SUPPORTING STATEMENT FOR THE
CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS
42 CFR PART 2

A. JUSTIFICATION

1. Circumstances of Information Collection

This is a request for an extension of OMB approval (OMB No. 0930-0092) of the information collection requirements in the Final Rule (42 CFR Part 2), Confidentiality of Alcohol and Drug Abuse Patient Records (Attachment A), which expires on December 31, 2019. Federally conducted, regulated, or assisted alcohol drug abuse programs are required by statute to keep patient records confidential. There is a criminal penalty for violation of the statutes or implementing regulations requiring confidentiality: a fine of not more than $500 in the first offense and not more than $5,000 in the subsequent offense. The statutory authority for the confidentiality of alcohol and drug abuse patient records is 42 U.S.C. 290dd-2.

A notice of proposed rulemaking was published in the Federal Register on August 26, 2019. https://www.govinfo.gov/app/details/FR-2019-08-26/2019-17817**. The final rule will likely not be published prior to the expiration of this current PRA package.**

Section 2.22 of the regulation requires public disclosure in a communication to each patient that Federal laws and regulations protect the confidentiality of alcohol and drug abuse patient records and a written summary of the effect of those laws and regulations.

The statutes permit disclosure of patient identifying information in a medical emergency but only to medical personnel. This provision is implemented at 42 CFR 2.51, which requires that a program document a disclosure to meet a medical emergency by entering in the patient's records the name of the medical personnel and their affiliation with any health care facility, the date and time of disclosure, the person who made the disclosure, and the nature of the emergency.

The information collection requirements in 42 CFR Part 2 for which OMB approval is requested are:

42 CFR Part 2 - Section 2.22 - Disclosure

Requires each program to make public disclosure in the form of communication to each patient that Federal laws and regulations protect the confidentiality of each patient and includes a written summary of the effect of these laws and regulations.

42 CFR Part 2 – Section 2.51 - Recordkeeping

This provision requires the program to document a disclosure of a patient record to authorized medical personnel in a medical emergency. The regulation is silent on retention period for keeping these records as this will vary according to State laws. It is expected that these records

will be kept as part of the patients' medical records.

2. Purpose and Use of Information

The information disclosed to patients pursuant to the public disclosure requirement in 42 CFR 2.22 will be used by the patient to understand permitted uses that may be made of his or her treatment records. Notice to each patient at the outset that the program must maintain the confidentiality of patient records will provide an incentive for the patient to be frank and open in the therapeutic relationship. Such information will also serve to notify each patient of the limitations of the confidentiality protection, e.g., no confidentiality protections are extended to criminal behavior (or threats thereof) on program premises or against program personnel, nor to information about suspected child abuse or neglect that must be reported under State law to appropriate State or local authorities. Awareness of the existence of the Federal confidentiality regulations/standards by program staff and patients will encourage diligence in program compliance and may deter certain behavior by patients.

Information documenting the "medical personnel" status of the recipient of a disclosure under 42 CFR 2.51 will be used by the program as a record that only medical personnel, i.e., only persons able to alleviate the medical emergency, were furnished patient identifying information in accordance with the statutes.

The Federal role in this activity is to ensure that alcohol and drug abuse patient records are kept confidential in accordance with Federal statutes and regulations.

3. Use of Information Technology

The information collected and retained by a program is the minimum amount necessary to comply with the statutory requirements. There are no technical or legal obstacles to reducing burden. It is not clear that use of information technology would be appropriate for these requirements, but nothing precludes use of information technology that may be available to individual treatment facilities or programs.

4. Effort to Identify Duplication

State law, professional and ethical standards, and the policies of a program or medical care facility may impose standards for maintaining confidentiality of all medical records, in addition to standards imposed for alcohol and drug abuse patient records by subject Federal law and regulations. Those same entities may impose public disclosure requirements. On the basis of professional knowledge and public comment received on publications of the regulation, SAMHSA staff are not aware of any other laws, standards, or policies that require documentation of the "medical personnel" status of persons to whom a disclosure is made to meet a medical emergency as set out in 42 CFR 2.51 or notice to the patient of the effect and limits of the Federal confidentiality requirements as set in 42 CFR 2.22. The events about which 42 CFR 2.22 and 2.51 require disclosure and recordkeeping are unique, and no similar information exists outside those events.

5. Involvement of Small Entities

The regulations require a minimum of information for all affected facilities, many of which are small entities and therefore, there is no significant impact involving small entities.

6. Consequences If Information Collected Less Frequently

In as much as information is disclosed to new patients and records of disclosure to medical personnel are generated on an "as needed" basis, a discussion of less frequent information collection is not applicable to these provisions. The public disclosure requirement that each patient be notified of the effect and limits of the Federal confidentiality laws and regulations in 42 CFR 2.22 is imposed for each patient admission. Less frequent disclosure would not provide each patient with notice.

7. Consistency with the Guidelines in 5 CFR 1320.5(d) (2)

This information collection fully complies with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on October 2, 2019 (84 FR 52522). No comments were received in response to this notice.

Consultation with alcohol and drug abuse programs and with general medical care facilities occurred in 1980 within the context of a Federal Register notice that the Department intended to rewrite 42 CFR Part 2 to make both substantive and editorial amendments. The notice solicited comments on 15 specific issues, including the notice to patient provision. More than 450 public comments were received and considered in the development of the Notice of Proposed Rulemaking. Approximately 150 comments were received in response to the Notice of Proposed Rulemaking and were taken into consideration in preparation of the final rule. Although SAMHSA continues to receive inquiries about the provisions of this regulation, no comments or complaints have been received from treatment programs regarding the specific disclosure and recordkeeping provisions.

