









42 CFR Part 2 Consent Requirements: Creating Electronic Consents

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





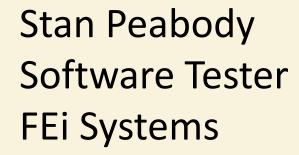
Housekeeping

- 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







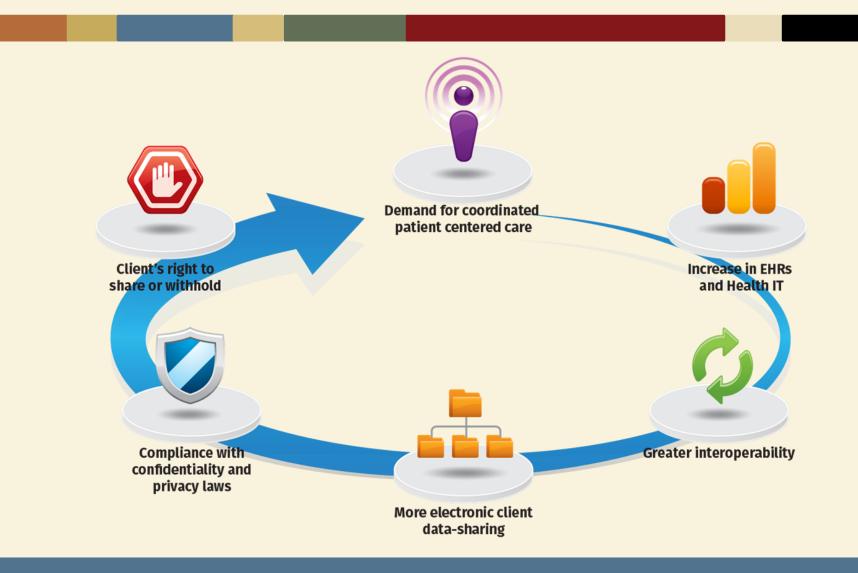
9/18/2017

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

9/18/2017

The Current Health Care Environment



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).



42 CFR Part 2 Origins: Legislation

- 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



42 CFR Part 2 Origins: The Basics

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.



42 CFR Part 2 Origins: A Key Purpose

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

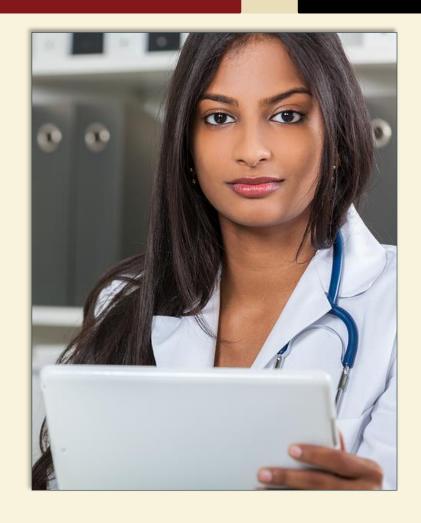
Consent Exclusions

- 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



6052

Federal Register/Vol. 82, No. 11/Wednesday, January 18, 2017/Rules and Regulations

DEPARTMENT OF HEALTH AND **HUMAN SERVICES**

Office of the Secretary

42 CFR Part 2

[SAMHSA-4162-20]

BIN 0930-AA21

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS. ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. These modifications also help clarify the regulations and reduce unnecessary burden.

- e. Withdrawal Management
- 2. Existing Definitions
- a. Central Registry
- b. Disclose or Disclosure
- c. Maintenance Treatment
- d. Member Program
- e. Patient
- f. Patient Identifying Information
- g. Person h. Program
- i. Qualified Service Organization
- i. Records
- k. Treatment
- 3. Terminology Changes E. Applicability (§ 2.12)
- 4. Other Comments on Definitions
- F. Confidentiality Restrictions and Safeguards (§ 2.13)
- 1. Delayed Implementation of List of Disclosures Provision
- 2. Responsibilities Under the List of Disclosures Process
- 3. Technological Challenges and Burden of the List of Disclosures Provision
- 4. Recommendations to Further Protect Patient Privacy
- 5. Other Comments and Recommendations on the List of Disclosures Provision
- G. Security for Records (§ 2.16)
- H. Disposition of Records by Discontinued Programs (§ 2.19)
- I. Notice to Patients of Federal Confidentiality Requirements (§ 2.22)

