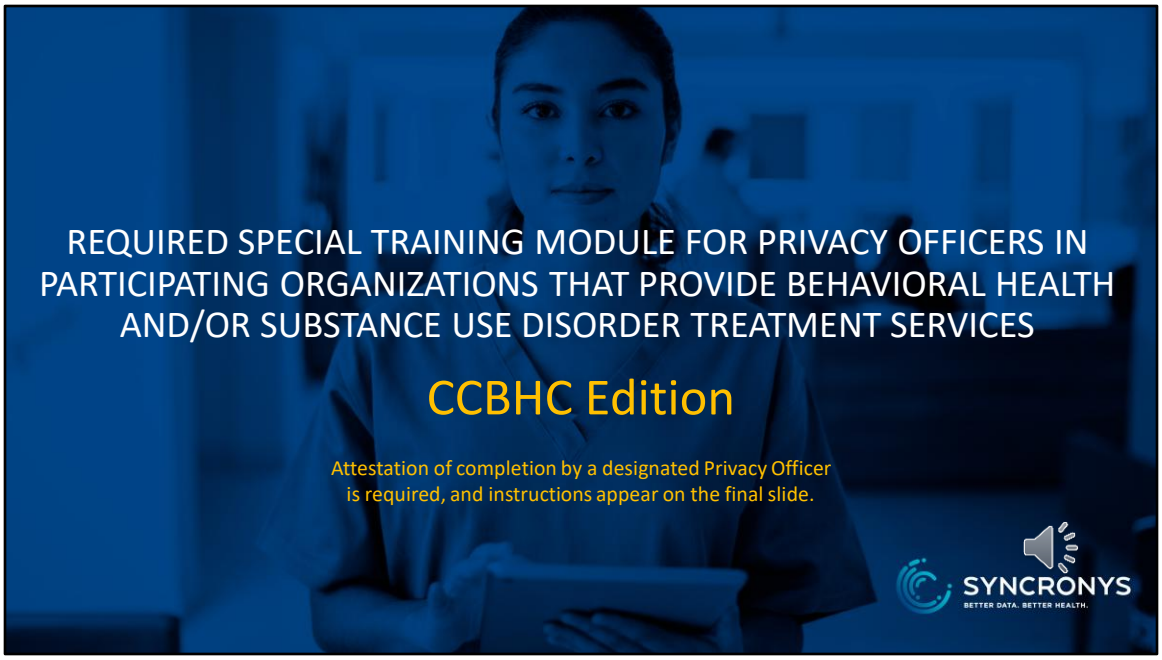


Thank you for viewing this special training module for privacy officers in organizations that offer behavioral health and substance use disorder treatment services and are part of the Certified Community Behavioral Health Clinic demonstration program. Attestation that this training module has been reviewed is required to ensure that sharing data complies with HIPAA and 42 CFR Part 2 regulations when applicable. Instructions to complete the attestation appear on the final slide.

The information in this module will help you answer questions about how federally protected substance use disorder treatment information may be shared and displayed in the HIE if consent is given by the patient at the source of that information. Organizations with programs subject to 42 CFR Part 2 protections have additional responsibilities regarding obtaining patient consent to share information and collaborating with SYNCRONYS to ensure non-consented information does not reach the clinical portal.

42 CFR PART 2 OVERVIEW

- Substance Use Disorder (SUD) records are covered by the Confidentiality of Substance Use Disorder Patient Records 2 USC 290dd-2 and 42 CFR Part 2 (known as "Part 2") regulations.
- 42 CFR Part 2 protects the privacy and security of records identifying individuals as seeking or receiving SUD treatment from a "Part 2 program." The purpose is to encourage people to enter and remain in SUD treatment by safeguarding confidentiality.
- The regulation requires patient consent for most disclosures, including for treatment, payment, and health care operations (TPO), with limited exceptions.

You can view the rule with this link: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2

Substance Use Disorder (SUD) records are covered by the federal regulations we refer to as "42 CFR Part 2." For this module, we'll simply refer to them as "Part 2".

