HIPAA & CFR Part 2 in Integrated Behavioral Health Settings

MT HIMSS 2018 SPRING CONFERENCE

Panelist

Amber Rogers	Kristen Schuster	Erin MacLean	Deb Anderson
			

Behavioral Health Integration in Montana

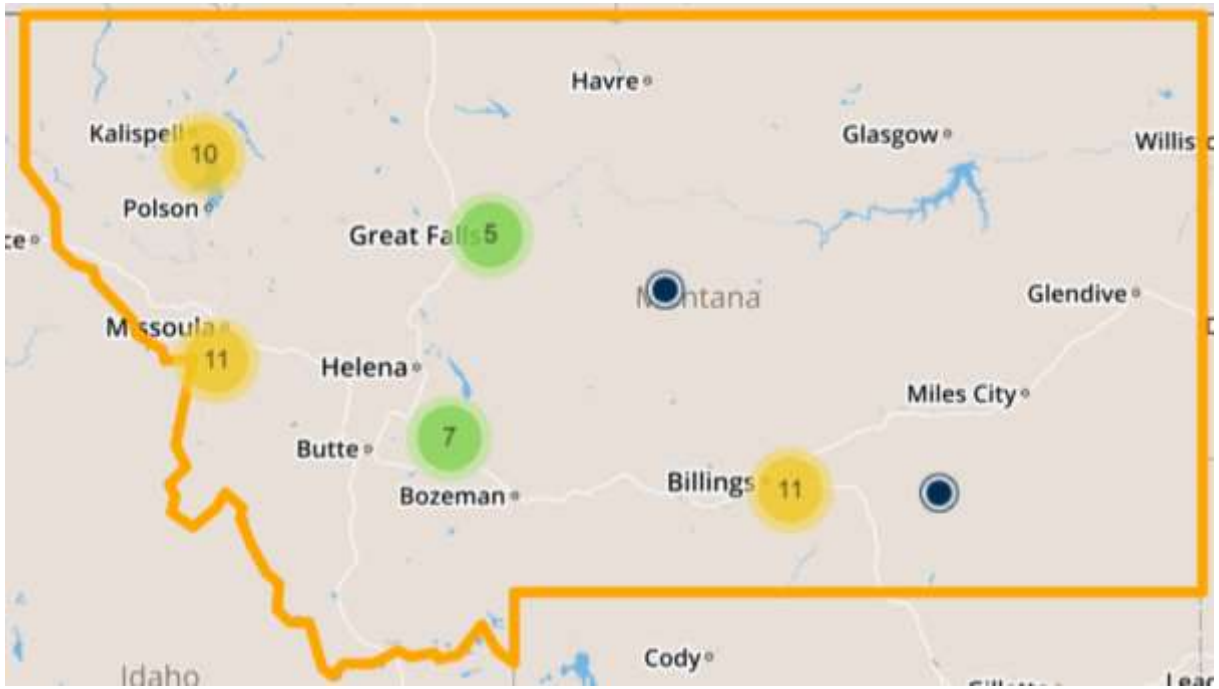
Kristen Schuster
Practice Facilitator - CPC+ Montana Region
Mountain-Pacific Quality Health
kschuster@mpqhf.org

Why Primary Care?

Behavioral health conditions in primary care

- 30 percent of patients have a BH co-morbidity
- Consider the obstacles your patients face when seeking the behavioral health care they require, along with how to overcome those obstacles
- 50 percent of patients with serious mental illness have ≥ 1 chronic medical condition
- Significant overall health care costs associated with BH conditions

Where is Behavioral Health Integration Being Developed?



Behavioral Health Integration Models in Montana

Strategies for Implementation of a BHI Model

Hire someone with a behavioral health background to provide all care management services

Train an existing care manager to provide protocol driven BH services

Offer space in your office for a behavioral health clinician to work out of if they agree to take referrals and provide crisis management

Co-op with other providers to share a BH clinicians time

Strategies for Implementation of a BHI Model

Contract with an existing BH agency or church counseling in your town

Look into telehealth options with outside organizations

Use telehealth options to cover multiple clinics within an organization (hub approach)

Work with a university for placement of interns or residents

What is the goal of BHI?

"…the care that results from a practice **team** of primary care and behavioral health clinicians, working together with patients and families, using a systematic and cost-effective approach to provide patient-centered care…"[1]

[1]Crowley, RA., Kirschner, N. (2015). The integration of care for mental health, substance abuse, and other behavioral health conditions into primary care: executive summary of an American College of Physicians position paper. *Health and Public Policy Committee of the American College of Physicians*, 163(4):298-9. doi: 10.7326/M15-0510.

