

SUMMARY OF SAMHSA’S JANUARY 2018 42 CFR PART 2 LISTENING SESSION

On December 13, 2016, the 21st Century Cures Act was signed into law ([Pub. L. 114-255](#)). Section 11002 of this law requires that, within one year of the effective date of the 42 CFR part 2 final rule (published [January 18, 2017](#)), “the Secretary [HHS] shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.” In response to this mandate, SAMHSA held a listening session on January 31, 2018, to provide stakeholders an opportunity to address these and other issues with respect to part 2. The announcement for this meeting was published in the *Federal Register* on January 9, 2018 (see <https://www.federalregister.gov/documents/2018/01/09/2018-00150/confidentiality-of-substance-use-disorder-patient-records>).

This document summarizes the oral and written comments from the Listening Session based on major issues raised. The document is organized into the following sections.

Section 1: Executive Summary

Section 2: Summary of Oral and Written Comments

Appendix A: List of Commenters

Appendix B: List of Additional Documentation Submitted by Commenters

Major topics discussed in Section 1, Executive Summary, contain hyperlinks that take readers to a more detailed description of the same issue in Section 2, Summary of Oral and Written Comments. A list of commenters, organized by stakeholder category, appears as Appendix A. Some commenters submitted additional documentation along with their written comments. Appendix B provides the title and a brief explanation of these documents, which are not included in the comment summaries below.

Comments are not attributed to specific commenters but are identified based on stakeholder categories. Commenters were assigned to stakeholder categories by the authors because the commenters’ self-selected registration categories were not available during the initial drafting of the summaries. The following stakeholder categories were used:

- Substance Use Disorder Provider/Association (SUD Provider)
- Behavioral Health Care Provider/Association (BH Provider)
- Medical Health Care Provider/Health System/Association (MedH Provider)
- Privacy/Consumer Advocate (Privacy Advocate)
- Patient/Consumer
- State/Local/Tribal Government/Association (S/L/T Government)
- Technology Vendor/Consulting/Association (Tech. Vendor)
- Third-Party Payer/Association (Payer)
- Other Stakeholder (Other)

SECTION 1: EXECUTIVE SUMMARY

This section contains an executive summary of the oral and written comments provided for the January 2018 SAMHSA Listening Session. Hyperlinks take the reader to a more detailed summary of these comments provided in Section 2, Summary of Oral and Written Comments.

1. [COMMENT: ALIGN PART 2 WITH HIPAA](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X	X			X	X	X	X

Summary of Comments:

- Wide support for aligning part 2 with HIPAA across most stakeholder groups represented
- Some commenters supporting alignment with HIPAA recommended retaining or enhancing certain part 2 provisions
- Rationales for aligning part 2 with HIPAA related to better information sharing, regulatory simplification, and enhanced enforcement

2. [COMMENT: PART 2 IS A BARRIER](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X	X			X	X	X	X

Summary of Comments:

- Part 2 is a barrier to:
 - coordinated/integrated care, information sharing, treatment of the whole person, patient safety and addressing the opioid crisis
 - medical parity
 - Electronic health records (EHR)/health information technology adoption
 - State laws, regulations, and reporting requirements
- Part 2's complexity and ambiguity are a barrier; new regulatory architecture is needed

3. [COMMENT: AGAINST ALIGNING PART 2 WITH HIPAA/SUPPORT RETAINING PART 2 PROTECTIONS](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X		X	X				

Summary of Comments:

- Part 2 protections are still critical to protecting patients, health outcomes and privacy
- HIPAA won't prevent patient records from being used in court proceedings
- Because of continued discrimination, substance use disorder patients should retain the power to decide when and to whom their records are disclosed

4. [COMMENT: PART 2 CREATES OR PERPETUATES DISCRIMINATION/STIGMA AGAINST SUBSTANCE USE DISORDER PATIENTS](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X	X				X	X	

Summary of Comments:

- Part 2 creates or perpetuates stigma/discrimination by treating substance use disorder patients differently than other patients; different treatment puts patients at risk

5. [COMMENT: PART 2 PROTECTS SUBSTANCE USE DISORDER PATIENTS FROM DISCRIMINATION AND STIGMA](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X	X	X	X				

Summary of Comments:

