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White Paper

PART 2: EVOLUTION

A Vision for Integrated Care and Enhanced Rights

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Preface

The Federal Confidentiality of Alcohol and Drug Abuse Patient Records law (the SUD Confidentiality Law) reflects Congress' longstanding concern that individuals not be made more vulnerable as a result of seeking treatment for a substance use disorder. Concerns about stigma and discrimination against people who receive substance use disorder treatment are as real now as they were when the statute was enacted in 1972. It remains important to take exceptional care to protect the privacy of people who seek treatment for addictions.

However, our nation's health care delivery system, including the landscape for the delivery of substance use disorder treatment, is dramatically changing. Thus, the thought leaders of our field must carefully address a number of interests that although appear competing, can be appropriately balanced to achieve a number of advancements for all stakeholders.

Providers are increasingly moving to an electronic health record, and while some health care providers are being incentivized by the federal government to adopt electronic health records through meaningful use regulations, most behavioral health providers are currently ineligible for such incentives. Nonetheless, paper records and written consents are becoming impractical and obsolete. Moreover, there is a very significant national interest in promoting the coordination of health services delivered by multiple providers through new integrated care models including health information exchanges (HIEs), health homes, accountable care organizations (ACOs) and other care coordination entities (CCEs).

The current statutory and regulatory framework for the Confidentiality Law provide no guidance on electronic health records because many of the concepts did not exist forty years ago. Likewise, such providers cannot effectively participate in HIEs, health homes, ACOs, or CCEs. When a patient wishes to consent to the release of his/her records to an HIE, health home, ACO or CCE, he/she must specifically identify every member of the

HIE, health home or CCE under the current regulations. HIE, health home, ACO and CCE members will change over time and could be voluminous. Accordingly, it is not realistic to assume that every HIE, health home, ACO or CCE member can be specifically identified on a patient consent. The unfortunate and unintended result is that the important benefits of electronic health records, HIEs, health homes, ACOs and CCEs as mechanisms to coordinate the continuum of care are significantly diminished by the SUD Confidentiality Law and attendant regulations at 42 CFR Part 2.

Similarly, since the SUD Confidentiality Law was implemented, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act have been enacted. It is imperative to address these laws in 42 CFR Part 2 to ensure that records covered by 42 CFR Part 2 are subject to its broader protections in all cases. This is especially true given the advent of electronic health records and the limited

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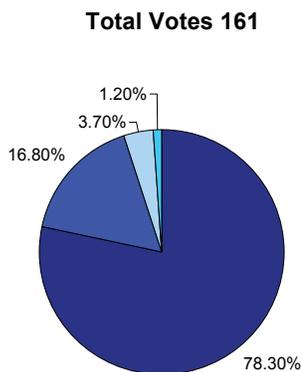
The authors would like to acknowledge Mike Lardieri, Vice President HIT and Strategic Development at the National Council for Behavioral Health, for his important contributions to and editing of this article.

data segmentation capabilities that exist at this time. Further, we believe providers who maintain 42 CFR Part 2 records should also have the ability to use those records to avert serious threats under an exception for a provider's duty to warn, consistent with HIPAA.

Finally, over the last forty years, we have gained a greater understanding of key areas of vulnerability for discrimination against patients seeking treatment for substance use disorders and witnessed a complete lack of enforcement of the SUD Confidentiality Law.

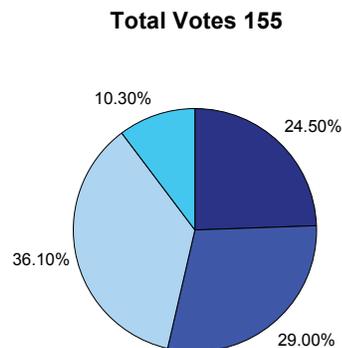
In an effort to further advance this important confidentiality conversation, we conducted randomized polling of interested stakeholders across the country regarding the impact the regulations at 42 CFR Part 2 have on patient choice, electronic health records and health information exchange, sharing of health information contemplated by the Affordable Care Act (ACA), and stigma and discrimination. Specifically, these polling questions were developed with the input of key field leaders and posed to behavioral health providers, the recovery community, and other interested stakeholders during the following sessions and conferences: the Vendome Group Webinar on Patient Choice, Confidentiality, and the Affordable Care Act on August 13, 2013; the Netsmart Connections Conference on September 17, 2013; the National Conference on Addiction Disorders and Behavioral Healthcare Leadership Summit on September 23, 2013; and the Catholic Charities Central States Institute 50th Anniversary Seminar on October 14, 2013. We intend to continue polling stakeholders to guide this important policy discussion at upcoming meetings, including the CiMH Behavioral Health Informatics Conference April 23-24, 2014 and the National Council Conference May 5-7, 2014. To illustrate, the results from the Vendome Group Webinar on August 13, 2013 are summarized in the pie graphs depicted below.

Integrated Care: How important do you think care coordination/integration of substance use, medical and mental health care is to improved outcomes for patients?



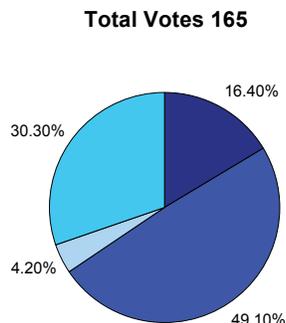
- Very Important 78.30%
- Important 16.80%
- Somewhat Important 3.70%
- Unimportant 1.20%

Sharing Information with Healthcare Providers: How concerned are you (or your patients) about MH/SUD information being shared with other health care providers?



