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Via Federal e-Rulemaking Portal

February 10, 2017

The Substance Abuse and Mental Health Services Administration
U. S. Department of Health and Human Services
Attn: Danielle Tarino, SAMHSA
5600 Fishers Lane, Room 13E89A
Rockville, Maryland 20857

Re: Legal Action Center Comments on Supplemental Notice of Proposed Rulemaking regarding 42 CFR Part 2 (SAMHSA-4162-20; RIN 0930-AA21)

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 appreciates the opportunity to comment on the Substance Abuse and Mental Health Services Administration’s (“SAMHSA”) January 18, 2017 Supplemental Notice of Proposed Rulemaking (“SNPRM”) soliciting input on proposed changes to the federal regulations governing the confidentiality of substance use disorder patient records, found at 42 C.F.R. Part 2 (“Part 2”).¹

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 Part 2 are reflected in the comments we submit in response to the SNPRM. 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 be affected by any changes to Part 2.

¹ Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 5485 (Jan. 18, 2017) (to be codified at 42 C.F.R. pt. 2).

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Summary of LAC's Response

The SNPRM proposes changes to the notice of the prohibition on re-disclosure. The SNPRM also seeks to clarify how lawful holders' contractors, subcontractors, and legal representatives ("contractors, etc.") may use and disclose substance use disorder ("SUD") information protected by Part 2 ("protected SUD information") for the purposes of carrying out payment, health care operations, and other health care related activities.²

As discussed with more specificity below, LAC does not support the proposed changes to the notice of the prohibition on re-disclosure. Additionally, while LAC understands that there may be a legitimate need for lawful holders to disclose protected SUD information to contractors, etc. for payment and health care operations purposes, we are concerned that the proposed changes are so broad that they may undermine core Part 2 protections—namely, giving SUD patients control over how their protected SUD information is disclosed so as not to make them more vulnerable to the negative consequences of such disclosures. These negative consequences may include loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, and arrest, prosecution, and incarceration. Therefore, LAC recommends that the changes proposed in the SNPRM be accompanied by additional protections to ensure SUD patients are not harmed and protected SUD information is used by lawful holders and contractors, etc. only for the purpose(s) listed in the patient's written consent.

In the SNPRM, SAMHSA seeks comments on three areas:

1. Prohibition on re-disclosure (§ 2.31);
2. Disclosures permitted with written consent (§ 2.33); and
3. Audit and evaluation (§ 2.53).

² SAMHSA has previously provided some guidance to this point. In the Final Rule released January 18, 2017, SAMHSA clarified that, when a patient consents to the disclosure of her protected SUD information to a Medicaid or Medicare agency or program for purposes of payment-related activities, that consent extends to contractors, subcontractors, and legal representatives of that agency or program if federal or state law authorizes or requires that the agency or program share data or enter into a contractual arrangement or other formal agreement to do so. *See Confidentiality of Substance Use Disorder Patient Records*, 82 Fed. Reg. 6052, 6084 (Jan. 18, 2017) (to be codified at 42 C.F.R. pt. 2).

SAMHSA has also previously addressed the issue of contractors and subcontractors in the context of Qualified Service Organization Agreements ("QSOAs"). In guidance released in 2010 and 2011, SAMSHA clarified that third parties who receive protected SUD information pursuant to a QSOA may re-disclose that information to their contractors to the extent necessary to provide the services described in the QSOA. *See Substance Abuse and Mental Health Services Administration, Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)* (2010), available at http://lac.org/wp-content/uploads/2014/12/SAMHSA_42CFRPART2FAQ.pdf; *see also Substance Abuse and Mental Health Services Administration, Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 (Revised)*, Q.3 (2011), available at http://lac.org/wp-content/uploads/2014/12/SAMHSA_42CFRPART2FAQII_Revised.pdf.

Notice of the Prohibition on Re-Disclosure (§ 2.31)

In the SNPRM, SAMHSA proposes permitting a shorter notice of the prohibition of re-disclosure (“notice”) to accompany disclosures in certain circumstances, such as for particular types of disclosures or through certain technical systems. (Part 2 requires the notice to be sent with any protected SUD information that is disclosed pursuant to patient consent.³) The abbreviated notice could read, for example, “Data is subject to 42 CFR part 2. Use/disclose in conformance with part 2.”⁴

LAC does not support this proposed change for two reasons. First, we do not believe most recipients will know what 42 CFR Part 2 is without the further explanation provided for under the existing regulations. LAC therefore doubts the proposed abbreviated notice would be sufficient to safeguard patients’ protected SUD information and prevent unauthorized disclosures. Second, to the extent stakeholders have concerns about the logistics of providing the notice, LAC does not believe that allowing for a shortened notice will alleviate those concerns. Regardless of the length of the notice, systems will need to be in place that are capable of tagging protected SUD information and sending the notice with that information when it is disclosed. Therefore, LAC recommends that SAMHSA retain the full notice requirement.

