DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 2

[SAMHSA-4162-20]

RIN 0930-AA30

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: HHS proposes to amend its Confidentiality of Substance Use Disorder Patient Records regulation, to clarify one of the conditions under which a court may authorize disclosure of confidential communications made by a patient to a part 2 program as defined in this regulation. This change will clarify that a court may authorize disclosure of confidential communications when the disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, even if the extremely serious crime was not allegedly committed by the patient.

DATES: To be assured consideration, comments must be received at one of the addresses provided below no later than 5PM on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0930-AA30, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

1. *Federal eRulemaking Portal:* You may submit comments electronically at http://www.regulations.gov. Follow the instructions for submitting comments. This is the preferred method for the submission of comments.
2. *Mail:* Written comments must be sent to the following address: Attn: Mitchell Berger, SAMHSA,5600 Fishers Lane, Room 18E89C, Rockville, Maryland 20857; or Suzette Brann, SAMHSA, 5600 Fishers Lane, Room 13E01B, Rockville, Maryland.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Inspection of Public Comments: All comments received before the close of the comment period will be available to the public in their entirety including any personally identifiable and/or confidential information. Submitted comments may be inspected on http://www.regulations.gov or in-person, by appointment (Monday through Friday from 8:30 a.m. to 4 p.m.), at the headquarters of the SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857. To schedule an appointment to view submitted comments at SAMHSA's headquarters, contact Mitchell Berger at (240) 276-1757 or Suzette Brann at (240) 276-1252.

FOR FURTHER INFORMATION CONTACT: Mitchell Berger at (240) 276-1757 or Suzette Brann at (240) 276-1252 or by email at: PrivacyRegulations@samhsa.hhs.gov.

Table of Contents

I. Legal Authority

HHS is proposing this rule under the authority of 42 U.S.C. 290dd-2.

II. Background and Summary

On January 18, 2017, HHS published a final rule (82 FR 6052) (2017 final rule) that made certain changes to the regulations governing the confidentiality of substance use disorder patient records at 42 CFR part 2 (part 2). The part 2 regulations apply to part 2 programs. Briefly, as stated in the 2017 final rule, SAMHSA defines a part 2 program as a federally assisted program (federally assisted as defined in § 2.12(b) and program as defined in § 2.11). See § 2.12(e)(1) for examples.[1]

HHS did not intend in the 2017 final rule to substantively revise the provision of part 2 governing confidential communications that appears in § 2.63. However, the phrase "allegedly committed by the patient" was erroneously added to § 2.63(a)(2) in the 2017 final rule. The fact that the preamble of the 2017 final rule did not address that change, or explain its intended reasoning, indicates that no substantive change was intended. What is more, since publication of the 2017 final rule, it has come to our attention that the erroneous addition of the phrase "allegedly committed by the patient" may hinder federal enforcement efforts targeted at rogue doctors and pill mills that have contributed to the opioid crisis.

The prompt revision of this rule is necessary to help address one of the largest drug crises in the nation's history. HHS and the U.S. Department of Justice (DOJ) have developed extensive information concerning the nature and magnitude of the crisis.[2] In particular, former HHS

[1] (See 82 FR 6052, 6061 (January 18, 2017)).

[2] See, e.g., Department of Health and Human Services (October 26, 2017). HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis. Retrieved from www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html; Centers for Disease Control and Prevention (n.d.). Retrieved from www.cdc.gov/drugoverdose/data; Centers for Disease Control and Prevention, National Center for Health Statistics (December 2017). Drug Overdose Deaths in the United States, 1999–2016. Retrieved from www.cdc.gov/nchs/products/databriefs/db294.htm; Substance Abuse and Mental Health Services Administration (September 2017). Key Substance Use and Mental Health Indicators in the United States:

Acting Secretary Eric Hargan declared a public health emergency on October 26, 2017, to address the national opioid crisis and, most recently, HHS Secretary Alex Azar renewed that declaration on July 23, 2018. The proposed correction of the part 2 rule would help to address this public health emergency by facilitating the prompt investigation and prosecution, if warranted, of opioid-related crimes allegedly committed by individuals other than patients. Specifically, this proposed rule would correct the error by removing the phrase "allegedly committed by the patient" from § 2.63(a)(2). 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.

III. Proposed Rule

HHS proposes to amend § 2.63(a)(2) by deleting the phrase "allegedly committed by the patient" that was erroneously added in the 2017 final rule.