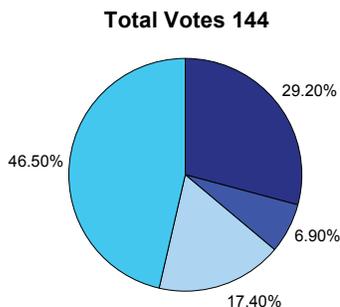
- Very concerned 24.50%
- Concerned 29.00%
- Somewhat concerned 36.10%
- Unconcerned 10.30%

Health Information Exchange Barriers: What is the most significant barrier to inclusion of MH/SUD information in health information exchange?



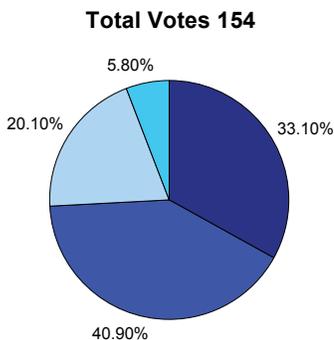
- The lack of incentives for the adoption of interoperable technologies 16.40%
- Confidentiality laws 49.10%
- Current payment models 4.20%
- The lack of technologies that enable the exchange of such information 30.30%

Part 2 Protections: What is your position on the confidentiality protections afforded SUD information under 42 CFR Part 2?



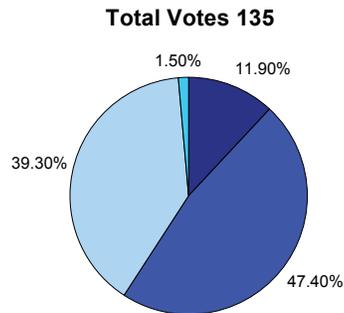
- The protections are sufficient in ensuring that such information remains confidential 29.20%
- The protections are insufficient in ensuring that such information remains confidential 6.90%
- The protections are overly restrictive 17.40%
- The protections are insufficient in some respects and overly restrictive in other respects 46.50%

Revising Part 2 Regulations: What is your position on revising the regulations at 42 CFR Part 2?



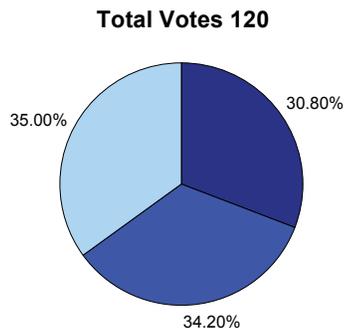
- I am in favor of revising 42CFR Part 2 to ease consent requirements in order to facilitate the sharing of SUD information among providers 33.10%
- I am in favor of revising 42 CFR Part 2 to make it more consistent with HIPAA 40.90%
- I am in favor of revising 42 CFR Part 2 to expand the protections to cover SUD information collected by all medical providers 20.10%
- I am against revising 42 CFR Part 2 5.80%

Sensitive Data: Do you feel that SUD information should be afforded greater privacy and confidentiality protections than MH information?



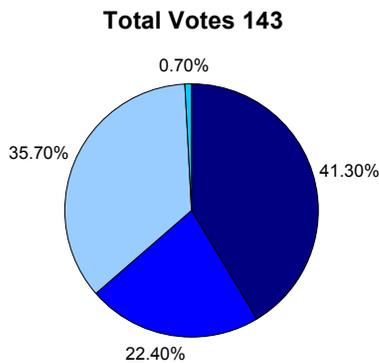
- Yes, SUD information should continue to receive greater federal confidentiality protections than MH information 11.90%
- No, SUD information and MH information should be treated similarly and the laws should be changed to increase the protections afforded MH information 47.40%
- No. SUD information and MH information should be treated similarly and laws should be changed to relax the protections afforded SUD information 39.30%
- Use the Q&A area below the slides for an alternative response 1.50%

Stigma: How do you think 42 CFR Part 2 impacts stigma as it relates to SUD treatment?



- I think 42 CFR Part 2 promotes stigma 30.80%
- I think 42 CFR Part 2 helps prevent stigma 34.20%
- I think 42 CFR Part 2 has no impact on stigma 35.00%

Penalties: What is your position on revising the regulations at 42 CFR Part 2 to increase the penalty/remedy provisions?



- I am in favor of revising 42 CFR Part 2 41.30%
- I am against revising 42 CFR Part 2 22.40%
- I am undecided 35.70%
- Use the Q&A area below the slides for an alternative response 0.70%

As evidenced by these polling results and other stakeholder opinion, it is time we address these critical information sharing and patient protection issues through appropriate revisions to 42 CFR Part 2.

Accordingly, we have drafted this proposal recommending eight specific updates to the regulations at 42 CFR Part 2 that are reflective of the changes that have taken place and lessons learned since the SUD Confidentiality Law and 42 CFR Part 2 were drafted. Cognizant of the arduous task of amending the SUD Confidentiality Law's statutory language, we have drafted each of our recommended updates as revisions to the regulations at 42 CFR Part 2. We strongly believe that these updates can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g). Specifically, 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g) provide that regulations promulgated under the SUD Confidentiality Law may contain such definitions, and may provide for such safeguards and procedures as are necessary or proper to effectuate the purposes of the law, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. We believe each of our suggested changes below constitutes a revision to the definitions, safeguards or procedures under the regulations intended to effectuate the purposes of, prevent circumvention of, or facilitate compliance with the SUD Confidentiality Law. Thus, these proposed revisions would not require an act of Congress. The statutory protections would remain in place and these proposed amendments could be accomplished through the regulatory process promulgated by the Substance Abuse and Mental Health Services Administration (SAMHSA). For each of the eight proposed provisions, we have summarized a description of: a) the concerns from the field;

b) the proposed remedy; c) the recommended regulatory language that is proposed (presented in red font).

