National Alliance for Medication Assisted Recovery

TEMPLATE FOR SAMHSA'S REQUEST FOR COMMENTS ON PROPOSED NEW RULE 42 CFR PART 2

[USE ORGANIZATION'S OR INDIVIDUAL'S LETTERHEAD; IF NO LETTERHEAD: INSERT ORGANIZATION'S OR INDIVIDUAL'S NAME & ADDRESS]

[DATE]

Substance Abuse and Mental Health Services Administration (SAMHSA)
U.S. Department of Health and Human Services
Attn: SAMHSA 4162-20
5600 Fishers Lane
Room 13N02B
Rockville, MD 20857

RE: Proposed Rule - 42 CFR Part 2 - Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (SAMHSA-4162-20) (Published Federal Register 2-9-2016: p 6987 -7024)

To Whom It May Concern:

[DESCRIBE YOUR PERSONAL REASON i.e. As a patient receiving …]

While SAMHSA has attempted to achieve an appropriate balance between preserving the confidentiality rights of substance use disorder patients and facilitating the sharing of health information to provide quality care in a new health care delivery environment I believe that more though needs to be put into any changes to 42 CFR Part 2. Once the door has been opened to allow for electronic sharing the records cannot be retrieved.

The announcement recognizes that the intention of 42 CFR Part 2 "were written out of great concern about the potential us of substance abuse information against individuals, causing individuals with substance use disorders to not seek needed treatment." Even more important is the concern about Substance Use Disorders (SUD) individuals not seeking needed treatment because of the fear that their names and information would be disclosed. The disclosure of medical records of SUD patients "has the potential to lead to a host of negative consequences including: loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution and incarceration."

Furthermore MAT patients currently in treatment entered with the knowledge and "promise" that information would not leave the Opioid Treatment Program (OTP) without their consent and told that their medical information was safe. Patients have over forty years placed their faith in programs that their information was safe. Any changes, or consequences to patients because of any changes in 42 CFR Part 2 would be seen as a breach in this trusted promise. This needs to be kept in mind when making changes to Part 2. It is important for OTPs to be able to maintain the trust that patients have in them.

Finally, the NPRM states that the purpose of regulations is to ensure that a patient receiving treatment for a substance use disorder in a substance abuse treatment program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment. Contrary to the statements made by organizations that patients did not care about 42 CFR Part 2 at the June 11, 2014 Listening Session, MAT patients and those seeking treatment for a SUD consider confidentiality an important issue and many may have not entered treatment if it were not for the "promise of confidentiality" that programs informed them about.

The concept of updating the mechanics of the federal alcohol and drug confidentiality regulations in a targeted way in order to facilitate the sharing of health information when needed is a good idea. However will this truly maintain the core purpose of 42 CFR Part 2? The health care system is still transitioning to electronic information systems and changes to Part 2 may result in unintended consequences. Currently there are still issues in the electronic health system and it would be more expedient for SAMHSA to wait until major issues are resolved and the electronic health information system is fully operational.

Although the Proposed Rule attempts to respond to the concern that SUD patients are not able to participate in new health care models like health information exchanges (HIEs) and accountable care organizations (ACOs) because those models were not equipped to handle certain requirements of Part 2. Why are these health care models concerned about 42 CFR Part 2? Typically health care providers do not want to treat SUD patients and if they do the care is often substandard or done grudgingly. The health care system is still a long way from treating SUD patients with dignity and respect and needs education. Perhaps a better way would be to include education for these providers and to put in place protection for SUD patients that are being used for financial gain. .

[INSERT ANY PERSONAL EXPERIENCE YOU HAVE HAD DEMONSTRATING THE IGNORANCE OF HEALTH CARE PROVIDERS OR PREJUDICE TOWARDS YOU.]

Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago. When patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment. This unfortunate reality should not be overlooked, particularly in light of the current national opioid crisis. If confidential SUD information is not protected, many individuals who could obtain needed treatment will not seek care. Therefore, SUD patients need to retain the power to decide when and to whom their records are disclosed, even for treatment and payment purposes, given the continued prevalence of discrimination in our society. Confidentiality breaches of electronic records systems (EHRs) of all types are far too common, making it even more critical that SUD patients have control of when their records will be included in EHRs.

Definitions

I support the updating and clarification of definitions.

Opiate Treatment Programs (OTPs)

Explaining the New Rule to patients is the responsibility of OTPs. Currently OTPs have had training about HIPPA but very little understanding of 42 CFR Part 2. For example, 42 CFR Part 2 is far more inflexible about confidentiality than HIPPA and yet professionals will often confuse them and state that HIPPA requires this requirement or that condition when it is actually 42 CFR Part 2. OTP staff need education about HIPPA and 42 CFR Part 2 their similarities and their differences.