- Part 2 protects patients from stigma and discrimination/does not cause it
 - Keeping existing part 2 safeguards protects patients from potential adverse impacts and being made more vulnerable by virtue of seeking treatment.
 - Patients face bias, including biased care from clinicians
 - Discrimination and stigma can affect long-term health and ability to receive treatment
 - Potential for arrest and prosecution causes stigma

6. [COMMENT: MAINTAIN OR EXPAND PART 2 PATIENT SAFEGUARDS](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
								X

Summary of Comments:

- Several commenters remarked on existing part 2 protections, stating current protections were sufficient or should be expanded, including using the authority under section (g) of the statute to enhance existing safeguards

7. [COMMENT: RECOMMENDATIONS FOR CHANGES TO SPECIFIC PART 2 PROVISIONS](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X	X	X		X	X	X	X

Summary of Comments:

- Revise certain definitions/terminology (§ 2.11): *Lawful Holder, Person, Program, and Qualified Service Organization*
- Unclear whether part 2 records require more robust security rule than HIPAA (§ 2.16)
- Some general support for recent changes made to provisions regarding Disclosures Permitted with Written Consent (§ 2.33) and Audit and Evaluation (§ 2.53)
- Revise or create exceptions to: Consent (§ 2.31), Prohibition on Re-disclosure (§ 2.32), Medical emergencies (§ 2.51), and Audit and Evaluation (§ 2.53)
- Eliminate: Prohibition on Re-disclosure (§ 2.32) and Court Orders Authorizing Disclosure and Use (Subpart E).

8. [COMMENT: BOLSTER ENFORCEMENT OF PART 2](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X		X	X				X

Summary of Comments:

- Enhance enforcement of part 2
 - Any additional rulemaking should strengthen patient protections and enforcement
 - Penalties are not enforced; work with DOJ to develop missing penalty provision under Title 18

9. [COMMENT: DEVELOP GUIDANCE AND OTHER EDUCATIONAL TOOLS](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X	X		X	X		X	X	X

Summary of Comments:

- In lieu of further changes to part 2, develop guidance, sample forms, training, and outreach (e.g., to providers and patients)

10. [COMMENT: CONDUCT RESEARCH ON IMPACT OF PART 2](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
			X					X

Summary of Comments:

- 21st Century Cures Act requires HHS to review and provide evidence on impact of part 2 repeal and integration with HIPAA
- Research needed on consequences to patients of changing part 2

11. [COMMENT: RECOMMENDATIONS RELATED TO PRESCRIPTION DRUG MONITORING PROGRAMS \(PDMPs\)](#)

Stakeholders Providing Comments								
SUD Provider	BH Provider	MedH Provider	Privacy Advocate	Patient/ Consumer	S/L/T Government	Tech. Vendor	Payer	Other
X		X						X

Summary of Comments:

- Law enforcement should not be permitted access to part 2 data disclosed to PDMPs
- Include methadone information in PDMPs but restrict PDMPs to clinical interventions

SECTION 2: SUMMARY OF ORAL AND WRITTEN COMMENTS

This section contains a more detailed summary of the major issues raised in oral and written comments provided for the January 2018 SAMHSA Listening Session.

1. COMMENT: ALIGN PART 2 WITH HIPAA

Summary of Comments:

- **Wide support for aligning part 2 with HIPAA across most stakeholder groups represented**
 - A number of commenters recommended proceeding with efforts to align part 2 with HIPAA in the following ways:
 - Align to the extent permitted by the statute (a state government association, a technology vendor, another stakeholder);
 - Work with Congress to obtain the authority to do so (a couple of substance use disorder providers, a behavioral health care provider, a couple of medical health care providers);
 - Support or ask the Administration to support S. 1850 and HR 3545 (a substance use provider, a couple of behavioral health care providers, a third-party payer);
 - Convene a task force to support the integration of HIPAA and part 2 (another stakeholder).
 - SAMHSA currently has the authority to align with HIPAA (a third-party payer).
- **Some commenters supporting alignment with HIPAA recommended retaining or enhancing certain part 2 provisions**
 - Specified provisions included:
 - Prohibition on re-disclosure outside the treatment area (a substance use disorder provider);
 - Existing part 2 protections (a substance use disorder provider, a couple of behavioral health care providers, a technology vendor, another stakeholder);
 - Existing and enhanced protections, including stronger penalties, breach notification, strong enforcement, non-discrimination provisions, and exclusion from evidence in court and administrative proceedings (another stakeholder);
 - Implementing 42 USC 290dd-1, which states: “Substance abusers shall not be discriminated against in admission or treatment solely because of their substance abuse” (another stakeholder).
- **Rationales for aligning part 2 with HIPAA related to better information sharing, regulatory simplification, and enhanced enforcement**
 - Rationales included:
 - Allowing for information sharing for health care operations and payment purposes, and/or treatment purposes, without consent (a substance use disorder provider, a medical health care provider, several behavior health care

providers, a couple of technology vendors, a third-party payer, another stakeholder);