1. Modernize Consent Requirements to Permit Disclosures to HIEs, Health Homes, ACOs, CCEs and Providers Involved in the Patient's Care

Concern from the Field: The requirements for patient consents to disclose medical records set forth at 42 CFR § 2.31 only contemplate *written* patient consent. However, providers now function in an electronic world where medical records, forms and notices are all available online for patients to easily access and use. Accordingly, a requirement to provide written consent on paper is impractical and burdensome.

Additionally, 42 CFR § 2.31 requires that a written consent to a disclosure under the regulations include the name or title of the individual or the name of the organization to which disclosure is to be made. This is commonly referred to as the "To Whom" issue with consents. This requirement prevents programs covered by 42 CFR Part 2 from participating in HIEs, health homes, ACOs and CCEs because it is impossible to specify every organization and/or individual who might possibly receive information via an HIE, health home, ACO or CCE. Thus, even when a program patient seeks to affirmatively consent to include his/her information in an HIE, health home, ACO or CCE, he or she cannot effectively provide such consent. Moreover, patients cannot broadly consent to disclosures to any providers involved in their care to assure that providers have access to the full scope of the patient's medical history when treating the patient.

This requirement that a single individual or organization be named on a 42 CFR Part 2 consent is wholly inconsistent with the important aims of the Affordable Care Act to achieve care coordination and integration. More importantly, this requirement functions to discriminate against Part 2 program patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but SUD patients are prevented from doing so. Second, SUD patients are actually excluded from participation in HIEs due to the complexity of the confidentiality regulations and the inability to uniformly segregate such data in accordance with the stringent requirements contained at 42 CFR Part 2. As a result, a digital divide exists and SUD patients are not given the choice to participate much less decide who should have access to their information. This unfortunate reality not only perpetuates discrimination against SUD patients (the very stigma that the SUD Confidentiality Law and 42 CFR Part 2 was intended to address) but it interferes with the important objectives of the Affordable Care Act.

Proposed Remedy: We seek a mechanism which enables patients to electronically consent to allow their program information to be shared. Moreover, we seek a mechanism which enables patients to consent to their program information being shared among providers in an HIE, ACO, health home or CCE and/or outside of such groups, when the providers to whom the information is disclosed are involved in treating the patients. However, we believe that in order for providers to be eligible to

participate in such exchanges of information they must demonstrate a willingness and ability to appropriately safeguard the information. Through stakeholder feedback we learned the importance of patient trust with the treating providers and the HIE. Fundamental to that trust is balancing responsibility for safeguarding sensitive health data entrusted to those treating the patient and those needing the information to better coordinate care. Accordingly, we suggest revising 42 CFR § 2.31 to allow patients to consent up front to the disclosure of program records to HIEs, health homes, ACOs and CCEs, including any provider-member of an HIE, health home, ACO or CCE who has a demonstrated treatment relationship with the patient. We further suggest revising the regulations to enable patients to authorize disclosure to any provider involved in their care.

To achieve protections for patients and ensure that the recipients of the information disclosed under these new, broader consents safeguard the information they receive, we further suggest adding new definitions for “health information exchange,” “health home,” “accountable care organization,” “care coordination entity,” “electronic consent,” “providers involved in the patient’s care,” “provider-member” and “demonstrated treatment relationship.” These definitions, among other things, clarify what it means for a patient to authorize disclosure to a “health information exchange,” “health home,” “accountable care organization,” “care coordination entity,” or “provider involved in the patient’s care” and add criteria that entities and providers must meet in order to be eligible to receive records the disclosure of which is authorized in this manner.

We emphasize that we are not suggesting that patients’ information be disclosed to such entities, their provider-members or other providers without consent. To do so would likely require a statutory change to federal law. Rather, we are recommending a regulatory change that balances the vital improvements that HIEs, health homes, ACOs and CCEs seek to make with respect to patient care with the importance of retaining patients’ rights to affirmatively consent to participate in the same. We are further recognizing that program patients should have the ability to authorize the disclosure of their records to all providers involved in their care. Stated differently, we only seek to give patients the option of consenting to have their 42 CFR Part 2 records included in an HIE, health home, ACO and/or CCE or otherwise disclosed to providers involved in their care. Surely, patients covered by the SUD Confidentiality Law deserve this opportunity every bit as much as patients whose records are not covered by this law.

Some privacy advocates may express concern about expanding this “To Whom” requirement through these definitions especially because many HIEs currently have an “all in” or “all out” approach. We emphasize it is the patient’s choice and right to choose what data he or she wishes to share. If this standard is not relaxed, the patient will be deprived of making the choice. If the patient is uncomfortable sharing all data and wishes to wait until technology advances to a stage where data segmentation becomes a standard reality, then it is the patient’s absolute right of privacy to opt out and providers should

honor and respect that right. Tantamount to ensuring the protection of these patient rights would be consumer education on meaningful choice, HIE opt out rights, revocation of consent procedures and audit rights.

Recommended Language:

§ 2.31 Form of written or electronic consent.

