VIA Federal e-Rulemaking Portal

April 11, 2016

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, Maryland 20857

Re: *Legal Action Center Comments on 42 CFR Part 2 - Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20)*

To Whom It May Concern:

The Legal Action Center ("LAC") is the only non-profit law and policy organization in the United States whose sole mission is to fight discrimination against people with histories of addiction, HIV/AIDS or criminal records, and to advocate for sound public policies in these areas.

LAC staff regularly consults about confidentiality and related legal issues with alcohol and drug prevention and treatment professionals around the country, as well as health, mental health, public health and managed care providers, welfare and child welfare systems, lawyers and law enforcement officials, courts and other criminal justice agencies, employment assistance programs, and federal, state and local policy makers. Nearly four decades of experience and expertise in applying and interpreting the federal law and regulations (42 C.F.R. Part 2) are reflected in our comments we submit in response to the Substance Abuse and Mental Health Services Administration's ("SAMHSA") February 9, 2016 Proposed Rule (81 Fed. Reg. 6988) ("Proposed Rule"). As you consider these and other comments from stakeholders, we urge you to give the greatest weight to the comments made by patients and consumers, as it is their rights and access to their sensitive health information that will affected by any changes to 42 C.F.R. Part 2.

OVERALL PRINCIPLES CONCERNING THE CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

LAC believes that behavioral health care should be integrated with physical health care, and that communication between health care providers should be encouraged. At the same time, 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, due to continued

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stigma and discrimination against people with substance use disorders ("SUD"). Therefore, patients seeking and receiving SUD treatment should retain the right to control how their records are disclosed, even for health and payment purposes.

LAC supports maximizing inclusion of SUD records in electronic health record ("EHR") systems and health information exchanges ("HIEs") while maintaining SUD patients' privacy. As SAMHSA acknowledges in the Proposed Rule, 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, including consent requirements and the prohibition on re-disclosure. We join SAMHSA in urging the continued development of technical solutions for consent management, especially in light of the myriad types of sensitive health information that are afforded additional confidentiality protections by law.

Support of these principles and goals must, of course, be balanced against the reality faced by SUD patients. Unfortunately, the need for Part 2's protections has not dissipated over the past 40 years. When patient records can be easily accessed in order to criminally investigate or prosecute patients, or deny them insurance or jobs, or be used against them in divorce or child custody proceeding, many patients will be afraid to enter treatment. This reality must remain front and center in any conversation about patient confidentiality, particularly in light of the opioid epidemic sweeping the nation.

Additionally, it is important to keep in mind that EHRs and HIEs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist. Because 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.

GENERAL RESPONSE TO PROPOSED RULE

LAC believes the Proposed Rule strikes an appropriate balance between two important objectives: preserving the confidentiality rights of SUD 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. We support updating the mechanics of 42 C.F.R. Part 2 ("Part 2") in a targeted way in order to achieve these goals while maintaining Part 2's core protections, including consent requirements and the prohibition on re-disclosure. We also appreciate the care SAMHSA took in soliciting and considering input from the field, including patients and consumers, prior to issuing this Proposed Rule.

The Proposed Rule responds to concerns that SUD patients were unable to participate in new health care models like HIEs and accountable care organizations ("ACOs") because those models were not equipped to handle certain requirements of Part 2. SAMHSA proposes a new, more flexible, consent option to address this issue. At the same time, SAMHSA 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. LAC agrees with this approach.

SPECIFIC COMMENTS ON THE PROPOSED RULE

A. Definitions (§ 2.11)

LAC applauds the Proposed Rule's efforts to make many clarifying changes in wording and definitions. While we agree with many of these revised or proposed definitions, we offer further commentary and requests for clarification for the following identified terms:

1. *"Part 2 Program"*

Proposed Rule:
SAMHSA proposes to retain the definitions of "program" (§ 2.11) and "federally assisted" (§ 2.12(b)), and proposes to add a definition for "part 2 program" to § 2.12. In addition, SAMHSA proposes to replace the term "program" with "Part 2 program" where appropriate, and replace "program" with "Part 2 program" in several other definitions.