- Simplifying regulatory complexity as health information exchange becomes nationwide (a technology vendor);
- Having one rule stakeholders can understand and adhere to (a substance use disorder provider; a technology vendor; and another stakeholder);
- Permitting one consent form (a technology vendor; a couple of other stakeholders);
- Permitting business associate agreements (another stakeholder);
- Permitting care coordination/case management (a few third-party payers);
- Enhancing enforcement because DOJ does little to enforce part 2, but OCR enforces HIPAA (several technology vendors).

2. COMMENT: PART 2 IS A BARRIER

Summary of Comments:

- **Part 2 is a barrier to coordinated/integrated care, information sharing, treatment of the whole person, patient safety, and addressing the opioid crisis.**
 - Commenters representing all types of providers and their associations, technology vendors and consultants, third-party payers, and a state government stakeholder, found that part 2 and its separate privacy structure is a barrier to integrated/coordinated care, treatment (particularly treatment of the whole person), population health programs, and effective communication, and needs to be addressed; behavioral health patient information cannot be shared in the same manner as other records.
 - Many of these commenters noted that such barriers create risk or cause harm to patients; incomplete medical records put part 2 patients at risk of experiencing adverse drug interactions, overdose and death.
 - Some of these commenters noted that addiction cannot be treated effectively in isolation from other conditions and that part 2 is a barrier to addressing the opioid crisis.
 - A behavioral health care provider stated that barriers to coordinated care can lead to overutilization of services and potentially support substance abuse.
 - A technology vendor noted that changes made to part 2 regarding disclosures for payment and operations still leave barriers to treatment, coordination of care and referrals.
 - A medical health care provider requested SAMHSA exempt integrated medication-assisted treatment (IMAT) and other substance use disorder treatment from part 2.
 - A behavioral health care provider requested the ability to disclose information to a minor's parents who are aware of and paying for addiction treatment
 - A behavioral health care provider questioned whether part 2 is too paternalistic.
 - A substance use disorder provider thought implementing penalties would further stymie innovative, integrated care models due to the lack of clarity regarding the part 2's scope.

- **Part 2 is a barrier to medical parity**
 - A third-party payer stated that enforcing separate privacy rules conflicts with the intent of medical parity and causes confusion.
 - A behavioral health care provider recommended that SAMHSA use existing authority to work with CMS to identify remaining barriers to integrating mental health and substance use disorder treatment into primary care.
 - A behavioral health care provider stated part 2 is antithetical to the mental health parity law; in practice part 2 often dictates that both substance use disorder and mental health records be kept separate from medical records.

- **Part 2 is a barrier to EHR/health information technology adoption**
 - Behavioral health care and substance use disorder providers and a state government stakeholder found that part 2 is a barrier to the adoption of EHRs/use of technology to improve patient care and patient safety.

- **Part 2 is a barrier to state laws, regulations, and reporting requirements**
 - A substance use disorder provider noted that part 2 contradicts many state facility and professional licensing regulations/laws, particularly with respect to mandated reporting requirements.
 - A third-party payer requested a state reporting exception under part 2 to permit disclosures without consent for public health purposes (to address the opioid crisis).

- **Part 2's complexity and ambiguity are a barrier/there is a need for a new regulatory architecture**
 - A medical health care provider commented that operationalizing terms such as "program" and "holds themselves out" is very difficult in a primary care setting.
 - A medical health care provider found the ambiguity around case management and care coordination under part 2 impedes the integration of the state's Medicaid delivery systems/pilot programs to better serve patients.
 - Several commenters noted the confusion caused part 2; a behavioral health care provider and two other stakeholders requested that SAMHSA not be constrained by the existing part 2 architecture and either rebuild the regulation (based on the statute) or incorporate it into HIPAA.

