

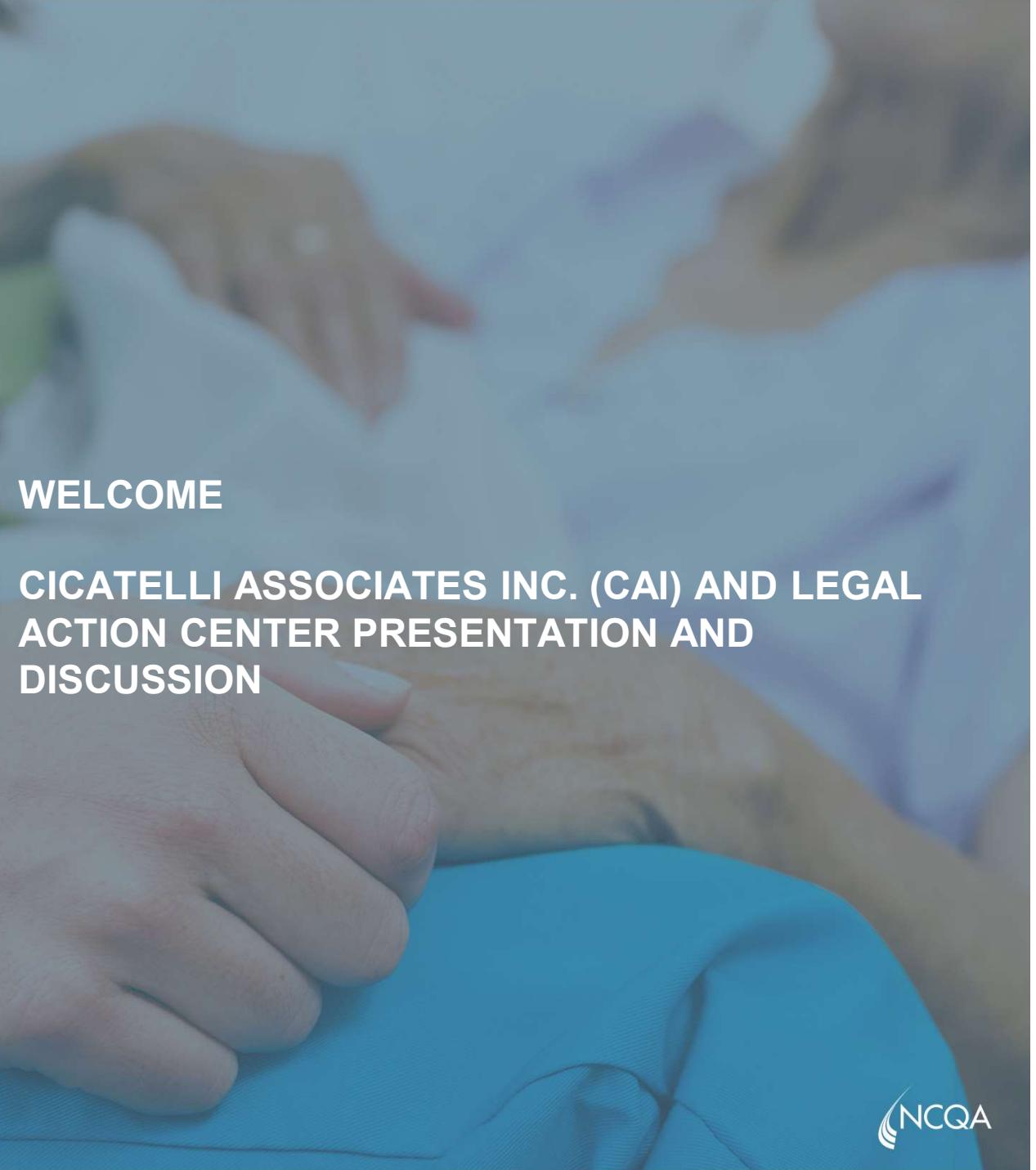


Alcohol Learning Collaborative: Bi-Monthly Collaborative Webinar

Privacy & Reporting
May 23, 2019



Agenda





CAI and Legal Action Center
Presentation and
Discussion





Center of Excellence for Protected Health Information
Funded by Substance Abuse and Mental Health Services Administration

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PRIVACY & REPORTING: UNHEALTHY ALCOHOL USE SCREENING AND FOLLOW UP PERFORMANCE MEASURE

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May 23, 2019

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Center of Excellence for Protected Health Information

Funded by SAMHSA, the CoE-PHI develops and disseminates resources, training, and TA for states, healthcare providers, school administrators and individuals and families to improve understanding and application of federal privacy laws and regulations, including FERPA, HIPAA, and 42 CFR Part 2, when providing and receiving treatment for SUD and mental illness.

