

Attn: Mitchell Berger, SAMHSA
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Date: September 17, 2019

Mr. Berger,

I wish to oppose the proposed changes to Section 2.63(a)(2) in the recent NPRM, and ask that SAMHSA not change this section of the current rule. This proposed change is a fundamental and substantive change to privacy regulations that will allow personal health information to be shared outside the healthcare system for criminal justice purposes.

- I. HHS-OS-2-19-0010-0001, RIN: 0930-AA30 Violates the Administrative Procedures Act Requirement for Notice and Comment, because of the 30 day Comment Period.

The proposed rule has only a 30 day Notice and Comment Period. A Rule that is a fundamental and substantive change from previous policy should have at least a 60 day Notice and Comment period, like the companion NPRM regarding 42 CFR Part 2 (RIN 0930-AA32) released on the same day. Thus, the NPRM is a violation of the Administrative Procedures Act Requirement for Notice and Comment.

- a. While the preamble of the proposed NPRM governing Section 2.63(a)(2) of 42 CFR Part 2, contends that this NPRM contends that it is a simple correction of the 2017 Final Rule governing 42 CFR part 2, the proposed inclusion of drug trafficking as an actionable crime represents a substantial and fundamental change from the 1987 interpretation of the applicability of Section 2.63(a)(2). See FR-1987-06-09, pages 21796 and 21802. Thus, the 30 day Notice and Comment Period is far too short for a change in interpretation of this magnitude. Thus, this would be a violation of the Administrative Procedures Act.
- b. Data contained in slides by Assistant Secretary Dr. Elinore F. McCance-Katz [www.samhsa.gov/data/] reveal that 1,172,371 individuals are receiving treatment for medication assisted treatment. Their records may be subject to the proposed new interpretation of Section 2.63(a)(2). The 30 day Notice and Comment period is far too short for these individuals to respond to the proposed change to 42 CFR Section 2.63(a)(2) and thus they would be deprived of a basic procedural right under the Administrative Procedures Act
- c. 2018 NSDUH data estimated that 21.2 million people aged 12 or older needed substance abuse treatment in 2018. [Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health, SAMHSA 2019] All of these individuals are affected by the proposed change, as they may be discouraged from seeking treatment once it is known that their personal health information may be disclosed even if, as the proposed NPRM suggests, they themselves committed no serious crime that posed a threat to life or serious bodily injury of another person. The 30 day Notice and Comment period is far too short for these individuals to respond to the proposed change to 42 CFR Section 2.63(a)(2)

and thus they would be deprived of a basic procedural right under the Administrative Procedures Act