LAC's Response:
We recommend that SAMHSA clarify that prevention and recovery support programs are covered by Part 2, as reflected in the authorizing statute (42 U.S.C. § 290dd-2(a)). Specifically, we recommend that programs which provide targeted prevention services -- aimed at those who in one way or another have been identified as having, or being at risk for, substance use disorders -- be included in the definition of "part 2 program." We recommend that programs that provide prevention information or services aimed at the general public not be included in the definition of "part 2 program." For example, a prevention program that targets the children of people already in recovery would be considered a "part 2 program." This clarification could be made either by: (1) defining "prevention" in the regulations and including "prevention" in the definition of "program" and "part 2 program;" or (2) issuing sub-regulatory guidance.

In addition, although the Proposed Rule states that a new definition for "Part 2 program" will be added to §2.12, it is not included in the proposed regulatory text in the Proposed Rule.

2. *"Treating Provider Relationship"*

Proposed Rule:
SAMHSA proposes to add a new definition for "treating provider relationship" to § 2.11. Under the Proposed Rule, a "treating provider relationship" means that,

regardless of whether there has been an actual in-person encounter: (1) a patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity, and (2) the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition.

LAC's Response:
LAC requests that "consultation" be added to sub-section (1) of the definition of "treating provider relationship," as well as in sub-section (2).

In addition, LAC recommends that the first sentence of the definition be edited to: "Patient is or agrees to be diagnosed, evaluated and or treated for any condition by an individual or entity. . . ." This adjustment would then cover treating providers in the context of mandatory treatment referrals.

3. "Patient"

Proposed Rule:
SAMHSA proposes to revise the definition of "patient" in § 2.11 to emphasize that the term "patient" refers to both current and former patients.

LAC's Response:
We recommend that SAMHSA further clarify the definition by specifying that "patient" includes individuals participating in prevention programs and recovery support programs, as indicated in the authorizing statute (42 U.S.C. §290dd-2(a)). Specifically, we recommend that individuals who receive targeted prevention services -- those aimed at individuals who in one way or another have been identified as having, or being at risk for, substance use disorders -- be included in the definition of "patient." We recommend that individuals receiving prevention information or services aimed at the general public not be included in the definition of "patient." For example, individuals participating in a prevention program that targets the children of people with substance use disorders would be considered "patients." This clarification could be made either by: (1) defining "prevention" in the regulations and including "prevention" in the definition of "patient;" or (2) SAMHSA could issue sub-regulatory guidance.

4. "Qualified Service Organization"

Proposed Rule:
SAMHSA proposes to revise the definition of "qualified service organization" ("QSO") in § 2.11 to include "population health management" in the list of examples of services a QSO may provide. SAMHSA does not propose to include a definition of "population health management" in the regulations, but states in the Proposed Rule that population health management "refers to increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group."[1]

[1] 42 C.F.R. Part 2 - Confidentiality of Substance Use Disorder Patient Records: Proposed Rule, 81 Fed. Reg. 6988, 6996 (Feb. 9, 2016).

LAC's Response:
LAC is concerned about the broad and vague definition of "population health management" in the Proposed Rule. The Final Rule should clarify several issues, such as: Who conducts population health management? Can insurers conduct population health management? We recommend that SAMHSA include a narrow meaning and definition of population health management in the regulations.

SAMHSA should also clarify how population health management differs from "care coordination," which is excluded from QSOs by the Proposed Rule. In addition, we presume that population health management encompasses public health reporting as required by law, but SAMHSA should confirm or clarify this presumption in the Final Rule.

B. Notice to Patients of Federal Confidentiality Requirements (§ 2.22)

Proposed Rule:
SAMHSA proposes to continue to require that patients be given a written summary ("Notice") of the federal law and regulations. The Proposed Rule clarifies that the term ''written'' includes both paper and electronic formats, and therefore this Notice may be provided to patients in either format.

SAMHSA also proposes to require the Notice to include the contact information for the appropriate authorities to whom patients may report violations of Part 2. SAMHSA is considering whether to issue guidance at a later date that includes a sample Notice.