Resources, training, technical assistance, and any other information provided through the CoE-PHI do not constitute legal advice.

Agenda

Section 1:
Relevant Privacy Regulation

Section 2:
HIPAA and Provider Reporting

Section 3:
Determining When 42 CFR Part 2 Applies

Section 4:
How to Share Part 2 Data

Section 5:
Best Practices to Support Reporting

Objectives

- Examine HIPAA and provider reporting of ASF HEDIS measure data
- Determine if Part 2 applies to provider reporting of ASF HEDIS measure data.
- Clarify the ways Part 2-protected information may be shared by providers for ASF HEDIS reporting purposes.
- Describe best practices submission of ASF HEDIS measure data by providers.

Key Takeaways

1

HIPAA permits – but does not require
– providers to disclose ASF HEDIS
measure data to health plans

2

42 CFR Part 2 only applies to ASF
data if conducted by a “Part 2
program”

3

Part 2 allows disclosure of ASF data
without consent when part of an
audit/evaluation (i.e. quality
improvement), and with patient
consent when not.

4

Insurance plans may re-disclose
de-identified Part 2 records without
consent.



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ASF HEDIS Measure Reporting

SECTION 1: RELEVANT PRIVACY REGULATION

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HIPAA

- **Applies to** covered entities (healthcare providers, health plans, healthcare clearinghouses) and BAs
 - Protects privacy and security of general health information
- **Purpose:** to protect health data integrity, confidentiality, and accessibility
- **Permits** disclosures without patient consent for treatment, payment, and healthcare operations (e.g.; quality improvement)

42 CFR Part 2

- **Applies to** SUD patient records from federally-assisted “Part 2 programs”
 - Protects privacy and security of records identifying individual as seeking/receiving SUD treatment
- **Purpose:** to encourage people to enter and remain in SUD treatment by guaranteeing confidentiality
- **Requires** patient consent for treatment, payment, and healthcare operations, with limited exception for “Audits and Evaluations” of programs

3 Key Considerations

SECTION 2: HIPAA AND PROVIDER REPORTING OF ASF HEDIS MEASURE DATA

HIPAA Permits Disclosure

Key Point: HIPAA permits – but does not require – disclosures of ASF results without patient consent, for the purpose of the health plan's quality-related healthcare operations.

- Plan must have/had relationship with individual.
- Provider may only disclose PHI for the period during which patient was enrolled in plan.

HIPAA and Patient Requests

Key point: Providers may agree to a patient's request to restrict disclosure of PHI.

- HIPAA requires covered entities to allow individuals to make specific privacy requests.
- In the case of reporting ASF data for QI purposes, a provider is not required to agree.
- If the provider agrees to honor the privacy request, it must comply (except in emergency situations).



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ASF HEDIS Measure Reporting

SECTION 3: DETERMINING WHEN 42 CFR PART 2 APPLIES

When does Part 2 apply?

Key point: Part 2 only applies to ASF HEDIS Measure data from Part 2 programs.

- Not all providers who offer SUD services are “Part 2 programs!”
- Many or most providers required to report ASF HEDIS measure data are NOT Part 2 programs.
- *If the data for the measure is not from a Part 2 program, 42 CFR Part 2 does not apply.*

Part 2 Program Definition

A “Part 2 program” is a SUD program (see definition) that is federally assisted (see definition).

Key Questions

I. Is Provider a SUD
“Program”?



II. Is Provider
Federally Assisted?

Key Questions

Is the healthcare provider...

