



**Association for Behavioral
Health and Wellness**

*Advancing benefits and services
in mental health, substance use
and behavior change.*

April 11, 2016

Kana Enomoto
Acting Administrator
The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, Maryland 20857

Submitted electronically via www.regulations.gov

RE: FR Doc. 2016-01841 – 42 CFR Part 2

Dear Ms. Enomoto:

The Association for Behavioral Health and Wellness (ABHW) is the national voice for companies that manage behavioral health and wellness services. ABHW member companies provide specialty services to treat mental health, substance use and other behaviors that impact health. ABHW supports effective federal, state and accrediting organization policies that ensure specialty behavioral health organizations (BHOs) can continue to increase quality, manage costs and promote wellness for the nearly 170 million people served by our members.

Our association was originally founded in 1994, The American Managed Behavioral Healthcare Association (AMBHA), to enable the leading specialty behavioral healthcare organizations to work together on key issues of public accountability, quality, public policy and communication. In recognition of the expanded role of wellness in comprehensive behavioral health care, AMBHA changed its name in 2006 to the Association for Behavioral Health and Wellness (ABHW). The change reflected an increased focus on coordination of care, treatment of the whole person and the development and offering of wellness programs that foster healthy behavior. Consistent with this vision for comprehensive wellness and coordinated care, ABHW appreciates the opportunity to provide comments to SAMHSA on the notice of proposed rulemaking (NPRM) for proposed revisions to 42 CFR Part 2 (Part 2).

In general, ABHW welcomes SAMHSA's efforts to modernize Part 2. Separation of substance use from the rest of medicine creates several problems and hinders patients from receiving safe, effective, high quality substance use treatment. ABHW supports protections against unlawful disclosure, limiting the sharing of information for non-health care purposes, and providing meaningful enforcement penalties. Consumers should not be made vulnerable as a result of seeking treatment for a substance use disorder, yet ABHW also wants to ensure that individuals

can access coordinated and integrated care. While some positive changes were included in the proposed rule, the rule as currently drafted does not achieve the optimal balance of promoting integrated care while enhancing patient protections.

Some of the proposed changes have the unintended consequence of making compliance even more complicated. Simplicity and clarity are critically important. Simple rules allow patients to understand their rights, provide plans with guideposts for protecting and accessing information, and explain parameters to providers for appropriate disclosures to better coordinate patient care with the larger health care ecosystem. Late last year ABHW released a paper, [*Now is the Time to Strengthen Protection of Substance Use Records by Revisiting the Substance Use Privacy Law*](#), expressing the need for changes to Part 2 regulations. A copy of that paper is attached to these comments. Before the government embarks on revising a rule that is projected to cost in excess of \$239 million over the next 10 years, serious consideration should be given to introducing an enforceable statute that harmonizes several of the provisions with the Health Insurance Portability and Accountability Act Privacy Regulations (HIPAA) and at the same time increases profound protections for patients. That being said, we offer the following comments to the NPRM for your consideration:

1. Any Part 2 revision should be cognizant of the opioid epidemic and align with the federal government's concrete steps taken to address this issue.

The current opioid epidemic has become a front and center issue under the Obama Administration as well as throughout the federal government. The changes that SAMHSA seeks should help address this epidemic. President Obama has addressed this issue by proposing \$1.1 billion in new funding. As recently as February 2, 2016, the President has made clear his intention of making this issue a priority. He highlighted tools that are effective in reducing drug use and overdose, such as evidence-based prevention programs, prescription drug monitoring, prescription drug take-back events, medication-assisted treatment, and the overdose reversal drug naloxone. All of the President's plans to address this epidemic are moot without removing communication barriers and promoting care coordination. Through its proposed revisions to Part 2, SAMHSA should seek to reduce the barriers that are plaguing the health care system for substance use disorder patients. These barriers take the form of lack of communication, lack of information, and lack of coordination. ABHW hopes SAMHSA's revisions will follow President Obama's lead and make conquering this epidemic a priority.

