



Association for Behavioral  
Health and Wellness

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

June 25, 2014

Submitted via Email: [PrivacyRegulations@SAMHSA.hhs.gov](mailto:PrivacyRegulations@SAMHSA.hhs.gov)  
Department of Health and Human Services  
The Substance Abuse and Mental Health Services Administration  
Room 5-1011  
1 Choke Cherry Road  
Rockville, MD 20857

Re: Confidentiality of Alcohol and Drug Abuse Patient Records; 42 C.F.R. Part 2 (FR Doc. 2014-10913)

Dear Sir or Madam:

The Association for Behavioral Health and Wellness (ABHW) is writing to offer comments on the potential changes to 42 C.F.R. Part 2 under consideration which address the confidentiality of substance abuse treatment information for persons receiving substance abuse treatment services from federally assisted programs, as published in the Federal Register on Monday, May 12, 2014, by the Department of Health and Human Services (DHHS) Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>1</sup>

ABHW is an association of the nation's leading behavioral health and wellness companies. These companies provide an array of services related to mental health, substance use, employee assistance, disease management, and other health and wellness programs to approximately 125 million people in both the public and private sectors. ABHW and its member companies use their behavioral health expertise to improve health care outcomes for individuals and families across the health care spectrum. On behalf of its members, ABHW appreciates the opportunity to comment and urges you to consider and include our recommendations described in more detail below during revision of the SAMHSA confidentiality and consent regulations, which will be critical to improving the treatment and care coordination provided to one of the nation's most vulnerable populations.

**I. SAMHSA should revise 42 C.F.R. § 2.31(a)'s consent requirements to mirror HIPAA's exceptions.**

Under 42 C.F.R. § 2.31(a), strict consent requirements are in place that mandate that written consent must include the name or title of the individual or the name of the organization to which disclosure can be made as well as numerous other form and descriptions requirements.<sup>2</sup>

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<sup>1</sup> "Confidentiality of Alcohol and Drug Abuse Patient Records," 79 Fed. Reg. 26929, 26929 (May 12, 2014).

<sup>2</sup> This is referred to as the "To Whom" consent requirement.

While the current regulations permit organizations to share information with a specific form of consent from the patient, obtaining this consent is challenging and creates barriers to member-centric, integrated approaches to care, which are part of our current health care framework. The consent requirements in 42 C.F.R. § 2.31 are, at times, impractical or even impossible, given the particularities and conditions of the population undergoing treatment and ultimately harms substance use disorder patients by denying them an opportunity for better and more integrated care. From a clinical standpoint, characteristics of certain conditions make it difficult for organizations to repeatedly request and obtain consent, given the state of the patient's conditions at certain points in time. For example, consumers with substance use disorders can exhibit paranoia that makes it difficult to obtain consent. The need to obtain numerous written consents and re-consents hampers the ability of providers to communicate and effectively treat consumers when they have the greatest need for treatment. Additionally, Medicaid populations are oftentimes difficult to reach to obtain such consent as they may not have residential stability; granted, if the consumer arrives at the hospital, consent can be obtained, but critical time periods lapse when consumers should be receiving treatment. The inability to obtain consent ensures that consumer has a more difficult time receiving the care that they need. Finally, obtaining consent for minors with substance use disorders poses great challenges as the parents may need to provide consent, and it is difficult to obtain consent without revealing potential substance use disorders.

Simply stated, the population that falls under the current regulations often has multiple health issues and would benefit the most from coordination of care and the integrated approaches to care that are available to all other populations. However, the current consent requirements in 42 C.F.R. Part 2 make these goals extremely challenging, if not impossible.

Because the regulations do not take into account the current model for health care delivery and ultimately create barriers to a medically needy population, ABHW agrees with SAMHSA that the regulations need to be revised; and the issue of consent is at the forefront of the changes. ABHW supports incorporating the exceptions present in the Health Insurance Portability and Accountability Act (HIPAA) regulations (allowing for disclosures related to treatment, payment, and - in some cases - healthcare operations) into the consent requirements under 42 C.F.R. Part 2.

## A. Treatment

HIPAA allows disclosures among providers for the treatment of a patient, a concept which should be reflected in the revised 42 C.F.R. Part 2 regulations proposed by SAMHSA. HIPAA provides that a "covered entity may disclose protected health information for treatment activities of a health care provider."<sup>3</sup> Treatment is defined as

... the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.<sup>4</sup>

However, the current regulations under 42 C.F.R. Part 2 do not allow organizations to effectively treat patients without written, specifically detailed consent, which is often impossible or impractical to obtain.