- (1) An ***individual or entity*** (other than a general medical facility) who **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment?; **or**
 - (2) An ***identified unit*** within a general medical facility that **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment?; **or**
 - (3) Medical personnel or other staff in a general medical facility whose ***primary function*** is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers?



“Program Holds Itself Out”

Q. What does it mean for a program to ***hold itself out*** as providing SUD diagnosis, treatment or referral for treatment?

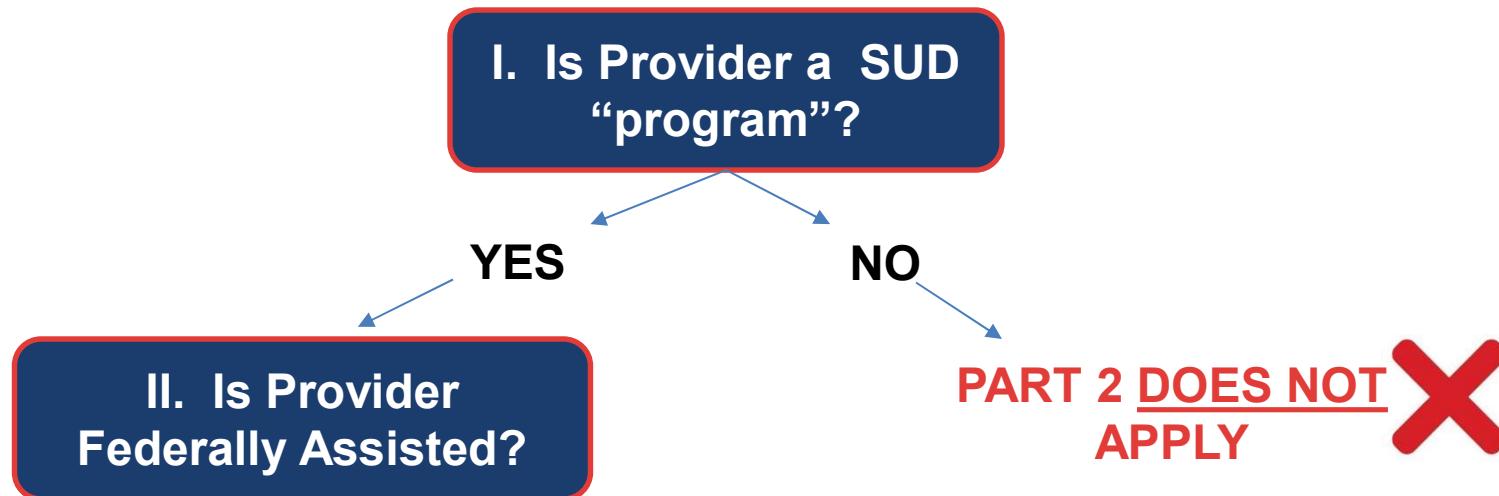
A. Any activity that reasonably indicates the program provides SUD services.

- Advertising, state licensing procedures, statements to community about providing SUD treatment, listings in SUD treatment registries, certifications in addiction treatment, and more.

Examples of SUD “Programs”

- Free-standing SUD clinic
- In-patient or out-patient SUD program at a general hospital
- SUD specialist in hospital ED, whose primary function is providing SUD services, and they are identified as providing SUD services

Key Questions



Key Questions

Is the healthcare provider...

- (1) Operated by the federal government, or by a state/local government that receives federal funding for SUD services; **or**
- (2) Authorized to conduct business by the federal government, including:
 - Participating provider in Medicare/Medicaid;
 - Authorized provider of maintenance treatment or withdrawal management (e.g., OTP);
 - Registered to dispense controlled substances for SUD treatment (e.g., methadone); **or**

I. Is Provider a SUD
“Program”?

YES

II. Is Provider
Federally Assisted?

Key Questions

Is the healthcare provider...