Although it is not a proposed requirement, SAMHSA encourages Part 2 programs to be sensitive to the cultural composition of its patient population when considering whether the Notice should also be provided in (a) language(s) other than English (e.g., Spanish).

LAC's Response:
Overall, we agree with the proposed changes to the Notice requirements, including allowing the Notice to be provided in paper or electronic format, requiring the Notice to include contact information for the appropriate authorities, and encouraging Part 2 programs to be sensitive to the cultural compositions of their patient populations. We offer the following additional recommendations:

- Patients should be given the option of receiving the Notice in either an electronic or a paper format, which is currently a patient right under HIPAA.[2]

- While the purpose of the Notice is to apprise patients of the circumstances under which patient identifying information can be shared, inexplicably the required elements of the Notice do not include two major mechanisms that allow for the sharing of Part 2 information – Qualified Service Organization Agreements ("QSOAs") and research. Part 2 programs should be required to include in the Notice any QSOAs they have in place and a description of how

[2] 45 C.F.R. §164.520.

patients' information may be disclosed under those QSOAs. Part 2 programs should also be required to include in the Notice a description of how patient information may be disclosed for scientific research.

- The content and format of the Notice should comply with the "plain language" requirements of the HIPAA Privacy Rule, particularly to assist individuals with low literacy levels.[3]

- Instead of "encouraging" Part 2 programs to be sensitive to the cultural composition of patient populations when deciding whether the Notice should be provided in languages other than in English, Part 2 programs that receive federal financial assistance from the U.S. Department of Health and Human Services ("HHS") should be required to comply with existing federal law and guidance. For example, HHS' revised *Guidance to Federal Financial Assistance Participants Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient ("LEP") Persons*, and 45 C.F.R. § 80.3(b)(2) requires recipients of federal financial assistance from HHS (such as Part 2 programs) to take reasonable steps to provide meaningful access to their programs and services to LEP persons.[4] Moreover, federal guidance requires recipients of HHS financial assistance (including, but not limited to physicians and other health providers, hospitals, and managed care organizations) to use a four-prong analysis to determine whether "vital documents" such as consent and complaint forms, must be translated for LEP individuals who are affected by or eligible for the federal recipients' programs and services.[5] Therefore, those Part 2 programs that receive federal financial assistance from HHS should conduct this analysis to determine if language assistance is needed for LEP patients who use their program's consent forms and other vital documents.

- We recommend that the Final Rule include a sample Notice and sample complaint forms with which to report alleged violations of Part 2. These samples will assist stakeholders in complying with Part 2's requirements. This request is consistent with actions of other governmental agencies that assist

[3] *See id.* §164.520(b)(1).
[4] U.S. Dep't of Health & Hum. Services, Off. for Civ. Rts., *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, available at http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/index.html.
[5] Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (Aug. 8, 2003). *But see id.* at 47313, n. 4. HHS' Title VI regulations do not apply to (i) Any federal financial assistance by way of insurance or guaranty contracts, (ii) the use of any assistance by any individual who is the ultimate beneficiary under any program which receives federal financial assistance, and (iii) any employment practice, under any such program, or any employer, employment agency, or labor organization, except as otherwise described in the Title VI regulations. 45 C.F.R. 80.2.

individuals with protecting their rights, while providing notice to federal or state agencies of possible violations of law.[6]

C. Consents and Disclosures

1. *"To Whom" (§2.31)*

Proposed Rule

The Proposed Rule offers a Proposed Approach and an Alternative Approach to the "To Whom" section of a consent form. Each approach has four options for the "To Whom" field of the consent form: (1) to an individual; (2) to an entity/organization with which the patient has a treating provider relationship; (3) to an entity/organization with which the patient does not have a treating provider relationship and which is a third party payer; and (4) to an entity/organization with which the patient does not have a treating provider relationship and which is not a third party payer. The Proposed Approach details each of the four options in new regulatory text at 42 C.F.R. §2.31 and, under the fourth option, requires patients to additionally specify participants of the organization/entity to whom their information may be disclosed. The Alternative Approach leaves the current text of §2.31 the same and includes a new definition in §2.11 of "organization."[7]

LAC's Response

- Overall, LAC favors the Proposed Approach instead of the Alternative Approach because the Proposed Approach allows for more patient control over disclosures of their SUD information, and because it is unclear how the Alternative Approach would actually operate. However, there are several aspects of the Proposed Approach which we believe need clarification.