2. Part 2 Regulations should reflect HHS's initiatives for improving connectivity with behavioral health.

Similarly, the Centers for Medicare and Medicaid Services (CMS) recently announced an initiative to support behavioral health and substance abuse treatment centers to purchase interoperable technology by allowing 90 percent matching funds to assist providers. CMS has stated:

“Doctors and other clinicians need access to the right information at the right time in a manner they can use to make decisions that impact their patient’s health. The free flow of information is hampered when not all doctors, facilities or other practice areas are able to make a complete circuit. Adding long-term care providers, behavioral health providers, and substance abuse treatment providers, for example, to statewide health information exchange systems will enable seamless sharing of a patients’ health information between doctors or other clinicians when it’s needed. This sharing helps create a more complete care team to collaborate on the best treatment plans and goals for Medicaid patients.”

The NPRM does not align with these important CMS goals. In fact, from an operational standpoint, the consent requirements proposed will not advance information sharing. If SAMHSA seeks to achieve its stated goals of revising Part 2 to integrate and improve coordination of care, it should take into account CMS’s initiative in support of such actions and promote easier ways of sharing substance use disorder information.

3. SAMHSA needs to revise the Part 2 Regulations consistent with the Law

SAMHSA has exceeded its statutory authority by crafting regulations inconsistent with the confidentiality law enacted by Congress.¹ Although these regulations have been in place for over forty years, the time has come to correct the longstanding misinterpretations. Part 2 is inconsistent with the law in the following ways:

- The law permits records to be disclosed in accordance with the prior written consent of the patient, but only to such extent, under such circumstances, and for such purposes as may be allowed under the regulations. The statute does not mandate the overly stringent consent requirements SAMHSA has created in Section 2.31. SAMHSA should harmonize with HIPAA authorization requirements.
- Nowhere does the law require a prohibition on redisclosure. This provision poses the greatest challenge to sharing of information among health providers and health plans, especially in health information exchanges. It is within SAMHSA’s authority to eliminate that requirement or refine it. After obtaining the initial consent, SAMHSA could allow disclosures for treatment, payment and healthcare operations (TPO) consistent with those terms as defined by HIPAA.
- The law is silent on consent relating to minors, yet Section 2.14 of the regulations erects unnecessary communication barriers among parents, providers and health plans thereby diminishing quality, coordinated care of minors.
- The law does not require accounting of disclosures, and the new proposed provisions in 2.13(d) conflict with existing HIPAA accounting of disclosure requirements and impose operational hurdles.

¹ 42 U.S.C. 290dd-2.

We will address each of these misinterpretations in turn below and provide what ABHW believes to be more effective solutions.

4. Part 2 should harmonize with HIPAA whenever possible to ensure effective, coordinated care.

We support the harmonization of Part 2 wherever possible with HIPAA and its implementing regulations. It is our strong belief that efforts to harmonize Part 2 with HIPAA would ensure increased care coordination among treating providers and other entities which share health information for care coordination and integration purposes, improve patient care and enhance privacy protections by making confidentiality restrictions more uniform across health care settings. This allows for the achievement of improved health outcomes through increased coordination of care for patients. **We also support preserving certain patient protections afforded under Part 2, such as the criminal penalties for violations of Part 2 at Section 2.4, and the stringent court order requirements at Sections 2.61-2.66 and harmonizing the consent elements in Section 2.31 with the authorization requirements in HIPAA.**

5. The applicability of Part 2 should be clarified and revised to ensure accurate and easy application by clearly identifying who is a Part 2 program.