9. Payment to Respondents

No payments are made to respondents for compliance with this regulation.

10. Assurance of Confidentiality

No assurance of confidentiality is provided to those parties required to document "medical personnel" status, or give notice to each patient (federally conducted, regulated, or assisted alcohol and drug abuse programs). They are the parties upon whom the Federal statutes and regulations impose confidentiality standards for the benefit of patients.

11. Questions of a Sensitive Nature

The public disclosure requirement in 42 CFR 2.22 provides notice to each patient rather than soliciting information. The nature of the records generated in compliance with 42 CFR 2.51

would not include sensitive material except insofar as the records generated become a part of an alcohol and drug abuse patient's record; i.e., except insofar as the documentation of "medical personnel" status is connected with an identified individual's treatment for alcohol and drug abuse.

Many of the treatment providers are covered also under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule applies to "covered entities" which are health plans, health care clearinghouses and health care providers who transmit health information in electronic form. The Privacy Rule permits uses and disclosures of protected health information (without patient authorization) to carry out treatment, payment and health care operations. HIPAA permits the exchange of information among providers for the purpose of treatment. Treating medical emergencies would fall under these permitted uses and disclosures. In this case, an authorization form would not be required.

Attachment A was developed by SAMHSA in consultation with the HHS Office of General Counsel, Office for Civil Rights and other offices and agencies within HHS, as guidance for treatment providers about the applicability of the Confidentiality Regulations and the HIPAA Privacy Rule. It explains which programs must also comply with the Privacy Rule and outlines what compliance will require.

Part 2 protects any and all information that could reasonably be used to identify and individual and requires that disclosures be limited to the information necessary to carry out the purpose of the disclosure. Under the Privacy Rule, a program may not use or disclose "protected health Information" (PHI) except as permitted or required by the Rule.

12. Estimates of Annualized Hour Burden

The annual burden for the information requirements in this subpart is summarized in the table that follows:

Annualized Burden Estimates

	Annual No. Respondents (Alcohol & Drug Programs)	**Responses per Respondent**	**Total Responses (No. of Tx Admissions)**	**Hours per Response**	**Total Hour Burden**	**Hourly Wage Cost**	**Total Hour Cost**
Disclosure							
42 CFR 2.22	11,779	163	1,920,844	.20	384,169	$21.23	$8,155,908
Recordkeeping							
42 CFR 2.51	11,779	2	23,558	.167	3,934	$18.80	$73,959
TOTAL	**11,779**	**-**	**1,944,402**	**-**	**388,103**	**-**	**$8,229,867**

The respondents for this collection of information are publicly (Federal, State, or local) funded, assisted, or regulated alcohol and drug treatment programs. The estimate of the number of such programs (respondents) is based on the results of the 2017 National Survey of Substance Abuse

Treatment Services (N-SSATS), and the average number of annual total responses is based on 2015-2017 information on patient admissions reported to the Treatment Episode Data Set (TEDS). N-SSATS is approved under OMB No. 0930-0106 and TEDS approved under OMB No. 0930-0335.

The mean hourly wage rates are based on 2018 information from the U.S. Bureau of Labor Statistics, www.bls.gov, (May 2018 National Occupational Employment and Wage Estimates, United States) for substance abuse and behavioral disorder counselors and for office and administrative support occupations.

Conversations with treatment provider representatives indicated a wide range in the amount of time spent on confidentiality disclosure which typically occurs during intake assessment. The amount of time for disclosure to a patient ranged from a low of 3-5 minutes to a high of almost 38 minutes; the approximately 12 minute estimate used to estimate burden above reflects a judgment about the time needed to adequately comply with the legal requirements and for basic training of counselors on the importance of patient confidentiality. The time estimate for recordkeeping for a clerk to locate a patient record, record the necessary information and re- file the record is 10 minutes. Providers consulted consider these confidentiality provisions essential to getting patients into treatment and report that they do not consider them to be burdensome.

13. Estimates of Annualized Cost Burden to Respondents

The only costs to treatment providers associated with these regulations are the cost to duplicate the disclosure statement: 1,725,625 pages at $.05 each = $86,281.

14. Estimates of Annualized Cost to Government

Staff for technical assistance and inquiries totals $30,851:

Office of General Counsel -1 GS-14 Step 5 x 5% time = $ 6,170

SAMHSA -1 GS-14 Step 5 x 20% time = $24,681

NOTE: This estimated annualized cost is for implementing the regulations in their entirety, not just for the information collection requirements.

15. Changes in Burden

Currently, there are 349,056 burden hours in the OMB inventory. SAMHSA is requesting 388,103 hours. This adjustment of 39,047 hours is due to an increase in the number of patient admissions to treatment.

16. Time Schedule, Publication and Analysis Plans

The information collections in this regulation are not used for statistical purposes nor are they published.

17. Display of Expiration Date

There are no forms associated with these regulations.

18. Exceptions to Certification Statement

The certification is included in this submission.

B. STATISTICAL METHODS

This collection of information does not employ statistical methodology.

ATTACHMENT

A. Notice of Proposed Rulemaking (NPRM) – August 26, 2019