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[6] *See e.g.*, U.S. Dep't of Educ., Off. for Civ. Rts., *Discrimination Complaint Form*, available at http://www2.ed.gov/about/offices/list/ocr/complaintform.pdf (records various alleged civil rights law violations); N.Y. State Educ. Dep't, *Revised Sample State Complaint Form* (Sept. 2012), available at http://www.p12.nysed.gov/specialed/formsnotices/statecomplaint/sampleform-912.pdf. The form records allegations of violations of Part B of the Individuals with Disabilities Education Act ("IDEA") or New York State laws and regulations related to the education of students living with disabilities.

[7] The Proposed Rule explains,

> Organization would mean, for purposes of § 2.31, (a) an organization that is a treating provider of the patient whose information is being disclosed; or (b) an organization that is a third-party payer that requires patient identifying information for the purpose of reimbursement for services rendered to the patient by a Part 2 program; or (c) an organization that is not a treating provider of the patient whose information is being disclosed but that serves as an intermediary in implementing the patient's consent by providing patient identifying information to its members or participants that have a treating provider relationship, as defined in § 2.11, or as otherwise specified by the patient.

81 Fed. Reg. at 7001-02.

- Under the Proposed Approach, §2.31 does not seem to allow patients to consent to disclosures to entities that are not health care entities or payers. For example, how would a patient consent to disclose her SUD information to a law office that is representing her? As a result, we recommend that the Proposed Approach be limited to disclosures to scientific research and health care related activities, and that the current rules be retained for other disclosures; hence we recommend the following changes to Proposed §2.31(a)(4), with additions indicated by underlines and deletions by strikethroughs below:

(4)

(i) The name(s) and/or title(s) of the individual(s) and/or the name(s) of the entity(-ies) to whom a disclosure is to be made; or

(ii) In the case of a disclosure to an entity(-ies) or individual(s) engaged in scientific research or health care related activities:

(A) If the entity has a treating provider relationship with the patient whose information is being disclosed, such as a hospital, a health care clinic, or a private practice, the name of that entity; or

(B) If the entity does not have a treating provider relationship with the patient whose information is being disclosed and is a third-party payer that requires patient identifying information for the purpose of reimbursement for services rendered to the patient by the Part 2 program, the name of the entity; or

(C) If the entity does not have a treating provider relationship with the patient whose information is being disclosed and is not covered by paragraph (a)(4)~~(iii)~~(B) of this section, such as an entity that facilitates the exchange of health information or a research institution, the name(s) of the entity(-ies); and

(1) The name(s) of an individual participant(s); or

(2) The name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or

(3) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.

(i) When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see §2.13(d)).

(ii) Upon request, patients who have consented to disclose their patient identifying information using a general designation pursuant to §2.31(a)(4)(ii)(C)(3) must be provided a list of current participants in the

entity(-ies) to which they have consented to disclosure.

- In addition, LAC supports SAMHSA's suggestion that entities must have an established mechanism for determining whether a treating provider relationship exists.

- The Proposed Rule indicates that patients "may" further designate past, present, and future treating providers. We recommend that SAMHSA require that the consent form clearly provide the opportunity to exclude past or future treating providers for patients who wish to do so.

- LAC does not favor the Alternative Approach, due to the following concerns and questions: Defining "organization" as an entity and all of its members could have unintended consequences elsewhere in the regulations. For example, would this definition of "organization" be included in the meaning of "Qualified Service Organization?" Furthermore, if the Alternative Approach automatically allows an organization to disclose to its members that have a treating provider relationship, how would patients have the ability to "otherwise specify" and how would this process work? Is it correct that the definition of "organization" in the Alternative Approach excludes research entities?