Not all substance use disorder information is protected. The setting sets the rules so the protections apply only to Part 2 programs and persons receiving information from Part 2 programs. Part 2 currently applies to federally funded individuals or entities that “hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or treatment referral”, including units within a general medical facility that hold themselves out as providing these services. As such, **we support the narrowing of the applicability of Part 2 to exclude “general medical facilities” and “general medical practices.”** In order to promote meaningful exchange of patient health information for the benefit of treatment, Part 2 applicability should not seek to encompass entities that do not hold themselves out as providing substance use disorder diagnosis, treatment, or referral for treatment. However, it would be helpful if SAMHSA provided a definition of medical practice and clarified how this rule applies to federally qualified health centers and other certified community behavioral health centers that do not necessarily “primarily” furnish substance abuse services, but rather provide a comprehensive approach to care.

We support SAMHSA’s desire to be consistent with the approach taken in 1987 because it essentially limits the applicability of Part 2 to specialized programs. We believe this helps accomplish SAMHSA’s stated goal of simplifying the administration of the regulations without significantly affecting those who seek treatment. **We support the clarification that the regulations at Part 2 apply only to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited as substance abuse treatment providers.** However, we remain concerned regarding the ambiguity of who qualifies as a Part 2 provider. Payers typically cannot readily identify what services an organization provides or how it “holds itself out” based off just claims data. Furthermore, many organizations

tend to be conservative and apply a notice to all disclosures that Part 2 could be compromised. Thus, recipients cannot reliably know if the information it received falls under the protection of Part 2. As a result, organizations tend to treat all substance use disorder diagnoses and treatments as protected, which ultimately hinders integrated care and creates barriers to coordination.

We believe changes to the applicability section of these regulations must focus on what is best for the patient. We strongly support confidentiality protections for patients; however, the continued separation of health information privacy requirements for substance abuse treatment patients from the rest of the medical information process does more harm to the patient than if a uniform health information privacy regulation was in place. We suggest clear, unambiguous, constant definitions of who providers are and what protected information in the context of Part 2 is in order to promote effective care.

6. SAMHSA should revise the consent requirements to permit more general descriptions of authorized recipients.

ABHW agrees with SAMHSA that the regulations do not take into account the current model for health care delivery and ultimately creates barriers to a medically needy population. Further, ABHW agrees that the regulations need to be revised with particular focus on the issue of consent. **ABHW supports incorporating the exceptions present in HIPAA regulations into the consent requirements under 42 CFR Part 2.**

A. Expiration Provision

We recognize and would support a clarification regarding the permissible length of time the consent is valid. In particular, ABHW supports the FAQs issued by SAMHSA indicating that an “event” can be death, and therefore, the consent may be valid for the life of the patient. **We request that this expiration provision permitting a consent form to be valid until death be expressly authorized in the regulation as stated in the FAQs.** This clarification is important so stakeholders do not erroneously interpret Section 2.31(8) as limiting the ability to have an effective consent for that period of time. Specifically, 2.31(8) currently states “the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.” This statement should be amended consistent with the FAQ.

B. To Whom

The underlying intent of the “To Whom” section of Part 2 was for the patient to be able to identify exactly who they are authorizing to receive the information at the point of initial consent. SAMSHA seeks to propose an amendment of the “To Whom” section by allowing, in certain circumstances, the patient to make a general designation. In theory, this general designation would allow the patient to permit access to their information to a broad class of individuals or entities such as the example provided by SAMSHA of “my treating providers”.

Although the general designation is a step in the right direction, the proposed rule adds extremely burdensome accounting of disclosures with this patient written authorization which are not required for HIPAA authorizations. The proposed rule requires that individuals who disclose their substance use disorder information to a general designee would also be able to request a list of individuals or entities (the general designees) who have received that patient's Part 2 information within the previous two years. In other words, those subject to Part 2 would have to track everyone to whom they have disclosed that person's Part 2 information even though the person had already provided consent to disclose to those general designees. To implement the proposed accounting requirements would be unnecessary, redundant, and costly and would be extremely burdensome to try and track every Part 2 disclosure, especially when the disclosure would have been for a legitimate TPO purpose. See 45 CFR 164.528(a)(1)(iv).