- d. 2018 NSDUH data estimated that 2.4 million people actually received treatment in a specialty facility in 2018. [Key Substance Use and Mental Health Indicators in the United States, see above]. Thus these people are directly affected by the proposed new interpretation that appears in the preamble of the proposed change to 42 CFR Section 2.63(a)(2). The 30 day Notice and Comment period is far too short for these individuals to respond to the proposed change and thus they would be deprived of a basic procedural right under the Administrative Procedures Act.
- e. It is estimated that only 46,500 physicians have buprenorphine waivers. Given that the maximum number of patients that a physician can have is 275, a number of these physicians will be classified as programs under 42 CFR Part 2. As a result, they have a vested interest in the proposed interpretation of 42 CFR Section 2.63(a)(2), as any of them may be targets of investigation and prosecution, as articulated by the preamble of the NPRM which proposes to change the interpretation of the 2017 final rule of 42 CFR Part 2. Thus, the 30 day Notice and Comment period is far too short for these individuals to respond to the proposed change in 42 CFR Section 2.63(a)(2); thus they would be deprived of a basic procedural right under the Administrative Procedures Act.
- f. While I cannot find specific numbers associated with the number of Physician Assistants and Advanced Practice Nurses (NPs, CNSs, CRNAs, and CNMs) who have buprenorphine waivers, a number of them will meet criteria for a Part 2 program under 42 CFR Part 2. Thus, they have a vested interest in the proposed interpretation of 42 CFR Section 2.63(a)(2). The 30 day Notice and Comment period is far too short for these individuals to respond to the proposed changes in 42 CFR Section 2.63(a)(2). Thus they would be deprived of a basic procedural right under the Administrative Procedures Act.
- g. Data from the 2017 National Survey of Substance Abuse Treatment Services (N-SSATS) documented 13,857 facilities providing substance abuse treatment. These facilities would be covered by 42 CFR Part 2. These facilities have a vested interest in 42 CFR Section 2.63(a)(2), as they would be subject to the activities permitted under this section. The 30 day Notice and Comment period is far too short for these entities to respond to the proposed changes in 42 CFR Section 2.63(a)(2). Thus they would be deprived of a basic procedural right under the Administrative Procedures Act.
- h. The NPRM for proposed changes in 42 CFR Section 2.63(a)(2) was released on the same day as the NPRM for proposed changes in the general 42 CFR part 2 {SAMHSA-4162-20} [RIN 0930-AA32] which has a 60 day Comment period. By releasing the shorter Section 2.63(a)(2) NPRM (3 pages) (RIN: 0930-AA30) at the same time as the larger 42 CFR part 2 NPRM, the Agency created an undue burden on respondents, especially the many patients whose information would be compromised and who do not have the resources to respond to both RIN 0930-AA32 and RIN 0930-AA30 in a timely manner. The 30 day Notice and Comment period is far too short for these entities to respond to the proposed changes in 42 CFR Section 2.63(a)(2). Thus they would be deprived of a basic procedural right under the Administrative Procedures Act.

2. HHS-OS-2-19-0010-0001, RIN: 0930-AA30 Violates the Administrative Procedures Act Requirement for Notice and Comment, because it fails to provide any substantive justification

for the proposed change. This deprives respondents of an adequate opportunity to scrutinize and challenge the rationale for the proposed changes, elevating the convenience of the bureaucracy over the potential harm of those directly and indirectly affected by the proposed changes.

a. The conclusions reached by the NPRM governing §2.63 of 42 CFR part 2 justifying the proposed changes are not supported by substantial evidence. It is argued by the NPRM that the proposed revision is necessary to help address the drug crisis in America, focusing primarily on the opioid crisis. However, what the NPRM fails to mention is that there are 67.1 million binge alcohol drinkers in the US in the past month and among those 16.6 million are heavy alcohol users. 42 CFR Part 2 applies to those who are alcohol dependent in need of treatment, not just those in need of treatment for opioid use. The NPRM offers no justification or explanation or evidence for by-passing the privacy interests of those who have a primary treatment need for alcohol use disorder. Thus, there is no rational basis for ignoring the privacy interests of individuals who are in treatment of alcohol use disorders in order to pursue possible crimes committed by individuals other than the patient.

1. In fact, the 2018 NSDUH data points out that of the substances for which last or current treatment was received among persons aged 12 or Older who received Substance use treatment, alcohol accounted for 56.8% of the substances, compared to 37.7% for opioids (18% for heroin and 19.7% for pain relievers). Thus, 2.1 million people were receiving treatment for alcohol use disorder compared to 1.4 million people receiving treatment for opioid use disorders. Since 42 USC 290dd-2, the parent legislation that spawned 42 CFR Part 2 applies to both alcohol and drugs, the NPRM for 42 CFR §2.63(a)(2) should address why the privacy interests of those with alcohol use disorders should be overridden by a concern for opioid use disorders.

2. The 2018 NSDUH data also notes that while 7.35 million people met criteria for needing treatment for illicit drugs but did not receive treatment at a speciality facility in 2018, 14.1 million people were classified as needing treatment for alcohol use. The proposed rule does not explain how those suffering from alcohol use disorder would not be discouraged from seeking treatment as a result of the proposed changes to 42 CFR § 2.63(a)(2).