More important is that OTP staff needs to be able to explain 42 CFR Part 2 to their patients. Since many OTP staff is confused themselves and need assistance in how to explain the New Rule to patients.

Consent Forms and Notice Requirements

I support SAMHSA's preservation of core consent requirements, including the use of specific patient consent forms and the prohibition on re-disclosure.

I do not support the approach of allowing a general designation in the "to whom" section of a consent form in certain circumstances related to health care and electronic records networks. Although this approach may create new flexibility by allowing patients to disclose their information to networks the problem is that these medical facilities have no understanding of SUD or 42 CFR Part 2 and the purpose of it. Furthermore knowing which organizations are involved rests on the OTP. Neither do I believe that OTP staff will be able to explain to patients that the information they are disclosing is not necessarily to a specific clinician or even a limited number of clinicians, but possibly to an entire system or a network.

Patients wanting to know where their information is going are required to make the request for it. Furthermore there is nothing about who will be obliged to pay for this request and considering the current health care system it is not hard to deduct that it will be the patient.

The existing 42 CFR Part 2, requires a notice to patients about federal confidentiality requirements and provides a sample notice. The New Rule only requires a notice to patients but does not provide what elements should be included.

SAMHSA also needs to clarify how the consent changes will work in the following scenarios:

o How may patients authorize disclosures to non-health related entities other than third-party payers under the Proposed Rule's consent requirements?

o How will the changes impact multi-party consent forms, which is an important tool for SUD programs and patients?

Design of Consent Form

The current Consent Form does not require the patient to understand what they are consenting to. The New Rule addresses this and requires that the patient understand what they have consented to and then sign the form to that effect.

The content and design of consent forms and Notice of Federal Confidentiality Requirements should be easy to understand for individuals with low literacy levels and meet HIPAA's "plain language"

requirements. Similarly, this information should adhere to existing Department of Health and Human Services guidance to provide meaningful access for individuals with limited English proficiency.

SAMHSA should include an updated sample consent and Notice of Prohibition on Re-disclosure forms in the Final Rule to provide greater assistance to stakeholders supporting Part 2's confidentiality requirements.

Medical Emergency Exception to Consent

I support the Proposed Rule's incorporation of the statutory language "bona fide" medical emergency. Consistent with the guidance SAMHSA provided in Frequently Asked Questions, Applying the Substance Abuse Confidentiality Regulations to the Health Information Exchange (HIE) and in a prior SAMHSA opinion defining a "bona fide" medical emergency. The Proposed Rule should explicitly state that the medical emergency exception continues to be limited to circumstances in which an individual needs immediate medical care and the patient's consent cannot be obtained -- for example, because s/he is unconscious -- and not to situations where the patient will not consent, since the medical emergency exception should not be used to avoid obtaining patient consent.

Research

I support scientific research activities that improve health outcomes for people with SUD and others. I support the Proposed Rule's approach, which maintains 42 CFR Part 2's core confidentiality safeguards, including a prohibition on re-disclosure and the requirement that researchers be bound by Part 2's requirements, while also allowing Part 2-protected information to be disclosed to scientific researchers. SAMHSA's proposed approach should enable the Centers for Medicare and Medicaid Services to resume including SUD patient information in data released to scientific researchers, thereby improving the quality of research and health care, while continuing to ensure SUD patient information is not re-disclosed beyond approved scientific researchers.

Qualified Service Organizations

I do not support the disclosure of patient information without consent to Qualified Service Organizations (QSO)

Prohibition on Re-disclosure

The Proposed Rule clarifies that the prohibition on re-disclosure applies only to information that would identify an individual, directly or indirectly, as having been diagnosed, treated, or referred for treating for a SUD. I understand this to be a restatement of existing law and agree with this interpretation.

Enforcement and Education

Since the Proposed Rule creates new avenues for the exchange of patients' substance use disorder information, especially to other parts of the health care system -- many of whom have little to no experience treating SUD or complying with 42 CFR Part 2, I urge SAMHSA to ensure strong enforcement of Part 2's requirements and to increase fines that are meaningful when amended regulations are adopted.

I also urge SAMHSA to provide trainings/webinars and technical assistance once the final rules are adopted, so that providers -- both SUD and other health care providers -- and patients alike will understand the changes.

Time

The New Rule needs to be put into effect in phases with stakeholders providing feedback of the outcomes. This will help to insure that unintended consequences do not occur.

Conclusion

Technology is improving health care and in particular the electronic health information system will give providers information about patients that they never had before. While the electronic health information systems may be positive for the average patient for those with SUD can be placed in situations where they are denied medical care because of ignorance and prejudice. It is essential that individuals enter an OTP for treatment knowing that their information will be protected and kept private.

Thank you for your consideration.

Sincerely,
/s/
[NAME]
[TITLE – If applicable]