Behavioral Health Teams and 42 CFR Part 2

The American Psychiatric Association, on 42 CFR Part 2 (March 2017):

"While the regulations make minor changes to align with the Health Insurance Portability and Accountability Act (HIPAA) in an effort to allow more Part 2 providers to take advantage of new models of care that promote value- and team-based care, the technological solutions needed to implement the final regulations are lacking. Until this issue is fully addressed, various components of Part 2 may continue to act as a barrier to integrated care efforts."

https://www.psychiatry.org/psychiatrists/practice/practice-management/hipaa/42-cfr-part-2

SAMHSA'S CHANGES TO 42 CFR Part 2

ERIN MACLEAN, ESQ.

FREEMAN & MACLEAN, PC

44 W. 6TH AVE., HELENA, MT 59601

EMACLEAN@FANDMPC.COM

HHS/SAMHSA FINAL RULE PUBLISHED 2017

On January 18th, 2017, a final rule from The Substance Abuse and Mental Health Services Administration (SAMHSA) was published in the Federal Register Notice to update Part 2. The rule was initially scheduled to go into effect 30 days after its publication but was pushed to March 21 to give the Trump Administration time to review the rule.

This final rule, the first rulemaking in 30 years from SAMHSA on Part 2 (since the last rulemaking in 1987), broadly revised requirements for Part 2 Substance Use Disorder Programs and other recipients of Part 2 information.

What is.... SAMHSA Substance Abuse and Mental Health Services Administration ?

SAMHSA is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation.

What is the Vision?

- *SAMHSA provides leadership and devotes its resources, including programs, policies, information and data, contracts and grants, to help the United States act on the knowledge that:*
  - *Behavioral Health is essential to health*
  - *Prevention works*
  - *Treatment is effective*
  - *People recover from mental and substance use disorders*

What is the Mission?

It is SAMHSA's mission to reduce the impact of substance abuse and mental illness on America's communities.

Opioid Drug Treatment and SAMHSA

SAMHSA Regulations Affect the Disclosure of Information related to Opioid Drug Treatment

- Treatment of opioid dependence with opioid medications is governed by Federal Regulation 42 CFR Part 8, which provides for an accreditation and certification based system for opioid treatment programs.
- The regulation acknowledges that addiction is a medical disorder that may require differing treatment protocols for different patients.

The Division of Pharmacologic Therapies, part of the SAMHSA Center for Substance Abuse Treatment, is responsible for overseeing accreditation standards and certification process.

Public statement from HHS When January 2017 New Rule Issued

Statement from said HHS Deputy Assistant Secretary, Kana Enomoto: ***"Today's changes will further enhance health services research, integrated treatment, quality assurance and health information exchange activities while at the same time safeguarding the essential privacy rights of people seeking treatment for substance use disorders…."***

"…These efforts clear the way for integrated health care models that can provide a better, more cost-effective health care system that also empowers people to make key decisions about their health care…."

HISTORY AND PURPOSE OF “PART 2”

The rules governing the confidentiality of substance use disorder records, often referred to as “Part 2,” were promulgated in 1975, *because of the concern that if the identities of people in treatment for substance use were revealed those patients might be subject to criminal prosecution and a wide range of other serious social consequences.*

These harmful consequences could deter people from seeking needed treatment.

Until 2017, No Rules Promulgated since 1975.

HISTORY AND PURPOSE OF “PART 2”

Then, in February 2016, HHS issued a notice of proposed rulemaking (NPRM) proposing changes to Part 2 to:

- *“reflect the current health care delivery system, promote health integration and permit appropriate research and data exchange activities.”*
- *“HHS stated the rule was proposed to carefully balances the public health benefits of information exchange and continued protection of patient privacy.”*

Part 2 Rule does not Directly Align with HIPAA

While the final rule takes helpful steps to modernize Part 2, **it does not align with HIPAA in many important ways.**

See **Comparison Chart** provided with this program comparing the components of the Final Rule issued in 2017 with HIPAA:

- Applicability
- Consent Requirements
- Prohibitions on Redisclosure
- Medical Emergency
- Audit trail/accounting of disclosures
- Qualified Services Organization
- Research

General Rule under Part 2

The General Rule under Part 2 restricts disclosure of Part 2 information. The restrictions on disclosure in the regulations in this part apply to any information, whether or not recorded, which:

- **(i) Would identify 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**; and
- **(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program)...**

Best Regulatory Website for Part 2 regs

Note on Part 2: The reading of all of the regulatory pieces together can be very confusing.