3. COMMENT: AGAINST ALIGNING PART 2 WITH HIPAA/SUPPORT RETAINING PART 2 PROTECTIONS

Summary of Comments:

- **Part 2 protections are still critical to protecting patients, health outcomes and privacy**
 - Commenters including substance use disorder and behavioral health care providers, privacy/consumer advocates, and patients stated that part 2's confidentiality protections are needed to ensure individuals with substance use disorders seek

- treatment (particularly individuals with criminal records); without them, patients may not seek treatment or would leave treatment prematurely.
- Many of these commenters recommended either no further changes to or no repeal of part 2 because aligning with HIPAA would harm patients and their families or create barriers to care; a few commenters said that just the discussion of repealing part 2 has caused some patients to leave or consider leaving treatment.
 - A behavioral health care provider commented that the current changes had gone too far in weakening confidentiality protections.
 - A number of patients stated that they had entered treatment based on the confidentiality protections afforded under part 2, and now they feel that promise is broken.
 - Commenters including a substance use disorder provider, a behavioral health care provider, patients, and a couple of privacy/consumer advocates noted that recent part 2 changes offered powerful new communications tools while maintaining confidentiality, so additional changes were not needed.
 - A privacy/consumer advocate recommended maintaining part 2 core protections and heightening privacy standards.
- **HIPAA won't prevent patient records from being used in court proceedings**
 - Commenters including behavioral health and substance use disorder providers, privacy/consumer advocates and patients stated that HIPAA's lower privacy standards would not prevent patient records from being used in divorce and child custody cases.
 - Some of these commenters noted that HIPAA would not provide the same patient protections and that aligning part 2 with HIPAA would weaken patient care.
 - A patient described being harmed by information maintained in a hospital's general EHR (after signing a release) which was only protected by HIPAA.
 - One substance use disorder provider argued that, unlike HIPAA, part 2 requires providers to better understand the need for disclosures.
 - A privacy/consumer advocate noted that concern over adverse drug interactions could be avoided if clinicians ask patients about medications.
 - **Because of continued discrimination, substance use disorder patients should retain the power to decide when and to whom their records are disclosed**
 - Commenters including substance use disorder and behavioral health care providers, privacy/consumer advocates, and patients wanted SAMHSA to retain part 2 confidentiality protections and patient control over disclosures, citing the need for protection from discrimination and from law enforcement or concern that releasing the information would cause patient harm.
 - One privacy/consumer advocate stated SAMHSA should honor the original intent of the part 2 authorizing statute (i.e., patients retain control over how their information is shared).
 - One behavioral health care provider recommended letting patients decide whether part 2 applies to their records.

- A patient did not want her records released without her prior approval.

4. COMMENT: PART 2 CREATES OR PERPETUATES DISCRIMINATION/STIGMA AGAINST SUBSTANCE USE DISORDER PATIENTS

Summary of Comments:

- **Part 2 creates/perpetuates stigma and discrimination**
 - Several commenters including substance use disorder, behavioral health care and medical health care providers; technology vendors, and third-party payers expressed concerns that part 2, by not evolving with the changes in health care delivery and treating substance use disorder patients differently from other patients, creates or perpetuates discrimination and stigma;
 - Several of these commenters said part 2 prevents substance use disorder parity with other medical conditions, and this different treatment puts patients at risk of harm.
 - A technology vendor stated that part 2 also discriminates between substance use disorder patients in federally-funded versus non-federally funded programs.

5. COMMENT: PART 2 PROTECTS SUBSTANCE USE DISORDER PATIENTS FROM DISCRIMINATION AND STIGMA

Summary of Comments:

- **Part 2 protects substance use disorder patients from stigma and discrimination**
 - Some substance use disorder, behavioral health care, and medical health care providers; patients; and privacy/consumer advocates recommended keeping existing part 2 safeguards to protect patients from potential adverse impacts (e.g., loss of job, loss of children, prosecution) and to not make them more vulnerable by virtue of seeking treatment.
 - Several patients and privacy/consumer advocates recognized the existence of and provided personal examples of discrimination, stigma, and biased care; one privacy/consumer advocate stated some clinicians equate patients taking methadone or buprenorphine to active addicts.
 - Several privacy/consumer advocates and patients, a substance use disorder provider, and a behavioral health provider, expressed strong disagreement that part 2 creates stigma; they argued that the potential for arrest and prosecution causes stigma.
 - A privacy/consumer advocate noted that disregard for patient privacy rights has a negative effect on patient's long-term health and ability to receive treatment.