(a) *Required elements.* A written or electronic consent to a disclosure under these regulations must include:

- (1) The specific name or general designation of the program or person permitted to make the disclosure.
- (2) The name or title of the individual, or the name of the organization, health information exchange, health home, accountable care organization, or other care coordination entity to which disclosure is to be made; or, language which authorizes disclosure to any and all providers involved in the patient’s care.
- (3) The name of the patient.
- (4) The purpose of the disclosure.
- (5) How much and what kind of information is to be disclosed.
- (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient. The signature may be electronic taking into account current and reasonable authentication techniques.
- (7) The date on which the consent is signed.
- (8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
- (9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

§ 2.11 Definitions

“*Accountable Care Organization*” means a network of physicians and hospitals who manage, provide and coordinate high quality care to patients and who are jointly accountable for the health of their patients, which meets the standards set forth in (i)-(iv) below and all provider-members of the organization who have a demonstrated treatment relationship with the patient. In order to be an accountable care organization, a qualified organization must (i) have in place a data participation agreement with each member of the accountable care organization that includes appropriate safeguards related to information disclosed under these regulations, (ii) maintain an audit trail for all records disclosed under these regulations, (iii) conduct audits of uses and disclosures of records covered by these regulations, and (iv) honor any patient’s request to revoke a consent to disclose records

to the accountable care organization and communicate the terms of such revocation to all members of the accountable care organization as soon as possible but not later than three business days after receipt of notice of revocation from the patient or a provider-member of the accountable care organization.

“*Care coordination entity*” means a network of providers who coordinate care for patients through an integrated delivery system, which meets the standards set forth in (i)-(iv) below and all provider-members of the entity who have a demonstrated treatment relationship with the patient. In order to be a care coordination entity, a qualified entity must (i) have in place a data participation agreement with each member of the care coordination entity that includes appropriate safeguards related to information disclosed under these regulations, (ii) maintain an audit trail for all records disclosed under these regulations, (iii) conduct audits of uses and disclosures of records covered by these regulations, and (iv) honor any patient’s request to revoke a consent to disclose records to the care coordination entity and communicate the terms of such revocation to all members of the care coordination entity as soon as possible but not later than three business days after receipt of notice of revocation from the patient or a provider-member of the care coordination entity.

“*Electronic consent*” means consent to a disclosure of alcohol and drug abuse patient records in electronic form which contains (i) the required elements of § 2.31 of these regulations, and (ii) the electronic signature of the patient to whom the records pertain and/or of a person authorized to give consent under § 2.14 or § 2.15 and which meets reasonable authentication standards. The disclosing entity can exercise its professional judgment in determining whether authentication standards are reasonable under the circumstances, taking into consideration then-currently available authentication technologies.

“*Health information exchange*” means an organization that provides services to enable the electronic sharing of health-related information that meets the standards set forth in (i)-(iv) below and all participating provider-members of the organization who have a demonstrated treatment relationship with the patient. In order to be a health information exchange, a qualified organization must (i) have in place a data participation agreement with each member of the health information exchange that includes appropriate safeguards related to information disclosed under these regulations, (ii) maintain an audit trail for all records disclosed under these regulations, (iii) conduct audits of uses and disclosures of records covered by these regulations, and (iv) honor any patient’s request to revoke a consent to disclose records to the health information exchange and communicate the terms of such revocation to all members of the health information exchange as soon as possible but not later than three business days after receipt of notice of revocation from the patient or a provider-member of the health information exchange.

“*Health home*” means an organization that coordinates care for patients who have chronic conditions in accordance with a Medicaid State Plan that meets the standards set forth in (i)-(iv) below and all participating provider-members of the organization who have a dem-

onstrated treatment relationship with the patient. In order to be a health home, a qualified organization must (i) have in place a data participation agreement with each member of the health home that includes appropriate safeguards related to information disclosed under these regulations, (ii) maintain an audit trail for all records disclosed under these regulations, (iii) conduct audits of uses and disclosures of records covered by these regulations, and (iv) honor any patient’s request to revoke a consent to disclose records to the health home and communicate the terms of such revocation to all members of the health home as soon as possible but not later than three business days after receipt of notice of revocation from the patient or a provider-member of the health home.

“*Providers involved in the patient’s care*” means any and all providers who have a demonstrated treatment relationship with the patient as defined in this section.

“*Provider-member*” means any provider who is a participant in the health information exchange, health home or accountable care organization who or which (i) has in place a data participation agreement with the health information exchange, health home or accountable care organization that includes appropriate safeguards related to information disclosed under these regulations, (ii) maintains an audit trail for all records disclosed under these regulations, (iii) conducts audits of uses and disclosures of records covered by these regulations, and (iv) honors any patient’s request to revoke a consent to disclose records to the health information exchange, health home or accountable care organization and communicates the terms of such revocation to the health information exchange, health home or accountable care organization within 2 business days of receiving notice of revocation from the patient.

“*Demonstrated treatment relationship*” means a provider who or which (i) has a scheduled appointment with the patient, (ii) has been specifically identified by the patient as a provider to whom he/she intends for his/her records to be disclosed, (iii) already has certain patient records on file and has a history of treating the patient in accordance with the prevailing standard of care and neither the patient nor the provider has provided any indication of an intent to terminate such treatment relationship, (iv) is actually treating the patient on an urgent basis; or (v) has received a referral from one of the patient’s treating providers.

Statutory Amendment: Not required. The revisions to § 2.31 make changes to the consent procedures. The revisions to § 2.11 add definitions of pertinent terms. Therefore all changes can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g).