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<sup>3</sup> 45 C.F.R. § 164.506(c)(2).

<sup>4</sup> *Id.* at § 164.501.

Under the current regulations, organizations cannot share consumer histories or treatment information or protocols with other providers or organizations. From a care delivery standpoint, outpatient providers may be unaware of care provided by inpatient providers. Similarly, inpatient providers may be unaware of care or medications provided in an outpatient setting. Or, if an individual who is in jail gets treatment from a hospital and the hospital cannot disclose the consumer's treatment records, the individual may end up relapsing without the proper follow-up care. This inability to coordinate member-centric care is to the detriment of the consumer and could subject the consumer to inappropriate or repetitive treatment and therapies. For example, a treating provider may be unaware of potential adverse drug interactions when providers are unable to communicate, and the consumer does not or cannot provide a complete and accurate medical profile and history. If health information for treatment was excepted from the consent rule under revised 42 C.F.R. Part 2, organizations would be able to better effectuate care coordination.

Evidence supports that when providers keep records separate, there is a detrimental effect on the consumer's treatment. A recent report from Johns Hopkins has shown that maintaining behavioral health documentation private and separate from the rest of a patient's medical record leads to a higher incidence of patient readmissions to the hospital when compared to cases where behavioral health and physical health records are shared in the inpatient setting.<sup>5</sup> Of the hospitals reviewed in that study, fewer than half had all inpatient psychiatric records in their electronic health record systems, and fewer than 25% gave non-psychiatrists full access to those records. Significantly, the study found that psychiatric patients were 40% less likely to be readmitted to the hospital within the first month after discharge in institutions that provided full access to those medical records.<sup>6</sup> The leader of the study explained, "there are unintended consequences of trying to protect the medical records of psychiatric patients. When you protect psychiatric patients in this way, you're protecting them from getting better care."<sup>7</sup> Thus, revising the consent requirements in 42 C.F.R. Part 2 to incorporate an exception for patient treatment will enable providers to achieve better consumer outcomes and have more care coordination.

## B. Payment

HIPAA allows for disclosures of information related to payment activities, which should be reflected in the revised 42 C.F.R. Part 2 regulations proposed by SAMHSA.<sup>8</sup> Payment encompasses the various activities of health care providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care.<sup>9</sup>

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<sup>5</sup> "Separate may not be equal: A preliminary investigation of clinical correlates of electronic psychiatric record accessibility in medical centers," *International Journal of Medical Informatics* (December 20102). The survey was taken from psychiatry departments at 18 of the top American hospitals as ranked by U.S. News & World Report's "Best Hospitals" in 2007. The discussion of this study was contained in Lardiere, Michael R. "Unlocking and Sharing Behavioral Health Records: Movement Emerges to Exchange Sensitive Records through HIEs." *Journal of AHIMA* 84, no.4 (April 2013): 36-40.

<sup>6</sup> Lardiere at 38.

<sup>7</sup> *Id.*

<sup>8</sup> A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information. 45 C.F.R. 145.506(c)(2).

<sup>9</sup> The general definition of payment in 45 C.F.R. 145.501 provides examples of common payment activities which include, but are not limited to determining eligibility or coverage under a plan and adjudicating claims; risk adjustments; billing and collection activities; reviewing health care services for medical necessity, coverage, justification of charges, and the like;

Without an exception to consent for payment, organizations find numerous challenges in conducting standard operations. If unable to release information, providers may be unable to obtain reimbursement for care provided, or may need to exclude information related to a secondary diagnosis which can negatively impact necessary follow-up care and coordination. Additionally, in some cases appeals can be delayed (or decided without full information) if, for example, a health plan needs to receive a second consent to provide information to the external review organization. The challenges presented to providers in obtaining consent become magnified for health plans – the ultimate result is the consumer may not receive a full and fair review of the claims at issue. Thus, 42 C.F.R. Part 2 should be revised to include a consent exception for payment.