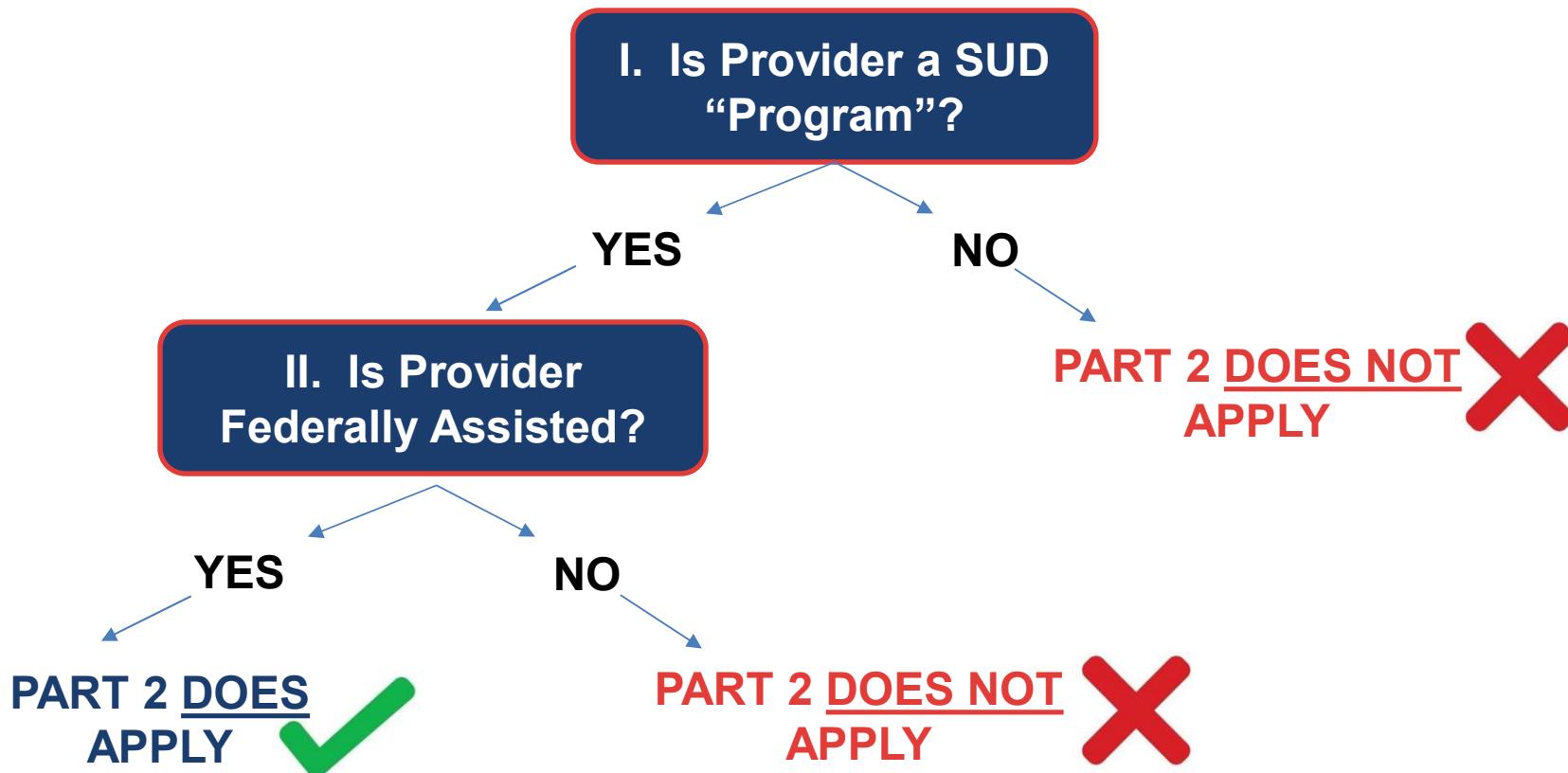
- (3) A recipient of federal funding in any form, even if the assistance does not directly pay for the SUD services; **or**
- (4) A recipient of tax-exempt status from the IRS (e.g., a 501(c)(3) non-profit organization).

I. Is Provider a SUD
“Program”?

YES

II. Is Provider
Federally Assisted?

Key Questions





QUESTIONS?

Case study – Integrated Care

Dr. A is a primary care provider in a general practice unit of a Federally Qualified Health Center (FQHC).

