August 14, 2020

STATEMENT ON THE CONFIDENTIALITY OF SUBSTANCE USE DISORDER RECORDS FINAL RULE: July 15, 2020 (RIN 0930-AA32)[1]

Introduction:

The Legal Action Center ("LAC") and our partners in the patient advocacy and recovery communities have continuously opposed weakening the long established federal confidentiality protections for substance use disorder ("SUD") information in 42 U.S.C. § 290dd-2 and its implementing regulations, 42 CFR Part 2 (referred to collectively as "Part 2") to conform with the Health Insurance Portability and Accountability Act ("HIPAA"). Nevertheless, despite strenuous concerns voiced by LAC and our partners, including those whose confidentiality rights are most affected by the weakening of privacy protections, those protections continue to be significantly watered down. Most recently, the Substance Abuse and Mental Health Services Administration ("SAMHSA") issued a Final Rule, discussed here, which unequivocally weakens patient privacy safeguards. While patient consent is still required for most disclosures, SAMHSA significantly expanded the ways information can be shared with law enforcement, contractors, and government agencies. SAMHSA also finalized its proposal to permit certain verbal disclosures of Part 2 records to lose their privacy protections, despite serious concerns raised during the comment period.

A brief summary of our concerns is described below, along with our analysis of the most recent changes made to Part 2 and followed by our recommendations on steps SAMHSA can take to mitigate the harms that will likely be caused by those changes.

Background:

LAC and our above-mentioned partners commented on and opposed many of the provisions of SAMHSA's August 26, 2019 Notice of Proposed Rulemaking,[2] which formed the basis of the latest Confidentiality of Substance Use Disorder Patient Records Final Rule AA32 ("the Final Rule"). The Final Rule was formally published in the *Federal Register* on July 15, 2020[3] and becomes effective on August 14, 2020. We continue to have serious concerns about the changes

[1] Confidentiality of Substance Use Disorder Patient Records, Final Rule, 85 Fed. Reg. 42986 (July 15, 2020) (RIN 0930-AA32) (to be codified at 42 CFR Part 2) [hereinafter cited as "Final Rule AA32"].

[2] Confidentiality of Substance Use Disorder Patient Records, Notice of Proposed Rulemaking, 84 Fed. Reg. 44568 (proposed Aug. 26, 2019) (to be codified at 42 CFR Part 2) (RIN 0930-AA32) [hereafter cited as "NPRM AA32"]. *See also* Legal Action Center, *Comments on Notice of Proposed Rulemaking regarding 42 CFR Part 2 (SAMHSA - 4162-20; RIN 0930-AA32)* (Oct. 25, 2019), available at https://www.lac.org/assets/files/LAC-comments-on-SAMHSA-4162-20-10-24-19.pdf.

[3] Confidentiality of Substance Use Disorder Patient Records, Final Rule, 85 Fed. Reg. 42986 (July 15, 2020) (RIN 0930-AA32) (to be codified at 42 CFR Part 2).

that weaken patient confidentiality protections for SUD records in favor of sharing information with law enforcement, insurance companies, and other third parties who do not provide care.[4]

As we discuss in more detail below, the Final Rule expands law enforcement agencies' access to confidential treatment records and allows law enforcement undercover agents on the premises of treatment centers for longer periods of time. We are concerned that these changes will discourage people from seeking or staying in treatment, particularly individuals living in areas that are already heavily policed (i.e., Black and brown neighborhoods, immigrant communities, and low-income neighborhoods).[5] We are concerned that the disparate impact of the Final Rule will undermine SAMHSA's initiative to advance behavioral health equity,[6] compound existing disparities in access to treatment and health outcomes for communities of color,[7] and lead to more unnecessary and harmful interventions with the criminal justice system.

Moreover, instead of the achieving the stated goals of the changes -- facilitating coordination of care between SUD and overall health providers -- we contend that the changes in the Final Rule and in the upcoming modifications to Part 2 required by the Senate's third coronavirus response bill, the Coronavirus Aid, Relief, and Economic Security ("CARES Act")) will very likely have the opposite effect. Many patients will be afraid to sign consent forms allowing for the sharing of their SUD information with their health care providers, knowing that once they do so, the information will no longer be protected -- for the first time since the confidentiality law was enacted in the 1970s. Moreover, there will be additional confusion among SUD stakeholders (especially patients, families, and providers), who were already having to grapple with changes to Part 2 that were made in 2017 and 2018.