2. Add New Section Establishing the Mandatory Exclusion from Evidence of Information Obtained in Violation of 42 CFR Part 2

Concern from Field: It is well settled that the penalties for violating the SUD Confidentiality Law are insufficient for deterring improper use and disclosure of alcohol and drug treatment information. Moreover, since the SUD Confidentiality Law was enacted in 1972 it has not been effectively enforced. The regulations must provide

a meaningful enforcement mechanism for the SUD Confidentiality Law in order to protect patients. Additionally, most patients and persons in recovery appear to be less concerned about sharing information with their health care providers but have expressed apprehension about the information in their medical record being disclosed or used for non-treatment purposes by law enforcement, employers, insurance companies, life insurance companies, divorce attorneys and others seeking to use the information against the patient.

While we have recommended relaxing some aspects of 42 CFR Part 2 to facilitate greater coordination of care among treatment providers for the benefit of patients, we also recognize the need to strengthen some aspects of 42 CFR Part 2 in order to further enhance patient protections. Notably, if an employer, insurance company or attorney illegally obtained Part 2 information, the court previously did not have a clear ability to protect the patient from such illegal use. Enhanced protections for patients in this context would be a welcomed safeguard and a very effective deterrent to wrongful use and disclosure without imposing additional criminal or civil penalties.

Proposed Remedy: The ideal scenario would be to revise penalties under 42 CFR Part 2 to be consistent with penalties under HIPAA. We are also strongly in favor of giving individuals whose information has been used or disclosed in violation of 42 CFR Part 2 a private right of action to seek damages from the offending program. However, we believe a statutory amendment would be required to effect these changes. As an alternative to a statutory amendment, we suggest adding a new protection for patients under 42 CFR Part 2 which would require the mandatory exclusion from evidence of information obtained in violation of 42 CFR Part 2. This would extend to all criminal and civil proceedings.

Recommended Language:

§ 2.69 Mandatory Exclusion from Evidence

Information obtained in violation of these regulations may not be entered as evidence in or otherwise considered in connection with any criminal, civil or other legal or administrative proceeding provided the patient or applicable party with standing in the proceeding reasonably demonstrates to the satisfaction of the judge or other arbitrator over the proceeding that the information at issue was obtained in violation of these regulations. The court shall issue a protective order and exclude the use of that evidence in any proceeding involving the patient.

Statutory Amendment: Not required. This creation of a § 2.69 provides yet another safeguard which prohibits the use of information obtained in violation of 42 CFR Part 2 as evidence in legal proceedings and therefore can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g). Similarly, § 2.69 is a specific order a court could issue excluding the evidence which could be considered consistent with regulatory authority to articulate procedures and criteria for the issuance and scope of court orders under 290 dd-3(b)(3)(C).

3. Add Section Addressing Use of Program Records in Civil Proceedings

Concern from Field: Patients are generally fearful of information covered by 42 CFR Part 2 being used against them in criminal *and* civil proceedings. For example, patients who are parties to child custody disputes, employment actions, malpractice actions, landlord/tenant disputes and professional licensure proceedings to name a few, could be significantly adversely affected if a history of treatment by a program is introduced into evidence in connection with such proceedings. However, the current statutory language only addresses use of such records in criminal proceedings.

Proposed Remedy: Add a new § 2.68 which would limit the use of information covered by 42 CFR Part 2 in civil proceedings and make corresponding changes in the regulations to sync limitations on the use of information in criminal proceedings and civil proceedings.

Recommended Language:

§ 2.68 Use of Program Information in Civil Proceedings

Except as authorized by a court order granted under Subpart E, no record covered by these regulations may be used (i) to initiate or substantiate any civil proceedings against a patient or (ii) to conduct any civil investigation of a patient. This restriction on use applies to any person who obtains the information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or whether the information was obtained in accordance with these regulations. This restriction bars, among other things, the introduction of that information as evidence in a civil proceeding and any other use of the information to seek judicial relief from a patient with respect to the civil action. This applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient records is subject to the restriction on use of his information to

initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1) **and the restriction on use with respect to civil proceedings as provided for under § 2.68.**

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors, and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal **or civil** investigation or prosecution of a patient **or to initiate or substantiate any civil proceedings against a patient.** However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

Statutory Amendment: Not required. This creation of a § 2.68 and revisions to § 2.23 and § 2.62 effectuate safeguards which limit the use of 42 CFR Part 2 information in civil and criminal proceedings and therefore can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g).

4. Add Anti-Discrimination Protections

Concern from the Field: In 1972 Congress adopted the SUD Confidentiality Law in response to growing stigma and discrimination against persons with substance use disorders. The law sought to ensure that individuals not be made more vulnerable as a result of seeking substance use disorder treatment. Yet, the statute itself is silent on these issues and provides no non-discrimination provisions or protections to address these fundamental vulnerabilities. By contrast, the federal Genetic Information Nondiscrimination Act of 2008 (GINA) contains a number of provisions protecting against discrimination by health insurers and employers on the basis of genetic information, long considered to be a subset of medical information which, like substance use disorder treatment information, makes patients particularly vulnerable to discrimination. In enacting GINA, Congress made the policy decision that it is crucial to specifically prohibit discrimination based on this subset of information rather than rely on a patchwork of state anti-discrimination laws and the limited applicability of the Americans with Disabilities Act and HIPAA. Likewise, we believe substance use disorder patients should be afforded specific and meaningful protection from discrimination, particularly because preventing stigma and discrimination is such an important component of encouraging persons to seek treatment.