- The FQHC routinely screens for SUD and it provides SUD care.
- Dr. A prescribes buprenorphine to approximately 30% of her patients, for the treatment of opioid use disorder.
- Even for her patients with opioid use disorder, the majority of her work is providing primary care services.

Is Dr. A a “Part 2 program?”



Case study – Integrated Care

No, Dr. A is not a Part 2 program, because she does not meet the definition of a “program” – her *primary function* is not SUD services.

- Dr. A works in a FQHC, so only definitions 2 and 3 of a “program” could possibly apply.
- It’s not option 2 (a specialized unit), because she works in a general practice unit.
- Even though she is medical personnel in a general medical facility that provides SUD services (option 3), it is not her *primary function*.



Case study – Integrated Care

Factors for determining Dr. A's
“primary function”

- Majority of her work is providing primary care services to her patients, regardless of their SUD diagnosis.
- She only prescribes buprenorphine to 30% of her patients.



Case Study – Integrated Care

When Dr. A performs a screening for unhealthy alcohol use, and provides treatment, is this information protected by Part 2?



Case Study – Integrated Care

No, the information about the ASF screening and treatment is not protected by Part 2, because Dr. A is not a Part 2 program.





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For AFS HEDIS Measure Data Reporting

SECTION 4: HOW TO SHARE PART 2-PROTECTED ASF DATA

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General Rule

- **Part 2-protected ASF data may be disclosed:**
 - During claims/reimbursement process – with patient consent; or
 - Separately from claims/reimbursement process – without patient consent, pursuant to Audit/Evaluation (i.e. quality improvement) section of 42 CFR Part 2
- **Unlike HIPAA, Part 2 *follows the protected information even once it is disclosed to the health plan.***
 - Health plan may only re-disclose Part 2 records received through consent/audit if de-identified or another Part 2 exception applies

ASF Data Reporting: Scenario 1

- If a health plan collects ASF data from Part 2 program during the reimbursement process (e.g., by looking at billing codes), it needs *written patient consent*
- Part 2 programs already need written patient consent to disclose information for reimbursement
 - Make sure consent forms identify the purpose of the disclosure as “payment and/or healthcare operations” so that the ASF data reporting is covered by the consent

Adapting Patient Consent Forms

Q. How can we use the “general designation” option in the “to whom” section of consent forms to facilitate data sharing about ASF results?

A. The “general designation” is not applicable for authorizing disclosures to health plans.

- Limited to providers with a “treating provider relationship.”
- Promotes data sharing within health networks and through Health Information Exchanges.

ASF Data Reporting: Scenario 2

- If a health plan collects ASF data from Part 2 program outside the reimbursement process (e.g., by extracting information from EHRs), it does *not* need written patient consent
- Health plan may collect ASF data from Part 2 programs for QI purposes as part of an “audit/evaluation” of the program, so long as health plan complies with the requirements for audits/evaluations, including written contract:
 - Agreeing that health plan understands data protected by Part 2, and will only use information for purpose of audit/evaluation (i.e., quality improvement), and will only re-disclose information back to the Part 2 program.

Sample Script

Health plans and HIEs can encourage sharing of ASF data by using a script similar to the one below when speaking with primary care providers:

We understand and appreciate your efforts to protect the privacy of patients' health information related to alcohol use screening and treatment. Most primary care providers required to report ASF HEDIS measure are NOT Part 2 programs and the Part 2 regulation does not apply. If a clinician in a primary care practice has a primary function of substance use treatment, then 42 CFR Part 2 may apply to that clinician's ASF data. For more information about whether Part 2 applies, visit the Center of Excellence for online resources and technical assistance.

See script, "Speaking with 42 CFR Part 2 programs" for more information.

Sample Script

Health plans and HIEs can encourage sharing of ASF data by using a script similar to the one below when speaking with substance use treatment providers (e.g. *SUD clinic, unit, specialist*):

We understand and appreciate your efforts to protect the privacy of patients' health information related to alcohol use screening and treatment. Not all SUD providers are Part 2 programs. If a SUD provider is "federally assisted" and meets the definition of a "program," then Part 2 applies to patient-level ASF data from the provider. For more information about whether Part 2 applies, visit the Center of Excellence for online resources and technical assistance.

