42 CFR Part 2 Consent Requirements: Creating Electronic Consents

Friday, September 15, 2:00 to 3:30 ET
Housekeeping

- Webinar is being recorded and will be posted to SAMHSA’s YouTube page
- All lines are muted—submit comments via chat
- Session will conclude with a Q&A session
Presenters

Danielle Tarino
Public Health Analyst
SAMHSA Health IT Team

Stan Peabody
Software Tester
FEi Systems
Focus of Today’s Webinar

- Background on 42 CFR Part 2
- 42 CFR Part 2 consent requirements
- SAMHSA’s Consent2Share to show examples how these requirements can be developed electronically
- Not a comprehensive training on 42 CFR Part 2
- Not comprehensive review of all Consent2Share features
The Current Health Care Environment

- Demand for coordinated patient centered care
- Increase in EHRs and Health IT
- Greater interoperability
- More electronic client data-sharing
- Compliance with confidentiality and privacy laws
- Client’s right to share or withhold
Need for Data Segmentation and Consent Management

- Elicit Client Consent
- Segment clinical data
- Comply with client choices
- Comply with 42 CFR Pt. 2
42 CFR Part 2: Overview

42 CFR Part 2 regulates the disclosure and use of patient records by a federally-assisted program that holds itself out as providing substance use disorder treatment, diagnosis, and/or referrals to treatment (as defined in the Rule).
Stigma and fear of prosecution deterred treatment

Intent: To ensure an individual’s right to privacy and confidentiality

Vanguard of personal privacy and the cornerstone of treatment programs
Protects confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research.
The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.
Programs Covered

- Programs conducted in whole or in part (directly or by contract) by any US department or agency
- Programs carried out under a license, certification, registration, or other authorization granted by any US department or agency including Medicare providers and DEA licensed entities that provide SUD treatment
- Programs supported by funds provided by any US department or agency as a recipient of federal financial assistance in any form
- Programs conducted by a state or local government unit that receives federal funds that could be spent for SUD
- Programs allowed federal income tax deductions for contributions to the program or granted federal tax exempt status by the IRS
Consent Exclusions

- Medical Emergency
- Qualified Research
- Audits and Evaluations
- Court Orders for Disclosure
- Direct Administrative Controls
- Qualified Service Organizations (QSO)
- Crime and Law Enforcement
- Child Abuse/Neglect
- Minors or Incompetent Patients
- Cause of Death
Changes Since Original 42 CFR Part 2

Law written in 1975 and updated in 1987. Since 1987:

- New models of integrated care
- Emphasis on information sharing to coordinate care
- Electronic infrastructure for information exchange and electronic health records
- Electronic devices to share data
42 CFR Part 2 Revisions and Final Rule

- Final Rule published in the Federal Register on 01/18/17
- Federal Register Revised Effective date: 03/21/2017
- Now in effect

The final rule is intended to:

- **Modernize** the Part 2 rules
- **Facilitate electronic exchange** of substance use disorder information for treatment and other health care purposes
- **Ensure appropriate confidentiality protections** for records that might identify an individual, directly or indirectly, as having a substance use disorder.
42 CFR Part 2: Consent Requirements

- Generally requires patient consent for disclosures of protected health information for the purposes of treatment, payment, or health care operations
- Consent for disclosure must be in writing
- Re-disclosures without patient written consent are prohibited, except in certain circumstances or under certain exceptions as described by Part 2
- Name of the entities making the disclosure ("From")
- Name of the entities to receive the disclosure ("To")
- Name of the patient who is the subject of the disclosure
- Specific purpose or need for the disclosure
- **How much and what type of information** to be disclosed
- The patient’s *right to revoke the consent* in writing and exceptions to the right to revoke
- The program’s *ability to condition treatment*, payment, enrollment, or eligibility of benefits on the patient
- The *date, event, or condition* on which the consent expires
- The *signature* of the patient (and/or other authorized person) (This may be signed on paper or via e-signature)
- The *date* that the consent is signed
Requirement: The “From Whom” Provider

Name of the entity making the disclosure

Must include the specific name(s) or the general designation(s) of the Part 2 program(s), entity(ies) or individual(s) permitted to make the disclosure.
Did not remove the *general designation* in the “From Whom” section of the consent form but did make terminology changes.