6. COMMENT: MAINTAIN OR EXPAND PART 2 PATIENT SAFEGUARDS

Summary of Comments:

- **Several commenters remarked on existing part 2 protections, stating current protections were sufficient or should be expanded**

- One other stakeholder found current part 2 safeguards to be adequate to protect patients from improper disclosure.
- One other stakeholder believes section (g) of the statute gives SAMHSA authority to enhance part 2 safeguards, and recommends additional safeguards and protections previously provided in NPRM comments (e.g., nondiscrimination provisions).
- One other stakeholder stated that ONC and SAMHSA need to address appropriate safeguards on information shared by patients (e.g., patient portals, personal health records).

7. COMMENT: RECOMMENDATIONS FOR CHANGES TO SPECIFIC PART 2 PROVISIONS

Summary of Comments:

- **Definitions/terminology (§ 2.11)**
 - *Lawful Holder:* A substance use disorder provider questioned how lawful holders are expected to understand their part 2 responsibilities, especially when they are outside the health care system and don't have the tools to track disclosures; another stakeholder wanted to allow lawful holders to disclose information to their contractors (in a manner similar to Qualified Service Organizations (QSOs)); another stakeholder thought that lawful holder should be defined in the regulation text.
 - *Person:* A medical health care provider recommended including care coordination and case management in this definition.
 - *Program:* A substance use disorder provider suggested SAMHSA give programs discretion in determining which of their units and providers meet the definition of "program," due to the difficulty of applying the definition in settings with co-occurring disorders using a team approach. A third-party payer requested that information from employee assistance programs that qualify as excepted benefits programs be exempted from part 2
 - *Qualified Service Organization:* A technology vendor recommended replacing "QSO" with "Business Associate" as defined in HIPAA; another such stakeholder suggested permitting QSOs to contract with lawful holders.
- **Security for Records (§ 2.16)**
 - A technology vendor questioned whether part 2 records require more robust security rule than HIPAA.
- **Consent (§ 2.31)**
 - *Entities without a treating provider relationship with the patient.*
 - Several substance use disorder and behavioral health care providers suggested SAMSHA revise this consent provision because it is not feasible when the patient does not know the name of their case worker, multiple individuals in an entity work with the patient, or there is high staff turnover (e.g., criminal justice agencies, social services departments, disability determination services, housing providers, etc.).

- Another stakeholder recommended permitting disclosure to any individual, entity, or class of individuals or entities.
 - *Exceptions to the consent requirements*
 - A few behavioral and medical health care providers and another stakeholder recommended various exceptions, including exceptions for: prescriptions and e-prescribing; a patient’s treating providers for diagnosis, treatment, and referral for treatment; covered entities for “treatment, payment and operations” as defined in HIPAA; and reporting to public health agencies.
 - One privacy/consumer advocate thought communication should be permitted on a “need-to-know” basis.
 - *Expand consent options*
 - A variety of stakeholders suggested certain expansions of existing consent options, such as: permitting the use of “general designations” in all circumstances; permitting consenting to share patient identifying information with specifically identified case management or care coordination programs; allow patients to “opt in” to sharing their information in any environment (subject to HIPAA), or “opt out” or “not opt in” to information sharing in an integrated care setting or, as an alternative, the federal government could mandate that EHRs include data segmentation functionality.
- **Prohibition on Re-disclosure (§ 2.32)**
 - A behavioral health care provider indicated that the notice prevents true integrated care. In contrast, a substance use disorder provider said that the notice is not a deterrent to redisclosure. That provider thought the requirement should be eliminated for coordination of care, payment and electronic operations of part 2 programs, including e-prescribing. A state government stakeholder expressed concern about the prohibition on re-disclosure as it relates to diagnosis, treatment, or referral for treatment.
- **Disclosures Permitted with Written Consent (§ 2.33)**
 - A behavioral health care provider asked for clarification on whether § 2.33 will be applied retroactively where consent was provided.
 - A behavioral health care provider and another stakeholder recommended including the list of payment and health care operations activities in the regulation text.
 - A behavioral health care provider and another stakeholder recommended including treatment activities in § 2.33.
 - Several third-party payers suggested adding the following to the list of payment and health care operations activities: care coordination (with expanded definition), health plan coordination, managed care, case management, and other integrated care activities. One of these commenters thought that excluding some of these elements undercuts a 21st Century Cures Act objective – “to provide access to updated information on behavioral health care providers and community-based