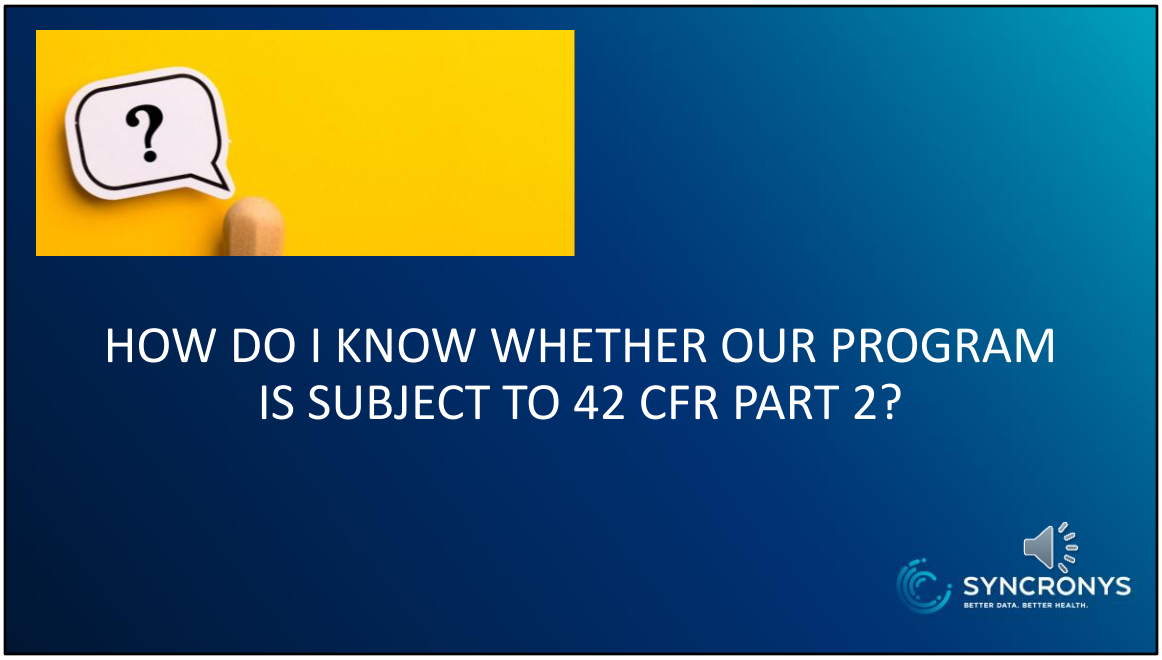
Part 2 protects the privacy and security of records identifying individuals as seeking or receiving SUD treatment from a "Part 2 program." The purpose is to encourage people to enter and remain in SUD treatment by safeguarding confidentiality. Not all providers of such treatment qualify as a Part 2 program.

On February 8, 2024, the U.S. Department of Health & Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights (OCR) announced a final rule modifying Part 2.

These changes attempted to align certain aspects of the regulations with the Health Insurance Portability and Accountability Act of 1996 Rules (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (known as HITECH).

This change allowed SYNCRONYS to begin sharing information we receive from

Part 2 organizations if the individual patient has consented to sharing their information for treatment, payment, or operations purposes as defined by HIPAA. This consent is managed by the Part 2 organization.



Not all providers of treatment are subject to this federal regulation, so how do you know if your program qualifies as a designated 42 CFR Part 2 program?