✓ The “From Whom” provision of the consent requirements specifies that a written consent to a disclosure of patient-identifying information *must* include the specific name(s) or general designation(s) of the Part 2 program(s), entity(s), or individual(s) permitted to make the disclosure.
Sally Uses the Authorization Page
Sally Selects the “From Whom” Provider
Requirement: The “To Whom” Provider

Name of the entities to receive the disclosure
The name(s) of the individual(s) or the name of the organization(s) to whom disclosure is to be made
**Requirement: The “To Whom” Provider**

<table>
<thead>
<tr>
<th>Individual or Entity To Whom</th>
<th>Treating Relationship</th>
<th>Primary designation</th>
<th>Required Additional Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>Yes</td>
<td>Name of individual(s) (e.g., Jane Doe, MD)</td>
<td>None</td>
</tr>
<tr>
<td>Individual</td>
<td>No</td>
<td>Name of individual(s) (e.g., John Doe)</td>
<td>None</td>
</tr>
<tr>
<td>Entity</td>
<td>Yes</td>
<td>Name of entity (e.g. Lakeview County Hospital)</td>
<td>None</td>
</tr>
<tr>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is a third-party payer as specified under § 2.31(a)(4)(iii)(A) (e.g., Medicare)</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Name of entity that is not covered by § 2.31(a)(4)(iii)(A) (e.g., HIE, or research institution)</td>
<td>At least one of the following: 1. The name(s) of an individual participant(s) (e.g., Jane Doe, MD, or John Doe) 2. The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (e.g., Lakeview County Hospital) 3. A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed</td>
</tr>
</tbody>
</table>

Notes: Patient may choose all providers with a relationship; patient may designate further to include “past”, “current,” or “future” treating providers; patient may specific one or more individuals on health care team whom they do not have a treating provider relationship.
Prohibition on Redisclosure

Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65.
Requirement: List of Entities

When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see §2.13(d)).
Revisions: General Designation

Allows, in certain circumstances, a patient to include a *general designation* in the “To Whom” section of the consent form.

- Can be used for those providers who have a treating provider relationship with the patient
- Requires an explicit description of the “amount and kind” of substance use disorder treatment information
- Patients must be informed of their right to obtain a list of entities to whom their information has been disclosed
- The intermediary is responsible for complying with the List of Disclosures requirement
- General designation is an option and not a requirement
Requirement: All My Treating Providers

If you include a General Designation, you must include options for:

✓ Current treating providers
✓ Past treating providers, and
✓ Future treating providers.
Sally Selects “To Whom” Provider
Sally Selects the “To” Provider
Requirement: The Patient Name

Name of the patient who is the subject of the disclosure

- Name of the patient
- 42 CFR does not require it, but patients’ names should be associated with a unique identifier number
- Unique identifier numbers prevent misidentification of patients
- Consent2Share assigns unique Medical Record Numbers
Sally’s Name Populates after Signin
Specific Purpose or Need for the Disclosure

- The purpose of the disclosure. In accordance with §2.13(a), the disclosure must be limited to that information which is necessary to carry out the stated purpose.
Sally Selects Purpose of the Disclosure
Sally Selects Purpose of the Disclosure

Purpose Of Use

Choose for what purposes your medical information may be used.

SHARE my medical record ONLY for the selected purposes of use.

Treatment

Share for selected purpose only

Share my information only for specified purposes of use.

Select All  Deselect All

- Treatment
- Healthcare Payment
- Healthcare Research
Requirement: Amount and Kind

Amount and Kind of Information to be Disclosed

➢ 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.
Amount and Kind  Examples

- All of my substance use disorder information
- None of my substance use disorder information
- Only my substance use disorder information specified below:
  - Medications & dosages
  - Diagnostic information (my diagnoses)
  - Lab test results
  - Allergies
  - Substance use history summaries
  - Trauma history summary
  - Employment information
  - Living situation & social supports
  - Claims/encounter data
  - Other ____________________________
Examples of Part 2 Categories

- Diagnostic Information
- Medications and Dosages
- Lab Tests
- Allergies
- Substance Use History
- Trauma History Summary
- Clinical Notes
- Discharge Summary
- Employment Information
- Living Situation and Social Supports
- Claims/encounter Data

- Examples not requirements
- The Rule calls these categories
- The Rule allows such broad categories, free text, or granular choices based on standard architecture (e.g., C-CDA) or specific document type (e.g., Summary of Care record)
- Data domains may be linked to CDA templates, FHIR resources, or HL7 V2 messages that may be allowed or redacted from exchange
Sally Selects Medical Information to Share

Medical Information

Select how you would like to share your medical information.