- organizations.” Another stakeholder disagreed with SAMHSA’s characterization of care coordination and case management activities as treatment and cited HHS guidance on definitions of treatment and health care operations.
- Another stakeholder was concerned that many entities will not get a copy of the consent form and will not be able to determine whether the information is being disclosed exclusively for treatment or for treatment, payment, and operations.
 - Another stakeholder thought that the rule’s limitations on disclosures to lawful holders who have received the information pursuant to an authorization specifically for payment and health care operations arbitrarily distinguishes between how part 2 programs can disclose information to a QSO and how lawful holders can disclose information to contractors who provide the same services as a QSO would to a part 2 program.
- **Disclosures Permitted with Written Consent (§ 2.33) and Audit and Evaluation (§ 2.53)**
 - A state government stakeholder supported the changes made to these provisions.
 - A technology vendor who preferred to align part 2 with HIPAA acknowledged that, under these provisions, patients will still be protected but providers, health plans, and health information exchanges (with patient consent) will be able to use contractors more easily.
 - **Medical Emergencies (§ 2.51)**
 - A behavioral health care provider urged SAMHSA to create a broader definition of “emergency” to include services to prevent a medical emergency.
 - A technology vendor suggested expanding this provision to account for crisis centers/teams.
 - In response to the declared opioid emergency, another technology vendor recommended permitting coordination of substance use disorder care between providers, and between providers and managed entities/pharmacies.
 - **Subpart E – Court Orders Authorizing Disclosure and Use**
 - One other stakeholder requested SAMHSA consider deleting this subpart.

8. COMMENT: BOLSTER ENFORCEMENT OF PART 2

Summary of Comments:

- **Enhance enforcement of part 2 and implementation of penalties**
 - Several patients, a couple of privacy/consumer advocates, a substance use disorder provider, and a behavioral health provider urged SAMHSA to clarify policies to enforce the rule; a substance use disorder provider and a privacy/consumer advocate indicated that any additional rulemaking should strengthen patient protections and enhance enforcement.
 - A couple of other stakeholders were concerned that the penalties are not enforced and may not be enforceable and recommended SAMHSA work with DOJ to develop the missing penalty provisions under Title 18.
 - A substance use disorder provider and a privacy/consumer advocate recommended SAMHSA not repeal part 2, but rather focus on enforcement and training providers.

9. COMMENT: DEVELOP GUIDANCE AND OTHER EDUCATIONAL TOOLS

Summary of Comments:

- **In lieu of further changes to part 2, develop guidance, sample forms, and training**
 - Several commenters, including substance use disorder and behavioral health care providers, patients, and privacy/consumer advocates, thought it was premature to further revise part 2 and recommended SAMHSA focus instead on developing subregulatory guidance, sample forms, training materials and provide training and other outreach. A couple of behavioral health care providers added that discussions with patients were needed.
 - Specific requests:
 - A privacy/consumer advocate and another stakeholder specifically recommended SAMHSA issue the subregulatory guidance identified in the 2017 final rule.
 - Several substance use disorder and behavioral health care providers, patients, and privacy/consumer advocates recommended various specific clarifications: permissible disclosures for entities without a treating provider relationship, enforcement protections, and guidance on how part 2 applies to integrated care and emergency room settings (including training and education materials similar to OCR's regarding the misperceptions that confidentiality inhibits medical care in emergency rooms).
 - These stakeholders also requested guidance on the definition of "program," including how part 2 applies to behavioral health organizations, mixed use facilities, and general medical facilities that employ specialized substance use disorder counselors.
 - Another stakeholder specifically requested guidance on the "general designation" provision.

- One third-party payer requested objective measures to discern part 2-protected information and another requested operational guidance on recent updates to part 2.
- A technology vendor urged SAMHSA to work with CMS, ONC, and the industry to establish detailed consent guidelines. Another stakeholder suggested SAMHSA work with DOJ and OCR to develop guidance for patients on enforcing their rights.