BEWARE:

Many websites referring to 42 CFR Part 2 are outdated.

The best cite to look up the Part 2 regulations is:

- https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2
  - This is the Electronic Code of Federal Regulations (eCFR.gov).

Eight Key Takeaways from 2017 Final Rule

1. Patient Consent Forms May Authorize a General Disclosure to Intermediate Entities Like Health Information Exchanges and Treating Providers

Part 2 requires that patient consent forms identify the recipients of confidential information.

The **Final Rule continues to permit consent forms to meet this requirement by authorizing disclosures to specific individuals or treating entities like hospitals or clinics**; in addition, consent forms may now authorize disclosures pursuant to a **general designation** if certain requirements are met.

- For instance, the **Final Rule allows a consent form to authorize disclosure to a health information exchange or other intermediate entity and "my current and future treating providers."**
  - When this kind of general designation is used, the intermediate entity may further disclose the patient identifying information it receives only to those providers it can verify have a treating provider relationship with the patient.
- Final Rule entitles patients who have consented to disclose their information using a **general designation to receive from the intermediate entity, upon written request, a list of entities to which their information has been disclosed within the last two years pursuant to the general designation.**

Patient Consent Form Revisions Compared to Previous Rule

Previously, a patient could designate an individual or an entity to receive Part 2 information (i.e. information held by a Part 2 program, including the name, address, social security number, fingerprints, photograph or similar information, that could be used to identify 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).

The recipient of the Part 2 information would then be prohibited from redisclosing the Part 2 information without an additional consent from the patient.

This previous consent requirement made it practically impossible to include Part 2 patient information in health information exchanges and placed an obstacle in the way of fully integrating patient care.

- The **final rule attempts to address this challenge by permitting recipients of Part 2 information to redisclose said information to a patient's treating providers pursuant to a "general designation" on a consent form**.

Contents of Consent Forms… Not Your HIPAA Authorization

Under the new final rule, patient consent forms for disclosure of Part 2 information are required to be **in writing** (electronic or paper) and to **include the following information**:

- The name of the patient;
- The date on which the consent is signed;
- The specific name(s) or general designation(s) of the Part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure;
- How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that is to be disclosed to each individual or entity;
- The purpose of the disclosure (the amount of Part 2 information disclosed must be limited to that information which is necessary to carry out this purpose);
- The name of the individual or entity that is to receive the information (multiple authorizations can be included on one form);
- A statement that a patient, when authorizing disclosure of his or her Part 2 information to a "general" recipient (e.g., "all future treating providers"), has a right to obtain, upon request, a list of the disclosures made of his or her Part 2 information;
- A statement that the consent is revocable at any time, except to the extent that the Part 2 program or other lawful holder of the Part 2 information has acted in reliance on the consent;
- The date, event or condition on which the consent will expire (if not revoked before this), ensuring that the consent form will last no longer than is necessary to serve the purpose for which the consent is provided; and
- The patient's signature or, if the patient is a minor or lacks legal capacity, the patient's guardian (electronic signatures are permissible).

Patient Designations under Part 2

Patient can designate the following individuals and entities (an expansion from the previous rule) to receive his or her Part 2 information:

- **Specifically named individuals**
- **A general designation to those individuals or entities with a treating provider relationship (see next slide).**
- **Third-Party Entities**

What is a Treating Provider Relationship?

A "**treating provider relationship**" is defined in the final rule as when a patient is **being, agrees to, or is legally required to be diagnosed, evaluated and/or treated, or agrees to accept consultation for any condition by an individual or entity, and the individual or entity undertakes the same or agrees to do so.**

In addition, a patient may designate, by name, one or more individuals on their health care team with whom they do not have a treating provider relationship.

Under the definition, **a treating provider relationship begins when an individual seeks health-related assistance from an individual or entity who may provide assistance**.

Patients may further designate their **treating providers as "past," "current," and/or "future" treating providers.**

More on a Treating Provider Relationship…

SAMHSA considers an **entity** (not an individual, previously designated in the regulation as an "organization") **to have a treating provider relationship with a patient if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.**

The term "agrees" as used in the definition does not necessarily imply a formal written agreement. **An agreement might be evidenced by, among other things, making an appointment or seeking a telephone consultation.**

Third-Party Entity

New under the Final Rule the Patient may consent to disclosure on the Consent form to a **third-party entity** with whom the **patient does not have a treating provider relationship** (e.g., a health information exchange) and,

On the same consent form, the **patient can permit this third-party entity to redisclose his or her Part 2 information to other named individuals or entities with whom the patient does have a treating provider relationship**:

- (e.g., "I consent to disclosure of my Part 2 information to the Western Health Information Exchange, and agree to permit the VHIE to redisclose my information to my current provider and all future providers with whom I have a treating provider relationship.").