2. *"From Whom" (§2.31)*

Proposed Rule
Because SAMHSA is now allowing, in certain instances, a general designation in the ''To Whom'' section of the consent form, SAMHSA proposes to require the ''From Whom'' section of the consent form to specifically name the Part 2 program(s) or other lawful holder(s) of the patient identifying information permitted to make the disclosure. Patients would no longer be permitted to include a general designation in the "From Whom" section.

LAC's Response
LAC believes multi-party consents are an important tool for Part 2 programs and patients. We are concerned that this approach may restrict multi-party consents and disclosures, such as consents that authorize disclosures "between and among" the parties listed. For example, if a consent form has a general designation in the "To Whom" section and the patient authorizes disclosures "between and among" the parties listed in the "To Whom" and "From Whom" sections, would the party in the "To Whom" section be unable to disclose? SAMHSA should clarify how multi-party consents could still be used under the revised regulations. We recommend that the use of multi-party consents be permissible even when the "To Whom" section contains a general designation, and that the party(ies) named in the "To Whom" section be permitted to re-disclose patient information if the patient has consented to such re-disclosures. This will allow patients' treating providers to communicate with each other (pursuant to patient consent) within networks like health information exchanges and integrated care organizations.

3. *"Amount and Kind" (§2.31)*

Proposed Rule
SAMHSA is proposing to require the ''Amount and Kind'' section of the consent form to explicitly describe the substance use disorder-related information to be disclosed. The types of information that might be requested include diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary, employment information, living situation and social supports, and claims/encounter data. Under the Proposed Rule, the designation of the ''Amount and Kind'' of information to be disclosed must have sufficient specificity to allow the disclosing program or other entity to comply with the request. For example, the description may include: ''medications and dosages, including substance use disorder-related medications,'' or ''all of my substance use disorder-related claims/encounter data.'' Examples of unacceptable descriptions would be ''all of my records'' (because this description does not address the substance use disorder-related information to be disclosed) and ''only my substance use disorder records my family knows about'' (because this description lacks specificity).

LAC's Response
We recommend that the Final Rule clarify that, while "all my records" would not be a permissible "Amount and Kind" specification, "all my substance use disorder records" would be permissible. For example, a patient may wish to disclose all of their SUD records from one Part 2 program to another, to a specialist for consultation, to an accountable care organization or health information exchange, or to a law office, and should be permitted to do so.

4. *New Consent Requirements (§2.31 and §2.13)*

Proposed Rule
SAMHSA proposes to add two new requirements related to patients signing the consent form. The first would require the Part 2 program or other lawful holder of patient-identifying information to include a statement on the consent form that patients understand the terms of their consent. The second would require the Part 2 program or other lawful holder of patient- identifying information to include a statement on the consent form that patients understand their right, pursuant to § 2.13(d), to request and be provided a list of entities to which their information has been disclosed when patients include a general designation on the consent form. In addition, the Part 2 program or other lawful holder of patient-identifying information would have to include a statement on the consent form that patients confirm their understanding of the terms of consent and § 2.13(d) by signing the consent form.

LAC's Response
LAC recommends that the patient information statements in the new consent requirements for §2.31 and §2.13 comply with the "plain language" requirements of

the HIPAA Privacy Rule, particularly to assist individuals with low literacy levels.[8] In addition, patient information provided in Part 2 programs who accept federal financial support from HHS should be required to comply with existing federal law and guidance. For example, the HHS revised *Guidance to Federal Financial Assistance Participants Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient ("LEP") Persons* and 45 C.F.R. § 80.3(b)(2), which requires recipients of federal financial assistance from HHS to take reasonable steps to provide meaningful access to their programs and services to LEP persons.[9] Part 2 programs that receive federal financial assistance from HHS should use the previously referenced four-prong analysis to determine whether vital documents and information must be translated for LEP patients who are affected by or eligible for the federal recipients' programs and services.

5. ***Prohibition on Re-Disclosure (§2.32)***

Proposed Rule

The Proposed Rule clarifies that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both, and allows other health-related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.