3. The 2018 NSDUH data reveals that 2.613 million people were treated for substances other than opioids or in addition to opioids in 2018. These substances included marijuana, cocaine, methamphetamine, and hallucinogens. The proposed rule does not explain how those suffering from use disorders other than opioid use disorder would not be discouraged from seeking treatment as a result of the proposed changes to 42 CFR §2.63(a)(2). The proposed rule does not offer any justification for ignoring the impact of the proposed changes to 42 CFR §2.63(a)(2) on these individuals. Invoking the opioid crisis as a justification for curtailing the privacy rights of those who are dependent on other illicit drugs is not compelling. Thus the proposed changes to 42 CFR § 2.63(a)(2) should be voided.

4. The 2018 NSDUH data also reveals that past year prescription pain reliever misuse among people 12 or Older has been declining since 2015. In fact, past year reduction in prescription pain reliever went from 4.7% in 2015 to 3.6% in 2018. Furthermore, NSDUH data show the percentage of people suffering from an opioid use disorder in the past year has been declining since 2015. Keep in mind that according to SAMHSA the vast majority of past year opioid users in 2018 misused prescription pain relievers. Clearly, NSDUH data show that

environmental strategies like prescription drug monitoring programs (PDMPs) and prescriber surveillance through CMS and Prescription Benefits Managers is working. Thus, there is no need to compromise the confidentiality of patients receiving substance use disorder treatment services as proposed in the NPRM. Rogue doctors and pill mills can be identified by PDMPs, vigilant pharmacists and other prescription monitoring activities. There is no need to convert federal confidentiality regulations into a law enforcement tool; there is no need to use the opioid crisis and patient substance abuse treatment records to launch a new war on drugs.

b. The background and summary section of the NPRM relating to 42 CFR §2.63(a)(2) states that “SAMHSA believes that this rule, if adopted as proposed, will not have an additional impact on part 2 programs or others as section 2.63 would revert to the pre-2017 language.” However, in neither Section II or Section III of the NPRM is there offered any tangible evidence of the lack of impact of these changes on either patients, providers or programs. Thus, respondents are deprived an the opportunity to substantively comment on the NPRM or to object to the need for the proposed changes to §2.63(a)(2). This certainly violates the Administrative Procedures Act

- II. HHS-OS-2-19-0010-0001, RIN: 0930-AA30 Violates the intent of 42 USC 290dd-2 by criminalizing substance use disorder treatment records.
- a. The purpose of 42 CFR Part 2 must be derived from the purpose of 42 USC 290dd-2, the authorizing legislation. An example of the judicial interpretation of 42 USC 290dd-2 can be found in a 2000 decision by the US Court of Appeals, 4th where the Court stated in *John Doe v. Garrett G. Broderick*, 225 F.3d 440:

“The language used in section 290dd-2 suggests that Congress was concerned primarily with fostering programs aimed at curtailing our nation's staggering substance abuse problems. The primary beneficiary is the public. Ensuring the confidentiality of patient records encourages voluntary participation in such programs which, in turn, improves public health. *See Chapa*, 168 F.3d at 1038 (“Like other criminal statutes, § 290dd-2 creates rights in favor of society, not just particular members of society . . . Addicts will be more likely to accept treatment—and the rest of society therefore will be better off—if treatment is confidential.”). Legislative history, moreover, confirms that Congress enacted the section as part of an effort to combat the American public's drug abuse problem and that Congress intended to encourage individuals to seek treatment.”

- b. The opioid crisis is an insufficient reason for permitting substance use disorder patient records to be used for investigation and/or prosecution of the patient or others. As the language in *John Doe v. Garrett G. Broderick*, 225 F.3d 440 (4th US Circuit Court of Appeals) demonstrates, the substance abuse crisis is not new. This 19 year old decision recognized that our nation suffers from a “staggering substance abuse problem.” The objective of both 42 USC 290dd-2 and 42 CFR Part 2 is to get people into treatment, not discourage people from seeking treatment. The proposed rule violates the intent of 42 USC 290dd-2 and discourages people in need of treatment from seeking treatment.