10. COMMENT: CONDUCT RESEARCH ON IMPACT OF PART 2

Summary of Comments:

- **21st Century Cures Act requires HHS to review and provide evidence on impact of part 2 repeal and integration with HIPAA**
 - One other stakeholder stated that HHS is not in compliance with the law and that three questions must be answered:
 - What is the essential function of part 2 not already covered by HIPAA (which is not addressed in the rule)?
 - Does part 2 cause harm to patients (based on health outcomes and exclusion of part 2 data from other providers, PDMPs, etc.)? The Act requires evaluation of effect of part 2 on health outcomes.
 - Is part 2 outdated? Make recommendations to Congress on what else is needed.
- **Research needed on consequences to patients of changing part 2**
 - One other stakeholder stated that little is understood regarding the consequences to patients of releasing their information into an EHR without consent.
 - One other stakeholder requested SAMHSA conduct research on the impact eliminating part 2 protections would have on methadone and buprenorphine patients, including attitudes of medical professionals, the criminal justice system and other professionals; SAMHSA needs to understand the repercussions and have strategies to protect patients.

11. COMMENT: RECOMMENDATIONS RELATED TO PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

Summary of Comments:

- **Law enforcement should not be permitted access to part 2 data disclosed to PDMPs**
 - A substance use disorder provider and another stakeholder recommended, if part 2 data are disclosed to PDMPs, that law enforcement should not be permitted to access it. In addition, the other stakeholder thought, if methadone data were included in PDMPs, ONC and SAMHSA should issue joint regulations that restrict access from law enforcement.
- **Include methadone information in PDMPs**

- A medical health care provider suggested including methadone data in PDMPs and another stakeholder echoed that sentiment but thought PDMPs should be used primarily for clinical interventions.

APPENDIX A: LIST OF COMMENTERS

Substance Use Disorder Provider/Association

- American Association for the Treatment of Opioid Dependence (AATOD) - Mark Parrino
- American Society of Addiction Medicine (ASAM) - Kelly Corredor
- Central City Concern – Rachel Solotaroff, MD, MCR
- Guadenzia, Inc. – Ken Martz, Psy.D., MBA, CAS
- Hazelden Betty Ford Foundation – Jennifer Lohse, JD, CHC
- Hennepin County Medical Center, Addiction Medicine Clinic - Christine Kern
- MISHA House, Baltimore - Monica Scott
- Operation PAR in Tampa, Florida - Karolina Austin
- Suzanne Tisne (works for outpatient substance use disorder treatment agency)
- Daniel Warren, MD (addiction medicine physician, University of Kansas, School of Medicine-Wichita)

Behavior Health Care Provider/Association

- American Psychiatric Association - Kristin Kroeger
- Anonymous, Concerned Social Worker
- Association for Behavioral Health and Wellness - Rebecca Klein
- Behavioral Treatment Services (BTS) - Amanda Laukant
- Caron Treatment Centers – Douglas Tieman
- Engolve People Care – Narendra H. Patel, MD, JD
- Frontier Behavioral Health - Tom Anderson
- Hartford Healthcare - Pat Reher
- Horizon Corporations – Herb Weis, Ph.D.
- Mark Jones, Mental Health Provider
- Kirk Kemling (Provider and consumer of mental health services)
- National Alliance on Mental Illness (NAMI) - Andrew Sperling
- National Association of State Mental Health Program Directors (NASMHPD) – Brian Hepburn, MD
- Shepard Pratt Health System – Harsh Trivedi
- University of Michigan School of Medicine, Department of Psychiatry – Gregory W. Dalack, MD

Medical Health Care Provider/Health System/Association

- California Association of Public Hospitals and Health Systems (CAPH) – Jackie Bender
- Maine Health – Katie Fullam Harris

- St. Vincent Health System/Ascension Health - Amy LaHood, Rev. Dennis H. Holtschneider, C.M.
- Trinity Health - Tonya K. Wells, ACC, CPA

Patient/Consumer (note: some patients used pseudonyms, others submitted comments with no identifying information and others asked to remain anonymous)

