economic return shall not be presumed to primarily serve the public interest.

Ruth Stevenson,
Attorney, Federal Compliance.

[FR Doc. 2019–18326 Filed 8–23–19; 8:45 am]
BILLING CODE 7710–12–P

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 5 p.m. on September 25, 2019.
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 1E893C, 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.

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 or others as section 2.63 of this regulation. In this final rule, SAMHSA defines a part 2 program as a federally assisted program (federally assisted defined in § 2.12(b) and program as defined in § 2.11). See § 2.12(e) for examples. 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.

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.

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, which authorizes the Secretary of Health and Human Services to declare a public health emergency and provide for a public health service. This proposed rule, if adopted as proposed, will have no additional impact on part 2 programs or others as section 2.63 would revert to the pre-2017 language.


3 See 52 FR 21796.
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 under which involves 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 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.

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

---

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 as follows:


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.

[FR Doc. 2019–17816 Filed 8–22–19; 4:15 pm]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 2

[SAMHSA–4162–20]

RIN 0930–AA32

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: This notice of proposed rulemaking proposes changes to the Confidentiality of Substance Use Disorder Patient Records regulations. These proposals were prompted by the need to continue aligning the regulations with advances in the U.S. health care delivery system, while retaining important privacy protections for individuals seeking treatment for substance use disorders (SUDs). SAMHSA strives to facilitate information exchange for safe and effective substance use disorder care, while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. Within the constraints of the statute, these proposals are also an effort to make the regulations more understandable and less burdensome.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 25, 2019.

ADDRESSES: In commenting, please refer to file code SAMHSA 4162–20. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (to avoid duplication, please submit your comments in only one of the ways listed):


2. By regular mail. Written comments mailed by regular mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attention: SAMHSA—Deepa Avula, 5600 Fishers Lane, Room 17E41, Rockville, MD 20857.

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

3. By express or overnight mail. Written comments sent by express or overnight mail must be sent to the following address ONLY:

The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attention: SAMHSA—Deepa Avula, 5600 Fishers Lane, Room 17E41, Rockville, MD 20857.

4. By hand or courier. Written comments delivered by hand or courier must be delivered to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attention: SAMHSA—Deepa Avula, 5600 Fishers Lane, Room 17E41, Rockville, MD 20857.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Ms. Deepa Avula, (240) 276–2542.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments.

Table of Contents

I. Background
II. Overview of the Proposed Regulations
III. Provisions of the Proposed Rule
A. Definitions (§ 2.11)
B. Applicability (§ 2.12)
C. Consent Requirements (§ 2.31)
D. Prohibition on Re-disclosure (§ 2.32)
E. Disclosures Permitted with Written Consent (§ 2.33)
F. Disclosures to Prevent Multiple Enrollments (§ 2.34)
G. Disclosures to Prescription Drug Monitoring Programs (§ 2.36)
H. Medical Emergencies (§ 2.51)
I. Research (§ 2.52)
J. Audit and Evaluation (§ 2.53)
K. Orders Authorizing the Use of Undercover Agents and Informants (§ 2.67)
IV. Collection of Information Requirements
V. Response to Comments
VI. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Alternatives Considered
D. Conclusion

Acronyms

ADAMHA—Alcohol, Drug Abuse, and Mental Health Administration

BILLING CODE P