- SHARE my medical record WITHOUT ANY EXCEPTION of medical information categories.
- SHARE my medical record WITH EXCEPTION of specific medical information categories.

Privacy Settings

Select the medical information that you wish to share.

- Federal Categories
  - Drug use information
  - Alcohol use and Alcoholism Information

- State Categories
  - HIV/AIDS information
  - Mental health information
  - Sexuality and reproductive health information
  - Communicable disease information

[Options to select and unselect the categories]
Requirement: Consent Revocation

The Patient’s Right to Revoke and Exceptions

- A statement that the consent is subject to revocation at any time except to the extent that the Part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer.
Revocation of Consent to Share My Health Information

Consent Reference Number: KWJguzjRCS
Patient Name: Sally Share
Patient DOB: Feb 15, 1962

I have previously signed a patient consent form allowing my providers to access my electronic health records through the Consent2Share system and now want to withdraw that consent. If I sign this form as the Patient’s Legal Representative, I understand that all references in this form to “me” or “my” refer to the Patient.

By withdrawing my Consent, I understand that:
1. I Deny Consent for all Participants to access my electronic health information through Consent2Share for any purpose, EXCEPT in a medical emergency.
2. Health care provider and health insurers that I am enrolled with will no longer be able to access health information about me through Consent2Share, except in an emergency.
3. The Withdrawal of Consent will not affect the exchange of my health information while my Consent was in effect.
4. No Consent2Share participating provider will deny me medical care and my insurance eligibility will not be affected based on my Withdrawal of Consent.
5. If I wish to reinstate Consent, I may do so by signing and completing a new Patient Consent form and returning it to a participating provider or payer.
6. Revoking my Consent does not prevent my health care provider from submitting claims to my health insurer for reimbursement for services rendered to me in reliance on the Consent while it was in effect.
7. I understand that I will get a copy of this form after I sign it.

I, Sally Share, hereby accept, and understand the terms of this consent.
Requirement: Expiration

The Date, Event, or Condition on which the Consent Expires

- The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.
Sally Selects Dates

I, Sally Share, hereby authorize...

Select Providers

Medical Information
Select how you would like to share:
- SHARE my medical record with...
- SHARE my medical record ONLY with...
- Treatment...

Purpose Of Use
Choose for what purposes your records will be shared:
- SHARE my medical record with...
- SHARE my medical record ONLY with...

Consent Terms
Enter a start and end date during which your medical records will be shared.

Start Date: 07/05/2017
End Date: 07/05/2018

Consent Terms
Enter a start and end date during which your medical records will be shared.

Start Date: 06/17/2017
End Date: 06/17/2018
Sally Reviews Disclosure Statement

Consent to Share My Medical Information

Consent Reference Number: KWJguzjRCS
Patient Name: Sally Share
Patient DOB: Feb 15, 1962

AUTHORIZATION TO DISCLOSE

Authorizes:
Provider Name: Midtown Medical Clinic
NPI Number: 1122324455
Phone: 3013098849
Address: 1234 Main Street, Baltimore, MD, 21201

To disclose to:
Provider Name: Uptown Medical Clinic
NPI Number: 944032211
Phone: 2022773381
Address: 2121 Weeping Willow Avenue, Towson, MD, 21022

HEALTH INFORMATION TO BE DISCLOSED

To SHARE the following medical information:
1. Drug use information
2. HIV/AIDS information

To SHARE for the following purpose(s):
1. Treatment

CONSENT TERMS

I, Sally Share, understand that my records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR part 2, and cannot be disclosed without my written permission or as otherwise permitted by 42 CFR part 2. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that any event this consent expires automatically as follows:

Effective Date: Aug 17, 2017
Expiration Date: Aug 17, 2018

I, Sally Share, hereby accept, and understand the terms of this consent.
The Signature of the Patient

- The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under §2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.
Revision: eSignatures

The Rules now addresses both paper and electronic documentation.