- Anonymous (5)
- Concerned Cali
- Charles D. MS, LADC-c, CMA, Addiction Counselor (provider, patient, and advocate)
- Eric McDonald, medical patient (comments also reflected in transcript)
- Danielle H.
- Amanda H.
- Sean M.
- Zac T.
- Zubsolv Zeke
- Mary Methadone

Privacy/Consumer Advocate

- Legal Action Center (LAC) - Deborah Reid, Jacqueline Seitz
- Heather Johnston (patient advocate)
- Mental Health America – Nathaniel Counts, JD
- National Alliance for Medication Assisted (NAMA) Recovery – Jocelyn Sue Woods, MA, CARC, CMA; Carmen Pearlman-Arlt, LCSW, LCAC, CMA
- Dr. George Patrin (retired Army pediatrician, Serendipity Alliance)
- Pennsylvania Recovery Organization Alliance (PRO-A) - William Stauffer, LSW, CCS, CADC
- Barbara Williams, Certified Americans with Disabilities Advocate and Consultant (CADAA)

State/Local/Tribal Government/Association

- Deschutes County Health Services – John Laherty, Assistant Legal Counsel, Deschutes County, Oregon
- National Association of Medicaid Directors – Jack Rollins, Judy Mohr Peterson, Kate McEvoy

Technology Vendor/Consulting/Association

- Guide Consulting Services on behalf of Netsmart - Al Guida
- Netsmart - Kevin Scalia
- New York eHealth Collaborative - Valerie Grey, Executive Director
- Orion Health - Gerard Scheitlin

- Reliance eHealth Collaborative - John Ownby-Hibner

Third Party Payer/Association

- Anthem Anthony Mader, Eric Bailly
- Association for Community Affiliated Plans (ACAP) – Deborah Kilstein
- Blue Cross Blue Shield Association – Joel Slackman
- Magellan Health - Teresa Berman, Meredith A. Delk, Ph.D., MSW

Other Stakeholder

- Attorneys at Oscislawski, LLC - Krystyna Monticello, Esq.
- Family Intervention Center and Services - Fr. Jack Kearney, M.Div, CATC IV
- NORC at the University of Chicago - Eric Gropelrud
- Popovits Law Group – Renee M. Popovits
- Psychologist, Former U.S. Congressman - Tim Murphy, Ph.D.
- Reid & Reige, PC - Adam Carter Rose

APPENDIX B: LIST OF ADDITIONAL DOCUMENTATION SUBMITTED BY COMMENTERS

The following entities submitted attachments with their written comments. These attachments were not included in the summary of the oral and written comments.

Substance Use Disorder Provider/Association

- Gaudenzia, Inc. - Ken Martz, Psy.D., MBA
 - Appendix A: Examples of Public Stigmatized Attitudes
 - Appendix B: Examples of Adverse Impacts
 - Appendix C: Examples of Historical Considerations Still Relevant Today
 - Appendix D: Data Breaches in the Modern World

- National Alliance for Medication Assisted Recovery – Carmen Pearman-Arlt, LCSW, LCAC, CMA; Joycelyn Sue Woods, MA, CARC, CMA
 - White Paper: Instances of Medical Care When You are a MAT Patient - Paper explores discrimination against MAT patients by health professionals and recommends that patients establish a relationship with a physician before revealing their status as an MAT patient
 - The Patients Speak - Interviews from Medical Methadone Maintenance: The Further Concealment of a Stigmatized Condition by Herman Joseph and from Grievance Reports filed with NAMA Recovery.

Behavior Health Care Provider/Association

- Association for Behavioral Health and Wellness -Rebecca Klein, Pamela Greenberg
 - Partnership to Amend 42 CFR Part 2 (Principles and Membership)

Technology Vendor/Consulting/Association

- Orion Health - Gerard Scheitlin
 - Refers to an attachment but there was no attachment

Other Stakeholder

- NORC at the University of Chicago - Eric Gropelrud
 - Synthesis Report for MACPAC on Expert Panel on Reg. 42 CFR Part 2: Draft Report - addresses harms caused by part 2, compliance problems and the need for education and regulatory and statutory changes to part 2
 - Background Report for MACPAC on Expert Panel on Reg. 42 CFR Part 2: Final Report
 - Appendix A: 42 U.S.C. 290dd-2 – The Federal Statute Underlying 42 CFR Part 2
 - Appendix B: Topic for Subregulatory Guidance Identified in the 2017 Part 2 Final Rule