The new proposed Section 2.31(a)(4)(iii) expressly permits the designation of the name of the entity for third-party payers that require patient identifying information for purposes of reimbursement of services rendered to the patient. However, it is not clear that such general designation could be used for other purposes such as care coordination, population health, or other services that may fall under the definition of health care operations within the meaning of HIPAA. We find this addition to be contrary to increasing efficiency and improving outcomes for patients. In today's health care environment, the health plans are at the center of care, coordinating services, authorizing care and helping to manage and improve population health. **We urge SAMHSA to expand Section 2.31(a)(4)(iii) to allow the general designation for health plans for purposes beyond reimbursement.**

Although the proposed amendment of the "To Whom" section of the regulations loosens the restrictions on consent, it does not accomplish the necessity and desire of a uniform standard between physical and mental health. Part 2 needs to conform to the HIPAA standard for treatment, payment, and health care operations if these regulations intend to achieve its purpose of efficient, coordinated care. By applying a different standard, it not only ignores the purpose of the legislation, but makes it more difficult for consumers by limiting access to coordinated care that is enjoyed by patients that suffer only from physical ailments, not mental. This overlooks the desire for parity in healthcare between physical and mental health. The lack of conformity with HIPAA increases safety risks because effective, coordinated care has not been reached. There is a risk that substance use disorder patients will be treated differently and with a lesser standard of care because of the excessive restrictions placed on the exchange of health care information by these regulations.

C. Amount and Kind

The proposed revision to the "Amount and Kind" provision seeks to require the consent form to explicitly describe the substance use disorder-related information to be disclosed. This proposed revision creates an undue burden on the patient and will further hinder the ability to coordinate care in the future. It is often difficult to locate Medicaid beneficiaries. These beneficiaries tend to lack the reading and writing capabilities necessary to comply with this burden. SAMHSA cites the phrase "all of my records" as an inadequate general designation because it does not think this

addresses the substance use disorder-related information to be disclosed. In order to ease this burden for patients and still address SAMHSA's desire for specificity, **patients should be able to choose via a check box "substance abuse treatment information" or authorize the entire medical record and list what cannot be disclosed.** This would create an assumption that promotes disclosure and coordinated care, rather than the current proposed revision that hinders the ability to exchange health information. In doing so, patients would be specific on what to withhold, as opposed to what to disclose. Patients will likely be more cognizant of what they wish to withhold from disclosure as opposed to what they want to disclose.

D. From Whom

The "From Whom" provision of Part 2 currently permits a patient to consent to either a disclosure from a category of facilities or from a single specified program. The current proposal seeks to narrow this provision by requiring the "From Whom" section of the consent form to specifically name the Part 2 program(s) or other lawful holder(s) of the patient identifying information permitted to make the disclosure. SAMHSA states its purpose for doing so is to offset any unintended consequences that may arise from a general designation of both the "To Whom" and "From Whom" section. By doing so however, this heightened specificity diminishes much of the benefits offered by permitting a general designation in the "To Whom" section in certain circumstances. This proposal just reworks the form to allow for general designation in the "To Whom" while eliminating the benefit derived from a general designation in the "From Whom" section. Switching the location of the general designation does not alleviate the burden on the exchange of health information, but rather shifts the specificity burden from the receiver to the sender. This revision unnecessarily restricts the positive step SAMHSA took in relaxing the "To Whom" standard.

E. Electronic Consent

In addition to revising the consent requirements, SAMHSA is proposing to permit electronic signatures to the extent that they are not prohibited by any applicable law. **We support the revision to allow for electronic consent when permissible.** Additionally, SAMHSA has indicated that it is considering whether to issue guidance at a later date that includes a sample consent form. We support the notion of being provided a sample consent form, however, we would not want its use to be mandated because different populations may require certain permutations of the sample consent form. Unless various consent forms were offered, limiting use to one particular form will hinder effective consent and coordination of care.