- 3. Documentation of Medical Emergency
- 4. Other Comments on Medical Emergency
- N. Research (§ 2.52)
- 1. General
- 2. Suggestions for Improvement of the Research Provisions
- 3. HIPAA and HHS Common Rule Requirements
- 4. Data Linkages
- 5. Multi-Payer Claims Database
- O. Audit and Evaluation (§ 2.53)
- P. Other Public Comments on the Proposed
- 1. Requests to Extend the Public Comment Period
- 2. Rulemaking Process
- 3. Implementation Timeline and Other Barriers to Implementation
- 4. Educational Opportunities
- 5. Increased Enforcement
- 6. Other Miscellaneous Comments on the Proposed Rule
- VI. Rulemaking Analyses
- A. Paperwork Reduction Act
- B. Regulatory Impact Analysis
- C. Regulatory Flexibility Act
- D. Unfunded Mandates Reform Act
- E. Federalism (Executive Order 13132)

Acronyms

ACO Accountable Care Organization ABAM American Board of Addiction

https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records

Revision: Modernize, Facilitate, & Protect

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

Patient Consent in Writing Re-disclosures w/o Consent Prohibited*

42 CFR Part 2 Consent Requirements, Pg. 1

- 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

	SAMPLE CONSENT TO INDIVIDUAL RECIPIENT			
	t 2 and HIPAA			
	Information disclosed pursuant to patient consent must be accompanied by the notice			
prohibiting re				
I,				
authorize	[patient's name of			
	[name or general designation of individual or entity making the disclosure]			
to disclose	[describe how much and what kind of information may be disclosed, including an			
	explicit description of what substance use disorder information may be disclosed;			
	axplicit description of what substance use alsorder information may be disclosed; as limited as possible!			
to				
for the purp	[name of individual(s) who will receive the information]			
	[describe the purpose of the disclosure; as specific as possible]			
I understan	d that my substance use disorder records are protected under the Federal			
	governing Confidentiality and Substance Use Disorder Patient Records, 42 C.F.R.			
	the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R.			
pts 160 & 1	64, and cannot be disclosed without my written consent unless otherwise provided			
for by the re	agulations.			
	data da a como de atrico de contra de co			
I understand that I may revoke this authorization at any time except to the extent that action has been taken in reliance on it. Unless I revoke my consent earlier, this consent will expire				
	ken in reliance on it. Onless i revoke my consent earlier, this consent will expire IIv as follows:			
automatica	ny as ronows.			
[descri	be date, event, or condition upon which consent will expire, which must be no longer than			
	reasonably necessary to serve the purpose of this consent]			
	d that I might be denied services if I refuse to consent to a disclosure for purposes o			
	payment, or health care operations, if permitted by state law. I will not be denied			
	refuse to consent to a disclosure for other purposes.			
	provided a copy of this form.			
Dated:				
	Signature of Patient			
	Signature of person signing form if not patient			
Describe aut	hority to sign on behalf of patient			

42 CFR Part 2 Consent Requirements, Pg. 2

- 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



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.