- i. In 2018, 21.2 million people were classified as need substance use disorder treatment, but only 2.4 million received treatment at a specialty treatment facility.
 - ii. With 88.9% of those needing treatment, not receiving treatment, exposing their substance use disorder treatment records without their consent to law enforcement for the purposes of investigating and/or prosecuting the patient, the patient’s program or the patient’s providers will only discourage patients from seeking treatment and will increase the demand for illicit drugs, further compromising the health of the community and the safety of the community.
 - iii. The proposed NPRM does not address the burden on substance use disorder treatment programs covered by 42 CFR Part 2 on explaining to patients that under the proposed rule, law enforcement would be able to seek the content of their treatment records without their consent for the purpose of investigation and/or prosecution of drug trafficking at or from the part 2 program, exposing the patient not only to personal criminal sanctions but also to reprisals from other patients and friends who realize that the patient is a “snitch”. Thus, substance use disorder treatment becomes an adversarial environment, not a safe haven where the problem of substance use can be addressed with confidentiality. Thus, I oppose the proposed regulation changes.

- III. HHS-OS-2-19-0010-0001, RIN: 0930-AA30 is unnecessary from the perspective of addressing deviant behavior by Part 2 covered programs. Consequently, the proposed NPRM [SAMHSA-4162-20] [RIN 0930-AA30 should not be made into a final rule.
 - a. Section III of the proposed rule contends:

“As demand for treatment increases and new entities become part 2 programs, the need to prevent drug trafficking and patient exploitation at or by part 2 programs makes it imperative to correct the error in § 2.63(a)(2), which if left in its current form could be interpreted to hamper or impede federal enforcement efforts, in situations where malfeasance by a patient is not involved, but access to covered records may be necessary for investigatory and enforcement purposes. “

The largest increase in Part 2 covered programs will be in the area of buprenorphine prescribers, with physicians, physician assistants and advanced practice nurses being the core of this increase. Because the prescribing behavior of these individuals is monitored by State Prescription Drug Monitoring Programs, CMS Surveillance programs, Pharmacy Benefits Programs, EHR tracking systems, and third party reimbursement monitoring, the use of unconsented disclosure of patient records for criminal justice purposes beyond violent crimes actually committed by the patient is unnecessary. Thus, the justification offered by the NPRM is inadequate, inappropriate and undermines the effort to treat patients suffering from substance use disorders. As a result, I oppose the proposed rule changes recommended by this NPRM.

- IV. The NPRM makes the following statement as a justification for including “drug trafficking” as a permissible activity to petition the Court for unconsented access to a patient’s record:

“It may be necessary to examine confidential communications of a part 2 program to investigate and prosecute, if warranted, individuals other than a patient who engage in drug trafficking related to the drug abuse crisis”