F. Defining "Organization"

SAMHSA notes that it has not explicitly defined the term "organization", but states that it has been interpreted narrowly in guidance to mean that information can be sent to a lead organization but the information cannot flow from the lead organization to organization members or participants. **ABHW would support a clear definition of "organization" provided such definition is not limited for third party payers to the purpose of reimbursement for services**

rendered to patients by a Part 2 program. Such narrow definition again fails to contemplate the important care coordination and population health services often provided by third party payers/managed care organizations. In doing so, it could create a workable framework for entities such as care coordination entities (CCEs) to exchange information. For instance, CCEs could be bound by data use agreements and allow for the exchange of Part 2 information.

7. SAMHSA should address the issue involving designation concerning HIEs, health homes, ACOs, and CCEs.

Although SAMHSA has proposed revisions that would permit a general designation in limited circumstances in order to permit a broader consent of information, SAMHSA fails to address the consent issues outside these limited circumstances concerning HIEs, health homes, ACOs, and CCEs because it is impossible to specify every organization or individual who might possibly receive information via an HIE, health home, ACO, or CCE. Thus, even when a patient seeks to affirmatively consent to include his or her information in an HIE, health home, ACO, or CCE, he or she cannot effectively provide consent under Part 2 if a general designation is not an option.

This requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important goals of achieving care coordination and integration. This disadvantages substance abuse treatment patients because of their inability to provide broader consent that is afforded general medical patients. Additionally, this restriction effectively excludes substance abuse treatment patients from participating in these programs because of the consent regulations and the inability to segregate substance abuse data in accordance with Part 2.

Given this, **we urge SAMSHA to specifically adopt regulations that would permit disclosures of substance abuse treatment information in a manner consistent with HIPAA.** Further, SAMHSA should adopt the HIPAA definitions of “treatment”, “payment”, and “health care operations.” This revision would permit patient substance abuse treatment information to be disclosed to one or more HIEs, health homes, ACOs or CCEs that have a direct treatment relationship with the patient, as treatment under HIPAA is defined to include the coordination or management of health care and related services by one or more health care providers and payers.

We strongly encourage any proposed changes to 42 CFR Part 2 be consistent with the direction of health care reform. Health care has become increasingly integrated and requires regulations to meet these advancements; otherwise patients find themselves disadvantaged by outdated, archaic rules. Harmonizing with HIPAA would be the first step towards integration and eliminate many of the self-imposed barriers the current Part 2 instills on vulnerable substance abuse disorder patients.

8. 42 CFR Part 2 should be revised to permit broader redisclosures and adopt HIPAA’s definition of treatment, payment and health care operations.

The prohibition on redisclosure in Section 2.32 effectively prevents providers participating in an HIE, health home, ACO, or CCE from disclosing substance abuse treatment information among

each other for treatment and care coordination purposes. Therefore, in addition to revising Part 2 to allow patients to consent to the disclosure of their substance abuse treatment information to an HIE, health home, ACO or CCE and its provider-members that are providing treatment to a patient (as recommended in Section (b) above), **we also recommend revising the regulations to allow for the redisclosure of substance abuse treatment information by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship for the purposes of treatment, payment or health care operations. Further, we recommend that the regulations be revised to establish that the prohibition on redisclosure does not apply to outside HIEs or provider-members of such exchanges who have a direct treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.**

To be clear, we are recommending that for purposes of treatment, payment and health care operations, substance abuse treatment information should be able to be disclosed and redisclosed by and among provider-members and payers of an HIE, health home, ACO or CCE with a direct treatment or payment relationship with the patient. However, this change would not allow for information to be further disclosed or redisclosed by an HIE, health home, ACO or CCE or its provider-members without a patient's consent for any purposes other than for treatment, payment and health care operations, or as permitted under applicable exceptions under Part 2. Moreover, Part 2 information would not be accessible to anyone outside of the HIE, health home, ACO or CCE unless a specific exception applies or the stringent court order requirements under Part 2 are met. In other words, Part 2 information would not be able to be disclosed for non-treatment purposes to law enforcement, employers, divorce attorneys or others seeking to use the information against the patient. Furthermore, **we urge SAMHSA to go one step further in order to protect patients against unlawful disclosure of their substance abuse treatment information by adding a mandatory exclusion from evidence provision to Part 2.**