See script, "Speaking with 42 CFR Part 2 programs" for more information.

Sample Script

Health plans and HIEs can encourage sharing of ASF data by using a script similar to the one below when speaking with 42 CFR Part 2 Programs (i.e. *federally assisted SUD program*):

We understand and appreciate your efforts to protect the privacy of patients' health information related to alcohol use screening and treatment. 42 CFR Part 2 regulation applies to ASF information from a Part 2 program. Part 2-protected ASF data may be disclosed during claims/reimbursement process with patient consent; or through audit/evaluation (i.e. quality improvement) without patient consent. We are aware of the requirements of 42 CFR Part 2. We have developed policies and procedures to ensure appropriate handling of Part 2-protected information to ensure that confidentiality is maintained. Here is a copy of our policy and procedure on 42 CFR Part 2 compliance.



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AFS HEDIS Measure Data Reporting

SECTION 5: BEST PRACTICES TO SUPPORT REPORTING

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Tools for Health Plans

- Confirm that 42 CFR Part 2 applies to data using analysis above
- If Part 2 does apply, and ...
 - ASF data will be collected through reimbursement process:
 - Make sure consent forms identify the purpose of disclosure as: “*payment and healthcare operations*”
 - ASF data will be collected outside claims process as audit/evaluation (i.e. quality improvement):
 - Make sure health plan has written audit/evaluation contract in place with provider

Supporting Providers

Provider Education

- FAQ documents
- Provider newsletters
- Required provider training (e.g., distance learning)

Provider Templates

- Patient consent templates
- Privacy notification templates

Patient Co-Design

- Co-design systems to obtain consent with patients and providers

Summary

1

HIPAA permits – but does not require – providers to disclose ASF HEDIS measure data to health plans

2

42 CFR Part 2 only applies to ASF data if conducted by a “Part 2 program”

3

Part 2 allows disclosure of ASF data without consent when part of an audit/evaluation (i.e. quality improvement), and with patient consent when not.

4

Insurance plans may re-disclose de-identified Part 2 records without consent.

Additional Resources

Resource Library

<https://www.coephi.org/resource-center>

Request Technical Assistance

<https://www.coephi.org/technical-assistance>

Contact: mgraziano@coephi.org



The screenshot shows the homepage of the CoE - PHI Resource Center. At the top, there is a red header bar with the text "CoE - PHI" and "Center of Excellence for Protected Health Information" below it. The main content area is white and features a sidebar on the left with "QUICK LINKS" including "PROJECT OVERVIEW", "WHO IS INVOLVED IN THE INITIATIVE?", "CORE PROJECT STAFF", "NATIONAL ADVISORY GROUP MEMBERS", "HOW WILL WE KNOW WE ARE SUCCESSFUL?", "REQUEST TA", "RESOURCE CENTER", and "CONTACT US". In the center, there is a red box with the text "Join Our Mailing List" and a "click here" button. On the right, there is a "RESOURCE CENTER" section with a sub-section titled "The resources within this section are provided to promote awareness and strengthen knowledge and skills for professionals who are seeking to understand and apply Protected Health Information (PHI) privacy laws and regulations on the job and for individuals and families when accessing services. Resources are presented by categories for Substance Use Disorder (SUD) Treatment Providers, Mental Health (MH) Treatment Providers, Healthcare Providers, for professionals working in Educational Institutions, and for Patients and Families. Resources included in each category address PHI Law and Regulations, Official Guidance, Tips for Implementing PHI, and Sample Templates and Forms and many are available in downloadable format." Below this, there is a list of categories with blue downward arrows: "SUBSTANCE USE DISORDER (SUD) TREATMENT PROVIDERS", "MENTAL HEALTH (MH) TREATMENT PROVIDERS", "OTHER HEALTHCARE PROVIDERS", "PROFESSIONALS WORKING IN EDUCATIONAL INSTITUTIONS", and "PATIENTS & FAMILIES".



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Appendix

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Supplemental Case Study

HIPAA PATIENT RIGHTS

Case Study – Mary

Mary's doctor conducts Unhealthy Alcohol Use screening. During the screening Mary asks how the results will be shared, and tells the doctor "you can submit a billing code for reimbursement but please do not share my information in any other way."