Eight Key Takeaways from 2017 Final Rule (cont.)

2. Patient Consent Forms Must Include an Explicit Description of the Substance Use Disorder Information that May be Disclosed (42 C.F.R. § 2.31(a)(3))

Consent forms must include the amount and kind of information to be disclosed by stating that there should be "an explicit description of the substance use disorder information that may be disclosed."

SAMHSA suggests that the types of information that could be specified include diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary elements of a medical record, employment information, living situation and social supports, and claims or encounter data.

The agency also states that it is permissible for a patient to make a selection like "all my substance use disorder information" as long as the consent form accommodates more specific limitations.

Patient Consent Options and Issue

Challenge posed by Rule:

- providers must give a patient the option on the consent form to choose specific subsets of his or her Part 2 information to be disclosed.
- The level of granularity that providers must offer to a patient in selecting what information is to be disclosed could be prohibitive since many electronic health records do not have the capacity to parse Part 2 patient information into specific subsets.
- Providers are still permitted to include an option for the patient to consent to "**all my substance use disorder-related information**", **as long as the more granular options with "explicit descriptions" are also included on the form**.

Exchange Under the New Rule and Issue

Additional provisions in the new rule continue to make the exchange of Part 2 information difficult and, in some cases, impossible, such as:

- For example, a **patient is entitled to receive a list of all entities to which his or her information has been disclosed pursuant to a general designation, including disclosures for treatment and health care operations purposes**.
- **Third-party entities without a treating provider relationship with the patient that have redisclosed Part 2 information** pursuant to a "**general designation**" on a consent form, including health information exchanges, **will need to be able to provide this list of disclosures to the patient before the entity can begin accepting and acting based on a "general designation" consent form**.

Eight Key Takeaways from 2017 Final Rule

3. A Qualified Services Organization May Provide Population Health Management Services

In **certain circumstances**, Part 2 **permits disclosure without patient consent to a Qualified Service Organization (QSO) that provides services to a Part 2 Program**.

- Population health management is one kind of service that may be provided by a QSO.
- SAMHSA defines "**population health management**" as "**increasing desired health outcomes and conditions through monitoring and identifying patients within a group**."
- **Disclosures for population health management** pursuant to a QSO agreement **must be limited to the specific offices or units that are tasked with carrying out population health management for the organization**.
- **Care coordination is not considered by SAMHSA to be population health management because it includes a patient treatment component.**

Eight Key Takeaways from 2017 Final Rule

4. Health Care Providers Do Not Become Part 2 Programs Simply Because They Provide Screening, Brief Intervention, or Referral to Treatment (SBIRT)

The preamble to the Final Rule states that **health care providers do not become a Part 2 "program" simply because they provide SBIRT** within the context of general health care.

Definition of Part 2 Program

To be a "**program**" that falls under 42 CFR Part 2, **an individual or entity must be federally assisted and hold itself out as providing, and provide, alcohol or drug abuse diagnosis, treatment or referral for treatment** (42 CFR § 2.11).

A program is "**federally assisted**" if it is:

- **1) authorized, licensed, certified, or registered by the federal government;**
- **2) receives federal funds in any form, even if the funds do not directly pay for the alcohol or drug abuse services; or**
- **3) is assisted by the Internal Revenue Service through a grant of tax exempt status or allowance of tax deductions for contributions; or**
- **4) is authorized to conduct business by the federal government (e.g., certified as a Medicare provider, authorized to conduct methadone maintenance treatment, or registered with the Drug Enforcement Agency (DEA) to dispense a controlled substance used in the treatment of alcohol or drug abuse); or 5) is conducted directly by the federal government.**

Part 2 Program Definition (cont.)

SAMHSA also reiterates that "**holds itself out**" means "**any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment.**"

- **This includes authorization such as licensure or certification by the state or federal government to provide such services; advertisements, notices, or statements related to such services; and consultation activities related to such services.**

Facility Based Part 2 Program Definition

A **different definition of a "program" applies when services are provided by a specialized unit or staff within a general medical facility** (or '**mixed use' facility**).