Moreover, the unfortunate truth is that stigma and discrimination against persons with substance use disorders is a reality. According to a February 2010 statement from Faces and Voices of Recovery (FAVOR), a 2001 survey of the recovery community conducted by Peter D. Hart Research Associates reported that 24 percent of people in recovery experienced employment and/or insurance

discrimination. FAVOR noted that these experiences occurred even with privacy protections in place. This statistic tells us that privacy protections alone are not enough. Persons in methadone treatment or other medication-assisted treatment routinely experience discrimination, even reportedly from health care providers not well informed about addiction, best practices or appropriate and successful medication management interventions.

The alarming effects of this failure to prohibit discrimination against persons with substance use disorders can be seen in an October, 2013 case originating in Wisconsin in which a 12-week pregnant woman was arrested and court-ordered to drug treatment after admitting to her clinician that she had previously struggled with addiction. Even after her pregnancy was determined to be healthy, the Wisconsin woman was ordered to spend 90 days in a drug treatment center and at trial could face termination of her parental rights once the child is born. She has filed suit in federal court challenging the constitutionality of a 1997 state law that gives Wisconsin courts jurisdiction over any pregnant woman who “habitually lacks self-control” in using alcohol or drugs “to a severe degree” such that the physical health of her “unborn child” will be “seriously affected or endangered.” Similar discriminatory treatment of individuals with substance use disorders has long been the norm in New York where the 40-year-old Rockefeller drug laws mandate lengthy sentences for nonviolent, first-time drug offenders and have done little to curtail drug use in New York. Unfortunately, comparable laws operate in various other states throughout the country where addicts are penalized instead of treated, leading to further discrimination against persons suffering with addiction.

As evidenced by these real life examples of discrimination, we must take better care to protect the privacy of those seeking treatment for substance use disorders by explicitly prohibiting discrimination on the basis of program records.

Clearly, if some standards will be relaxed to facilitate integrated care and better coordination for improved outcomes, careful consideration must be given to providing patients enhanced protections. Enhanced patient protections are crucial because patients will need and expect additional safeguards and positive changes in these regulations, especially if patients will consider and agree to share their information electronically. Although we cannot guarantee an end to stigma and discrimination, we firmly believe, and stakeholder polling suggests that addiction should be treated as a chronic brain disease, just like other medical conditions. The additional recommended language below is intended to provide a strong deterrent to discrimination and prevent stigma.

Proposed Remedy: Add a provision to the regulations that prohibits discrimination against persons receiving alcohol or drug abuse treatment. The language set forth in new 42 CFR § 2.24 is modeled after anti-discrimination provisions set forth in GINA. You will note in the employment language we have recognized the unique challenges this field encounters when hiring persons in recovery and the need to establish certain reasonable sobriety/recovery guidelines for the benefit of patients and to ensure program integrity. This language attempts

to strike that balance with patients' rights under ADA and EEOC guidelines.

Recommended Language:

§ 2.24 Nondiscrimination

- (a) *Discrimination in Health Coverage.* It shall be unlawful for any health plan or health insurance program to use records covered by these regulations to deny or condition the issuance or effectiveness of a plan, policy or coverage (including the imposition of any exclusion of benefits under the plan, policy, or coverage based on a preexisting condition) or to discriminate in the pricing of the plan, policy or coverage (including adjusting the premium rates) of an individual on the basis of the contents of such records.
- (b) *Discrimination in Provision of Health Care Services.* It shall be unlawful for any health care provider to deny access to or discriminate in the provision of medically necessary health care services to an individual who is the subject of a record covered by these regulations on the basis of the contents of such record. Nothing in this subsection is intended to require a health care provider to deliver a service which is clinically inappropriate or which the health care provider does not ordinarily provide to the general public. Nor is anything in this section intended to prevent a substance abuse recovery program, residential program, or other program from conditioning access to and continuing participation in the program on maintenance of sobriety or non-possession of alcohol or drugs.
- (c) *Discrimination in Employment.* It shall be unlawful for any employer to deny access to or discriminate in the provision of potential employment and/or continued employment to an individual who is the subject of a record covered by these regulations on the basis of the contents of such record. Nothing in this subsection is intended to prohibit employers from establishing reasonable recovery or sobriety timeframes related to job functions.

Statutory Amendment: Not required. This creation of a § 2.24 establishes safeguards for patients by making it unlawful for providers, plans, and employers to discriminate against patients with 42 CFR Part 2 information and therefore can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g).

5. Add Duty to Warn Provision

Concern from the Field: Section 164.512(j) of HIPAA and most state laws expressly permit a health care provider to disclose patient information without consent, including information from mental health records, if the provider in good faith believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. However, the regulations at 42 CFR Part 2 do not contain an exception which allows alcohol and drug abuse treatment providers to make disclosures of patient information in

such situations. Ironically, many treatment providers erroneously believe a duty to warn exception exists now under the regulations. The Newtown, Connecticut tragedy that occurred in December of 2012 shocked and pained the entire nation. In search of answers and recognition of the unacceptability of the status quo, national experts gathered to address gun violence, our mental health system's treatment, funding needs and prevention strategies to reduce the potential for reoccurrence of such horrific events. As part of that process, the duty to warn laws were front and center of that discussion. On January 15, 2013 HHS issued confusing guidance to health care providers indicating that no federal law prohibited them from reporting threats of violence to law enforcement authorities. While this was intended to reassure providers who were uncertain about exercising their duty to warn under federal statutes, it was inaccurate. While HIPAA is by far the best known and most widely used federal privacy protection, the federal confidentiality statute and regulations (42 U.S.C. 290 dd-3 and 42 CFR Part 2) govern many behavioral health providers. This guidance caused some treatment providers to wonder whether 42 CFR Part 2 was now preempted by the Executive Order issued and requires clarification.