- a. The NPRM offers no evidence that it may be necessary to examine confidential communications of a part 2 program to investigate and prosecute individuals other than a patient who engages in drug trafficking related to the drug abuse crisis. This language is also extremely speculative. The very language of this rationale creates the impression that the change is being requested for administrative convenience rather than addressing a violent act or child abuse which threatens the safety of the community.
 - b. Because a Part 2 program that engaged in drug trafficking would be highly unlikely to memorialize such illegal activities in a patient chart, the rationale offered in the NPRM is untenable. In fact, this proposed rule would be used either against the patient or against entities other than the Part 2 program with which the patient is familiar. The proposed rule would leave the patient vulnerable to the vagaries of the criminal justice system through self-incrimination. Alternatively, the patient may be subject to reprisals from other entities outside of the Part 2 program, once it becomes known that the patient has implicated those entities through the investigative and prosecutorial activities of the criminal justice system.
 - c. Because the NPRM offers nothing more than speculation, anecdotal statements, and possibilities, there is no justification for the proposed rule. And, since so few people are in substance use disorder treatment compared to those who meet criteria for needing treatment, corrupting 42 CFR §2.63(a)(2) for the possibility that searching through the patient’s records “might” reveal that the part 2 program or an affiliated medical professional is trafficking drugs rather than providing appropriate treatment for substance abuse can only discourage people in need of treatment from seeking treatment, exposing the community to greater harm. Keep in mind that the treatment in recovery process is not spontaneous and that relapse happens often enough that it is considered a part of the Recovery process. I encourage the Department of Health and Human Services and SAMHSA to embrace the intent of 42 USC 290dd-2 and not adopt the proposed rule.
- V. Because substantial changes in the interpretation of 42 CFR Part 2 [RIN 0930-AA32] are being entertained in the companion NPRM to RIN 0930-AA30, a disconnect between RIN 0930-AA32 and RIN 0930-AA30 was created, making suggesting that the focus of 42 CFR Part 2 is not the promotion of treatment by preserving confidentiality, but the use of patient treatment records for the purpose of investigation and prosecution. NPRM RIN 0930-AA32 purports to revise 42 CFR Part 2 to facilitate better coordination of care for SUDs. In a Press Release of August 22, 2019, HHS contended that the RIN 0930-AA32 would not alter the basic framework for confidentiality protection of SUD patient records. [See <https://www.hhs.gov/about/news/2019/08/22/hhs-42-cfr-part-2-proposed-rule-fact-sheet.html>]; that press release goes on to state: “Part 2 will continue to prohibit law enforcement use of SUD patient records in criminal prosecution against the patient.” Given that NPRM RIN 09-AA30 released as a companion to NPRM RIN 09-AA32 makes it clear that its objective is to use SUD patient records for the

purpose of investigation and/or prosecution of drug trafficking by the patient, the contradiction between these two NPRMs creates confusion as to the intended purpose of 42 CFR Part 2, on the one hand. On the other hand, the concurrent release of two NPRMs dealing with provisions of 42 CFR Part 2 can give the impression that the Department is being disingenuous about its view of the intended purpose of 42 CFR Part 2.

- a. NPRM RIN 09-AA30 governing 42 CFR § 2.63 should be abrogated and nullified as it should have been an integral part of NPRM RIN 09-AA32. Because its primary focus is the investigation and prosecution of patients, the Part 2 program in which a patient is or has been enrolled, and the providers of the patient, NPRM RIN 09-AA30 is out of alignment with the stated purpose of NPRM RIN 09-AA32 and 42 USC 290dd-2.
- b. The case cited above, *John Doe v. Garrett G. Broderick*, 225 F.3d 440 (2000) (US Court of Appeals, 4th Circuit) demonstrates the gravity of the situation that would be caused by a revision of 42 CFR § 2.63(a)(2). Should the Proposed rule (NPRM RIN 09-AA30) become a final rule, all that would be required for law enforcement to gain access to a patient's records is to aver that suspected drug trafficking has occurred at a Part 2 program. In *Doe v. Broderick*, a jewelry store was the victim of a grand larceny; a stolen car used in the larceny was traced to a garage situated near a methadone clinic. The detective on the case hypothesized that because "drug addicts often engage in criminal activity to support their habits", the suspect could have been a patient at the methadone clinic. The detective then telephoned the clinic and indicated that he wanted to examine records that would reveal who was at the clinic at the time of the grand larceny.

The clinic refused to disclose information in the absence of a court order. The detective prepared a proposed search warrant that directed the clinic be searched for "records, documents and photographs." The detective drafted a supporting affidavit in which he requested that the search include the following.

." the full names of all patients, dates of birth, social security numbers, photographs, home addresses and work locations if available[,] the opening of any file cabinets, desks, closets, locked safes, boxes, bags, compartments or things in the nature ther[e]of, found in or upon said premises to include any and all electronically stored computer data."