Disclosures Permitted with Written Consent (§ 2.33)

SAMHSA also proposes to permit lawful holders who receive protected SUD information pursuant to a patient consent for the purpose(s) of payment and/or health care operations to re-disclose that protected SUD information to contractors, etc. to the extent necessary to fulfill the payment and health care operations purpose(s) of the patient’s written consent.

Unlike Part 2, the Health Insurance Portability and Accountability Act (“HIPAA”) allows disclosures of most types of health information to be made without the patient’s consent for payment and health care operations. Under Part 2, patient consent is required for disclosure of protected SUD information for payment and health care operations, and protected SUD information may not be re-disclosed without the patient’s express consent. The SNPRM’s proposed changes would still require patient consent for protected SUD information to be disclosed for payment or health care operations, but once the information is disclosed pursuant to that consent, the lawful holder to whom it was disclosed would be permitted to re-disclose the protected SUD information to its contractors, etc., in order to fulfill the payment or health care operations purpose of the consent. The term “health care operations” is adopted—though not in its entirety—from HIPAA, and is quite broad.⁵

³ See 42 C.F.R. § 2.32.

⁴ See Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 5487.

⁵ Under HIPAA, and under the SNPRM’s proposed changes to Part 2, health care operations includes claims management, collections activities, health care data processing, clinical professional support services, patient safety activities, activities pertaining to the training of students and non-health care professionals, accreditation, licensing, credentialing, underwriting, premium rating, determinations of eligibility for coverage, business planning development, risk adjusting, and more. See 42 C.F.R. § 2.33(b); see also 45 C.F.R. § 164.501.

LAC is concerned about the proposed changes for a number of reasons. First, LAC is concerned that, as written, the activities included in the term “health care operations” at proposed § 2.33(b) are so wide-ranging that they could be interpreted as permitting activities that could harm SUD patients. For example, proposed §§ 2.33(b)(15) & (16) could be interpreted as allowing protected SUD information to be used to limit or deny health insurance coverage for SUD patients. Proposed § 2.33(b)(2) could be interpreted as allowing protected SUD information to be disclosed to employers.⁶ Although we do not think it is SAMHSA’s intent to allow these types of disclosures, we believe additional protections are warranted in light of the broad nature of the proposed language and the fact that patients will not fully control to whom their protected substance use disorder information is disclosed for payment and health care operations purposes.

Specifically, LAC strongly recommends the inclusion of anti-discrimination protections that forbid the use of any information disclosed pursuant to § 2.33(b) for the purposes of: limiting access to health, life, or disability insurance coverage; limiting access to health care; criminal or civil investigation or prosecution; sharing information with the patient’s employer; sharing information with child welfare agencies or family courts; or limiting or denying the patient’s rights or opportunities in any way. LAC also recommends that §§ 2.33(b)(15) & (16) be removed or narrowed to ensure patients’ protected SUD information will not be used to limit or deny insurance coverage or access to health care. These recommended protections would help to ensure—consistent with the purpose of Part 2 and its authorizing statute—that a patient receiving treatment for a SUD is not made more vulnerable by reason of the availability of their patient record than an individual with a SUD who does not seek treatment.⁷

LAC also recommends that SAMHSA state in the regulatory text that care coordination and case management are not health care operations for the purposes of § 2.33(b). This would be consistent with what SAMHSA states in the preamble to the SNPRM, where it clarifies that disclosures may not be made under proposed § 2.33(b) for activities related to the patient’s diagnosis, treatment, or referral for treatment, such as care coordination and case management.⁸

LAC is also concerned that the proposed changes to § 2.33 would greatly expand access to patients’ Part 2-protected information by individuals and entities to whom the patient did not

⁶ According to guidance from the U.S. Department of Health and Human Services about the meaning of “health care operations” in the context of HIPAA, quality-related health care operations permit the disclosure of health information to health plans for their Health Plan Employer Data and Information Set (HEDIS). See U.S. Dep’t of Health & Human Services, HIPAA for Professionals FAQs, <https://www.hhs.gov/hipaa/for-professionals/fag/265/may-a-health-care-provider-disclose-protected-health-information-to-a-health-plan/index.html>. According to the National Committee for Quality Assurance, many health plans report HEDIS data to employers. See National Committee for Quality Assurance, HEDIS and Quality Compass, <http://www.ncqa.org/hedis-quality-measurement/what-is-hedis>.

⁷ See, e.g., Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6053.

