**The Protection and Advocacy Program for Individuals with Mental Illness (PAIMI) Regulations (42 CFR Part 51)**

**SUPPORTING STATEMENT**

**A. JUSTIFICATION**

1. **Circumstances of Information Collection**

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting Office of Management and Budget (OMB) approval for an extension of the information collection requirements associated with the PAIMI Final Rule (42 CFR Part 51). The current approval under OMB Control Number 0930-0172 will expire on August 31, 2019. On July 27, 2015, the Administration on Intellectual and Developmental Disabilities (AIDD) within the Administration for Community Living (ACL) published its final rules for the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 et seq.), commonly known as the DD Act, in the *Federal Register*. The DD Rules (45 CFR Parts 1326, 1327, and 1328) became effective on August 26, 2015. SAMHSA reviewed the DD Rules and determined that no revisions to the PAIMI Rules were needed. This approach is consistent with methods of legal analysis.

The DD Act of 1975 (42 U.S.C. 15001 *et seq*.), established the state protection and advocacy (P&A) systems to protect and advocate the rights of persons with developmental disabilities. In 1986, the Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act (42 U.S.C. 10801 *et seq.)* extended the DD Act’s protections to eligible individuals with significant (severe) mental illnesses (adults) and significant emotional impairments (children/youth) at risk for abuse and neglect while residing in public or private residential care and treatment facilities.

The PAIMI Act was amended in 2000 and a 57th PAIMI Program for the American Indian Consortium was established [42 U.S.C. 10802 (8)]. The PAIMI Act of 2000 states that the term “individual with mental illness” means, except as provided in [section 10804 (d)](http://web2.westlaw.com/find/default.wl?DB=1000546&DocName=42USCAS10804&FindType=L&ReferencePositionType=T&ReferencePosition=SP%3B5ba1000067d06&AP=&fn=_top&rs=WLW6.06&mt=Westlaw&vr=2.0&sv=Split) of this title, an individual…who satisfies the requirements of subparagraph (A) and lives in a community setting, including their own [home [ibid at 42 U.S.C](http://home.). 10802 (4) (B) (ii)]. P&A systems may serve persons living in a community setting, including their own homes (ibid); however, ***they*** ***must give service priority to representing PAIMI-eligible persons with mental illness as defined in subparagraphs (A) and (B) (i) of section 10802 (4) of this title*** [ibid at42 U.S.C. 10804 (d)].

The Children’s Health Act of 2000 (at 42 U.S.C. 290ii) added requirements to protect and promote the rights of residents of general hospitals, nursing, intermediate care or other health care facilities. Entities supported with funds appropriated to any federal department or agency are mandated to be free from physical or mental abuse, corporal punishment or other restraints or involuntary seclusions imposed for purpose of discipline or convenience. Each facility, to which the PAIMI Act applies, is mandated to notify an appropriate agency, determined by the Secretary of the Department of Health and Human Services (HHS), of each death at the facility while a patient is restrained or placed in seclusion.

Under the PAIMI Act, SAMHSA provides formula grants that support 57 governor-designated, AIDD-approved P&A systems located in each of the 50 states, American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, U.S. Virgin Islands, the District of Columbia (Mayor) and the tribal councils for Navajo Nation and Hopi who comprise the American Indian Consortium located in the Four Corners region of the Southwest. At the federal level, AIDD/ACL is the lead agency for the federal protection and advocacy (P&A) programs. Per 42 U.S.C. 290bb-31 (b) (8), the Director of the Center for Mental Health Services (CMHS) is responsible for carrying out the mandates of the PAIMI program.

The PAIMI Act at 42 U.S.C. 10826 (b) requires the Secretary of HHS to promulgate final regulations to carry out the legislation. On October 15, 1997, SAMHSA promulgated the final PAIMI Rules, which implemented authorized activities of state P&A systems that serve individuals with severe mental health disabilities and severe emotional impairments, at risk for abuse, neglect, and rights violations, as defined in the Act.

During the current three year cycle (2016 - 2019), AIDD/ACL finalized the DD Rules, which SAMHSA reviewed and determined that no revisions to the PAIMI Rules were needed. On August 31, 2019, the PAIMI Rules will expire. SAMHSA is requesting that the rules be extended for another three years (2019 - 2022).