### **C. Health Care Operations**

HIPAA permits disclosures for healthcare operations under limited circumstances, which should be reflected in the revised 42 C.F.R. Part 2 regulations proposed by SAMHSA. HIPAA provides that a

covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is: for conducting quality assessment and improvement activities,...population-based activities..., contacting of health care providers and patients with information about treatment alternatives, and related functions that do not include treatment; [r]eviewing the competence or qualifications of health care professionals, evaluating performance...conducting training programs...; or [f]or the purpose of health care fraud and abuse detection or compliance.<sup>10</sup>

Under the current regulations, providers and organizations are unable to disclose the information covered by 42 C.F.R. Part 2 for health care operations. Obtaining consent to conduct health care operations is impractical and denies this population the full benefits of quality assessment and improvement activities. These barriers produced by the lack of an exception for health care operations affect consumer care as a whole, and the benefits achieved by care integration are often lost on this at-risk population because of the current regulations.

The current limitations are detrimental to health care operations and negatively impact care coordination activities for the consumers. Allowing such disclosures would facilitate programs that monitor and aid in eliminating gaps in care for this vulnerable population. Additionally, patients in hospitals could receive better care coordination with the consent exception for health care operations, as managed care organizations often have information that can fill in gaps in a provider's records. Allowing care coordination through a "health care operations" exception would facilitate better treatment for these consumers. With this exception for disclosure, the managed care organizations could coordinate the care with the hospital which would ultimately lead to more effective outcomes.

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utilization review activities; and disclosures to consumer reporting agencies (limited to specified identifying information about the individual, his or her payment history, and identifying information about the covered entity).

<sup>10</sup> (internal numbering omitted) 45 C.F.R. § 164.506(c)(4). Health care operations activities are listed to those included in the definition at 45 C.F.R. § 164.501.

## **II. At a minimum, SAMHSA should revise the consent requirements to permit more general descriptions of authorized recipients.**

In the event that SAMHSA is unwilling to consider incorporating the HIPAA exceptions to allow for disclosures for treatment, payment, and health care operations, SAMHSA should still revise the consent regulations. These revisions should enable organizations to more easily share certain health information and ultimately effectuate better care, while at the same time meet privacy and confidentiality concerns.

ABHW greatly appreciates the discussion of the difficulties the “To Whom” disclosure requirement presents to Health Information Exchanges (HIEs) and those coordinating care for substance abuse patients.<sup>11</sup> We fully support allowing consents to include more general descriptions of authorized recipients. We believe this will allow organizations to obtain the informed consent of an individual in an environment where new providers might join a care team or health information exchange with regularity, without requiring multiple re-consents. Thus, consumers would be able to receive better care coordination among their providers, as they would be able to communicate; and the consent would not need to be obtained each time. Alternatively, this method of more generalized description of authorized recipients would still protect privacy interest of those consumers who wish to have more limited and stringent consent parameters. Those consumers concerned about excessive re-disclosure or the consent being too broad could simply opt not to give a general description, and list only their intended recipients specifically.

Individuals authorizing the release of their private information should be presented their options in a simple and manageable way, rather than multiple forms. Therefore, we also suggest that the rules expressly permit the combination of written or electronic consents for the release of Part 2-protected information with other similar consents, such as authorization to release PHI pursuant to 42 CFR 164.508, or consents to participate in a Health Information Exchange. The decision to release Part 2 information could be indicated by a check-box, initiating or other additional indicium of consent specific to Part 2, but on the combined form.

As to the issue of recipients receiving a list of providers or organizations that may access their information, and be notified regularly of changes to the list, ABHW suggests that disclosers of such lists be permitted to do so via websites. Alternatively, we suggest that disclosers be permitted to refer individuals to other existing lists, such as provider directories, rather than an individualized list. This requirement would align with the more general descriptions of authorized recipients of the information.

## **III. The applicability of 42 C.F.R. Part 2 should be clarified in revised regulations to ensure ease of application.**

42 C.F.R. 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 diagnosis, treatment or treatment referral.<sup>12</sup> ABHW agrees with SAMHSA’s assessment that the current construction of applicable entities poses difficulties for identifying which providers are subject to the requirements of 42 C.F.R. Part 2, and thus which information is implicated, particularly which electronic

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<sup>11</sup> 79 Fed. Reg. at 26,931.

<sup>12</sup> 42 C.F.R. § 2.11. 79 Fed. Reg. at 26,930.

information. For example, payers cannot readily or easily verify what services an organization provides or how it holds itself out based on claims data. Moreover, many organizations conservatively apply a notice to all disclosures that 42 C.F.R. Part 2 could be implicated; thus, recipients of the information cannot reliably know which information is actually protected information under 42 C.F.R. Part 2. This results in organizations treating all mental health or alcohol or substance use disorder diagnosis and treatment information as protected under 42 C.F.R. Part 2, which creates barriers to integrated care.