LAC's Response

This clarification is consistent with LAC's -- and SAMSHA's -- long-standing interpretation of Part 2, and we therefore agree with this interpretation.

We recommend that SAMHSA clarify that the following statement in the Proposed Rule applies only to Part 2 programs: "if a prescription for a medication used for substance use disorder treatment is revealed without further clarification of a non-substance disorder use (e.g., methadone used for the treatment of cancer), it would suggest that the individual has a substance use disorder and also would be prohibited."[10] Because of lingering confusion among stakeholders, SAMHSA should clarify that non-Part 2 programs that prescribe SUD medications would not be forbidden from disclosing such prescriptions, nor required to specify the purpose of such prescriptions.

In addition, our current interpretation of Part 2 would permit a Part 2 provider to disclose information about a medication that is used for both SUD and non-SUD purposes, even when it is being prescribed for the purpose of SUD treatment, without patient consent if the provider does not identify herself -- and thereby the patient -- as being affiliated with a Part 2 program or prescribing the SUD medication for SUD

[8] *See* 45 C.F.R. §164.520(b)(1).
[9] U.S. Dep't of Health & Hum. Services, Off. for Civ. Rts., *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*.
[10] 81 Fed. Reg. at 7003.

treatment. For example, if Dr. Smith works for a Part 2 program, Dr. Smith could send a buprenorphine prescription (since buprenorphine can be prescribed for the non-SUD purpose of pain management) to a pharmacy without patient consent if it is written on Dr. Smith's prescription pad, which does not identify the Part 2 program for which Dr. Smith works. However, in light of the language in the Proposed Rule (referenced in the previous paragraph) it seems this would no longer be permissible.[11] We ask SAMSHA to clarify whether it intends to prohibit providers in Part 2 programs, who do not reveal their Part 2 program affiliation, from disclosing information about SUD prescriptions which are also prescribed for non-SUD purposes unless the patient has consented to the disclosure.

We also recommend that the Final Rule include an updated sample Notice Prohibiting Re-disclosure to assist stakeholders in complying with Part 2's requirements.

6. *Sample Consent Form*

We recommend that the Final Rule include updated sample consent forms to assist stakeholders in complying with Part 2's requirements.

D. Exceptions to Patient Consent

1. Medical Emergencies (§2.51)

Proposed Rule

SAMHSA proposes to adapt the medical emergency exception to give providers more discretion to determine when a ''bona fide medical emergency'' (42 U.S.C. 290dd–2(b)(2)(A)) exists. The proposed language states that patient-identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency, in which the patient's prior informed consent cannot be obtained.

SAMHSA proposes to continue to require the Part 2 program to immediately document, in writing, specific information related to the medical emergency. Before a Part 2 program enters into an affiliation with an HIE, it should consider whether the HIE has the capability to comply with all Part 2 requirements, including the capacity to immediately notify the Part 2 program when its records have been disclosed pursuant to a medical emergency. To promote compliance, SAMHSA recommends that the notification include all the information that the Part 2 program is required to document in the patient's records (e.g., date and time of disclosure, the nature of the emergency, etc.). Similarly, SAMHSA recommends that the Part 2 program consider whether the HIE has the technology, rules, and procedures to appropriately protect patient-identifying information.

LAC's Response

LAC supports the Proposed Rule's incorporation of the statutory language "bona fide medical emergency," but recommends the following to ensure the medical emergency exception is not used to avoid obtaining patient consent.

[11] 81 Fed. Reg. at 7003.

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 HHS opinion defining a "bona fide medical emergency," which we have attached to these comments, we recommend the Final Rule state that a bona fide medical emergency continues to be limited to circumstances in which an individual needs immediate medical care because of an immediate (not future) threat to the person's health.[12]

The Final Rule should also clarify that the phrase, "in which the patient's prior consent cannot be obtained," does not include situations where a patient refuses to give consent. Lastly, SAMHSA should clarify that Part 2 information disclosed in a medical emergency may not be re-disclosed for criminal investigation or prosecution, pursuant to Part 2's authorizing statute.