A **general medical facility** has a Part 2 program if:

- 1) there is "**an identified unit within a medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment**;" or
- 2) there are "**medical personnel or other staff in a general medical facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers."**

A **mixed use facility** can be defined as a **service provider organization that provides substance abuse treatment services as well as other health services such as primary care, dental care, mental health services, social services, etc**.

Note: Most drug and alcohol treatment programs are federally assisted.

Eight Key Takeaways from 2017 Final Rule

5. The Prohibition on Re-Disclosure Applies Only to Identifying Information

Final Rule clarifies that the Part 2 **prohibition on re-disclosure provision applies only to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder**.

Other health-related information that is unrelated to the substance abuse disorder, such as treatment for an unrelated health condition, **may be re-disclosed, if permissible under the applicable law (such as HIPAA)**.

In addition, **if the origin of the data (such as a treatment clinic) would reveal that the individual has a substance abuse disorder, then the disclosure would be prohibited**.

Eight Key Takeaways from 2017 Final Rule

6. Confidential Information May Be Disclosed Without Consent to Meet a Bona Fide Medical Emergency

The Final Rule aligns the definition of "**medical emergency**" with the statutory definition.

The revised language states that a **patient's identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency, in which the patient's prior informed consent cannot be obtained**.

SAMHSA continues to require the Part 2 program to **immediately document, in writing, specific information related to the medical emergency**

Eight Key Takeaways from 2017 Final Rule

7. Part 2 Security Requirements Apply to Both Electronic and Paper Records

The Final Rule **incorporates electronic records in the security requirements under Part 2.**

Part 2 programs and other lawful holders of patient identifying information are **required to have in place formal policies and procedures for the security of both paper and electronic records**.

Part 2 programs must have formal policies and procedures in place to protect against threats or hazards to the security of Part 2 information.

- This is similar to the requirements under HIPAA's Security Rule

Final Rule also establishes procedures for sanitizing electronic media for handling electronic records subsequent to the discontinuation of a Part 2 program (i.e. destruction).

Note: Electronic records are included in the exception for disclosure without consent for audit and evaluation activities.

Elements of Policies and Protocols

The formal policies and procedures required of Part 2 programs must address the following elements:

Paper records

- **Transferring and removing such records;**
- **Destroying such records (including sanitizing the hard copy media associated with the paper printouts);**
- **Maintaining such records in a secure room, locked file cabinet, safe or other similar container, or storage facility when not in use;**
- **Using and accessing workstations, secure rooms, locked file cabinets, safes or other similar containers and storage facilities; and**
- **Rendering patient identifying information non-identifiable in a manner that creates a very low risk of re-identification.**

Electronic records

- **Creating, receiving, maintaining, and transmitting such records;**
- **Destroying such records, including sanitizing the electronic media on which such records are stored, to render the patient identifying information non-retrievable;**
- **Using and accessing electronic media containing patient identifying information; and**
- **Rendering the patient identifying information non-identifiable in a manner that creates a very low risk of re-identification.**

Eight Key Takeaways from 2017 Final Rule

8. Confidential Information May Be Disclosed For Scientific Research Without Patient Consent to Recipients Who Meet Relevant HIPAA and Common Rule Reqs

The Final Rule **liberalizes the Part 2 exception allowing patient information to be disclosed without consent** for the purpose of **conducting scientific research**. if the program director makes a determination that specified requirements have been met

It allows any **individual in lawful possession of Part 2 data to disclose the information to qualified research personnel** for the **purpose of conducting scientific research if applicable requirements are satisfied**, **including privacy regulations under HIPAA and regulations for the protection of human subjects under the "Common Rule."**

The Final Rule also addresses data linkages to enable researchers holding Part 2 data to link to federal data sets.

Exceptions to General Rule in Part 2

The New Rule Provided for a number of Exceptions to the provisions of the rule -

EXCEPTION 1: Department of Veterans Affairs. These regulations **do not apply to information on substance use disorder patients maintained in connection with the Department of Veterans Affairs' provision of hospital care, nursing home care, domiciliary care, and medical services** under Title 38, U.S.C. Those records are governed by 38 U.S.C. 7332 and regulations issued under that authority by the Secretary of Veterans Affairs.

EXCEPTION 2: Armed Forces. The regulations **do apply** to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice **except**:

- **(i) Any interchange of that information within the Armed Forces; and**
- **(ii) Any interchange of that information between the Armed Forces and those components of the Department of Veterans Affairs furnishing health care to veterans.**

Exceptions (cont.)