Under this proposal, the text would revert to the language that appeared in the part 2 rule since 1987.[3]

This proposed change is further compelled by the opioid crisis, which was declared a public health emergency by the former Acting Secretary of HHS, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d and renewed by HHS Secretary Azar. According to the Centers for Disease Control and Prevention, as many as 350,000 Americans have died from

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Results from the 2016 National Survey on Drug Use and Health. Retrieved from www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf; National Institute on Drug Abuse (March 2018). Opioid Overdose Crisis. Retrieved from www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis; Drug Enforcement Administration, 2017 National Drug Threat Assessment (Oct. 2017), at v, 25-43.

[3] See 52 FR 21796

an opioid overdose between 1999 and 2016.[4] A November 2017 report from the President's Council of Economic Advisors entitled "The Underestimated Costs of the Opioid Crisis" estimates that in 2015, the economic cost of the opioid crisis was $504 billion, or 2.8 percent of Gross Domestic Product that year.[5] The President's Commission on Combatting Drug Addiction and the Opioid Crisis in its 2017 final report identifies the gravity of the opioid crisis and notes the importance of a comprehensive effort by federal partners, including DOJ and the Drug Enforcement Administration, to address this crisis.[6]

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 proposed correction to § 2.63(a)(2) is necessary to encourage valid enforcement efforts in the fight to address the opioid crisis, including investigations that involve disclosures of part 2 program records authorized by court orders under Subpart E of 42 CFR part 2. HHS believes reverting to the previous language for this section is necessary to help reduce and deter drug trafficking at or from part 2 programs, and thereby to prevent the occurrence of extremely serious crimes from interfering with the delivery by part 2 programs of high quality, medically necessary treatment to patients with substance use disorders.

[4]Centers for Disease Control and Prevention (n.d.). Understanding the Epidemic. Retrieved from https://www.cdc.gov/drugoverdose/epidemic/index.html
[5]The Council of Economic Advisers (2017). Retrieved from https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf
[6]Office of National Drug Control Policy (n.d.). Retrieved from https://www.whitehouse.gov/ondcp/presidents-commission/

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. Specifically, these records may be necessary to establish that the part 2 program or an affiliated medical professional is trafficking drugs rather than providing appropriate treatment for substance abuse. Accordingly, HHS proposes to amend the text of § 2.63(a)(2) to remove the phrase "allegedly committed by a patient."

IV. Regulatory Impact Analysis

HHS has examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (Pub. L. 96-354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). HHS does not believe the proposed change constitutes an unfunded mandate, additional regulatory activity or imposes a cost or economic burden on part 2 programs.

Executive Orders 12866, 13563, 13132, and 13771

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review, as established in Executive Order 12866. The proposed changes in this rule will not have an annual effect on the economy of $100 million or more in at least one year. HHS notes that these proposed changes do not characterize a significant regulatory action under Executive Order 12866. The proposed

change to 2.63 has no discernible economic impact, is consistent with the policies of such agencies as the Department of Justice, does not alter program budgets or obligations of grant or loan recipients and raises no novel legal or policy questions. Indeed, as explained, this rule reverts to the pre-2017 language for this section, which had remained unchanged for more than 30 years.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule does not impose any costs on state or local governments, therefore, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 directs Agencies to identify at least two existing regulations to repeal for every new regulation unless prohibited by law. The total incremental cost of all regulations issued in a given fiscal year must have costs within the amount of incremental costs allowed by the Director of the Office of Management and Budget, unless otherwise required by law or approved in writing by the Director of the Office of Management and Budget. This proposed rule is not expected to lead to the promulgation of a rule constituting a "regulatory action" under Executive Order 13771.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of "small entity"). For

similar rules, HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least five percent of small entities experience an impact of more than three percent of revenue. HHS determines that this proposed rule does not have a significant economic impact on a substantial number of small entities. The proposed rule would merely correct an erroneous change made in 2017 to the longstanding regulations in 42 CFR 2.63, in order to avoid a possible interpretation that could hamper or impede federal enforcement efforts in the fight to address the opioid crisis, including investigations that involve disclosures of part 2 program records authorized by court orders.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." In 2018 that threshold level is approximately $150 million. HHS does not expect the proposed rule to exceed the threshold.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The change proposed in this rulemaking would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. § 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. § 804(2)."

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Drug abuse, Grant programs—Health, Health records, Privacy, Reporting, and Recordkeeping requirements.

For the reasons stated in the preamble, HHS proposes to amend 42 CFR part 2 as follows:

PART 2–CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

1. The authority citation for part 2 continues to read follows:

Authority: 42 U.S.C. 290dd-2.

Subpart E – Court Orders Authorizing Disclosure and Use

§ 2.63 [Amended]

2. Amend § 2.63(a)(2) by removing the phrase "allegedly committed by the patient".

Dated: August 1, 2019.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use,

Substance Abuse and Mental Health Services Administration.

Alex M. Azar II,

Secretary.

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