Similarly, we continue to believe that no legislative amendments to Part 2 were needed, because we maintain that the law sufficiently allowed for the exchange of information for the purpose of integrating behavioral healthcare with physical healthcare, a goal we supported, while protecting critical patient privacy protections. Therefore, we opposed as unnecessary those provisions in the CARES Act that amended previously existing federal confidentiality rules for SUD information in Part 2 and weakened overall confidentiality protections for SUD records.[8] Nonetheless, the

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[4] 85 Fed. Reg, 42986. *See also* Legal Action Center, *Comments on Notice of Proposed Rulemaking regarding 42 CFR Part 2 (SAMHSA -4162-20; RIN 0930-AA30)* (Sept. 25, 2019), available at https://www.lac.org/assets/files/LAC-Comments-on-SAMHSA-4162-20-RIN-0930-AA30-submitted.pdf.

[5] *See generally* Jonathan Mummolo, *Police Militarization Fails to Protect Officers and Targets Black Communities, Study Finds*, PROC. NAT'L. ACAD. SCI. (Sept. 11, 2018), available at https://www.pnas.org/content/pnas/115/37/9181.full.pdf (The study shows that militarized police units are more often deployed in communities with large numbers of African American residents, even after controlling for local crime rates); Mycah Hatfield, *Immigrant Communities A "Ghost Time" During Threat of ICE Raids in Houston,* ABC13 EYEWITNESS NEWS, (July 15, 2019), available at https://abc13.com/immigration-ice-raids-houston-immigrants/5394994/

[6] SAMHSA, SAMHSA BEHAVIORAL HEALTH EQUITY, available at https://www.samhsa.gov/behavioral-health-equity (last visited July 17, 2020).

[7] *See, e.g.,* Kendal Orgera and Samantha Artiga, *Disparities in Health and Healthcare*, KAISER FAMILY FOUNDATION (Aug. 18, 2018).

[8] *See generally* Legal Action Center, *Overview of the Coronavirus Aid, Relief, and Economic Security Act's Amendment of Federal Confidentiality Rules for Substance Use Disorder Information* (April 17, 2020), available at https://www.lac.org/news/cares-act-sud-privacy-amend-overview.

CARES Act was signed into law on March 27, 2020, and takes effect one year from that date, at which point SAMHSA will also have to make changes to the privacy rule.

Overall Recommendations for Implementing for the Part 2 Final Rule – July 15, 2020:
While we have a list of specific recommendations following our summary of the changes in the Final Rule, our overall recommendation is that SAMHSA, at a minimum, should provide subsequent sub-regulatory guidance and ongoing training for all SUD stakeholders (including patients and their families, recovery organizations, providers, insurers, policy advocates, etc.) to update them on changes to confidentiality protections for SUD records, including how to maintain and protect confidential health information while coordinating SUD information with overall healthcare by using existing federal and more stringent state confidentiality laws.

Summary of Major Privacy Changes in Final Rule AA32:
Definition of a SUD Record - 42 CFR §2.11:

- Previously, Part 2-protected records were defined as information, whether recorded or not, created by, received, or acquired by a Part 2 program.[9] This included both oral and written information that identified a patient as applying for or receiving treatment for a substance use disorder from a Part 2 program. The Part 2 privacy protections followed a record even after it was disclosed, meaning that the recipient of the information could only share the record as permitted by Part 2 (with patient consent or pursuant to an exception).

- Under the Final Rule, information that is verbally conveyed by a Part 2 program to a non-Part 2 provider with the consent of the patient does not become a "record," even if the non-Part 2 provider who receives the patient's SUD information includes the information into the medical record -- the newly written SUD information is not considered as a "record" if it was transmitted verbally.[10] As a result, sensitive health information that is disclosed in this manner is no longer subject to Part 2's confidentiality protections, and may be re-disclosed as permitted by HIPAA and any other applicable privacy law.