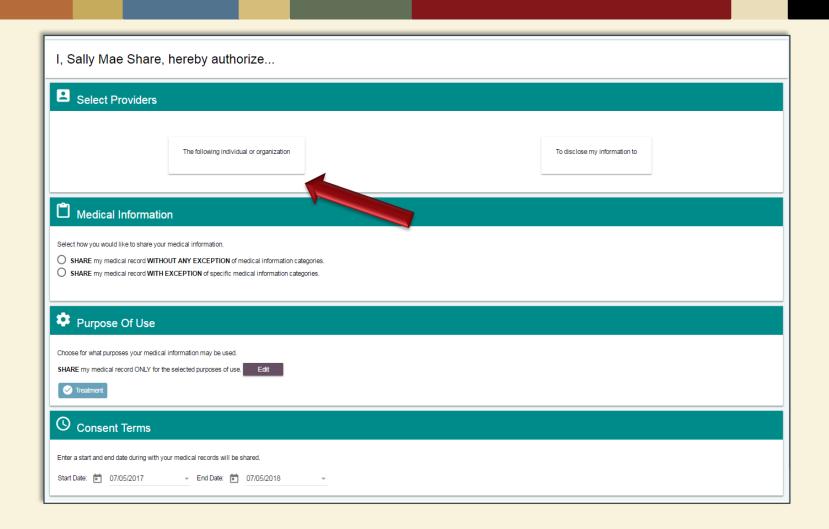
Revisions: General Designation



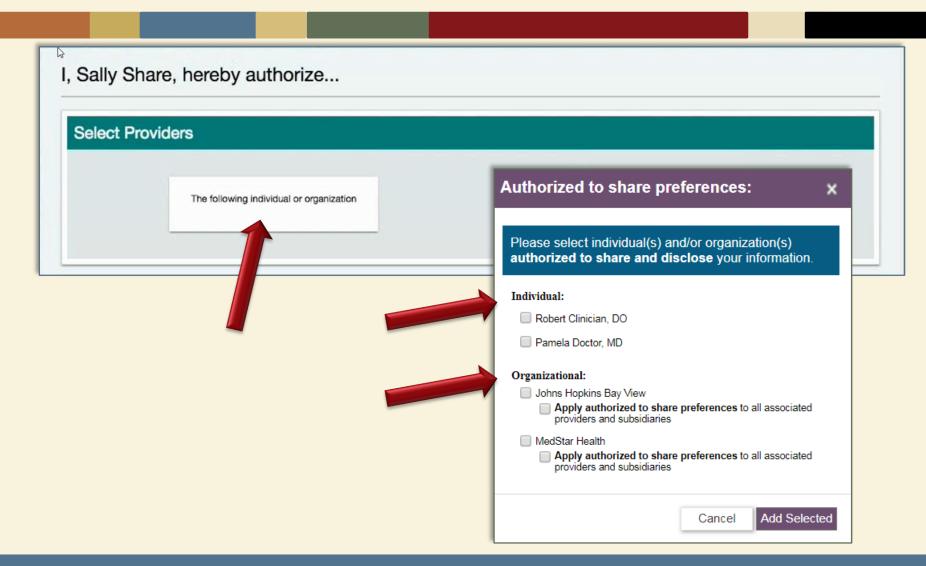
Did not remove the *general designation* in the "From Whom" section of the consent form but did make terminology changes.

✓ 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



To Whom Provider

Requirement: The "To Whom" Provider

Individual or Entity To Whom	Treating Relationship	Primary designation	Required Additional Designation
Individual	Yes	Name of individual(s) (e.g., Jane Doe, MD)	None
Individual	INO	Name of individual(s) (e.g., John Doe)	None
Entity	YAS	Name of entity (e.g. Lakeview County Hospital)	None
Entity	No	Name of entity that is a third-party payer as specified under § 2.31(a)(4)(iii)(A) (e.g., Medicare)	None
Entity	No		 At least one of the following: The name(s) of an individual participant(s) (e.g., Jane Doe, MD, or John Doe) 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) 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 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.

