposal to permit electronic signatures (to the extent that they are not prohibit by any applicable law).
- Digital Signatures

CONSENT – COMPREHENSION

Issue in Understanding Consent

- Readability
- Patient comprehension
  - Language, multi-cultural
  - Readability, level of education

CONSENT

- Federal Confidentiality Requirements section §2.22

SAMHSA finalized its proposal to clarify that the written summary of federal law and regulations may be provided to patients in either paper or electronic format. And to require the statement regarding the reporting of violations to include contact information for the appropriate authorities.

SECURITY FOR RECORDS (§2.16)

- SAMHSA finalized its proposals to
  - Address both paper and electronic records
  - Clarify that both part 2 programs and other lawful holders of patient identifying information must have in place formal policies and procedures for the security of records including sanitizing media associated with both paper and electronic media.

SECURITY FOR RECORDS (§2.16) CONT.

- Must reasonably protect again unauthorized uses and disclosures of patient identifying information and protect against reasonably anticipated threats or hazards to the security of patient identifying information
- Replace relevant language in other sections with reference to the policies and procedures requirement in §2.16

→SAMHSA may provide sub-regulatory guidance on this provision

CONSENT REQUIREMENTS (§2.31)

SAMHSA finalized its proposal to Allow, in certain circumstances, a patient to include a general designation in the "To Whom" section of the consent form

- Distinction between those with and without a treating provider relationship with the patient

- Require an explicit description of the "Amount and Kind" of substance use disorder treatment information
- SAMHSA did not finalize in the "From Whom" section of the consent form, but did make minor updates to the terminology.
- The final "From Whom" provision of the consent form requirement specifies that a written consent to a disclosure of patient identifying information must include the specific names or general designations of the part 2 programs, entities or individuals permitted to make the disclosure

CONSENT REQUIREMENTS (§2.31), CONT.

In the NPRM, SAMHSA proposed to require that the consent form to require two new statements that the patient understands the terms of their consent, which was *not finalized.*

- When using a general designation in the "To Whom" section, patients have the right to obtain, upon request, a list of entities to whom their information has been disclosed pursuant to the general designation. *Finalized*
  - This change eliminates the requirement that the patient execute a new consent for each treating provider in the HIE

CONSENT REQUIREMENTS (§2.31), CONT.

Required elements for written paper or electronic consent must include

(1) The name of the patient.

(2) The specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.

(3) How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.

Explicit Description of SUD Information to be Disclosed

INFORMATION SHARING & INTEROPERABILITY

- Issue
  - What is the most recent/latest consent from a patient?
  - Does the most recent/latest consent override other consents for Specific Data / Specific Purpose?

INFORMATION SHARING & INTEROPERABILITY

- Issue
  - Cross-Validation and verification of conflicting consents
  - Where can one find various consents issued by a consumer ?

NATIONAL STANDARDS

- **National standards and technology solutions – Interoperability**

HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1

- Creates constraints to standards for Meaningful Use consistent with federal and state privacy policies
- Enables the exchange of protected/sensitive personal health information
- Supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements

NATIONAL STANDARDS

- **National standards and technology solutions – exchanging signed Consents**

HL7 CDA® R2 Implementation Guide: Privacy Consent Directives, Release 1

…a structured document specification to exchange signed Consent Directives.
…makes use of the concepts identified in the Composite Privacy Consent Directive - Domain Analysis Model - and the CDA R2 specification.
…intended to provide a computable representation of a consent directive but the resulting structured documents could be used to generate enforceable assertions or rules (e.g. SAML, XACML).
This project is intended to support the management of consent directives and policies. CDA R2 supports the multiple representations of a Consent Directive as a narrative, signed document (wet signature), and computable statements/entries using standard-based terminology.