OMB approval is requested for the following list of citations related to information collection language (reporting):

**42 CFR 51.5 (b), (c), and (d) - Annual Application**.To receive an annual allotment each state P&A system is required to submit an annual application with specific information. [Note: The PAIMI Program is an OMB-approved user of the Public Health Service (PHS) Grant Application (Form PHS 5161-1) under OMB control number 0920-0428].

**42 CFR 51.8 - Annual Report**. Each state P&A system that receives a formula grant funded under the PAIMI Act is required to submit an *Annual Program* *Performance Report* (PPR) in a format designated by the Secretary of HHS. The PPR includes a section completed by the system’s PAIMI Advisory Council – the *Advisory Council Report* (ACR). [Note: The response burden for the PPR was approved by OMB in 2017 under control number 0930-0169].

**42 CFR 51.10 - Remedial Actions**. Each state P&A system selected for an on-site monitoring visit or desk audit/document review shall provide written responses to any programmatic or fiscal findings and recommendations issued by SAMHSA, the grantor agency. SAMHSA PAIMI Program Officers and Division of Grants Management (DGM) Grants Management Specialists regularly collaborate on P&A system fiscal issues and information provided by the federal P&A system partners (AIDD, the Social Security Administration (SSA), and the Rehabilitation Services Administration (RSA) within the Department of Education). Regular intra-agency and inter-agency communication facilitates assessment of a state P&A system’s compliance with federal programmatic, administrative, operational, and fiscal/grant management requirements and the identification of grantee remedial actions to resolve them. Each state P&A system with compliance issues must develop and submit a written Corrective Action Plan (CAP) and quarterly Implementation Status Reports (ISR) on the progress of its corrective or remedial actions. Each fiscal year (FY), approximately five state P&A systems are monitored by SAMHSA—at least three on-site visits and two desk audits/document reviews.

CAPs and ISRs are used to evaluate and monitor the progress made by PAIMI program grantees following a federal on-site visit or desk audit/review. The monitoring report summarizes SAMHSA’s recommendations and compliance findings of the state P&A system’s PAIMI Program in the following areas: 1) Governance; 2) Advisory council; 3) The administration of legal and advocacy services; and 4) Fiscal/financial management system.

**42 CFR 51.23 (a) (3) Advisory Council Report** **(ACR**): Each state P&A system’s PAIMI Advisory Council (PAC) must submit an annual report to SAMHSA. The ACR is the council’s independent assessment of its P&A system’s PAIMI program activities. The report is submitted with the annual PPR required under 42 CFR 51.8. [Note: The response burden for this report is approved by OMB under control number 0930-0169; expiration date July 31, 2020].

**42 CFR 51.23 (c)** **Materials for Advisory Counci**l:At least annually, each state P&A system shall provide its PAC with reports, materials, and fiscal data to facilitate its review of existing PAIMI program policies, priorities, and performance outcomes. This information shall include its expenditures for the past two FYs; its projected expenses for the next FY; the identification of each expense by budget category, e.g., salary and wages, contract services, administrative expenses, etc.; and the amounts allotted for training of staff, PAC and governing board members (as applicable).

**42 CFR 51.25 (b) (2) Grievance procedure report**s:Each state P&A system is required to provide its governing authority and PAC with an annual report that describes the number of individual (from P&A system clients) and systemic (from any state resident) grievances received, processed, and resolved by the system.

**42 CFR 51.43** **Facility written statement of delay or denia**l:Specifies that any facility that delays or denies a state P&A system access to facilities, programs, residents or records covered by the Act or these regulations must promptly provide a written statement of reasons.

1. **Use of Information**

**Annual Application [42 CFR 51.5 (b-d)]:** Each state P&A system must use the SAMHSA-approved Web-based Block Grant Application System (WebBGAS) to apply for its annual PAIMI program grant allotment. Information in a P&A system’s application is mandated by the PAIMI Act and Rules at 42 U.S.C. 10805 and 42 CFR Part 51, respectively, including, the HHS Code of Regulations, Title 45 CFR Part 75 and the HHS Grants Policy. SAMHSA PAIMI Program Officers (PPO) and Grants Management Specialist (GMS) review each state P&A grant application for programmatic and fiscal compliance. P&A grantees are contacted by their assigned PPO or GMS when additional information or revisions are needed. Each annual application is compared with the grantees PPR and ACR for that same FY. The review ensures that the information provided by each P&A grantee is accurate and fully compliant with the requirements of the PAIMI Act, PAIMI Rules, the PAIMI Program Assurances and the Terms and Conditions of Award.