- Impact of this Provision in the Final Rule:
    - The new rule creates a double standard that will no doubt confuse patients and providers -- if a patient authorizes their Part 2 program to share information with another provider, information shared *verbally* will not be protected by Part 2, but information shared in writing will continue to

[9] 42 CFR § 2.11 (definition of "records"); *id. §* 2.11 (definition of a "program")
(1) Any individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment, or
(2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
(3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.
Id. Id. §2.11 (definition of "Part 2 program") "A Part 2 program means a federally assisted program (federally assisted as defined in 42 CFR §2.12(b). . . and program defined in this section."
[10] 85 Fed. Reg. 42986, 43036 (referring to 42 CFR §2.11). *See also id*. at 42993 (preamble).

have the same protections as always. This change undermines patients' ability to make informed decisions about their treatment records, and SAMHSA did not address how providers and patients should navigate this confusing new landscape.

- Not only does it make no sense that the same information, conveyed in different ways, would have different privacy protections, but it will inject additional confusion into primary care settings by creating different privacy standards for information disclosed orally and information disclosed in writing. Non-Part 2 providers will still have to understand how to apply Part 2's provisions when they receive protected written information from a Part 2 program.
- SAMHSA stated that it does not intend to permit wholesale transcription of the patient's Part 2 records into the primary care record, and gave assurances that this newly modified provision will not "immunize the misconduct of a non-Part 2 provider who engages in the wholesale transcription of a received SUD patient record, with her own director patient encounter and without clinical purpose"[11] Nonetheless, the proposed change as currently written may lead to this outcome, especially given the availability of text-to-speech technology applications.[12]
- While HIPAA may offer some protection of this type of SUD information, this general health privacy law is not sufficiently protective of health conditions that may be highly stigmatized or criminalized. In particular, HIPAA permits much greater access to patient records through re-disclosures of the information by and to law enforcement, insurance companies, and entities performing "healthcare operations" and courts.

Consent Requirements – 42 CFR § 2.31(a)(4):

- Previously the 2017 revision to Part 2 changed the consent form requirements for designating recipients of disclosures. Under that change, if the recipient entity did not have a treating provider relationship with the patient and was not a third-party payer, the written consent form had to include *the name of the individual recipients of the information (e.g., Anna Sue).*[13]

[11] 85 Fed. Reg. 41986, 42994.

[12] *See also* Andy Wolber, *4 Text-to-Speech Apps that will Read Online articles to You*, Mobility (July 15, 2017), available at https://www.techrepublic.com/article/4-text-to-speech-apps-that-will-read-online-articles-to-you/.

[13] The consent form had to also include [in addition to the name of the recipient entity]: The name(s) of an individual participant(s); the name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or 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.

- Under the Final Rule, SAMHSA returned to the pre-2017 Part 2 standard, which permitted consent forms to authorize disclosure to any entity, regardless of whether they have a treating provider relationship with the patient or not.

- Impact of this Provision in Final Rule AA32: This amendment was a welcome change that will facilitate patients' ability to authorize disclosure to the parties and entities of their choosing. Patients still have the right to designate individual(s) by name, if they wish to limit disclosures within a larger entity.

Re-disclosures with Written Patient Consent – 42 CFR § 2.33:

- Previously, if patients provided written consent to disclose their SUD records to a lawful holder for payment or healthcare operations purposes, the lawful holder could then re-disclose the minimum necessary of these records to their contractors, subcontractors, or legal representative to fulfill those purposes (without additional patient consent).[14] The 2018 Final Rule included a list of examples of payment and healthcare operations functions in the preamble section of the rule (instead of in the actual regulation) to indicate that these functions were illustrative instead of exhaustive.[15] This provision, however, prohibited re-disclosures of SUD records by lawful holders to subcontractors, contractors, and legal representatives for treatment purposes, in order to allow patients to determine where their patient-identifying information would be re-disclosed for treatment purposes.[16]
    - When this change was made, SAMHSA specifically maintained that care coordination and case management functions were not considered part of payment and healthcare operations activities, since care coordination and case management functions contained a patient treatment component that should require patient consent prior to re-disclosures of patient-identifying information.[17]