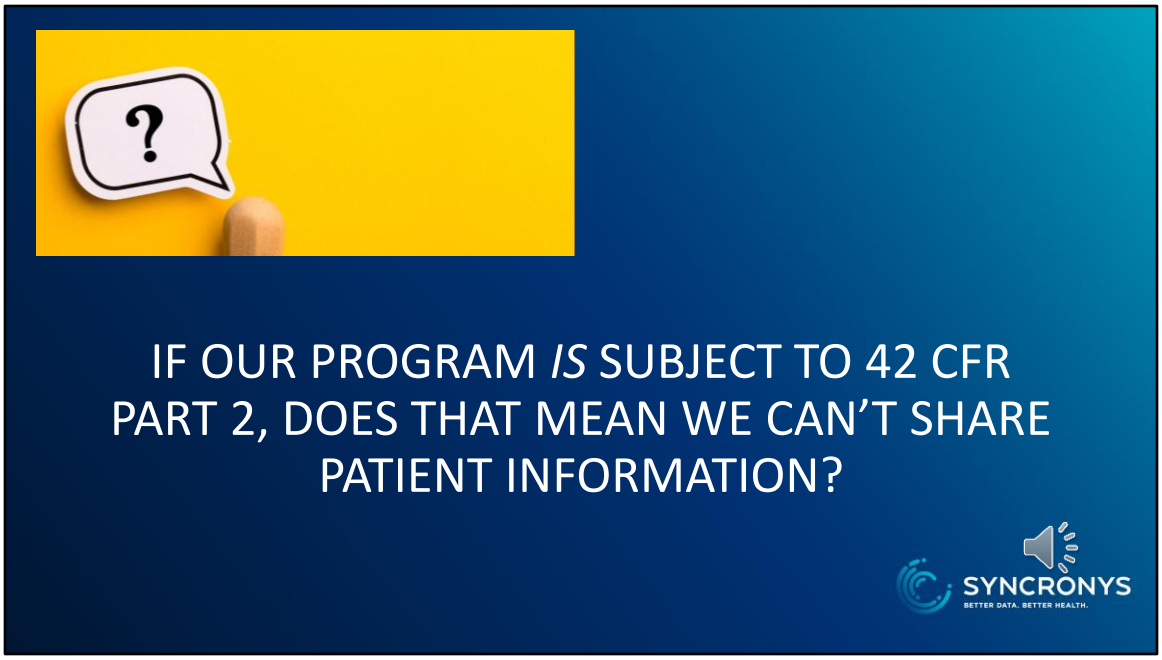
WHO IS SUBJECT TO 42 CFR PART 2?

A mental health clinic is generally subject to 42 CFR Part 2 if it is a "federally assisted" program that specifically holds itself out as providing, and actually provides, alcohol or drug abuse diagnosis, treatment, or referral. It applies to specialized, identifiable SUD units rather than general medical care, though it can cover specific counselors within a larger facility.

Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf

Ask yourself, do we receive federal funding?
Do we promote our clinic as a provider of alcohol or drug abuse diagnosis, treatment, or referral?
Do I have providers in our clinic that fit that description?
If so, you need to notify SYNCRONYS and work with your team to ensure compliance with Part 2.

If you are unsure or have any questions, please consult your compliance officer or legal counsel before sending this type of treatment data to SYNCRONYS. Our goal with this module is to offer you some guidance, but the responsibility remains with your organization, so you'll want to be certain.



If your program is subject to 42 CFR Part 2, you can still share this important patient information, which may be critical for the patient's healthcare team to know.

YOU *CAN* SHARE—WITH PATIENT CONSENT FOR TREATMENT, PAYMENT, OR HEALTHCARE OPERATIONS (TPO) UNDER HIPAA

- Consent from the patient:
  - Must be documented on your consent form
  - Correctly recorded on the patient roster you submit to SYNCRONYS
  - Withdrawn using a **Revocation Roster** immediately if the patient changes their mind

What's required to share this information is to manage patient consent. It should be documented in your practice, correctly reflected on the roster you submit to SYNCRONYS, and withdrawn using a Revocation Roster if the patient changes their mind.

COMPLETING THE SYNCRONYS BH ROSTER

BL	Consent	I = Consent granted O = Consent Denied For non-CFR part 2, place N in Column BQ.	For all 42CFR part 2	I or O Blank for non-CFR part 2
BM	Enrollment Start	Member enrollment date with payer	No	YYYYMMDD
BN	Enrollment End	Member enrollment end date with payer	No	YYYYMMDD
BO	Line of Business	Medicaid CHIP Medicare Medicare/Medicaid duals Military Insurance (VHA/Tricare) Commercial Uninsured Cash Pay Falling Colors Other payers (this would include county indigent program)	Yes	Use appropriate code.
BP	Consent End Date 42 CFR part 2 ORG	Expiration Date	Optional	No longer required YYYYMMDD
BQ	42 CFR part 2 Patient	Is this patient a 42 CFR part 2 designation? All must reply-do NOT leave blank. Y = Yes N = No	Yes, leaving this column blank, block the data	Y or N

PLEASE REFER TO THE DATA DICTIONARY

REQUEST IT AT HELP@SYNCRONYS.ORG

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The SYNCRONYS Behavioral Health patient roster is the gatekeeper for how your data is shared with SYNCRONYS. By understanding how to use two important columns, your practice can ensure alignment with 42 CFR Part 2 regulations. A "Data Dictionary" has been shared with the individuals responsible for your clinic's roster and is your go-to reference for completing the roster correctly. If you need a copy, please reach out to either your SYNCRONYS Customer Relationship Manager or our Service Desk, and ask for the Behavioral Health Roster Data Dictionary.