**Annual Reports [42 U.S.C. 10805 (a) (7), 42 CFR 51.8, and 42 CFR 51.23(a) (3)]:** On January 1, each state P&A system is required to submit an annual PAIMI PPR, including an ACR section prepared by the PAC and signed by the council’s Chairperson [PAIMI Act 42 U.S.C. 10807 (a) (7)]. Each PPR highlights a PAIMI grantee’s activities and accomplishments for the preceding FY. Each year, SAMHSA uses the PPR and ACR information to prepare a summary report, the SAMHSA *PAIMI Program Activities Report* of aggregated data, e.g., the number of clients served, issues resolved, individuals trained/educated, facilities visited, etc. The summary reports shall include specific PPR and ACR information required under the PAIMI Act [at 42 U.S.C. 10824 (1) (A) – (E), (2) (A) – (D), (3) and (4) and (b)]. The SAMHSA annual summary reports are included as an appendix to the Secretary’s biennial report of federal agency disability activities prepared by AIDD/ACL (The DD Act at 42 U.S.C. 15005) and submitted to the President, the Congress and the National Council on Disability (NCD) (ibid). *The Biennial Report to the Congress* is listed under AIDD Publications at https://acl.gov/news-and-events/fact-sheets/publications-and-fact-sheets.

1. **Improved Information Technology**

Efforts to improve information technology and reduce the PAIMI program data collection and reporting burdens for the P&A systems are reviewed in three year cycles when the PPR is due to expire. The current PAIMI PPR, including the ACR was approved in April 2017 and will expire on July 31, 2020 (OMB 0930-0169). Each state P&A system must submit its annual PAIMI program applications, PPR and ACR electronically to SAMHSA through WebBGAS. WebBGAS provides each PAIMI program grantee with access to complete and submit its annual PAIMI application, PPR, ACR, and respond to the PPO’s request for revisions, etc.

1. **Efforts to Identify Duplication**

The PAIMI program is a singular, unduplicated program, and its information is not available or accessible from other sources.

1. **Information Collection Involving Small Businesses**

Small businesses or other small entities are not involved in or impacted by this program.

1. **Consequences if Information is Collected Less Frequently**

The PAIMI Act requires each state P&A system to submit an annual PAIMI PPR, including a section prepared by the PAC [42 U.S.C. 10805(7)]. SAMHSA aggregates the data from each PPR and summarizes the information. SAMHSA submits a biennial PAIMI activity summary report to AIDD/ACL. SAMHSA’s report is included in the appendices to AIDD’s biennial report on disability activities to the President, the Congress, and the NCD (PAIMI Act at 42 U.S.C. 10824 and the DD Act at 42 U.S.C. 15005). To collect PPR data less frequently violates the statutory requirement that each state P&A system submit a report to the Secretary on January 1 of each year [42 U.S.C. 10805 (7)]. Late PPR submissions result in untimely, inaccurate, and incomplete information on P&A system activities (e.g., GPRA data, SAMHSA’s biennial report for the Secretary, etc.). The CAP and ISR enable SAMHSA program-, grants management-, and financial resource officials to monitor and evaluate the effectiveness of a state P&A system’s activities initiated after a PAIMI Program monitoring visit.

1. **Consistency with the Guidelines**

The data collection complies with 5 CFR 1320.5(d) (2).

1. **Consultation Outside the Agency**

As required by 5 CFR 1320.8(d), the 60-Day Notice was published in the *Federal Register* on June 11, 2019 (84 FR 27146). One comment was received (see Attachment A). See Attachment B for the Program’s response.

To keep abreast of state P&A system trends, issues and activities, SAMHSA currently partners with other federal P&A agencies, which are AIDD/ACL (the lead), SSA, and RSA within the Department of Education. These federal partners meet at least once a month (in person at AIDD or via teleconference) to discuss, coordinate and collaborate on P&A system issues. AIDD, SAMHSA, and RSA fund the annual training and technical assistance (T/TA) contract for their respective P&A program grantees through separate annual inter-agency agreements (IAAs) with AIDD. AIDD administers the T/TA contract.