- Under Final Rule AA32, SAMSHA changed this provision by incorporating HIPAA's definition of healthcare operations into Part 2, which includes care coordination and case management activities as healthcare operations functions.[18] As a result, once a patient provides written consent to disclose their SUD records to a lawful holder for payment or healthcare operations purposes, that information can be redisclosed to subcontractors or legal representatives for the purposes of care coordination and case management. Re-

[14] 83 Fed. Reg. 239, 243 (preamble). These activities included billing, utilization review, accreditation, customer safety, determinations of eligibility of coverage, and others which were the same as described in the 2017 Final Rule.
[15] 83 Fed. Reg. 239, 241 (preamble).
[16] 83 Fed. Reg. 239, 244 (preamble). Lawful holders were required to satisfy other provisions of Part 2, such as providing a Prohibition on Re-disclosure Notice to their contractors, subcontractors, and legal representatives if re-disclosure of the protected SUD information was required to fulfill the purpose of the original disclosure.
[17] 83 Fed. Reg. 239, 244 (preamble).
[18] 45 CFR § 164.501; *see also* HHS, Office for Civil Rights, *Uses and Disclosures for Treatment, Payment, and Health Care Operations* (April 3, 2003), available at https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/sharingfortpo.pdf.

disclosures by lawful holders to contractors for treatment purposes are still prohibited under this provision.
    - SAMHSA also added the previously illustrative list of payment and healthcare operations examples that were in the preamble, into the regulations themselves.

- Impact of this Provision in Final Rule AA32: Because care coordination and case management are now part of payment and healthcare operations functions, once patients initially consent to the disclosure of their SUD records for these purposes, they will no longer be able to control where or to whom their sensitive health information may be re-disclosed for case management or care coordination purposes. This could be problematic for patients who do not want their records disclosed for those purposes, e.g., where they had a bad experience with an entity providing those services in the past.[19]

Disclosures to Prevent Multiple Enrollments – 42 CFR § 2.34:

- Previously, a Part 2 program could disclose SUD records to any withdrawal management program, maintenance treatment program, or central registry (with member programs)[20] to prevent multiple enrollments, and always with the written consent of the patient. The central registries were only accessible to withdrawal management programs and maintenance treatment programs for the limited purpose of preventing multiple enrollments.

- Under the Final Rule, SAMHSA expanded access to states' central registries by permitting other treating providers (such as a patient's primary care provider) to request information from the database about an individual's medication for opioid use disorder. SAMHSA's defended this change by arguing that non-Part 2 providers need any available information to make safe prescribing decisions, since opioids like methadone and buprenorphine may have serious interactions with other drugs.[21]

- Impact of this Provision in the Final Rule: It remains to be seen whether this will have a chilling effect on patients' willingness to sign consent forms that allow their information to be put into central registries, or seek care with non-Part 2 providers.

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[19] *See, e.g.*, Cecelia Kathleen Mendiola, BA, *et. al*, *An Exploration of Emergency Physicians' Attitudes Toward Patients With Substance Use Disorder*, AM. SOC. ADDICTION MED. (Mar./Apr. 2018), available at https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-20180321-SD500.pdf.

[20] 82 Fed. Reg. 6052, 6116 (citing 42 CFR § 2.11 (definitions)). A member program "means a withdrawal management or maintenance treatment program which reports patient-identifying information to a central registry and which is in the same state as that central registry or is in a state that participates in data sharing with the central registry of the program in question." *Id.*

[21] 85 Fed. Reg. 42986, 43014 (preamble).

Disclosures to Prescription Drug Monitoring Programs ("PDMPs")[22] *– 42 CFR § 2.34:*

- Previously, SAMHSA prohibited opioid treatment programs ("OTPs") from entering data into PDMPs due to privacy concerns, and encouraged them to routinely check PDMPs to ensure that their patients are not receiving prescriptions that would interfere with their substance use disorder medications.[23]

- Under the Final Rule, SAMHSA is now permitting Part 2 programs or any other lawful holder to report any prescribed or dispensed SUD medication to the applicable PDMP, if required by state law. However, the Part 2 program or lawful holder must still obtain the patient's written consent before the information is reported to the PDMP.

