

Comments on Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2

Submitted by the National Center on Domestic Violence, Trauma & Mental Health (NCDVTMH)

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The National Center on Domestic Violence, Trauma & Mental Health (NCDVTMH) is a national special issue resource center funded by the Family Violence Prevention & Services Program (FVPSP); Administration on Children, Youth and Families; Department of Health & Human Services.¹ We are grateful for this opportunity to submit comments.

As we move toward more coordinated care models, advances in health information technology (HIT) create new possibilities for advancements in patient care while maintaining protections for sensitive patient information. Developing the technological solutions for ensuring the protection of sensitive health- and behavioral health-related information is possible—and can be critical to patient safety and well-being.

The domestic violence (DV) field has an important role to play in these conversations. First, the regulatory and technical solutions for handling sensitive *substance use treatment* information have implications for how we will be able to handle sensitive *DV-related* information, such as disclosures of abuse. We know that health and behavioral health care providers are places where DV survivors frequently seek assistance and support. Trust and confidentiality can be critical factors to survivors in making the decision to disclose abuse, while maintaining confidentiality related to disclosures of abuse can be critical to patient safety. Thus, information about abuse derived from these disclosures must be protected to ensure that patients have an opportunity to safely disclose abuse to their providers and to ensure that patients' safety is protected after disclosure is made.

Second, we are interested in the direct implications of changes to 42 CFR Part 2 for those survivors who have sought treatment for a substance use disorder. The number of survivors potentially impacted is significant. Studies show that

¹ These comments are not submitted on behalf of and do not necessarily reflect the opinions of Family Violence Prevention & Services Program (FVPSP); Administration on Children, Youth and Families; and/or the Department of Health & Human Services.

between 67%–80% of women in substance abuse treatment are survivors of domestic violence.² Survivors may use substances to cope with the impact of past experiences of trauma or to emotionally survive ongoing abuse. Abusive partners may also use coercive tactics related to the substance use—including forcing or coercing their partners to use drugs or alcohol or to use more than they wanted, interfering with treatment and/or undermining recovery efforts, and using substance use or intoxication to justify emotional or sexual abuse. At the same time, abusers may use substance use treatment information against their partners to impugn their credibility with family and friends, undermine potential sources of support and assistance (e.g., by telling survivors they will be arrested for drug-related crimes if they call the police), and challenge their parenting ability in custody cases.³

Thus, the disclosure of documentation of abuse and documentation related to substance use treatment poses risks for survivors. Additionally, this information may be linked together, such as when documentation of interpersonal violence is included in substance abuse treatment records, the disclosure of which poses additional risks for survivors. These risks can place survivors in the bind of having to choose between seeking treatment which can be used against them or not accessing services that are important for their health and well-being—a dilemma that directly echoes the originally stated intentions of Congress in creating heightened protections for substance use treatment records via 42 USC § 290dd-2.

While regulatory changes may partially address some of the immediate needs of the field introduced by recent changes in the health care system, achieving advances in patient care while maintaining protections for sensitive patient information will ultimately require true data segmentation. HIT developers and vendors must build the software and hardware necessary to deal with sensitive information and give patients the authority over their own data without unduly burdening their providers. We encourage SAMHSA and other federal agencies to provide adequate incentives (carrots and sticks) to ensure developers and vendors make significant advances in data segmentation.

In the meantime, we are grateful for the opportunity to provide the following comments on specific regulation changes being considered by SAMHSA.

² Patricia Bland, M.A., CDP, *In Harm's Way: Substance Abuse and Safety Issues in the Context of Violence Against Women* (citing studies by Bennett & Lawson, 1994; Downs, 2001; Ogle & Baer, 2003).

³ Warshaw, Lyon, Bland, Phillips & Hooper, *Mental Health and Substance Use Coercion Survey: Report on Findings from the National Center on Domestic Violence, Trauma & Mental Health and the National Domestic Violence Hotline*. NCDVTMH 2014 (forthcoming).

Applicability

NCDVTMH supports changing the applicability of 42 CFR Part 2 so that covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. Documentation related to substance abuse treatment services should be considered sensitive information and subject to the heightened protections of 42 USC § 290dd-2 and 42 CFR Part 2, regardless of the type of facility at which the patient received treatment. As behavioral health services are increasingly integrated into primary health settings, this change in the applicability of 42 CFR Part 2 would represent a necessary and appropriate modernization of the regulation.

We understand that broadening the applicability of the rule to additional classes of providers will have an impact on service delivery in the short term. We strongly encourage SAMHSA and other agencies to put significant pressure on HIT developers and vendors to integrate automatic data segmentation, coding, and prompts to give providers the tools necessary to automatically and easily protect data without interrupting service delivery. Technology could and should be developed and used to balance these competing concerns.

Consent Requirements

NCDVTMH does not support changes to 42 CFR Part 2.31(a)(2), the “to whom” requirement. While the inclusion of programs currently covered by 42 CFR Part 2 in HIEs, health homes, ACOs, and CCOs is an important goal and necessary to providing holistic patient care, this cannot—and need not—be achieved at the expense of equally important privacy protections.