The following slides should help you understand how the flow of patient information is managed in respect to the patient's wishes.

COMPLETING THE SYNCRONYS BH ROSTER

SYNCRONYS
BETTER DATA. BETTER HEALTH.

BL	Consent	I = Consent granted O = Consent Denied For non-CFR part 2, place N in Column BQ.	For all 42CFR part 2	I or O Blank for non-CFR part 2
BQ	42 CFR part 2 Patient	Is this patient a 42 CFR part 2 designation? All must reply-do NOT leave blank. Y = Yes N = No	Yes, leaving this column blank, block the data	Y or N

- Column BL (Consent) is dependent on how Column BQ (42 CFR Part 2 Patient) is populated.
- If Column BQ is marked **N**, then Column BL must be left **blank**.
- If Column BQ is marked **Y**, then Column BL must be populated with either **I** or **O**.
- If Column BL is marked **I** (organization has consent on file), a "**break the seal**" indicator is applied in the clinical portal.
- If Column BL is marked **O** (no consent on file or consent denied), the **data is blocked**.

These two columns, BL and BQ, work together to control the flow of data according to
whether the patient is a Part 2 patient and whether the patient has given consent to share their data.

- Column BL (Consent) is dependent on how Column BQ (42 CFR Part 2 Patient) is populated.
- If Column BQ is marked **N**, then Column BL must be left **blank**.
- If Column BQ is marked **Y**, then Column BL must be populated with either **I** or **O**.
- If Column BL is marked **I** (organization has consent on file), a "**break the seal**" indicator is applied in the clinical portal.
- If Column BL is marked **O** (no consent on file or consent denied), the **data is blocked**.

If there is any question, please refer to the full Data Dictionary.

This version of the training module for Privacy Officers offers additional information about the CCBHC Demonstration Program and its requirement that all data related to the CCBHC's services is included in aggregate level reporting to SAMHSA, including both consented and non-consented 42 CFR P2.

You may choose to send identified data using the roster shown in the previous slides.

However, if you prefer, you have the option to submit this data using the Deidentified Method, which we'll discuss in the next few slides.

DATA SUBMISSION METHODS

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#	Option	Description	Relevant Processes	Considerations
1	De-Identified Data Submission	Share de-identified non-consented 42CFR P2 data Details on data fields that will be included in the new submission process are located on the next slide	• Separate submission process would be implemented for de-identified data submission	• Application of alternative unique identifiers responsibility of the CCBHC • Inability to revoke consent for prior data submitted, *this has been flagged as a potential risk by the SYNCRONYS Team* • 42CFR P2 non-consented patient data would be de-identified to all users • Cannot retrofit the CCBHC Dashboard with previously submitted and processed de-identified non-consented data Reference the "CCBHC Quality Measures: Deidentified Data (DID) Submission – Data Dictionary" when submitting de-identified data.
2	Identified Data Submission	Share identified non-consented 42CFR P2 data	• Update data submission templates will be created and will follow the same submission process as today	• SYNCRONYS HIE bears responsibility for appropriately segmenting and limiting access to non-consented 42CFR P2 data under QSOAs Reference the "CCBHC Quality Measures: Data Dictionary" when submitting identified data.

This slide illustrates the two data submission methods available to CCBHCs. Your team will receive support from the SYNCRONYS CCBHC Project Management team to ensure understanding of data submissions processes and procedures.

DID SUBMISSION – DATA FIELDS

Reference the "CCBHC Quality Measures: Deidentified Data (DID) Submission – Data Dictionary" when submitting de-identified data.