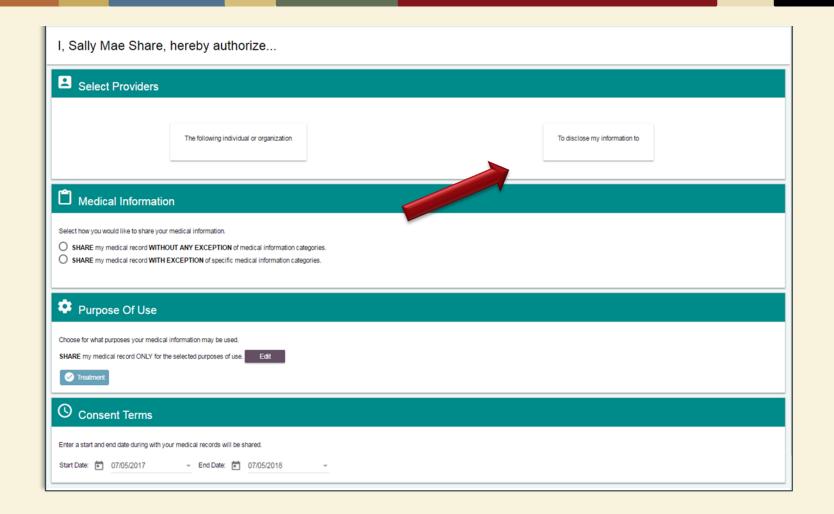
- ✓ Can be used for those providers who have a treating provider relationship with the patient
- ✓ Requires an explicit description of the "amount and kind" of substance use disorder treatment information
- ✓ Patients must be informed of their right to obtain a list of entities to whom their information 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

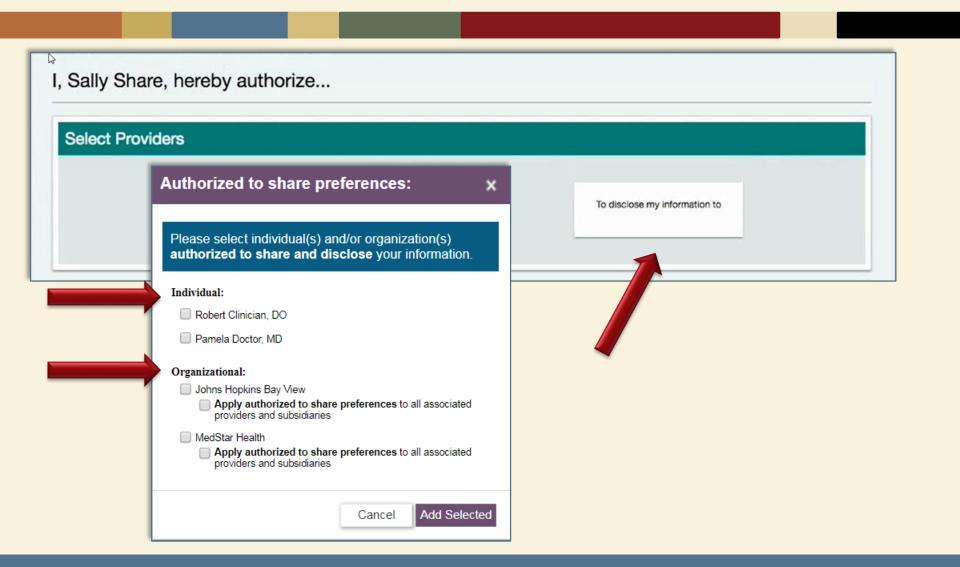
If you include a General Designation, you must include options for:

- ✓ Current treating providers
- ✓ Past treating providers, and
- ✓ Future treating providers.