SAMHSA's proposal to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information to be redisclosed is appreciated, but still does not accomplish the goal of coordinated care. The end result of these revisions would still be the presentation of a clinically incomplete record of a patient's treatment, since the substance abuse information cannot be redisclosed. Health care providers and plans will still be working with incomplete data and still pose the same clinical risks, failure to coordinate care, and lack of an integrated approach. This results in less effective care, less reliable health records, and less coordination.

9. SAMHSA should address the issues concerning minor patients and information disclosure to parents.

Although SAMSHA's proposed revisions do not address §2.14 concerning minor patients, ABHW has concerns with the ability to share information with parents of a minor. If states allow a minor to consent to treatment, information cannot be given to a parent unless the minor consents, even in the circumstance where the minor did not consent to treatment in the first place. This creates an unworkable framework for the exchange of health information and

coordination of care and merits consideration for revision with the current proposal. In practice, parents receive billing information from their insurance carriers when a covered minor receives treatment without parental consent. Parents are unable to receive any protected information despite them being the policyholder. By not addressing this issue, substance abuse-related information of minors will continue to be withheld resulting in less informed and less effective care. It also provides a misperception that health plans are withholding information from the family when in reality the plan is trying to comply with a nonsensical regulation.

10. The medical emergency exception should be expanded and eliminate the requirement for immediate documentation by the Part 2 program.

SAMHSA is considering aligning the regulatory language with the statutory language regarding the medical emergency exception though revising the current provision by providing providers with more discretion to determine when a “bona fide medical emergency” exists. **We support the increase of discretion given to providers to determine when a “bona fide emergency” exists.** However, SAMHSA’s continued requirement of immediate documentation, in writing, by the Part 2 program specifying information related to the medical emergency does not address the already unworkable framework this requirement presents. **We believe the requirement that a Part 2 program immediately document a disclosure pursuant to a medical emergency should be removed from the regulations.** Under the new provisions of §2.51, information covered by Part 2 may be disclosed to treat the patient in a “bona fide emergency.” Under the current and proposed provision, disclosures in these urgent scenarios must be “immediately” documented in writing setting forth the name of the personnel to whom the disclosure was made and their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the emergency. This documentation requirement is unduly burdensome in a crisis situation.

In the current framework of §2.51, if a hospital “breaks the glass”, the Part 2 program may not know whose record was accessed except through an audit trail and would have difficulty documenting this timely or accurately. Expansion to allow a provider’s discretion to determine a “Bona fide medical emergency” is a step in the right direction, but does not address the difficulty in the documentation requirements that arises in real time medical emergencies.

SAMHSA also outlines certain considerations regarding affiliations with an HIE involving medical emergencies. SAMHSA recommends that before a Part 2 program enters into an affiliation with an HIE, it should consider whether the HIE has the capability to comply with all Part 2 requirements, including the capacity to immediately notify the Part 2 program when its records have been disclosed pursuant to a medical emergency. This adds additional burdens to HIEs by necessitating certain technology, rules and procedures. This further exemplifies the unworkable framework that the immediate documentation and disclosure requirement imposes in a medical emergency.

Furthermore, **ABHW believes it would be beneficial for SAMSHA to provide examples of emergency situations where a consent form is not needed to disclose information.** The

proposed revisions allow for health care providers to have greater discretion, but examples highlighting situations where consent is not needed would be beneficial. For instance, is it an emergency when someone addicted to opiates goes for dental work that will likely result in a prescription for opiates for the pain? In circumstances like this, in order to prevent a foreseeable emergency from occurring, disclosure would be necessary.

11. Confirming or denying substance use disorder effectively identifies substance use disorder patients and opens up potential discrimination.