What should the doctor do?



Case Study - Mary

The doctor can choose whether or not to agree to Mary's request

If the doctor agrees:

- Then the doctor and the entire practice must honor Mary's request to restrict disclosures of her screening results.
- The results could not be shared with the health plan for the purpose of healthcare operations



Supplemental Case Study

WHEN DOES 42 CFR PART 2 APPLY TO ASF DATA?

Case Study – SUD Facility

An opioid treatment program (OTP) screens a patient for unhealthy alcohol use, and then provides treatment.

Is the OTP a Part 2 program?



Case Study – SUD Facility

Yes, the OTP is a Part 2 program.

- **Step 1:** it meets the definition of a “program,” because it is not a general medical facility, and it holds itself out as providing, and does provide, SUD services.
- **Step 2:** it is federally assisted, because it needs federal authorization to conduct methadone maintenance.



Case Study – SUD Facility

When a nurse at the OTP performs a screening for unhealthy alcohol use, and provides treatment, is this information protected by Part 2?



Case Study - SUD Facility

Yes, the information about the ASF screening is protected by Part 2, because the nurse works in a Part 2 program.

- HIPAA and state laws still apply, but Part 2 is (likely) the most protective of these laws, so Part 2 is the applicable standard.





STATE PRIVACY LAW

What About State Law?

- Many states have health privacy laws that are stricter than HIPAA, especially for SUD-related information.
- ***Key point: If state law is more protective of patient privacy than federal privacy law, state law applies.***
- Consult with local counsel about state privacy protections in your state.

42 CFR PART 2: THE BASICS

What Information is Protected?

- Part 2 protects written or oral records with *patient identifying information*:
 - Information that *identifies* an individual...
 - As someone who has applied for or received SUD services at a *Part 2 program*.

What Isn't Protected?

- De-identified information
 - Redacted records, with patient identifiers removed
- Aggregate information
 - With patient identifiers removed
- Information that does not connect the patient to a Part 2 program
 - e.g.; hospital directory

Patient Consent Form

Key Elements for Part 2 disclosures:

- Patient name
- Information about who is authorized to disclose and receive information
- Description of information to be disclosed
- Purpose of disclosure
- Statement that consent may be revoked by patient
- Expiration date/event/condition
- Patient signature and date

Notice Prohibiting Re-disclosure

- Disclosures of Part 2-protected records, including ASF HEDIS Measure data when it is from a Part 2 program, must be accompanied by the **notice prohibiting re-disclosure**.
- The recipient of the information – the health plan – then becomes a “lawful holder” and must follow Part 2.

See Handout:
Notice Prohibiting Re-disclosure

Practical Application

COMPLYING WITH PART 2

You're a lawful holder: Now what?

Health plans that receive Part 2-protected ASF data can re-disclose by:

- Removing the patient-identifying information
 - Aggregate reports
 - Redacted reports
- Signing a contract with a party authorized to conduct an audit or evaluation.

“Flag” Part 2 Data

It is important to “flag” your Part 2 information so that:

- You only re-disclose Part 2 data in ways permitted by law
- You remember to include the Notice Prohibiting Re-disclosure when you share Part 2-protected records



Policies and Procedures

Put in place policies and procedures to “flag” when data is protected by Part 2

- Tag data in database/E.H.R.
- Password-protect electronic files
- For paper files, stamp, separate, or otherwise signal which files are Part 2-protected



Technology

- Technology can help
- Consent2Share
 - Free, open source software application, developed by SAMHSA to comply with Part 2
 - Integrates with existing electronic health record systems (EHRs) and health information exchanges (HIEs)



Encouraging Sharing of ASF Data by Part 2 Programs

- Health plans and/or State HIEs can facilitate sharing of ASF data from Part 2 programs by:
 - demonstrating an understanding of Part 2 requirements
 - demonstrating the technical capacity to comply with Part 2 requirements, including:
 - creating policies/procedures to ensure compliance
 - flagging Part 2 records and only re-disclosing in ways permitted by Part 2
 - disclosing Part 2 records with copy of notice prohibiting re-disclosure