SYNCRONYS Data Field	Required for SAMHSA Reporting?	Field required for de-identified reporting?	Notes
Patient ID	No	No	Will be replaced with an alternate unique identifier
Race	Yes	Yes	Used for equity analysis; must remain in identifiable format for stratification
Ethnicity	Yes	Yes	Required for federal reporting and disparity monitoring, required for stratification
Preferred Language	No	No	May be grouped or generalized if needed
Sex Assigned at Birth	Yes	Yes	Can be generalized (e.g., male/female/other)
Gender Identity	Optional	No	Can be categorized broadly (e.g., cisgender, transgender, nonbinary)
Age	Yes	Yes	Can be reported in age bands if needed, align with bands required for CCBHC stratification
Date of Birth	No	No	DOB is used to calculate age; generalization may reduce matching ability and proper stratification per SYNCRONYS' capabilities. Reporting age in age bands is sufficient for reporting needs, DOB is preferred for accuracy
ZIP Code	No	No	Can be truncated to ZIP3 or removed if county is retained
County of Residence	No	No	Can be retained or generalized by region
Insurance Type	Yes	Yes	Can be categorized by public/private/uninsured
Veteran Status	Yes	Yes	Used to identify veteran-specific services
Disability Status	No	No	Important for accessibility planning
Homelessness Status	No	No	Used for housing stability support metrics
Employment Status	No	No	Used for employment-related outcome measures
Household Income	No	No	Used for SES stratification
Education Level	No	No	Required for education-based disparity reporting

This image shows the fields that are required for de-identified patients. Note that you will replace the Patient ID number with your new unique identifier for that patient.

Your CCBHC dashboard users also have access to the SYNCRONYS clinical portal, as do many other healthcare providers. Data that reaches the patient record in the clinical portal has protections to ensure viewing the information complies with HIPAA and 42 CFR Part 2. When legislation changed SYNCRONYS updated its portal to allow this sensitive information to be used responsibly, securely, and in compliance with the law.

MAJOR CHANGES IN THE NEW 42 CFR PART 2 FINAL RULE – FAST FACTS

- Allows a single consent for all future uses and disclosures for treatment, payment, and health care operations (TPO).
- Allows HIPAA covered entities and business associates that receive records under this consent to redisclose the records in accordance with the HIPAA regulations.[1]
- Prohibits combining patient consent for the use and disclosure of records for civil, criminal, administrative, or legislative proceedings with patient consent for any other use or disclosure.
- Requires a separate patient consent for the use and disclosure of SUD counseling notes. (Similar to HIPAA protected psychotherapy notes)
- Requires that each disclosure made with patient consent include a copy of the consent or **a clear explanation of the scope of the consent**.

[1] However, these records cannot be used in legal proceedings against the patient without specific consent or a court order, which is more stringent than the HIPAA standard.

This slide offers additional details about the regulations that may help you understand the changes we have made to the HIE clinical portal.
Part 2 allows a single consent for all HIPAA TPO uses, now and in the future
It allows HIPAA covered entities and their business associates to receive and redisclose records in accordance with HIPAA regulations.
It protects patients by not allowing such consent to be used as consent for legal uses.
It requires a separate patient consent for SUD counseling notes, like psychotherapy notes)
And requires that each disclosure of the patient's information be accompanied with a clear explanation of the scope of the consent.

These provisions were all considered when SYNCRONYS modified its clinical portal to protect data subject to 42 CFR Part 2.

CONSENT FOR HIPAA TPO AND OPT-IN/OUT, WHAT'S THE DIFFERENCE?

- Consent management applies only to data sharing organizations (DSOs) designated as 42 CFR Part 2.
- If a Part 2 patient provides consent for TPO, their 42 CFR Part 2 data will be available within the HIE upon acknowledgement by the viewer.
- Such consent can be revoked by the patient at the 42 CFR Part 2-designated clinic/agency.

  Note: *If the patient's Part 2 data was already shared with the HIE, the 42 CFR Part 2 clinic/agency can submit a revocation roster. After the revocation is processed, the patient's Part 2 data will be blocked in the HIE/clinical portal going forward.*

Consent management applies only to data sharing organizations (DSOs) designated as 42 CFR Part 2. Again, not every treatment provider is designated as a Part 2 program.

If a Part 2 patient provides consent for their information to be shared for a HIPAA compliant purpose (TPO), their 42 CFR Part 2 data will be available within the clinical portal when a user acknowledges that their access complies with HIPAA. Such consent can be revoked by the patient at the 42 CFR Part 2-designated clinic/agency, and the patient's data from that provider will be blocked. Other information not coming from a Part 2 provider would be unaffected.