Sally Selects "To Whom" Provider



Sally Selects the "To" Provider

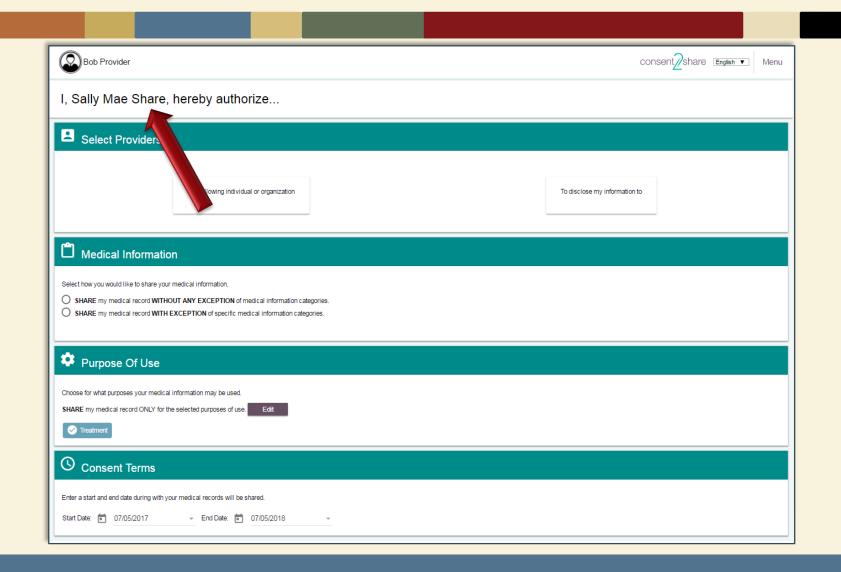


Requirement: The Patient Name

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

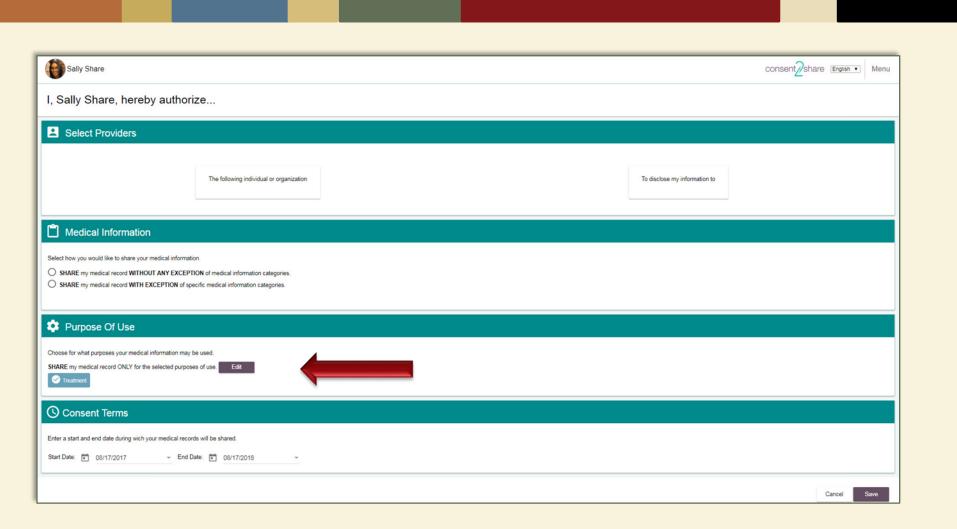


Requirement: Purpose of the Disclosure

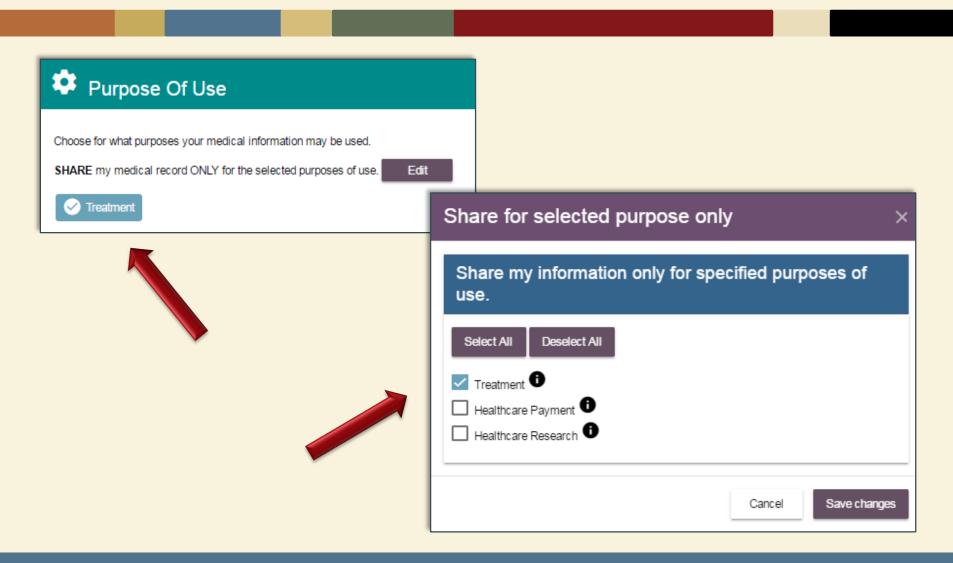
Specific Purpose or Need for the Disclosure