- Electronic signatures (eSignatures) a permitted to the extent that they are not prohibited by any other applicable laws.
Sally Selects eSignature
Sally First Selects Attestation Box
Sally Receives Success Notification

![Success Notification Image]
Requirement: Date Signed

The Date that the Consent is Signed

- The date on which the consent is signed
Sally Confirms Consent and Date

<table>
<thead>
<tr>
<th>Authorized to share:</th>
<th>Sharing with:</th>
<th>Effective Dates:</th>
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</thead>
<tbody>
<tr>
<td>SANAGA SERVICES AND CARE LLC</td>
<td>CAPITOL DIALYSIS, LLC</td>
<td>Jun 28, 2017 - Jun 28, 2018</td>
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<tr>
<td>Consent State:</td>
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<tr>
<td>SIGNED</td>
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<tbody>
<tr>
<td>CAPITOL DIALYSIS, LLC</td>
<td>SANAGA SERVICES AND CARE LLC</td>
<td>Jun 26, 2017 - Jun 26, 2018</td>
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<tr>
<td>Consent State:</td>
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<td></td>
</tr>
<tr>
<td>SIGNED</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Consent to Share My Health Information

Consent Reference Number: ms3x6I6Y6E
Patient Name: Sally Share
Patient DOB: Feb 15, 1962

AUTHORIZATION TO DISCLOSURE

Authorizes:
Provider Name: SANAGA SERVICES AND CARE LLC
NPI Number: 1023318206
Address: 1943 BENNETT PL NE, WASHINGTON, DC, 200024113
Phone: 2024888888

To disclose to:
Provider Name: CAPITOL DIALYSIS, LLC
NPI Number: 1083722763
Address: 140 Q ST NE, SUITE 100, WASHINGTON, DC, 200022101
Phone: 2026869411

HEALTH INFORMATION TO BE DISCLOSED

To SHARE the following medical information:
Sensitivity Categories:
- Drug use information
- Alcohol use and Alcoholism Information
- HIV/AIDS information
- Communicable disease information
- Mental health information
- Sexuality and reproductive health information

To SHARE for the following purpose(s):
- Treatment

CONSENT TERMS

I, Sally Share, understand that my records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR part 2, and cannot be disclosed without my written permission or as otherwise permitted by 42 CFR part 2. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that any event this consent expires automatically as follows:

Effective Date: Aug 23, 2017  Expiration Date: Aug 23, 2018

Signed by: Sally Share
Email: sallyshare@mailinator.com
Signed on: Aug 23, 2017
42 CFR Part 2 and other regulations provide ground rules. How these rules are applied to ensure privacy and the best care requires careful analysis and monitoring.

- Who needs what information and when?
- Who determines who needs what information and when?
- What are the consequences and outcomes?
- Comply with all applicable laws:
  - Other parts of 42 CFR Part 2 such as security, etc.
  - Your State laws
  - HIPAA
  - Etc.
Federal Government Resources

- eCFR Current (Revised) 42 CFR Part 2
  http://www.ecfr.gov/cgi-bin/text-idx?node=pt42.1.2

- Federal Register—Regulation Changes Text

- SAMHSA—Announcement with Change Summary

- SAMHSA—2016 Webinar Introducing the Proposed Rule/NPRM

- SAMHSA—General Part 2 FAQs
  https://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs

- SAMHSA—Part 2 FAQs for HIE

- SAMHSA—Comparison of Part 2 and CFR 2004
Consent2Share Resources

Consent2Share on GitHub
https://bhits-dev.github.io/consent2share/index.html
Questions?

Questions about SAMHSA resources?
Visit: https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines

Questions to SAMHSA about 42 CFR Part 2
Email: privacyregulations@samhsa.hhs.gov

Information about Consent2Share
Visit: https://bhits-dev.github.io/consent2share/index.html
Thanks!