While providers and protected information could be defined in numerous ways under 42 C.F.R. Part 2, we suggest that the definitions be unambiguous, constant, and applied in a manner that facilitates ease of application so as not to result in over inclusiveness. If the definition is to be based on the provider type from which the information originated, providers covered under 42 C.F.R. Part 2 should be easily identifiable, perhaps through a national index of such entities. Additionally, if a sub-unit of a large provider organization is to be covered under 42 C.F.R. Part 2, it should be required to identify itself to recipients of information as separate from the larger organization (i.e., through a separate provider identification number). When the definition of who is covered under 42 C.F.R. Part 2 is ambiguous, the result is that recipients of information include more providers and information than are actually protected, resulting in less integration and more challenges to patient care.

#### **IV. The redisclosure provision should be revised to be broader, but limitations would still exist that pose issues for care.**

SAMHSA is considering revising the redisclosure provision 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, if legally permissible. ABHW appreciates the proposed revisions which would allow other health related information to be redisclosed without authorization. However, these revisions still pose two problems for organizations. First, given the limitations on data segmentation that have been acknowledged, it may not be possible to release only non-substance abuse information. This is particularly the case if an HIE must perform a “provenance” test, which may be difficult to administer electronically. Second, the end result of these revisions would still be the presentation of a clinically incomplete record of a patient’s treatment, since substance abuse information cannot be redisclosed. This would still pose the same clinical risks, failure to coordinate care, and lack of an integrated approach, which threaten the reliability of electronically shared health records.

#### **V. The Medical emergency exception should be broadened to be proactive in preventing emergencies.**

The current regulations regarding the medical emergency exception state that information may be disclosed without consent “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.”<sup>13</sup> SAMHSA is considering amending this standard to allow providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication.<sup>14</sup> ABHW commends SAMHSA in its goal of preventing emergencies and believes that the standard should be expanded. The exception should encompass more than intoxication situations involving consent. Providers should be able to utilize their

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<sup>13</sup> 42 C.F.R. § 2.51; 79 Fed. Reg. at 26,931.

<sup>14</sup> 79 Fed. Reg. at 26,931.

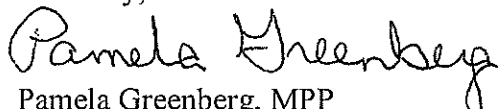
knowledge of the consumer's treatment to be proactive in preventing emergencies rather than reactive after the emergency has occurred. For example, if a consumer arrives at the hospital and is in danger of alcohol withdrawal, without the knowledge of the consumer's history, the treating team may not be aware of whether the consumer will go into withdrawal. In order to prevent a medical emergency, providers should be able to utilize the medical emergency exception in broader circumstances, and the updated regulations should be revised to achieve this goal.

**VI. Qualified service organizations should be able to enter into multi-party agreements for the sharing of health information.**

One potential solution SAMHSA is considering includes expanding the definition of a qualified service organization (QSO). The definition would explicitly include care coordination services and allow a QSO Agreement (QSOA) to be executed between an entity that stores 42 C.F.R. Part 2 information, such as a payer or an ACO that is not itself covered under 42 C.F.R. Part 2, and a service provider.<sup>15</sup> ABHW supports expanding the use of QSOAs as a useful means of enabling data sharing amongst payers and providers, ACOs or HIEs. However, we suggest that in evaluating this option, SAMHSA consider broadening this idea further, to include developing an agreement that is not merely a two-party, one-way arrangement for the storage or use of data, but rather a multi-party agreement for the multi-directional sharing of information covered under 42 C.F.R. Part 2. The multi-party agreement could establish a baseline of collective responsibilities for ensuring privacy of the disclosed information. ABHW supports that such disclosure of information through agreements would enable better care coordination and population health management. The ability to enter into these multi-party agreements would enable organizations to identify and care for consumers with a need for more intensive outreach, which ultimately would lead to more effective care.

We appreciate the opportunity to comment on the potential revisions of 42 C.F.R. Part 2. If you would like to discuss our comments, please contact Pamela Greenberg, President and CEO, at (202) 449-7660 or [greenberg@abhw.org](mailto:greenberg@abhw.org).

Sincerely,



Pamela Greenberg, MPP  
President and CEO

Association for Behavioral Health and Wellness

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<sup>15</sup> 42 C.F.R. § 2.11; 79 Fed. Reg. at 26,931.