- A description of the accomplishments resulting from such activities;
- A description of systems to protect and advocate the rights of individuals with mental illness supported with payments from PAIMI Program allotments;
- A description of activities conducted by States to protect and advocate such rights;
- A description of mechanisms established by residential facilities for individuals with mental illness to protect such rights;
- A description of the coordination among such systems, activities and mechanisms;
- Specification of the number of public and nonprofit P&A systems established with PAIMI Program allotments; and
- Recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of the need for such activities and services that were not met by the state P&A systems established under the PAIMI Act due to resource or annual program priority limitations.

Each PAIMI grantee's annual PPR must include a separate section, prepared by its PAIMI Advisory Council (PAC), that describes the council's activities and its assessment of the state P&A system's operations per the PAIMI Act at 42 U.S.C. 10805(7).

In 2017, SAMHSA included the annual PAIMI PPR in the Web-based Block Grant Application System (WebBGAS). WebBGAS, SAMHSAs electronic data system, is used to collect grantee information for the following reasons:

(1) To meet the OMB requirements for data collection for mandatory (formula) grant programs;

(2) To comply with the annual program reporting requirements of the PAIMI Act 42 U.S.C. 10801 *et seq.* and the PAIMI Rules 42 CFR, Part 51;

(3) To simplify the submission of PAIMI program data by the state P&A systems;

(4) To meet the Government Performance Results Act (GPRA) requirements;

(5) To comply with the Government Accountability Office (GAO) evaluation recommendations that SAMHSA obtain information that closely measures the actual outcomes of the programs it funds;

(6) To reduce the grantee data collection burden by removing information that did not facilitate evaluation of a PAIMI grantee's programmatic and financial management systems;

(7) To provide immediate access to the PAIMI program data used to prepare a section of the Secretary's biennial report to the President, Congress, and National Council on Disability in accordance with the *Developmental Disabilities Assistance Act of 2000* at 42 U.S.C. 15005. Reports of the Secretary;

(8) To improve SAMHSA's ability to create reports, analyze trends and provide timely feedback to the P&A grantees when PPR revisions are needed.

On July 17, 2017, OMB approved SAMHSA's PPR and Advisory Council Report (Control No. 0930–0169, Expiration Date July 31, 2020). The burden estimate for the annual State P&A system reporting requirements for these regulations is as follows:

42 CFR citation	Number of respondents	Responses per respondent	Burden/ response (hrs.)	Total hour burden
51.8(a)(2) Program Performance Report [1]	.....	.....	.....	.....
51.8(8)(a)(8) Advisory Council Report *	.....	.....	.....	.....
51.10 Remedial Actions: Corrective Action Plans & Implementation	5	2	8	80
Status Reports.	5	3	2	30
51.23(c) Reports, materials and fiscal data provided to the Advisory Council	57	1	1	57
51.25(b)(3) Grievance Procedure	57	1	0.5	28.5
51.43 Written denial of access by P&A system **	.....	.....	.....	.....
Total	57	.....	11.5	195.5

Note: Burden for the annual application [42 CFR 51.5(b–d)] is approved at a standard level per application under OMB control number 0920–0428.

* Responses and burden hours associated with these reports are approved under OMB No. 0930–0169.

** There is no burden estimate associated with this program provision. State P&A systems report that when a facility denies a P&A system access to the facility, a client, or records, the P&A attempts to resolve the dispute through negotiation, conciliation, mediation, and other non-adversarial techniques. Only after exhausting the non-legal remedies provided under state and federal laws will a P&A system file a formal complaint in the appropriate federal district court. See also, the PAIMI Act at 42 U.S.C. 10807(a)—Legal Actions and the PAIMI Final Rule at 42 CFR 51.32—Resolving Disputes.

Written comments and recommendations concerning the proposed information collection should be sent by September 12, 2019 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, OMB. To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: (202) 395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these

documents, call the SAMHSA Reports Clearance Officer on (240) 276–1112.

Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930–0206) and Opioid Treatment Programs (OTPs)—Extension

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA–163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious non-compliance.	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3).	Revocation notification to Accredited OTPs.	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	185	0.3	55.0
Subtotal		54		1,407		394.20

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA–162)	35	1	35	1.17	40.95

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(e)(1)	Application for provisional certification	42	1	42	1	42.00
8.11(e)(2)	Application for extension of provisional certification.	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1,680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	2	5.00	10.00
Subtotal		1,775		24,594		1,868.95
Total		1,829		26,001		2,263.15

Written comments and recommendations concerning the proposed information collection should be sent by September 12, 2019 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1112.

Project: 2020 National Survey on Drug Use and Health, Clinical Validation Study and Redesign Field Test (OMB No. 0930–0110)—Revision to 2019 NSDUH Collection

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

2020 NSDUH Main Study

NSDUH must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data. For the 2020 NSDUH main study the following changes from 2019 are planned: (1) The addition of lifetime and recency questions about vaping anything and vaping nicotine or tobacco; the addition of lifetime and recency questions on synthetic marijuana and synthetic stimulants; (2) the addition of questions in concordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition criteria (*DSM–5*) to measure the occurrence of marijuana withdrawal symptoms, occurrence of prescription tranquilizer misuse withdrawal symptoms and occurrence of craving for all substances; (3) minor revisions to the marijuana marketplace module; and (4) other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

By including these new questions in NSDUH, estimates may be generated on the use of these substances among the general population and allow SAMHSA to provide national-level estimates among adults and adolescents on the