- Impact of this Provision in Final Rule AA32: It is questionable how Part 2 programs can share information with PDMPs without violating Part 2. Part 2 still prohibits law enforcement from using Part 2-protected information to criminally investigate or prosecute a patient, absent a court order. Many PDMPs send both solicited and unsolicited reports to law enforcement authorities, and several state PDMPs permit law enforcement to access data at its own discretion or are operated by law enforcement entities.[24] Moreover, even with patient consent to disclose OTP records to the PDMP, the re-disclosure of these records is still prohibited by Part 2.
    - This impermissible expansion of law enforcement authorities' access to confidential treatment records may discourage people from seeking or staying in treatment, particularly for individuals living in areas that are already heavily policed (e.g., communities of color, immigrant communities, and low-income neighborhoods).

Medical Emergencies – 42 CFR § 2.51:

- Previously, patient-identifiable SUD information could be disclosed to medical personnel during a bona fide medical emergency, in which the patient's prior informed consent could not be obtained.

- Under Final Rule AA32, SAMHSA added to the medical emergency exception that disclosures of SUD records without the patient's consent are also permitted to treat a

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[22] HHS, SAMHSA, *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers* (Winter 2017), available at https://store.samhsa.gov/sites/default/files/d7/priv/sma16-4997.pdf. Prescription Drug Monitoring Programs are state-wide electronic databases that track and analyze data on prescription-dispensed controlled substances, and substances with misuse potential (e.g., ephedrine, which can be used to make methamphetamines). PDMP subscribers (e.g., opioid treatment program providers, pharmacists, and others) can then access PDMPs according to their states' guidelines. Most PDMPs are housed within a licensing g or public health agencies, but some are located within law enforcement agencies.

[23] HHS, SAMHSA, *Dear Colleague Letter* (Sept. 27, 2011), available at https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf.

[24] As of August 15, 2019, the following PDMPs have the authority to send unsolicited reports to law enforcement entities: AZ, AR, CO, CT, DE, FL, GA, Guam, HI, ID, IN, KS, LA MA, MS, MO, NV, NJ, NM, NC, ND, OH, OK, SC, TN, UT, VA. WV, WI, and WY. Prescription Drug Monitoring Program Training and Technical Assistance Center, *PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Law Enforcement Entities* (Aug. 15, 2019), available at https://www.pdmpassist.org/pdf/Insurance_Entity_Table_20190816.pdf.

bona fide medical emergency when the Part 2 program is closed and unable to provide services or obtain the prior written consent of the patient, during a temporary state of emergency declared by a state or federal authority as the result of a natural or major disaster, until such time that the Part 2 program resumes operations.

- Impact of this Provision in Final Rule AA32: This addition of a natural or major disaster (that impacts the ability of medical personnel to obtain the patient's consent) to the definition of the bona fide emergency exception should be helpful to improve patient care during disasters, although notably it does not apply to programs that remain open during the disaster.

Research – 42 CFR § 2.52:

- Previously, Part 2 programs and lawful holders of Part 2 records were permitted to disclose patient-identifiable SUD information for research purposes to HIPAA-covered entities or to those entities who were subject to the Common Rule,[25] as permitted by HIPAA or the Common Rule.[26]
- Under Final Rule AA32, SAMHSA will permit disclosures of Part 2 data to individuals and organizations who are neither HIPAA covered entities nor subject to the Common Rule, provided that any such data will be disclosed pursuant to the HIPAA Privacy Rule (45 CFR 164.512(i)). Part 2 programs will also be able to disclose information for research purposes to entities regulated by the Food and Drug Administration regulations for the protection of human subjects in clinical investigations.
- Impact of this Provision in Final Rule AA32: SAMHSA noted that this change will allow a greater range of stakeholders, such as state agencies, to access Part 2 data for research purposes.