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



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
□ <i>Allergies</i>
☐ Substance use history summaries
☐ Trauma history summary
☐ Employment information
☐ Living situation & social supports
□ Claims/encounter data
□ <i>Other</i>

Kind: Categories

Examples of Part 2 Categories

Diagnostic Information

Medications and Dosages

Lab Tests

Allergies

Substance Use History

Trauma History Summary

Clinical Notes

Discharge Summary

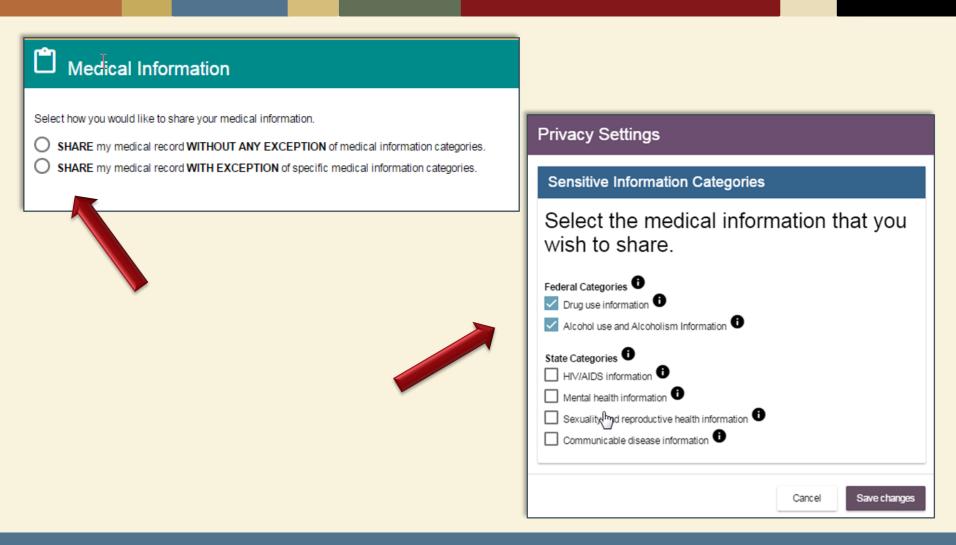
Employment Information

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

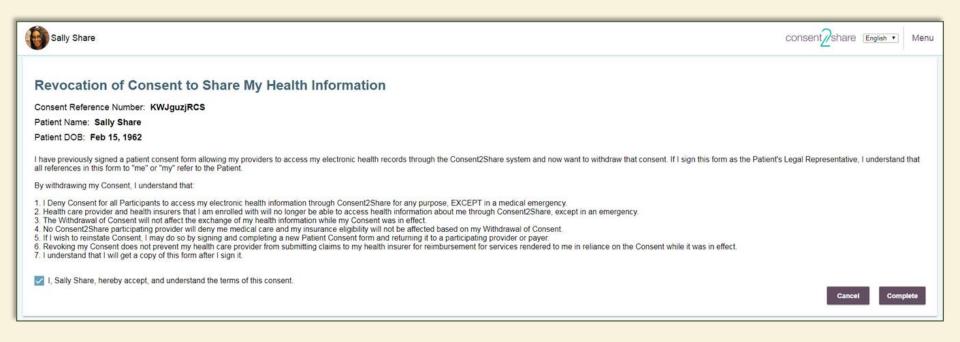


Requirement: Consent Revocation