Key consultants on reporting issueswere:

Federal P&A System Program Officials

Steven Dettwyler Public Health Analyst, SAMHSA/CMHS (240) 276-0311

Jeffrey Hunter Auditor, SAMHSA/OFR/OFAS (240) 276-1008

Wendy Pang Grants Management Specialist (GMS) (240) 276-1419

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 AIDD/ACL

Wilma Roberts Program Specialist, AIDD/ACL (202) 795-7449

Non-Federal Organizations

On September 2015, a five year sole-source P&A system T/TA contract was awarded by AIDD to the Technical Assistance and Support Center/National Disability Rights Network. AIDD administers the contract, which is funded by an annual IAA. The IAA is funded by AIDD, SAMHSA, and RSA. The PAIMI Act (at 42 U.S.C. 10825 Technical assistance) states: “the Secretary shall use not more than two percent of the amounts appropriated under section 10827 of this title (ibid, Authorization of appropriations) to provide technical assistance to eligible systems…”

SAMHSA’s current annual PAIMI PPR and ACR (OMB Approval 0930-0169) expires on July 31, 2020. SAMHSA will publish 60- and 30-day *Federal Register* Notices for public comments on proposed revisions to the PAIMI PPR and ACR reporting requirements.

1. **Payments to Respondents**

Other than the annual formula grants awarded by SAMHSA to each state P&A system for activities mandated under the PAIMI Act, no additional payments or gifts are made.

1. **Assurance of Confidentiality**

The PAIMI Act requires state P&A systems to “keep the records private to the extent of the law” [42 U.S.C. at 10806 (a) and the exceptions cited at 10806 (b)]. Each state P&A system must protect all client records and identifying data from loss, damage, tampering, or use by unauthorized individuals. P&A system compliance with the privacy provisions of PAIMI Rules (42 CFR 51.45 and 51.46) is evaluated by SAMHSA during the annual PAIMI program monitoring visits or desk audits/reviews of selected P&A systems.

The information collection and report requirements cited in the Final Rule are composed of “aggregated summary” statistical data and no personal identifiers.

1. **Questions of a Sensitive Nature**

There are no questions of a sensitive, individual nature included in this report.

**12. Estimate of Annual Hour Burden**

The estimated annual burden under the PAIMI Final Rule is summarized below:

| 42 CFR Citation | Number of Respondents | Responses per Respondent | Burden/ Response (Hrs.) | Total Hour Burden  | Hourly Wage Cost ($) | Total Hour Cost ($) |
| --- | --- | --- | --- | --- | --- | --- |
| 51.8(a)(2) Program Performance Report(1)51.8(8)(a)(8) Advisory Council Report(\*) | -- | -- | -- | -- | -- | -- |
| 51.10 Remedial Actions: Corrective Action Plans &Implementation Status Reports | 55 | 23 | 82 | 8030 | $100$100 | $ 8,000$ 3,000 |
| 51.23(c) Reports, materials and fiscal data provided to the Advisory Council | 57 | 1 | 1 | 57 | $100 | $ 5,700 |
| 51.25(b)(3) Grievance Procedure | 57 | 1 | 0.5 | 28.5 | $100 | $ 2,580 |
| 51.43 Written denial of access by P&A system(\*\*) |  | - | - | - | - | - |
| **Total**  | **57** | - | **11.5** | **195.5** | - | **$19,280** |

**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.

**13. Estimated Annual Cost to Respondents**

There are no capital, start-up, operations, maintenance, or purchase of services costs that exceed standard business expenses associated with these regulations.

**14. Estimated Annual Cost Burden to the Government**

It is estimated that PPOs need 285 hours (five hours per review x 57 grantees) to complete the first-level review of the 57 PAIMI grantee PPRs (including the advisory council’s section) and the application for the same FY, PPO revision information or revision requests, emails to the grantees (follow-up) and to WebBGAS (requesting access to new P&A staff, etc.). The estimated cost for the 12 PPOs (two GS-12, seven GS-13, and three GS-14) to complete the first-level review of the annual PAIMI Program applications and PPRs is $17,214.00 (based on the average GS-13/step 10 hourly rate of $60.40 (per OPM Salary table 2018-DCB) x 285 hours to review 114 documents.

Salary for the second-level review conducted by the PAIMI Team Lead/Program Coordinator (GS-14/Step 5) is estimated as follows: $7,094 (57 grantees x 2 hours (one-hour for each application and PPR/ACR) x $62.23 and $7,094.22 for the third-level review by the two Branch Chiefs (one-hour at 30 minutes per report) x 114 (57 applications and PPRs) x $62.23) to review the annual applications and PPR/ACR. The total costs associated with the PPR and application reviews for the PAIMI PPOs, Team Lead and the two Branch Chiefs is estimated at $31,402.

