LEGAL ACTION CENTER'S TEMPLATE FOR SAMHSA COMMENTS
ON 42 PART 2 PROPOSED RULE

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

SUBMITTED VIA [E-RULEMAKING PORTAL/ HAND DELIVERY/ COURIER/ OVERNIGHT/ OR U.S. MAIL]

[DATE]

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

RE: 42 C.F.R. Part 2 - Confidentiality of Alcohol and Drug Abuse Patient Records Regulations Proposed Rule, (SAMHSA-4162-20)

To Whom It May Concern:

[I/ORGANIZATION] offer comments regarding the modifications to 42 C.F.R. Part 2 ("Part 2") included in the Substance Abuse and Mental Health Services Administration ("SAMHSA")'s February 9, 2016 Proposed Rule (81 Fed. Reg. 6988) ("Proposed Rule").

[DESCRIBE THE MISSION OF YOUR ORGANIZATION OR YOUR PERSONAL EXPERIENCE]

Overall, [I/we] believe SAMHSA struck an appropriate balance in its attempt to achieve two important objectives: preserving the confidentiality rights of substance use disorder patients, while also facilitating the sharing of health information as needed to provide quality care in a new health care delivery environment, including through the use of the electronic exchange of health information.

[I/ORGANIZATION] support(s) 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 to provide quality care, while maintaining 42 C.F.R. Part 2's core privacy protections, including consent requirements and the prohibition on re-disclosure. [I/We] also applaud the Proposed Rule's efforts to make many clarifying changes in wording and definitions.

The Proposed Rule responds to concerns that substance use disorder ("SUD") patients were unable 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. While SAMHSA proposes a new, more flexible, consent option to address this concern, SAMHSA also proposes to continue requiring SUD patients' consent to disclose their information, thereby maintaining patient control over disclosures. The impact of this solution is to allow patient information to flow to and through new health care models *when the patient chooses to do so, an approach with which* [*I/we*] *agree*.

[INSERT ANY PERSONAL EXPERIENCE YOUR ORGANIZATION HAS HAD HIGHLIGHTING THE CONTINUED IMPORTANCE OF 42 CFR PART 2, E.G., PATIENT/CLIENT STORIES, PROGRAM EXPERIENCE PREVENTING PATIENT INFORMATION FROM BEING DISCLOSED, ETC.]

As the above experience shows, 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, [I/we] believe that patients in SUD programs should 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. It is important to note that confidentiality breaches of electronic records systems ("EHRs") of all types are far too common, making it even more critical that patients retain control of when their records will be included in EHRs.

It also is important to keep in mind that EHRs are required to accommodate enhanced protections for the medical records of some illnesses in order to be Health Insurance Portability and Accountability Act ("HIPAA") compliant even if 42 C.F.R. Part 2 did not exist. Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, EHRs, HIEs, and integrated care systems must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. These systems must also be capable of complying with the Health Information Technology for Economic and Clinical Health ("HITECH") Act's requirement that patients have the right to restrict disclosure of their health information when they pay out-of-pocket for services provided. It is both necessary and technologically possible

to integrate SUD and other health care and effectively exchange SUD treatment data while maintaining the core protections of Part 2. [I/we] urge the continued development of technical solutions for consent management.

[My/Our] specific comments on the Proposed Rule are as follows:

Consent Forms and Notice Requirements

- [I/We] support SAMHSA's preservation of core consent requirements, including the use of specific patient consent forms and the prohibition on re-disclosure.
- [I/We] support the approach of maintaining the more specific consent requirements and the prohibition on redisclosure while also adding the flexibility 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. This approach creates new flexibility by allowing patients to consent to the disclosure of their information to an entity such as a Health Information Exchange, an Accountable Care Organization, and other health care and electronic records networks, together with a class of participants in that entity who have a treating provider relationship with the patient (e.g., all of the patient's treating providers who are members of the HIE or ACO).
- [I/We] support SAMHSA's proposal to allow patients to consent to disclose their SUD information to their past, current, and/or and future treating providers. This approach makes it easier to share information with health care entities that continually add new members, such as HIEs, while at the same time allowing patients to choose whether they are comfortable consenting to disclosures to future treating providers who are unknown to them at the time they sign the consent form.
- While [I/we] support the above proposed changes,[I/we] request that SAMHSA clarify how the consent changes will work in the following scenarios:
    - How may patients authorize disclosures to non-health related entities other than third-party payers under the Proposed Rule's consent requirements? [I/We] support the continued ability of patients to consent to disclosures -- specifically, not by general designation -- to individuals and entities with whom they do not have treating provider relationships (such as family members and legal representatives).
    - How will the process of patients designating past, present, and/or future treating providers work? For example if the patient does not specify past, present, or future, what assumption is made about the patient's intent?
    - How will the changes impact multi-party consent forms, which is an important tool for SUD programs and patients? Patients often sign consent forms allowing disclosure "among and between" all the

parties listed on the form. Under the Proposed Rule, a patient can include a general designation in the "To Whom" section of the consent form, but no longer can in the "From Whom" section. In this type of multi-party consent, the parties listed all become both "From Whom" disclosers and "To Whom" recipients of protected information. How can parties listed via general designation in the "To Whom" section also disclose information as part of a multi-party consent that permits disclosure "among and between" all named parties?

- 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.
- [I/We] recommend that SAMHSA include 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/We] 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, [I/we] recommend that the Proposed Rule 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.[1]

Research

- [I/We] support scientific research activities that improve health outcomes for people with SUD and others. [I/We] support the Proposed Rule's approach, which maintains 42 C.F.R. 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

[1] *See* U.S. DEP'T OF HEALTH & HUM. SERVICES, OPINION 77-18, DISCLOSURES TO PUBLIC HEALTH OFFICIALS OF POSITIVE VENEREAL DISEASE REPORTS – DEFINITION OF "BONA FIDE MEDICAL EMERGENCY" (2.51), July 18, 1977.

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

- The Proposed Rule clarifies that "population health management" is a service that can be provided by a Qualified Service Organization ("QSO") to a Part 2 program and its patients via a Qualified Service Organization Agreement ("QSOA"), which allows patient information to be disclosed to the QSO without patient consent so that the QSO can provide the service. Given how broadly "population health management" can be interpreted, [I/we] recommend that the Proposed Rule include an appropriately narrow definition of this term in the Final Rule.
- The Proposed Rule also states patient information may not be disclosed via QSOA for purposes of "care coordination," but rather can only be disclosed for that purpose pursuant to patient consent. [I/We] recommend that the Proposed Rule clarify the meaning of "care coordination" and how it differs from "population health management."

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/We] understand this to be a re-statement of existing law and agree with this interpretation.
- SAMHSA should clarify the meaning of its statement on page 7,003 of the Proposed Rule that, if a prescription for a medication used for SUD treatment is revealed without further clarification of a non-SUD use (e.g., methadone used for pain management), it would suggest that the individual has a SUD and would be prohibited. Does this mean that a prescription for a SUD treatment medication may only be disclosed without patient consent if the prescriber specifies that the prescription is not for SUD treatment?

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/we] urge SAMHSA to ensure strong enforcement of Part 2's requirements when amended regulations are adopted. [I/We] 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.

Lastly, [I/we] also support the comments on the Proposed Rule submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

/s/

[NAME]
[TITLE – If applicable]