The affidavit relied only on the detective's training, experience and participation in other criminal investigations to petition the a magistrate judge for a search warrant; the detective was granted the search warrant, despite the fact he had no real probable cause to demand the information he sought. This case captures the substantive limitations of the Proposed Rule. Well intended judges influenced by inflammatory language of a public health crisis will be petitioned by well-intentioned officers of the law on a fishing expedition for incriminating evidence to address the drug crisis; in this scenario, patient confidentiality and privacy will

be sacrificed, something that will be quickly known by people in need of treatment. The purpose of 42 CFR Part 2 regulations is not just to protect patient records created by federally funded programs for the treatment of SUDs; as the Court of Appeals noted in the case of *Doe v. Garrett*, the purpose of 42 CFR Part 2 should be to encourage people to seek treatment. Therefore, I oppose the Proposed rule and recommend that the existing interpretation of 42 CFR §2.63 (a)(2) be retained.

VI. Should the proposed changes to 42 CFR §2.63(a)(2) be implemented, additional burdens and responsibilities will be imposed on Part 2 programs. Prospective patients will have to be informed about the new interpretations of 42 CFR §2.63(a)(2); patients will have to be told that law enforcement could petition the Court to examine the patient's records in the absence of a crime of violence or of child abuse in furtherance of an investigation or to prosecute. Part 2 programs that fail to inform patients of this potential intrusion, unfortunately, are not likely to suffer any consequences, however. Because 42 USC 290dd-2 is a criminal statute, and because it conveys no private right of action when it is violated, the patient cannot sue under 42 USC 290dd-2 or 42 CFR Part 2 for any harm caused by the violation of 42 CFR Part 2. Thus, patients will be compelled to sue under theories of fraud, negligence or some other cause of action.

VII: The NPRM RIN 0930-AA30, in error, contends that the 2017 final rule of 42 CFR Part 2 erroneously added the phrase "allegedly committed by the patient" and that the 2017 final rule did not address that change, or explain its intended reasoning, even though the meaning of the phrase "allegedly committed by the patient" is self-evident and clearly means that the focus of the phrase is on the acts of the patient, rather than the acts of others.

- a. Although the NPRM contends that the insertion of the phrase "allegedly committed by the patient" is a substantive change made by the 2017 final rule of 42 CFR Part 2, the NPRM offers no evidence that this change nullified an interpretation that had existed since 1987. No prosecution was cited and no case law was cited to demonstrate that in fact that 42 CFR §2.63(a)(2) was used by law enforcement for the investigation and/or prosecution of crimes committed by the patient, the program or patient's providers prior to 2017. Furthermore, no real, quantitative or substantive evidence was presented to support the contention that the 2017 version of 42 CFR §2.63(a)(2) in fact hinder federal enforcement efforts targeted at rogue doctors and pill mills.
- b. Given the rigor of the rule making process and given the self-evident meaning of the phrase crimes "allegedly committed by the patient", it is logical to conclude that the intent of the change in 2017 was to make it clear that the focus of the change was to keep the patient's records from being used for purposes other than on behaviors of the patient. In short, I believe the Department is in error when it concludes that the 2017 version of 42 CFR §2.63(a)(2) is in error or otherwise a mistake.

b. It is the NPRM RIN 0930-AA30 that proposes to make a substantive change to the interpretation of 42 CFR §2.63(a)(2) by extending the reach of this section to include drug trafficking and to include acts of others. This extension opens up the patient's records for scrutiny by law enforcement and by defendants other than the patient, compromising the patient's confidentiality and privacy in the service of administrative convenience.

c. Since the 2017 final rule for 42 CFR Part 2 was a product of several years of scrutiny and debate about the warp and woof of confidentiality of patients seeking treatment, in treatment and post-treatment for substance use disorders and since NPRM RIN 0930-AA30 offers no proof of error other than the assertion that law enforcement seeks a convenient doorway into a patient's drug related activities, changing the 2017 final rule's clarification of 42 CFR § 2.63(a)(2) would be detrimental to patient care and would make the provision of patient care unattractive to providers of health care. The language of the 2017 final rule for 42 CFR § 2.63(a)(2) should remain as was promulgated in 2017.

d. Additional rationale offered by NPRM RIN 0930-AA30 is that the 2017 revision might hinder federal valid enforcement efforts in the fight to address the opioid crisis. In addition, NPRM RIN 0930-AA30 proposes to use the patient's substance use disorder treatment records to "encourage valid enforcement efforts in the fight to address the opioid crisis." However, the purpose of 42 USC 290dd-2 and 42 CFR Part 2 is to encourage people to enter treatment and thereby reduce the demand for illegal drugs and reduce the adverse effects of unmitigated alcohol consumption. NPRM RIN 0930-AA30 would change the entire meaning of 42 CFR Part 2 by making it a law enforcement tool rather than a limited exception to patient confidentiality that balances the need for substance use treatment and public safety.