2. Research (§2.52)

Proposed Rule

The Proposed Rule permits data to be disclosed to qualified personnel for the purpose of conducting scientific research, if the researcher provides documentation of meeting certain requirements, such as protections for human research. The Proposed Rule maintains Part 2's core confidentiality safeguards, including a prohibition on re-disclosure and the requirement that researchers be bound by Part 2's requirements

LAC's Response

We support scientific research activities that improve health outcomes for people with SUD and others. While we are not research experts, we are pleased that the new provisions of §2.52 maintain Part 2's core protections, 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 & 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 data is not re-disclosed beyond approved scientific researchers.

E. Reporting of Suspected Abuse and Neglect (§2.12(c)(6))

Proposed Rule

The Proposed Rule does not change the current requirements relating to disclosure of information for reporting of suspected child abuse and neglect purposes.[13]

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[12] *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 (the opinion is attached to LAC's comments for reference purposes); U.S. Dep't of Health & Hum. Services, *Frequently Asked Questions - Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)* (2010), available at http://archive.samhsa.gov/healthPrivacy/docs/EHR-FAQs.pdf.

[13] Section 2.12(c)(6) states,

LAC's Response
LAC recommends that SAMHSA add a new section to §2.12(c)(6) for suspected elder abuse and neglect notification that is modeled after the provision for child abuse and neglect reporting.

F. 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 limited experience treating SUD or complying with Part 2 -- we urge SAMHSA to ensure strong enforcement of Part 2's requirements when amended regulations are adopted. We also recommend that SAMHSA provide trainings, webinars, and technical assistance once the final rules are adopted, so SUD and other health care providers, as well as patients, understand the Final Rule's changes and requirements.

Thank you for your consideration of these comments. We look forward to working with SAMHSA and other stakeholders to preserve the confidentiality rights of substance use disorder patients, while facilitating the sharing of health information to provide quality care in today's health care delivery environment.

Sincerely,

Paul N. Samuels
Director/President

Attachment

The restrictions on disclosure and use in these regulations do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the Part 2 program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

Id.

OPINION 77-18, July 18, 1977

DISCLOSURES TO PUBLIC HEALTH OFFICIALS OF POSITIVE VENEREAL DISEASE REPORTS--DEFINITION OF "BONA FIDE MEDICAL EMERGENCY" (2.51)

To Ms. Young, St. Louis Comprehensive Drug Treatment Program, St. Louis, MO

The Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 CFR Part 2, which implement 21 U.S.C. 1175, the Federal confidentiality statute pertaining to drug abuse patient records (and 42 U.S.C. 4582 pertaining to alcohol abuse patient records) apply to programs which are directly or indirectly federally assisted, including federally licensed methadone programs and State programs in States which receive revenue sharing funds (See 42 CFR 2.12 and 2.12-1). Therefore, the confidentiality regulations apply to the methadone program in question.

As your letter suggests, if a disclosure is to meet a "bona fide medical emergency," a disclosure of a patient's address and telephone number may be made pursuant to section (b)(2)(A) of the drug abuse confidentiality statute, 21 U.S.C. 1175, and section 2.51 of the confidentiality regulations, 42 CFR Part 2, without the patient's written consent, but only to "medical personnel" to "meet the emergency." The terms of these statutory and regulatory provisions suggest that the "medical emergency" exemption from the written consent requirements is designed to enable treatment providers to give appropriate medical care to individuals requiring attention immediately, i.e., before a written consent can be obtained or before a court order authorizing disclosures can be obtained (or in circumstances not relevant here, before a qualified service organization agreement 1/ can be negotiated). In our opinion a positive venereal test is not a "bona fide medical emergency" as that term is used in the statute and regulations.

1/ See definition of qualified service organization in 42 CFR 2.11(n).

As a routine matter individuals should, at the time of the test, be asked to give a written consent to disclose his or her address and phone number to public health officials if the test administered to the patient yields positive results. If no written consent is obtained either at that time or when the officials subsequently seek the patient's address and phone number, the methadone program where the individual was tested may not disclose the patient information in question unless authorized by a court order pursuant to Subpart E of the regulations.