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

Sally Reviews Revocation Statement

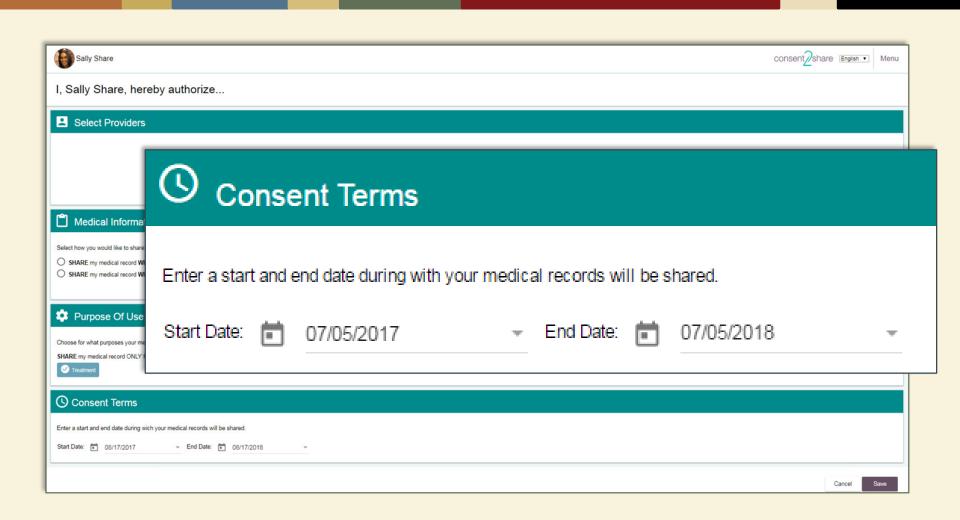


Requirement: Expiration

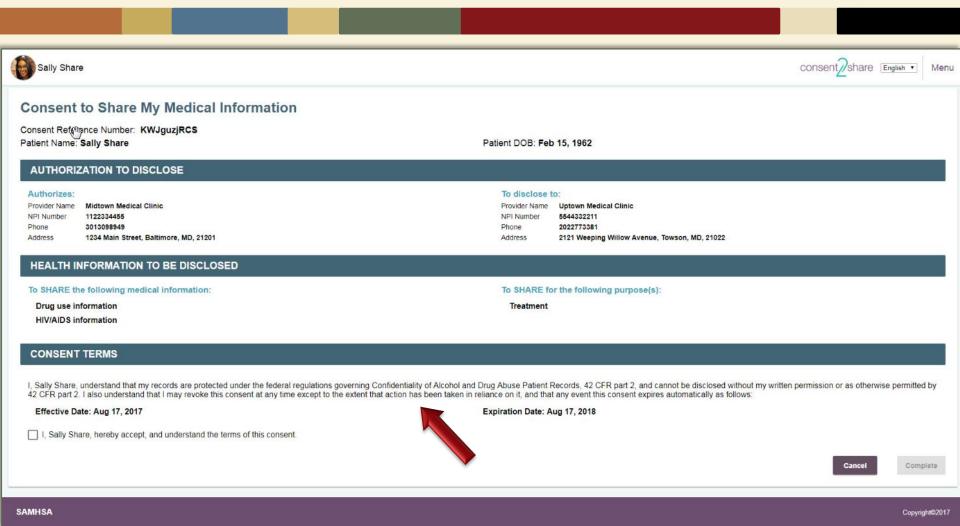
The Date, Event, or Condition on which the Consent Expires

➤ 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



Sally Reviews Disclosure Statement



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Requirement: Patient Signature

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.

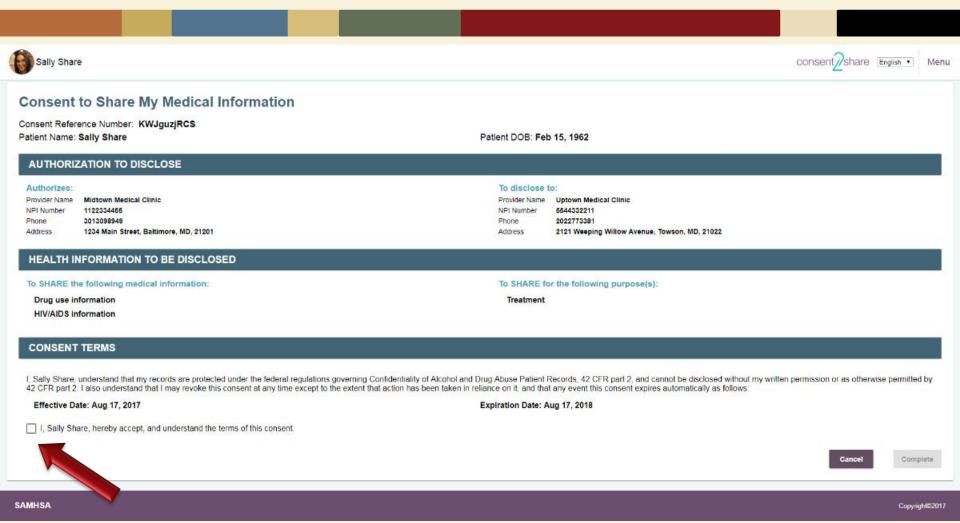
➤ Electronic signatures (eSignatures) a permitted to the extent that they are not prohibited by any other applicable laws.