1. As stated elsewhere in this document, far too few people in need of substance use disorder treatment receive treatment. Creating an unnecessary barrier to treatment, in fact, will compromise public health and public safety. Therefore, the justification for reverting to the pre-2017 version of §2.63 is not only weak, but illogical.
2. NPRM RIN 0930-AA30 makes it clear that one of its targets is the very people providing substance use disorder treatment, without offering any substantive evidence that there is rampant abuse of patients by substance use disorder treatment providers, including those offering treatment services to those with opioid use disorders. At a time when major efforts are being made to broaden the involvement of qualified treatment providers to address the issue of substance use disorder in America, using 42 CFR §2.63(a)(2) to promote a "fishing expedition" in search of deviant behavior by treatment providers will make the perception of patients with substance use disorders as "radioactive" and undesirable. The proposed interpretation of 42 CFR §2.63(a)(2) converts a public health strategy into a law enforcement strategy and is counter to the intent of 42 USC 290dd-2. As a result, the proposed changes to the language of 42 CFR §2.63(a)(2) and to the interpretation of the reach of 42 CFR §2.63(a)(2), including the investigation and prosecution of others using the unconsented scrutiny of the patient's records should be rejected.

3. (a) The Proposed Rule in NPRM RIN 0930-AA30 would accomplish for law enforcement what the 4th US Circuit Court of Appeals rejected in *Doe v. Garrett*, previously cited in this document. It would provide a basis for local courts to issue subpoena's and authorizing court orders without probable cause and upon the flimsiest of justification, compromising the confidentiality of patients in treatment for substance use disorders for well-intentioned law enforcement agents.

(b) The 2017 version of 42 CFR §2.63(a)(2) should remain as is and the interpretation of this section should not be broadened to include drug trafficking or the behavior of others. By restricting the interpretation to crimes allegedly committed by the patient, it is made clear to all that patient substance use disorder treatment confidentiality is important and that exceptions to that confidentiality should be extremely limited.

For the first time in history, drug trafficking is being specifically included as a serious crime in this proposed rule. The definition of "serious crimes" has historically been limited to violent crimes such as rape and murder. Since dependence on illegal drugs almost by definition involves some form of illegal drug activity, which could easily be classified as drug trafficking, the criminalization of substance use disorders is not the answer to this public health crisis.

Use of records for investigating and prosecuting alleged crimes beyond the patient (e.g., family, friends, associates, treatment providers and researchers) has never been included in the past. **The language in section 2.63(a)(2) must remain as stated in the current rule limiting such court ordered release of records to very serious crimes allegedly committed by the client.**

If these proposed language remains in the proposed rule change, the only way that a person can avoid potential investigation and prosecution is to not to go into treatment. Twelve - step programs, Oxford Houses, and other self-help programs that operate off the grid would be the only rational option for anyone trying to protect their privacy and seek help.

This proposed change is not in line with the best interests of society or patients seeking treatment for substance use disorders and their families. *A change of this nature will deter people in need of treatment from seeking care out of fear of law enforcement involvement, which goes against the fundamental purpose of 42 CFR part 2.* "Part 2" was created to encourage people to seek care without fear of legal repercussions or stigma.

SAMHSA should also extend the comment period immediately. The proposed change, which affects hundreds of thousands of people, is significant. This proposed rule change needed more than 30 days to analyze and respond to this NPRM.

Submitted by

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Santa Clara University, former Director of the Center for Substance Abuse Treatment