EXCEPTION 3: ***Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.***

The **restrictions on disclosure** **do not apply** **to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are**:

- **(i) Within a part 2 program; or**
- **(ii) Between a part 2 program and an entity that has direct administrative control over the program.**

Specifically, **when a substance use disorder unit is a component of a larger behavioral health program or of a general health program, specific information about a patient arising out of that patient's diagnosis, treatment or referral to treatment can be exchanged without patient consent among the Part 2 program personnel and with administrative personnel who, in connection with their duties, need to know information** (42 CFR § 2.12(c)(3)).

- Patient **information may not be exchanged among all of the programs** and personnel that fall under the umbrella of the entity that has administrative control over the Part 2 program
  - **A QSOA would be required to enable information exchange without patient consent in this situation (See next slide).**

Exceptions (cont.)

EXCEPTION 4: *Qualified service organizations.* Where a **Part 2 program has entered into a QSOA with an entity that provides any of the covered services**, and **where the information exchanged is needed to provide the covered services**, **patient consent is not required.**

This is unlike HIPAA, which allows use and disclosure for TPO.

What is a QSO and What is a QSOA?

Under Part 2, some information exchange may take place without patient consent when a qualified service organization agreement **Qualified Servicer Organization Agreement (QSOA)** exists with the Part 2 program Qualified Service Organization.

A **Qualified Service Organization (QSO),** defined as:

- **a person or organization that:**
  - **1) provides services to a [Part 2] program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting or other professional services or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and**
  - **2) has entered into a written agreement with a program under which that person**
    - **a) acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and**
    - **b) if necessary, will resist in judicial proceedings any efforts to obtain access to patient records, except as permitted by these regulations.**

Exceptions (cont.)

EXCEPTION 5: ***Crimes on part 2 program premises or against part 2 program personnel.***

The restrictions on disclosure and use in Part 2 **do not apply to communications from part 2 program personnel to law enforcement agencies or officials which**:

- **(i) Are directly related to a patient's commission of a crime on the premises of the part 2 program or against part 2 program personnel or to a threat to commit such a crime**; and
- **(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts**.

EXCEPTION 6: ***Reports of suspected child abuse and neglect.*** The restrictions on disclosure and use in the regulations in this part do not apply to the **reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities**.

- However, the **restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect**.

New Rule Did Not Live Up to Hopes of Providers to Streamline HIPAA and Part 2

Despite hopes that this revision of Part 2 would bring Part 2 privacy regulations more in line with HIPAA privacy and security regulations, there are **still significant differences between the confidentiality requirements of HIPAA and those pertaining to Part 2 patient identifying information**.

- See, again, comparison with HIPAA provided with presentation.

Also, **the exceptions to the rule prove to be difficult to understand and manage, internally, for Part 2 and non-Part 2 providers receiving Part 2 information**

Then....in January of 2018...Final Rule Update

Providers were just getting their heads wrapped around their obligations under the 2017 Final Rule, when...

On January 3, 2018, SAMHSA **issued another Final Rule on 42 CFR Part 2**, intended to **"update and modernize the Confidentiality of Substance Use Disorder Patient Records regulations at Part 2."**

The Final Rule **builds upon the previous regulations** issued by SAMHSA in January 2017.

2018 New Final Rule Provides

The **option** for Part 2 programs and lawful holders to use an **abbreviated notice of the re-disclosure prohibition when disclosing Part 2 information.**

The ability of **lawful holders** to **disclose Part 2 information to contractors, subcontractors and legal representatives ("contractors") for payment and health care operations without additional patient consent**, if certain conditions are met; and

The **ability of lawful holders** to **disclose Part 2 information for Medicaid, Medicare or Children's Health Insurance Program ("CHIP") audit or evaluation activities** if certain conditions are met.

How 2018 Rule Revised
Prohibition on Re-Disclosure Notice

Part 2 requires that a **notice prohibiting re-disclosure** accompany disclosures of Part 2 information.

Under the 2018 Final Rule, SAMHSA has adopted **an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems**.

It reads "*Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records*."

How 2018 Rule Revised
Disclosures Permitted with Written Consent

Under the 2018 Final Rule, **if a patient consents to a disclosure of their Part 2 information for payment and/or health care operations activities, the lawful holder who receives such information may now further disclose those records to its contractors as necessary to carry out payment and/or health care operations purposes on behalf of such lawful holder but may not do so for treatment purposes.**

- SAMSHA provided a list of 17 specific types of payment and health care operations activities as illustrative examples; however, the list is not exhaustive.