CONSENT FOR HIPAA TPO AND OPT-IN/OUT, WHAT'S THE DIFFERENCE? (CONTINUED)

- **However, if a patient opts out of the HIE, no information, not even demographics, would be found in our portal.**
- Opting-out blocks all patient data from all users of SYNCRONYS, even in the event of a life-threatening emergency.
- Opting-out is initiated by the patient contacting SYNCRONYS.
- The Opt-out / Opt-back-in form is available to patients:

info@syncronys.org | 505-938-9900

https://www.syncronys.org/resources/#for-patients

However, if a patient opts out of the HIE entirely, no information, not even demographics, would be found in our portal.
Opting-out blocks all patient data from all users of SYNCRONYS.
To request this, the patient contacts SYNCRONYS directly. The form is available at the SYNCRONYS website, or by calling or emailing SYNCRONYS to request the form.

FUTURE USES AND DISCLOSURES FOR TPO

- Future disclosures made with patient consent must be accompanied by a statement notifying the recipient that redisclosure is prohibited, unless the purpose of the further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by Part 2.
- Limited redisclosures without obtaining the patient's consent are permitted, such as medical emergencies, child abuse reporting, crimes on program premises or against program personnel, and court ordered disclosures when procedures and criteria are met.

The regulations require that when we disclose the covered information to users, we need to show a statement about the scope of the consent. They also allow for limited redisclosure of the information without patient consent under circumstances described in this second bullet.

WHAT CLINICAL PORTAL END-USERS WILL SEE

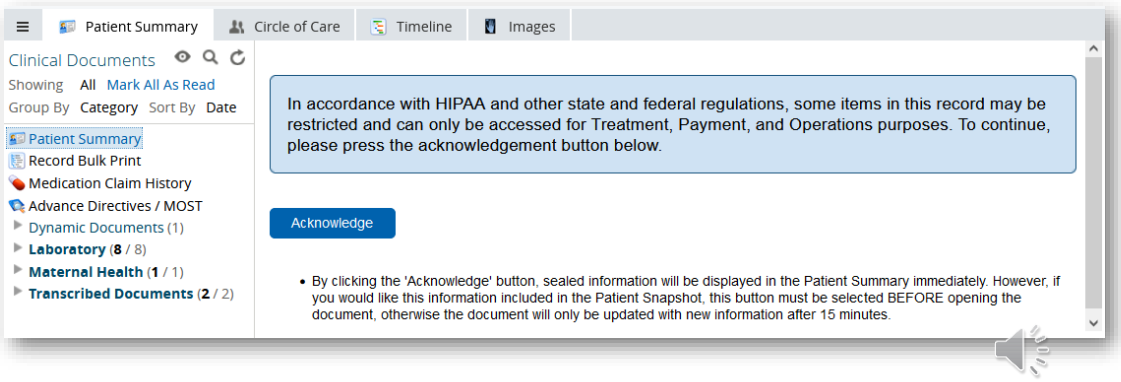
- Authorized clinical portal users may encounter patient records that have specially protected information, such as 42 CFR Part 2 substance use disorder (SUD).

- Treatment
- Payment
- Operations

- In these cases, **the patient has provided consent at the source of that data**, allowing SYNCRONYS to share this information with HIE users for **Treatment, Payment, or Healthcare Operations** (TPO) purposes only.

When protected information is contained in a patient's record in the SYNCRONYS clinical portal, users will see an alert as an indication that the patient has provided consent at the source of that data. An example is shown on the next slide. The patient's consent for part 2 data allows SYNCRONYS to share this information with HIE users for **Treatment, Payment, or Healthcare Operations** (TPO) purposes only.