Section 164.512(j) of HIPAA permits disclosures of this kind to any of the following: law enforcement officials, family members of the patient or others who may reasonably be able to prevent or lessen the threat. In contrast, the only exceptions under 42 CFR Part 2 which allow for disclosure of patient information without consent in situations in which a threat to the health or safety of a person or the public exists are the following: (i) disclosures pursuant to a valid court order (42 C.F.R. § 2.61-2.66); (ii) disclosures to law enforcement if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel (42 C.F.R. § 2.12(c)(5)); (iii) reports to health care personnel under the medical emergency exception for purposes of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention (42 C.F.R. § 2.51); and (iv) anonymous disclosures made without divulging patient identifying information. Due to the lack of a "duty to warn" exception under 42 CFR Part 2, substance use disorder treatment providers regularly face ethical dilemmas of patient rights versus public safety.

With the increased number of patients with co-morbid mental health conditions, the SUD treatment community is a critical intervention source that must understand its role in assisting complex patients with their recovery while appropriately identifying potential threats and communicating with law enforcement if greater public safety interests exist. Adding a "duty to warn" exception to 42 CFR Part 2 is a crucial and necessary change that will give providers the flexibility they need to mitigate serious danger to their patients and others. This "duty to warn" concept is a fixture of not just HIPAA, but also state common and licensure laws. It is taken very seriously by providers and does not, we believe, pose a potential area for abuse.

Moreover, although some have suggested including a permissible disclosure for purposes of homeland security

investigations, we do not suggest adding such an exception at this time. We believe patients will be suspicious of such a change and that a duty to warn exception could be invoked, when appropriate, for homeland security purposes.

Proposed Remedy: Add a “duty to warn” exception to the regulations which permits disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, thereby harmonizing 42 CFR Part 2 with HIPAA in this regard.

Recommended Language:

§ 2.54 Duty to warn.

(a) Patient identifying information may be disclosed in order to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, provided the disclosure:

- (1) Is limited to that information which is necessary to carry out the purpose of the disclosure; and
- (2) Is made to law enforcement officials, family members of the patient or others who may reasonably be able to prevent or lessen the threat.

Statutory Amendment: Not required. We believe that § 2.54 created above constitutes a safeguard under the regulations in that it ensures the appropriate use and disclosure of 42 CFR Part 2 information in order to protect the safety of patients and the public. Therefore, we believe the change can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g). However, we recognize that further examination may be required to determine whether a change to the statutory language may also be necessary to ensure compliance with the spirit and intent of 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g). We recognize that the child abuse reporting exemption in § 2.12(c)(6) was added only after Congress adopted a statutory amendment.

6. Remove Requirement to Document “Breaking of the Glass”

Concern from the Field: Under 42 CFR § 2.51, information covered by 42 CFR Part 2 may be disclosed to treat the patient for a condition which poses an immediate threat to the patient’s health and which requires immediate medical intervention. However, 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. More importantly, if a hospital “breaks the glass” in this scenario, the Part 2 program may not know whose record was accessed except through an audit trail. The hospital logically would be the appropriate provider to document the justification for the medical emergency but the regulations currently impose that requirement on the Part 2 program.

One irony that exists in this debate is that the redisclosure prohibition exists for consents but not for medical emergencies. Thus, when Part 2 information is disclosed pursuant to a medical emergency, that information loses its Part 2 protections and can therefore be further disclosed by the entity (such as a hospital or physician) in receipt of the information. Unfortunately, many patients and Part 2 providers do not understand this nuance under 42 CFR Part 2. Yet, this longstanding exception exists both in statute and in regulation.

Proposed Remedy: Two options for consideration—the clearest direction and first option would be to remove 42 CFR § 2.51(c) from the regulations entirely. The second option would be to require non-Part 2 providers to document the medical emergency justification in their records. The elements for such documentation can mirror the existing § 2.51(c) but apply only to the receiving agency (likely an enforcement problem but more logical from an operational standpoint).

Recommended Language:

§ 2.51 Medical Emergencies

~~(c) Procedures. Immediately following disclosure, the program shall document the disclosure in the patient’s records, setting forth in writing:~~

- ~~(1) The name of the medical personnel to whom disclosure was made and their affiliation with any healthcare facility;~~
- ~~(2) The name of the individual making the disclosure;~~
- ~~(3) The date and time of the disclosure; and~~
- ~~(4) The nature of the emergency (or error, if the report was to FDA).~~

Statutory Amendment: Not required. This revision to § 2.51 constitutes a change in procedure as it relates to medical emergencies and therefore can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g).

7. Clarify the Prohibition on Redisclosure

Concern from the Field: Although implied, the regulations do not clearly state that recipients of information protected by the SUD Confidentiality Law are only permitted to use, disclose, and redisclose such information as permitted by 42 CFR Part 2. One option for addressing this issue is to eliminate the prohibition on redisclosure provision from 42 CFR Part 2, making 42 CFR Part 2 consistent with HIPAA on the topic of redisclosure. The statute itself does not contain the prohibition on redisclosure, therefore a revision to the statute would not be required in order to eliminate this provision from the SUD Confidentiality Law. However, we recognize that patients may have concerns about removing the prohibition on redisclosure from the SUD Confidentiality Law, so a more tempered solution may be better accepted.