PAIMI Program Monitors (PPM) prepare each CAP and the PPO assigned to that state is responsible for reviewing each ISR. The costs for these tasks are estimated at two PPM x five CAPs x eight hours at $60.40 per CAP = $4,832.00. The PPO, whose state was monitored, is responsible for reviewing the ISR submitted in response to the CAP. The estimated costs for the PPO reviews are five CAPS x three ISRs per CAP x four hours per ISR x $60.40 an hour = $3,624. The estimated costs for the CAP/ISR review by the Branch Chiefs is estimated as follows: 20 reports (five CAP and 15 ISR) x $62.23 (hourly rate for GS-14/Step 5) x 2-hours per report) are $2,489.20.

The annualized cost to the government is $59,561.

**15. Changes in Burden**

There is no burden change.

**16. Time Schedule, Publication, and Analysis Plan**

Each state P&A system has 90-days, from October 1, the start of the new FY, until December 31 to prepare its annual PAIMI PPR, including the advisory council’s section [PAIMI Rule 42 U.S.C. 10805 (a) (7)].

The PPR must be submitted to SAMHSA through WebBGAS by January 1. WebBGAS captures all grantee activities in real time (e.g., date application and PPR started, percentage of progress, completion, and submission dates, etc.). PPOs send e-mails through WebBGAS to request revisions, clarifications, and/or additional information.

The DD Act of 2000 requires the Secretary to submit a biennial report on federal disability program activities to the President, Congress, and NCD. SAMHSA prepares and submits its section of that report to AIDD, which is included in the appendices to the Secretary’s biennial report. AIDD makes the report available to the public when the Secretary’s final report is released.to the President, Congress, and NCD.

**Time Table for Report Activities**

Tasks Target Completion Date

Preparation of PPRs by respondents October 1 - December 31

Respondents submit annual PPR to SAMHSA January 1

1-level PPR/ACR review by PPOs. March 1

2-and 3-level PPR/ACR reviews by Team Lead April 30

and Branch Chief

Prepare the Secretary’s biennial June 30

report on PAIMI Program activities

SAMHSA approves and submits the PAIMI September 30 (alternate

activities report to AIDD/ACL for inclusion years).

in the Secretary’s biennial report to the President.

**Corrective Action Plan (CAP) and Implementation Status Reports (ISR)**

The final findings, recommendation reports, and if applicable, the CAP for the state P&A systems selected for annual on-site monitoring visits and desk audits/reviews must be completed with 180-calendar days. The 180-days includes preparation of the draft report, supervisory review of report, P&A report review for factual corrections, and issuance of the final report to the P&A. If a CAP is required, the P&A has 60-calendar days to submit its plan. The PPO has 30-calendar days to review, approve, or disapprove the CAP. If disapproved, the P&A must submit a revised CAP within 30-calendar days. Once the CAP is approved, the P&A must submit its first ISR within 120-calendar days. Subsequent ISRs must be submitted every quarter until all CAP issues are resolved to the satisfaction of the PPO.

**Time Table for PAIMI CAP and ISR Activities**

Tasks Target Completion Date

PPM prepares the 60-calendar days

monitoring visit/desk audit report & CAP.

The Branch Chief (BC) reviews the PPM’s draft 30-calendar days of receipt

report and CAP.

P&A sent draft monitoring report for factual 30-calendar days after BC review. review.

The P&A responds to its draft report. 30-calendar days.

PPM/BC responds and issues final monitoring 30-calendar days.

report.

When required, the P&A submits its CAP. 60-calendar days from receipt

 of the final report and CAP.

PPO & PPM review, approve, or disapprove 30-calendar days.

the CAP

P&A ISR due each quarter. 1st ISR due 120-days after the CAP is approved. An ISP is due every 120-calendar days until all programmatic issues are resolved.

**17. Display of Expiration Date**

This item is not applicable to the Final Rule.

The Annual PPR, which includes the ACR section, displays the OMB approval number, and expiration date on the cover page in the upper right-hand corner (OMB 0930-

0169 that will expire on July 31, 2020).

**18. Exceptions to Certification Statement**

This collection of information involves no exceptions to the Certification for

Paperwork Reduction Act submissions.

**B. STATISTICAL METHODS**

This regulation does not involve the use of statistical methods.

**LIST OF ATTACHMENTS**

1. Comment
2. Response