SAMSHA has proposed to clarify that the prohibition on re-disclosure provision (§ 2.32) only applies to information that would identify a patient directly or indirectly as having been diagnosed, treated, or referred for treatment for a substance use disorder. Although clarification is needed, the proposed revisions do not address the underlying issue caused by this prohibition. As noted in the comments, SAMSHA recognizes that certain illnesses such as cirrhosis or pancreatitis could reveal a substance use disorder, and thus should not be disclosed. This prohibition on disclosure creates a worse situation for the patient because the lack of release of medical information not only infers that the patient has a substance use disorder, but jeopardizes treatment. Certain diseases or disorders can arise from both substance use disorders as well as non-substance related causes. As such, providers refrain from disclosing because of the potential Part 2 violation. However, in doing so, their refraining from disclosing certain information creates an inference of a substance use disorder which may or may not actually exist.

12. The qualified service organization (QSO) definition should be expanded to include care coordination and permit multi-party agreements for the sharing of health information.

ABHW supports expanding the QSO definition to enable increased sharing of health information for care coordination purposes. ABHW believes an explicit definition of care coordination will alleviate confusion and align with SAMHSA's goals. SAMHSA references the need for care coordination in the preamble but fails to address a definitional framework for QSOs to use to operate. SAMSHA's current proposal seeks to include population health management in its definition referencing that in order to achieve the best outcomes, providers must supply proactive, preventive, and chronic care to all of their patients, both during and between encounters with the health care system but does not include care coordination. **ABHW believes expanding the definition even further will help achieve greater care coordination while respecting the goal of patient privacy.** SAMHSA should not only add the definitions of peers and coordinated care, but broaden the concept of the QSO. ABHW believes the concept of the QSO should include the development of an agreement that is not merely a two-party, one-way arrangement for the storage and use of data, but rather a multi-party agreement for the multi-directional sharing of information covered under 42 CFR Part 2. This agreement could establish a baseline of collective responsibilities for ensuring privacy of the disclosed information. ABHW believes this type of dynamic and disclosure of information would enable better care coordination and population health management. The ability to exchange information more freely through these agreements would enable organizations to provide more comprehensive, effective, coordinated care.

13. ABHW supports mirroring HIPAA requirements for the release and use of information for the purpose of research.

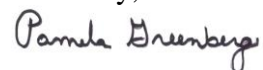
ABHW supports the proposed revisions regarding the release and use of information for the purpose of research contained in Section 2.52. Under HIPAA, a health care entity may disclose protected health information (PHI) for the purpose of research if: (1) the recipient researcher has obtained approval by its institutional review board; (2) the patient consented to the release of his or her information; (3) the PHI is part of a limited data set; or (4) the data is first de-identified. SAMSHA's current proposed expansion of the research exception would align Part 2 more closely to the requirements of HIPAA. Specifically, permitting data protected by Part 2 to be disclosed to qualified personnel for the purpose of conducting scientific research by a Part 2 program or any other individual or entity that is in lawful possession of Part 2 data. SAMSHA seeks to mirror HIPAA by requiring authorization from the participant's authorization, or a waiver by an Institutional Review Board (IRB) or privacy board. We support this change in Part 2 and are generally supportive of any changes to Part 2 which harmonize Part 2 with the rules under HIPAA.

Conclusion

Thank you for your consideration of our comments. We appreciate the opportunity to comment on SAMHSA's proposals to update Part 2. We appreciate the strong commitment SAMHSA has made to improve coordination of care. While we support many of the revisions SAMHSA is pursuing for Part 2 to enable increased exchange of health information for care coordination purposes, we are extremely concerned that the proposed rule continues to hamper integrated care and endorses a lesser standard of care for individuals with substance use disorders. Therefore, we reiterate the desire for the changes recommended in this letter, including harmonization with HIPAA wherever possible.

If you have any questions or would like to discuss any of these issues with ABHW, please contact Pamela Greenberg at (202) 449-7660 or greenberg@abhw.org.

Sincerely,



Pamela Greenberg
President and CEO, ABHW