⁸ See Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 5487.

specifically consent, and for purposes which the patient likely will not fully understand. While LAC understands it may not be feasible to list all of a recipient's contractors, etc. on a consent form, LAC recommends that if SAMHSA proceeds with the changes proposed in the SNPRM it require the consent form to include, at a minimum, a notification to patients that they are consenting to the disclosure of their protected SUD information to both the recipient and the recipient's contractors, subcontractors, and legal representatives to the extent those contractors, subcontractors, and legal representatives need the information to carry out payment or health care operations purposes listed on the consent form.

While LAC supports the requirements at proposed § 2.33(c), we also believe additional protections are needed. Specifically, we support the requirements that lawful holders who wish to disclose protected SUD information pursuant to § 2.33(b) must:

1. Enter into written agreements with contractors, etc. which provide that the contractors, etc. are fully bound by Part 2 upon receipt of protected SUD information and, as such, that each disclosure must be accompanied by the notice on the prohibition of re-disclosure;
2. Specify permitted uses of the protected SUD information by contractors, etc. consistent with the patient's written consent;
3. Require contractors, etc. to implement appropriate safeguards to prevent unauthorized uses and disclosures and require contractors, etc. to report any unauthorized uses, disclosures, or breaches of protected SUD information to the lawful holder;
4. Only disclose protected SUD information to contractors, etc. that is necessary for the contractors, etc. to perform their duties under the contract;
5. Ensure the contract does not permit contractors, etc. to re-disclose information to a third party unless that third party is a contract agent of the contractors, etc. helping the contractors, etc. provide services described in the contract, and only as long as the third party only discloses the protected SUD information back to the contractors, etc. or lawful holder from which the information originated.

LAC recommends an additional protection be added to § 2.33(c). Because contractors, etc. who receive protected SUD information to assist lawful holders in carrying out the payment and health care operations purposes of a patient's written consent serve a similar function to Qualified Service Organizations ("QSOs"), LAC recommends that they be bound by all of the requirements which apply to QSOs.⁹ Therefore, the written contracts required by proposed § 2.33(c) should also require contractors, etc. to agree that, if necessary, they will resist in judicial proceedings any efforts to obtain access to patient records identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by Part 2.

⁹ See 42 C.F.R. § 2.11.

LAC also recommends that lawful holders who wish to re-disclose protected SUD information to their contractors, etc., be subject to the same List of Disclosures requirement that applies to intermediaries who disclose protected SUD information pursuant to a general designation on a patient's written consent.¹⁰ Just as SAMHSA balanced the flexibility afforded by the general designation option in the "To Whom" section of the consent form by adding the List of Disclosures as a new confidentiality safeguard, so too should SAMHSA balance the flexibility afforded by permitting lawful holders to disclose protected SUD information to their contractors, etc. without patients' express consent with an additional List of Disclosures requirement.

Audit and Evaluation (§ 2.53)

SAMHSA also proposes to expand how protected SUD information can be disclosed for audit and evaluation purposes. Under 42 C.F.R. § 2.53, Part 2 programs may disclose protected SUD information without patient consent for audit or evaluation activities performed by individuals and entities who: are government agencies which are authorized by law to regulate the Part 2 program; provide financial assistance to the Part 2 program; are third-party payers covering patients in the Part 2 program; are quality improvement organizations performing utilization or quality control review; or are determined by the Part 2 program to be qualified to conduct an audit or evaluation of the Part 2 program.

SAMHSA's proposed changes would allow protected SUD information to be disclosed to individuals and entities who conduct audit and evaluation of lawful holders as well as Part 2 programs. The changes would also permit disclosure of protected SUD information to these individuals' and entities' contractors, etc. These changes have the potential to greatly expand the universe of individuals and entities who may receive protected SUD information without patient consent for audit and evaluation purposes.

LAC understands that there may be a legitimate need for contractors, etc. to have access to protected SUD information for audit and evaluation purposes. However, we believe increased flexibility should be balanced by increased protections in circumstances where protected SUD information will be disclosed without patient consent to a wide range of individuals and entities for broadly-defined purposes. Therefore, we recommend including anti-discrimination protections in § 2.53, consistent with those we recommended be included in § 2.33.

Specifically, LAC recommends the inclusion of anti-discrimination protections that forbid the use of any information disclosed pursuant to § 2.53 for the purposes of: limiting access to health, life, or disability insurance coverage; limiting access to health care; criminal or civil investigation or prosecution; sharing information with the patient's employer; sharing information with child welfare agencies or family courts; or limiting or denying the patient's rights or opportunities in any way.

¹⁰ See 42 C.F.R. § 2.13(d).

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,

A handwritten signature in blue ink, appearing to read "Paul N. Samuels". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Paul N. Samuels
Director/President