ACKNOWLEDGING RESPONSIBILITY

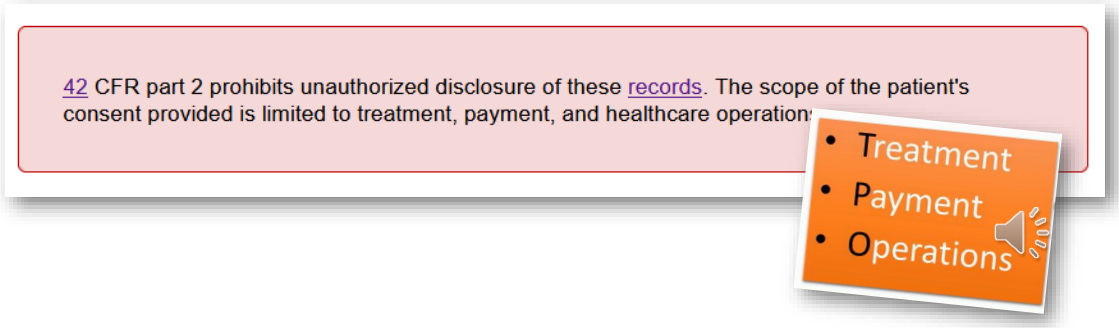


By clicking on this acknowledgement, the user is attesting that they have a TPO relationship with the patient whose record they are about to view will reveal. By clicking the 'Acknowledge' button, sealed information will be displayed in the Patient Summary immediately.

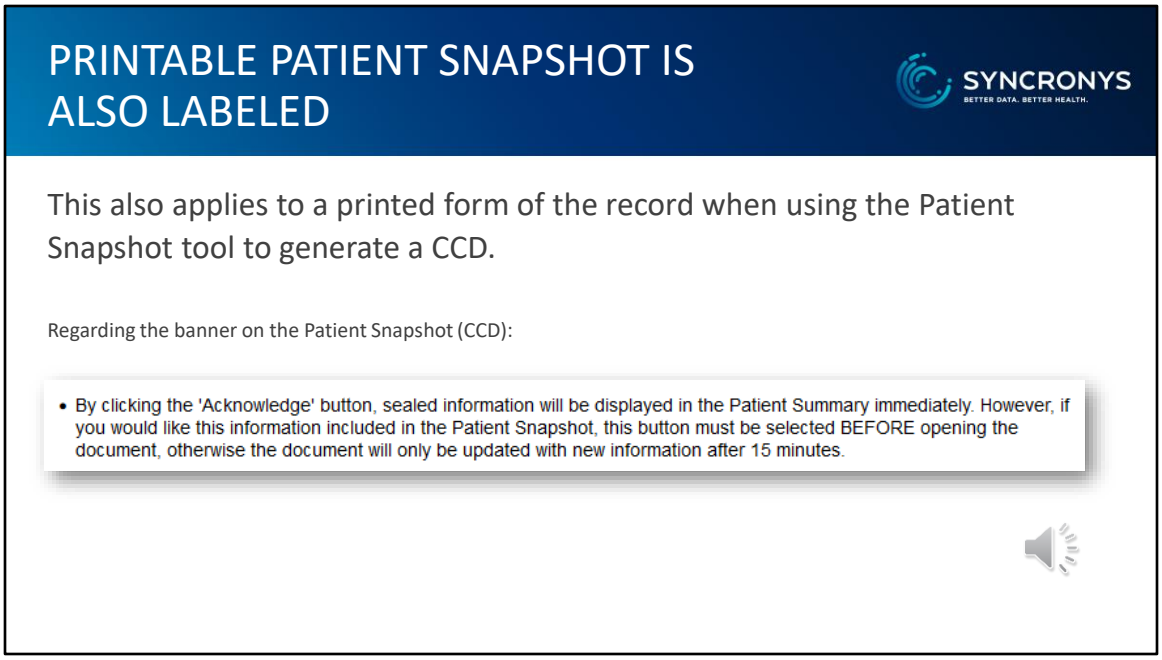
SCOPE OF THE CONSENT

Each disclosure made with the patient's written consent **must be accompanied** by a clear explanation of the scope of the consent provided.

How it looks in the HIE Portal:



The regulations require that when we disclose the covered information to users, we need to show a statement about the scope of the consent. So, when the user acknowledges the statement shown in the previous slide, they will see this banner that restates that use of the information is limited to the purpose of treatment, payment, or healthcare operations. It also has some helpful links to explain the specifics of 42 CFR Part 2 and a definition of Records used in those regulations.



Users viewing a patient record in the HIE may want to generate a continuity of care document, known as a patient snapshot. If you would like Part 2 information included in document, make sure you click the acknowledgement button BEFORE generating the patient snapshot. If you click the acknowledgement button after generating the patient snapshot, you would need to wait about 15 minutes to print an updated document that includes the SUD information. In other words, if you intend to print or download a CCD of this record, click the Acknowledge button before generating a patient snapshot so it will also include the restricted items.