In this context, **treatment means diagnosis, treatment or referral for treatment, care coordination or case management**.

- SAMSHA explained that it "**believes it is important to maintain patient choice in disclosing health information to health care providers with whom patients have direct contact**."

Previously, lawful holders, such as other treating providers or HIEs, struggled with whether they had the ability to further **disclose Part 2 information to their contractors**. Now they may do so for limited purposes.

How 2018 Rule Revised 2017 Rule **Contract Provisions for Disclosures**

The Final Rule requires a **lawful holder**, **who engages a contractor to carry out payment and or health care operations activities**, **to have in place a written contract or comparable legal instrument specifically requiring the contractor to comply with Part 2**. (Similar to Business Associate Agreement under HIPAA).

- The lawful holders must **require recipients of the Part 2 information to implement appropriate safeguards to prevent unauthorized uses and disclosures and to report any unauthorized uses, disclosures or breaches of Part 2 information to the lawful holder**.

SAMHSA did not specify particular contract language to meet this requirement but did state that "**referencing Part 2 in contracts will help to underscore the importance of compliance with Part 2 provisions**." (In Contrast, HHS did provide specific language for Business Associate Agreements under HIPAA.

- This is taken to mean that **simple "compliance with law" language in existing agreements is likely insufficient for Part 2 compliance**.

It is anticipated that some lawful holders who are subject to HIPAA will incorporate a Part 2 provision into their standard business associate agreements.

How 2018 Rule Revised
CMS Audit and Evaluation Disclosures

- Under the Final Rule, a **lawful holder** may now disclose Part 2 information to its contractors if the disclosure is for "**a Medicare, Medicaid or CHIP audit or evaluation, including a civil investigation or administrative remedy**."

- Note: **Business associates under HIPAA have typically been permitted to make these types of disclosures**.

NOT a HIPAA “Fix” for Providers

Commentator:

“While the Final Rule and the previous regulations issued by SAMHSA make some progress toward reconciling the two sets of regulations, it is expected the industry will continue to experience difficulty in operationalizing the remaining differences.”

More Comments…

Mental Health of America's (MHA) Statement on Revisions to 42 CFR Part 2 (January 3, 2018):

"By requiring a separate and more restrictive authorization than [HIPAA] in order to share substance use treatment records…[the New Part 2 Rule] inadvertently impeded the efforts toward comprehensive, whole-person health care and reinforced historical discrimination against behavioral health…

MHA appreciates SAMHSA's statement that it "plans to explore additional alignment with HIPAA, and may consider additional rulemaking for 42 CFR part 2…."

Fully conforming [Part 2] to HIPAA is imperative to realize the goal of full integration of health and behavioral health care, because you can't treat a whole person with half a record…

MHA looks forward to working with the agency to address remaining barriers to integration, as well as to working with Congress to address statutory limitations where SAMHSA does not have the authority…

While the road to fully integrated services for mental health and substance use is still long, removing barriers is a critical first step."

Effective and Implementation Dates of 2018 Revisions to “Part 2”

The effective date of the new Final Rule was **February 2, 2018**.

After this date, **Part 2 programs and lawful holders may start using the abbreviated notice, and lawful holders may start disclosing Part 2 information to contractors for payment and health care operations under certain circumstances**.

By **February 2, 2020**, lawful holders must ensure that their agreements with contractors are in compliance with the Final Rule.

Practical Takeaways

In response to the Final Rule, by **February 2, 2018**, health care organizations should:

- **Re-affirm whether they are a Part 2 program, QSO or other lawful holder** of Part 2 information;
- **Review and revise policies and procedures** as needed to adopt the abbreviated re-disclosure notice to accompany electronic and paper disclosures of Part 2 information;
- **Review and revise patient consent forms as needed to allow for the disclosure of Part 2 information for payment and/or health care operations** to contractors to **ensure the "purpose" section of the consent form is consistent with the purpose of the disclosure**;

Review and revise agreements as needed between lawful holders and contractors, if the contractor will receiving and disclosing Part 2 information for **payment and health care operations**, for compliance by **February 2, 2020)**

Thank you!

ERIN MACLEAN, ESQ.

FREEMAN & MACLEAN, P.C.