Sally Selects eSignature



Sally First Selects Attestation Box



Sally Receives Success Notification



Requirement: Date Signed

The Date that the Consent is Signed

> The date on which the consent is signed



Sally Confirms Consent and Date



Consent to Share My Health Information

Consent Reference Number: ns3x6I6Y6E

Patient Name: Sally Share Patient DOB: Feb 15, 1962

AUTHORIZATION TO DISCLOSE

Authorizes:

Provider Name NPI Number Address Phone SANAGA SERVICES AND 1023132966 1943 BENNETT PL NE. 2023418888 WASHINGTON, DC, CARE LLC

200024113

To disclose to:

Provider Name NPI Number Address Phone CAPITOL DIALYSIS, LLC 1083722763 140 Q ST NE, SUITE 100, 2026369411

WASHINGTON, DC, 200022101

HEALTH INFORMATION TO BE DISCLOSED

To SHARE the following medical information: To SHARE for the following purpose(s):

Sensitivity Categories: - Treatment

- Drug use information

- Alcohol use and Alcoholism Information
- HIV/AIDS information
- Communicable disease information
- Mental health information
- Sexuality and reproductive health information

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

Privacy and & Best Care: Final Thoughts

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.

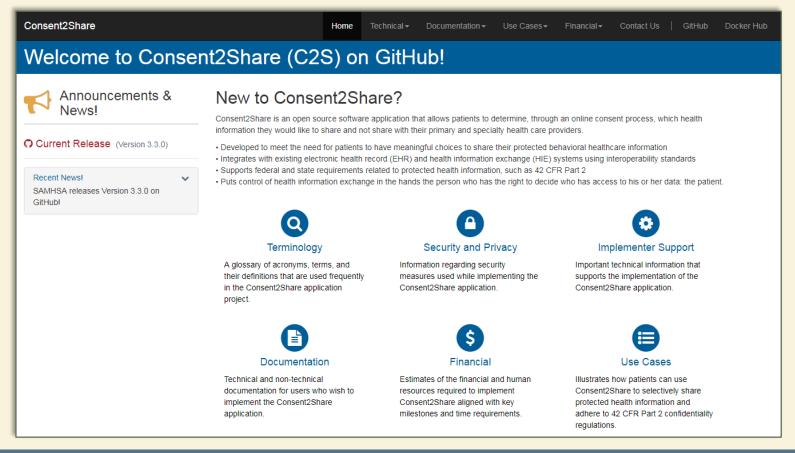
Federal Government Resources

- eCFR Current (Revised) 42 CFR Part2
 - http://www.ecfr.gov/cgi-bin/text-idx?node=pt42.1.2
- Federal Register—Regulation Changes Text https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records
- SAMHSA—Announcement with Change Summary https://www.samhsa.gov/newsroom/press-announcements/201701131200
- SAMHSA—2016 Webinar Introducing the Proposed Rule/NPRM
 https://www.samhsa.gov/sites/default/files/topics/health_info_tech/42-cfr-part-2-proposed-rule-webinar-slides.pdf
- SAMHSA—General Part2 FAQs
 https://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs
- SAMHSA—Part2 FAQs for HIE
 https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf
- SAMHSA—Comparison of Part2 and CFR 2004
 http://archive.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf

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!