Another option for addressing this issue is to make the prohibition on redisclosure 100% clear in the regula-

tions. In other words, it could be made explicit in the regulations that the prohibition on redisclosure “follows” the alcohol and drug abuse patient records. Therefore, if the program records become integrated into a patient’s general medical record by another provider, that provider is prohibited from redisclosing the patient’s entire medical record without patient consent or as otherwise permitted by the regulations. Given the limited data segmentation technologies that exist and the practical realities of administering a medical practice, we recognize that this situation creates a technological and administrative burden for providers. Specifically, providers must either keep alcohol and drug abuse patient records separate from the rest of the patient’s medical record or comply with the regulations at 42 CFR Part 2 with regard to the patient’s entire medical record if such record contains alcohol and drug abuse patient records and the information cannot be segregated. This is particularly problematic in the context of subpoenas or other mandated disclosures under HIPAA that are not permissible under 42 CFR Part 2. We are hopeful that technology will soon be developed which allows for data segmentation, however that technology does not currently exist.

Secondly, the prohibition on redisclosure prevents providers participating in an HIE, health home, ACO, or CCE from disclosing alcohol and drug abuse patient records among each other for treatment and care coordination purposes. Although we believe the new definitions of “accountable care organization,” “health information exchange,” “health home,” “care coordination entity,” “provider-member” and “demonstrated treatment relationship” above adequately provide for disclosure of alcohol and drug abuse patient records within such contexts, we believe it is also important that it be made very clear that when a patient consents to disclosure of his or her alcohol and drug abuse patient records to an HIE, health home, ACO, or CCE, he or she is also consenting to redisclosure of his or her alcohol and drug abuse patient records within such HIE, health home, ACO, or CCE as necessary for treatment and care coordination purposes.

Additionally, we believe that a “health information exchange” and a “provider-member” of a “health information exchange” that meet the definitional criteria above, but to which/whom a patient has not authorized disclosure of 42 Part 2 information should be able to access 42 CFR Part 2 information from a different “health information exchange” or “provider-member” of that different “health information exchange” when such access is necessary for treatment purposes on an emergent basis.

Of course, a patient could also expressly consent to redisclosure of information to any parties, entities or organizations named in an authorization.

Proposed Remedy: Clarify that recipients of information covered by 42 CFR Part 2 are explicitly bound by its terms. Further clarify that the prohibition on re-disclosure in 42 CFR § 2.32 does not apply to provider-members of the HIE, health home, ACO or CCE with a demonstrated treatment relationship with the patient. Establish that the prohibitions on re-disclosure in 42 CFR § 2.32 do not apply to outside health information exchanges or provider-members of such exchanges who have a demonstrated

treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.

Recommended Language:

§ 2.32 Prohibition on re-disclosure.

A recipient of any record protected by Federal confidentiality rules at 42 CFR Part 2 may only use or redisclose such records as permitted by 42 CFR Part 2. Each disclosure made with the patient’s written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. Specifically, but without limitation, information that has been disclosed pursuant to an appropriate written consent as set forth in 42 CFR Part 2 or as otherwise permitted by 42 CFR Part 2 and thereafter becomes integrated into a patient’s general medical record may not be redisclosed without the patient’s written consent or as otherwise permitted by 42 CFR Part 2. However, information that has been disclosed to a health information exchange, health home, accountable care organization, or care coordination entity pursuant to an appropriate written consent as set forth in 42 CFR Part 2 may be re-disclosed among provider-members of the health information exchange, health home, accountable care organization, or care coordination entity who have a demonstrated treatment relationship with the patient without necessitating additional patient consent. Moreover, a health information exchange may disclose information to a different health information exchange if such information is sought by a provider-member of that health information exchange with a demonstrated treatment relationship with the patient for purposes of treating the patient under emergent or other circumstances in which a patient cannot reasonably provide written consent to such redisclosure, as reasonably determined by the provider requesting the information. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Statutory Amendment: Not required. The revisions to § 2.32 constitute safeguards which ensure that 42 CFR Part 2 information is not redisclosed in violation of the regulations and therefore such revisions can be accomplished through regulatory revisions pursuant to the authority granted under 42 U.S.C. 290ee-3(g) and 42 U.S.C 290dd-3(g).

Conclusion

Since the SUD Confidentiality Law and 42 CFR Part 2 were passed more than 40 years ago, our nation’s health care delivery system has undergone tremendous change. With the advent of electronic health records and health information exchange, as well as the passage of the Affordable Care Act, it has become increasingly clear how necessary the sharing of health information is to the delivery of quality, cost-conscious health care. Society is

beginning to recognize and understand the importance of access to effective behavioral health care in ensuring the overall health and wellness of our population. Given this, it is essential that we re-examine and re-evaluate the confidentiality regulations at 42 CFR Part 2 that govern the sharing of SUD information. However, it is imperative that any revisions made to the regulations address the concerns of all interested stakeholders. As we continue to solicit input and feedback from these various individuals and organizations, it is our hope that the regulations at 42 CFR Part 2 can be practically revised to contemplate this new era of health care and ensure that individuals requiring treatment receive the best possible care and are afforded the confidentiality protections they deserve. ❖

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