FIVE THINGS YOU SHOULD DO **SOON**

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1. Verify whether your organization, program, or any providers are subject to 42 CFR Part 2.
2. If so, you should execute a special addendum with SYNCRONYS called a QSOA.
3. Meet with the person responsible for submitting your patient encounters and/or rosters to ensure they understand how to manage patient consent.
4. Review current consent form to ensure it aligns with the Part 2 requirements.
5. Validate rosters to confirm your process (and EHR) is accurately reporting patient consent choices.

As a privacy officer in an organization that provides the services we've discussed in this module, we recommend that you complete these tasks.

1. Verify whether your organization, program, or any providers are subject to 42 CFR Part 2.
2. If so, you should execute a special addendum, called a QSOA, with SYNCRONYS.
3. Meet with the person responsible for submitting your patient encounters and/or rosters to ensure they understand how to manage patient consent.
4. Review current consent form to ensure it aligns with the Part 2 requirements.
5. Check rosters to validate whether your process and EHR system for generating them accurately reports patient consent choices.

WHAT ELSE SHOULD I BE DOING AS OUR DESIGNATED HIE PRIVACY OFFICER?

- Run a list of your current clinical view users (NMHIC Level 1, 2, or 3 users).
- Direct them to our training library for a brief module on 42 CFR Part 2 information.
- Schedule time with your Customer Relationship Manager if you want to request additional training or to get clarification.
- Notify your Customer Relationship Manager or the SYNCRONYS service desk if you have any problems or concerns regarding the safeguards in our portal.

SYNCRONYS is requesting help from *all* privacy officers to safeguard the privacy of our patients.

- Run a list of your current clinical portal users to ensure it's up to date
- Direct your clinical view users (NMHIC Level 1, 2, or 3 users) to our training library for a brief module on 42 CFR Part 2 information.
- Schedule time with your Customer Relationship Manager if you want to schedule additional training or to get clarification.
- Notify us if you have any problems or concerns regarding the new safeguards in our portal.

ADDITIONAL RECOMMENDED PRIVACY OFFICER TRAINING RESOURCES

SYNCRONYS
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- Getting Help or Reporting Problems (1:15 min.)
- Privacy Officer 6b Training #1 – Overview (10 mins)
- Privacy Officer 6b Training #3 – Tools for Monitoring Patient Privacy (7 mins)

https://www.syncronys.org/resources/#training

Additional 42 CFR Part 2 references are provided in the next three slides and the links are click-able in the PDF handout of this training module.

Remember to send your attestation that you have completed this training. Instructions appear on the last slide.

Our website has a training library of brief modules for you and your staff. We recommend these three for all Privacy Officers.
You will find additional references on the next three slides.
Please remember that we need you to attest that you completed this training, so please advance to the final slide for instructions.
Thank you!

MORE INFORMATION ABOUT 42 CFR PART 2!

PART 2 - CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2

Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule
https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#ftn1

Code of Federal Regulations: 42 CFR Part 2 - Confidentiality of Substance Use Disorder Patient Records https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2

The links on the next few slides are provided for your reference and convenience.

MORE INFORMATION ABOUT 42 CFR PART 2!
(CONTINUED)

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Notice of Proposed Rulemaking: 42 CFR Part2 - Confidentiality of Substance Use Disorder Patient Records
https://www.federalregister.gov/documents/2024/02/16/2024-02544/confidentiality-of-substance-use-disorder-sud-patient-records

Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule
https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#ftn1

MORE INFORMATION ABOUT 42 CFR PART 2!
(CONTINUED)

Center of Excellence for Protected Health Information **The Center of Excellence for Protected Health Information (also known as the CoE-PHI) is funded by SAMHSA to assist people and organizations in understanding and applying these federal health privacy laws and regulations.*
https://www.coephi.org

FAQs About 42 CFR Part 2 https://www.asam.org/docs/default-source/advocacy/coe-phi-faqs-about-42-cfr-part-2.pdf

ATTESTATION OF COMPLETION IS REQUIRED FOR THIS TRAINING MODULE.

PLEASE EMAIL MNORBY@SYNCRONYS.ORG TO CONFIRM YOU HAVE REVIEWED THE MATERIAL ON BEHALF OF YOUR ORGANIZATION.

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Thank you for your time. We ask that you send an email message to our SYNCRONYS Privacy and Security Director, Mark Norby, to attest that you have completed this module on behalf of your organization.