Strong privacy protections in the context of sharing information among groups with changing membership are critical to survivor safety. While some patients may choose to provide more generalized consents if they were permitted by 42 CFR Part 2, the risks associated with providing such consent are significant—especially for survivors of domestic violence. While some members of health care entities may be aware of the interrelated safety and confidentiality needs of survivors and may be fully trained and prepared to take the precautions necessary to ensure the safety of DV survivors, others may not be. Furthermore, in some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas, when records are disclosed to new members of health care entities. The records protected by 42 CFR Part 2 can include a range of highly sensitive personal information that abusers can use against their partners in a number of ways. For these reasons, providing consent to the disclosure of records to a general entity

with changing membership will rarely be in the best interests of survivors. Notification to a patient of regular changes to the list of providers or organizations that may access their information is insufficient to mitigate these safety risks. While recognizing that some patients may nonetheless wish to provide such a generalized release, such decisions would need to be made in the context of a robust informed consent process beyond what is currently the industry standard and what is required by any current or proposed regulation or law. Given these current realities, requiring consent forms to specifically identify the entities “to whom” disclosure is permitted is critical to survivor safety.

In addition, we note that allowing a consent form to include a more general description of the individual, organization, or health care entity to which disclosure can be made does not solve the need to provide for technological solutions when patients do not wish to provide this type of consent. Thus, the very real concerns raised by stakeholders that prompted SAMHSA to consider these changes will not be addressed by this proposed change because not all patients will find such generalized disclosures to be within their best interests. Such stakeholders will still need to find technological solutions to ensure these patients are included in coordinated care efforts. We are encouraged by recent technological advancements that will allow for these concerns to be accurately addressed in the near future, allowing for more patient privacy options without unnecessarily sacrificing privacy and safety protections.

Redisclosure

NCDVTMH supports clarification of 42 CFR Part 2.32 to clarify that the prohibition of redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible.

The prohibition on redisclosure is critical to survivor safety, as well as being a necessary privacy protection for all patients. As described in the previous section, while some providers may be fully trained and prepared to respond to the interrelated safety and confidentiality needs of survivors, others may not be. In some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas, if redisclosure were permitted absent heightened protections.

Thus, all privacy and signed consents should follow the data, regardless of who is using it. If a provider “pulls” data on a patient, the data received should be automatically subject to the same consents that a patient signed in the originating encounter. Responsibility for adhering to these consents must be built in to the formal health information exchange trust documents—and there must be strong penalties for breaching these privacy concerns. Policy on redisclosure of privacy and signed consents—as well as the technology to do it—

is still in a nascent stage of development. The principle remains that authorizations should follow the data. Thus, once again, we strongly encourage SAMHSA and other agencies to put significant pressure on developers and vendors to develop the technology structure necessary to provide the necessary protection for patient information.

Medical Emergency

42 USC § 290dd-2 provides for an exception to the consent requirements to “meet a bona fide medical emergency.” Clearly, this statutory exception is critical for the safety of patients. Having access to medical information necessary to meet an emergency situation can be life saving. NCDVTMH is concerned that changes to 42 CFR Part 2 to allow providers to use the medical emergency provision to “prevent” emergencies (in addition to merely to “meet” emergencies) would be an overly broad interpretation of the statute. Such an exception would potentially provide access to otherwise sensitive information in a wide range of circumstances, based on the justification that access to the information may prevent an emergency in the indeterminate future. More clarification is needed to determine whether such an exception could be written to facilitate increased patient care while also staying within the scope of the statute and upholding necessary privacy protections.

Qualified Service Organization

At this time, NCDVTMH does not support expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

The goals of improving care coordination and helping providers to identify patients with chronic conditions in need of more intensive outreach are important ones. But while new opportunities for improving care coordination are exciting, they do not negate the need for strong privacy protections for highly sensitive information such as substance abuse treatment records. On the contrary, patient consent must remain a necessary prerequisite for sharing of highly sensitive information. Allowing the redisclosure of Part 2 information on the basis of a QSOA between a payer or an ACO and a service provider would circumvent the prohibition on redisclosure and other necessary protections provided by this regulation.

As explained above, sharing highly sensitive information regarding substance abuse treatment presents many risks for survivors. As discussed, while some members of health care entities may be prepared to take the precautions necessary to ensure the safety of DV survivors, others may not be. Furthermore,

in some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas. For these reasons, sharing of sensitive information should require the patient's informed consent, given in the context of a robust informed consent process that includes a discussion of the potential risks and benefits of information sharing, so that patients can determine what is in their best interest.

With regard to the goal of population health management, NCDVTMH is concerned that the release of much of the information protected by 42 USC § 290dd-2 and 42 CFR Part 2 is unnecessary for this purpose. To the extent that substance abuse treatment records are released for this purpose, de-identification of records is critical. Thus, to the extent that SAMHSA modifies 42 CFR Part 2 to facilitate access to records for the purpose of population health management, we encourage SAMHSA to require de-identification of records.

Conclusion

Thank you for this opportunity to provide comments. We appreciate your consideration and look forward to the next steps in this process. Please do not hesitate to contact us if we can be of additional assistance. You may reach Carole Warshaw, MD, Director, at cwarshaw@ncdvtmh.org or Rachel White-Domain, JD, Project Manager, at rwhitedomain@ncdvtmh.org. We can both be reached at 312-726-7020.