EMACLEAN@FANDMPC.COM

A Broader Perspective of SAMHSA Application

Deb Anderson, CPHIMS

HIT/QI Consultant

Mountain-Pacific Quality Health
Health Technology Services

SAMHSA IS HHS'S MENTAL HEALTH/SUBSTANCE ABUSE DIGNITY ENFORCER

"SAMHSA works to protect the rights of the most vulnerable individuals with mental and/or substance use disorders by ensuring they are treated with dignity"

Overview

A **number of specific laws, regulations, and guidelines are directly relevant to SAMHSA**, **SAMHSA-funded activities, and to the fields of mental health and substance abuse**. These cover such areas as:

- **Behavioral health services financing, access, and delivery**
- **Civil rights protections**
- **Medical records privacy and confidentiality**
- **Substance use regulations and drug-free workplace mandates and testing**

Behavioral Health Services Financing, Access, and Delivery

Many federal laws and regulations impact behavioral health services financing, access, and delivery. Several of the key laws and regulations fall into the following five areas:

- **Patient Protection and Affordable Care Act**
- **Mental Health Parity and Addiction Equity Act (MHPAEA)**
- **SAMHSA Laws and Regulations**
- **Emergency Response**
- **Charitable Choice**

SAMHSA v. HIPAA

In this corner: SAMHSA

In this corner: HIPAA

SAMSHA is a little like HIPAA on Steroids – ***although HIPAA is dangerous in more subtle ways***

HIPAA Compliance Auditors will be Looking for SAMHSA Compliance

On the HHS website for HIPAA, under "HIPAA Related Links":

- The Substance Abuse and Mental Health Services Administration (SAMHSA) issued *The Confidentiality Of Alcohol And Drug Abuse Patient Records Regulation And The HIPAA Privacy Rule: Implications For Alcohol And Substance Abuse Programs* as guidance for substance abuse treatment programs that are subject to the confidentiality requirements of "Part 2" Regulations (The Part 2 regulations apply to substance abuse treatment "programs" as defined by 42 CFR § 2.11 that are "federally assisted" as defined by 42 CFR § 2.12(b)).
- **"It explains which programs must also comply with the Privacy Rule and outlines some compliance requirements."**
  - See https://www.hhs.gov/hipaa/for-professionals/special-topics/related-links/index.html

Remember that these programs are all under HHS

At the HIPAA website under "**Information Related to Mental and Behavioral Health, including Opioid Overdose**"

Substance Use Disorder Treatment Records:

- The protected health information of individuals who receive drug and alcohol abuse treatment in federally-funded programs is subject to additional privacy protections under 42 USC § 290dd-2 and 42 CFR § 2.11 (Part 2).
- **These federal rules are administered by HHS's Substance Abuse and Mental Health Services Administration (SAMHSA).**

See https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html

Enforcement

AS OF 2018

YOU can be arrested for wrongful disclosure of protected health information under HIPAA and SAMHSA?

YES!!

CONSTANTLY REINFORCE THIS TO STAFF

Commentators Believe We Will See More Enforcement of SAMHSA

There has never been a prosecution under SAMHSA's Part 2, **HOWEVER**,

- **Some commentators believe that the increased HIPAA Enforcement efforts expected will bring about never before seen enforcement and prosecution of Part 2 violations, if Part 2 violations are found through the HIPAA audit and enforcement process.**

The Office of Civil Rights (OCR) is now in Phase 2 of the Audit process:

- Every covered entity and business associate is eligible for an audit. These include covered individual and organizational providers of health services; health plans of all sizes and functions; health care clearinghouses; and a range of business associates of these entities. We expect covered entities and business associates to provide the auditors their full cooperation and support.

  See https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html#when

Protecting Patient Health Information

The Protecting Patient Health Information objective for Meaningful Use and MIPS Advancing Care Information states:

- **"Conduct or review a security risk analysis including addressing the security (to include encryption) of ePHI data created or maintained by certified HER technology in accordance with requirements and implement security updates as necessary and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process."**

This reference to 45 CFR points directly to the HIPAA Security Rule.

Protecting Patient Health Information (cont.)

The reference to the Security Rule means that the practice must complete a Security Risk Analysis that addresses the security of information within the CEHRT the practice is using.

It also references implementing security updates to correct deficiencies.

A critical change from 2017 is that the risk assessment and remediation must be completed before the end of the calendar year.

- **• In the past, it this objective only needed to be completed prior to attestation, which gave some practices a little extra leeway to complete it.**

Practices are advised to arrange for their Security Risk Analysis as early as possible to avoid missing the deadline!

Health Information Exchange

https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs

In 2010, the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) and the HHS Office of the National Coordinator (ONC) published FAQs "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)." The 2010 FAQs are available at Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE) (PDF | 381 KB).

Time for discussion!

THANK YOU!