NATIONAL STANDARDS

- **National standards and technology solutions – Comprehension**

HL7 CDA® R2 Implementation Guide: Patient-Friendly Language for Consumer User Interfaces, Release 1 Natural Language`

Creates constraints to standards for Meaningful Use consistent with federal and state privacy policies

Enables the exchange of protected/sensitive personal health information

Supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements

NATIONAL STANDARDS

- **National standards and technology solutions – Secure Interoperability Exchange of protected health information**

HL7 Healthcare Privacy and Security Classification System (HCS), Release 1

… suitable for automated labeling and segmentation of protected health care information by access control systems to enforce privacy and security policies

NATIONAL STANDARDS

- **National standards and technology solutions– Implementation and Interoperability**

HL7 Fast Healthcare Interoperability Resources Specification (FHIR®), Release 1
A next generation framework created by HL7, utilizing features of HL7's Version 2, Version 3 and CDA® product lines while leveraging the latest web standards.
Using modular components called "Resources" which can be assembled into systems that solve real world clinical and administrative problems.
FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, etc.

OPT-IN/OPT-OUT PROOF OF CONCEPT/ LEGISLATIVE RELIEF (COMING SOON)

To-Be

Share millions of records,

Eliminate paperwork bottlenecks, Reduce [government entity] burden.

As-Is

<200K shareable records

OPT-IN/OPT-OUT PROOF OF CONCEPT/ LEGISLATIVE RELIEF (COMING SOON)

A successful [government entity] proof of concept which uses Data Segmentation for Privacy (DS4P) techniques to distinguish records containing 38 U.S. Code § 7332 - Confidentiality of certain medical records (protected conditions requiring authorizations) from those that are not sensitive and do not require an authorization.

Proof of Concept offered the possibility to make millions of records shareable which today is limited to less than 200,000.

VA is simultaneously seeking legislative relief to allow sharing without Authorization for treatment purposes only.

DEMO - DATA SEGMENTATION USING HEALTHCARE PRIVACY AND SECURITY LABELS

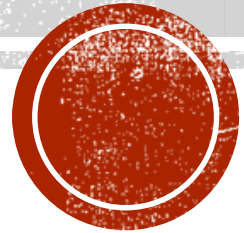
ONC has been leading efforts in privacy, patient mediated consent, and computable consent for some time. Much work is has been done in HL7 to create core standards. VHA Security and Privacy currently participates in ongoing ONC "Patient Choice" discussions

- **Technical:** In 2013 with ONC/FHA/SAMHSA/HL7 we demonstrated basic technical "*security labeling services"* (SLS),
- **Business:** In 2015 we applied "*SLS to business"* use cases with patient at the center of "Privacy on FHIR" and added privacy protective services (PPS),
- **Veteran:** In 2017 we greatly extended patient control of their information with "*SLS to Veteran"* via "Patient Mediated Exchange".

A self-running FHIR demonstration of SLS and PPS demonstrating concepts and potential for Veteran customization and control can be found at:

http://va.edmondsci.com:8080/ehtac/sof/test.html

QUESTIONS



Remind of what consent is

Informed consent

DEMO…STEP BY STEP

- Alice Recruit

- Invoke Security Labeling System, Select: PTSD
- Basic Patient Choice

1. Create &Manage
    1. MiHIN checking ok to send to VA
2. MiHIN sending to VA

- _____
- 3. Patient consented exchange:
- VA returning information to MiHIN
- checking her consent directive (at USPS) to see if ok…yes VA requires consent
- In pt right of access, bypasses pat consent

CONSENT AND DATA REDISCLOSURE

- (from SAMHSA slide deck)
- Prohibition on redisclosure
- On re-Disclosure we also made some additional minor clarifying revisions around the use of general authorizations and the restrictions on using information to criminally investigate or prosecute a patient with a substance use disorder.

Under the Medical Emergencies exception we finalized our proposal to revise the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a "bona fide medical emergency" exists. In response to comments, SAMHSA plans to issue subregulatory guidance to address this provision including examples of what constitutes a "bona fide medical emergency".