Audit and Evaluation – 42 CFR § 2.53:

- Previously, it was permissible to disclose patient-identifiable SUD information to any individual or entity who was performing an audit/evaluation on behalf of:
    - Any state, federal, or local entity that: provided federal financial assistance to the Part 2 to program, or was authorized by law to regulate its activities, was a third party payor covering patients in the Part 2 program, or was a quality improvement organization performing utilization review activities.
- Under the Final Rule AA32, SAMHSA expanded and clarified which entities can conduct audits/evaluations and the activities that are permitted to be undertaken when an audit or evaluation takes place.
- Impact of this Provision in Final Rule AA32: The changes in the final rule permit greater disclosures of patient-identifying information without consent through the audit and

[25] 45 CFR part 46 (2018) (basic ethical principles in research involving humans); HHS, Office for Human Research Protections, *Federal Policy for the Protection of Human Subjects ("Common Rule")* (Mar. 18, 2016), available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.
[26] *See generally* 82 Fed. Reg. 6052, 6123.

evaluation exception to Part 2. SAMHSA has stated that the purpose of these changes is to improve patient care and outcomes. However new language added to the audit and evaluation provision indicates -- that audits and evaluations can include review of the appropriateness of medical care, medical necessity and utilization of services, which may harm patients by leading to denials of coverage or adjusted rates.

Orders Authorizing the Use of Undercover Agents and Informants – 42 CFR § 2.67:

- Previously, a court order authorized the placement of undercover agents and informants in Part 2 program for six months to determine if employees or agents of the Part 2 program are engaged in criminal misconduct. After six months if more time was needed, law enforcement entities were required to return to court and request an extension of the court order for the placement of its agents and informants for an additional six months.
- Under the Final Rule, SAMHSA has extended the length of time of a court-ordered placement of undercover agents and informants at a Part 2 program to 12 months for this purpose. SAMHSA defended this change by citing concerns from the Department of Justice, which found that the six-month period was too ambiguous and burdensome.
- Impact of this Provision in Final Rule AA32: This provision lessens judicial oversight of the placement of undercover agents and informants at a treatment facility by increasing the court order requirement to 12 months before a court can determine the necessity for its renewal. As a result, there is an increased likelihood that law enforcement will be interacting with greater numbers of patients, increasing the likelihood of the confidentiality of all patients becoming compromised at such treatment facilities.

Recommendations:

As noted above, we recommend that SAMHSA continue to provide ongoing training for all SUD stakeholders and provide subsequent sub-regulatory guidance. We are pleased that SAMHSA has indicated in the Final Rule that it will issue such guidance.[27] Specifically, we recommend that SAMHSA provide sub-regulatory information and training to clarify the following issues:

Definition of SUD record:

- How should providers counsel patients about the difference between authorizing an oral disclosure and a written disclosure, to ensure that patients are sufficiently informed to make a knowledgeable decision?
- What will be the standard for "too much" transcription of Part 2 records into the general medical record?
- What is the remedy for patients if a provider fails to properly explain the different standards for oral and written disclosures, or if a provider inappropriately transcribes too much information into the patient's general medical record?

[27] *See, e.g.*, 85 Fed. Reg. 41986, 42993-94.

- We also recommend that SAMHSA issue a practical guide for implementing a segmentation protocol.

Consent:

- SAMHSA should provide model consent forms for stakeholder use.

PDMPs:

- Because no PDMP is set up to prevent disclosures to law enforcement, SAMHSA should issue sub-regulatory guidance reiterating that it is forbidden for law enforcement to use Part 2 information to criminally investigate or prosecute a patient, absent a court order. SAMHSA should clarify that until PDMPs can demonstrate that they can provide sufficient privacy protections for the sensitive Part 2 information contained in PDMP, no OTP is permitted to disclose protected Part 2 information to a PDMP.

Medical Emergency:

- SAMHSA should clarify that a state's declaration of a natural or major disaster only satisfies the medical emergency exception if the natural or major disaster is substantially similar to the way those terms are defined by federal law.

Research:

- SAMHSA should address the security and privacy of the SUD data once it is disclosed for research purposes.

Audit and Evaluation:

- SAMHSA should identify the factors that federal, state, and local agencies must meet to show why de-identified data cannot be used during an audit or evaluation, and why access to patient-identifying information is necessary.

- SAMHSA should also include greater specificity about the nature of the federal, state, or local law mandating the audit/evaluation, and clarify that such laws must be consistent with the purpose of the audit/evaluation section, and should never be used to authorize disclosure to law enforcement agencies or for law enforcement purposes.