

Generic Supporting Statement
Generic Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions
(CMS-10398, OMB 0938-1148)

Generic Information Collection # 57 (Revision)
Medicaid Section 1115 Substance Use Disorder (SUD) Demonstration:
Monitoring Reports Documents and Templates

Center for Medicaid and CHIP Services (CMCS)
Centers for Medicare & Medicaid Services (CMS)

A. Background

The Centers for Medicare & Medicaid Services (CMS) work in partnership with states to implement Medicaid and the Children’s Health Insurance Program (CHIP). Together these programs provide health coverage to millions of Americans. Medicaid and CHIP are based in Federal statute, associated regulations and policy guidance, and the approved state plan documents that serve as a contract between CMS and states about how Medicaid and CHIP will be operated in that state. CMS works collaboratively with states in the ongoing management of programs and policies, and CMS continues to develop implementing guidance and templates for states to use to elect new options available because of the Affordable Care Act or to comply with new statutory provisions. CMS also continues to work with states through other methods to further the goals of health reform, including program waivers and demonstrations, and other technical assistance initiatives.

Under section 1115(a) of the Social Security Act, the Secretary of Health and Human Services (“Secretary”) may authorize a state to conduct experimental, pilot, or demonstration projects that, in the judgment of the Secretary, promote the objectives of title XIX of the Act. The Secretary (1) may, under section 1115(a)(1), waive provisions in section 1902 of the Act; and/or (2) may, under section 1115(a)(2)(A), authorize federal matching funds for state expenditures that would not otherwise be matchable (i.e., expenditure authority) under section 1903 of the Act. Section 1902 of the Act lists what elements the Medicaid state plan must include, such as provisions relating to eligibility, beneficiary protections, benefits and services and cost sharing. Section 1903, “Payments to States,” describes expenditures that may be “matched” with federal title XIX dollars, allowable sources of non-federal share, and managed care requirements.

On November 1, 2017, CMS released a letter #17-003 to all state Medicaid Directors announcing new directions on how CMS would like to work with states on section 1115(a) demonstrations to improve access to and quality of treatment for Medicaid beneficiaries as part of a Department-wide effort to combat the ongoing opioid crisis. The letter also announced that CMS is now offering a more flexible, streamlined approach to accelerate states’ ability to respond to the national opioid crisis while enhancing states’ monitoring and reporting of the impact of any changes implemented through these demonstrations.

Medicaid Section 1115 demonstration monitoring and evaluation Special Terms and Conditions (STC), and the letter #17-003, make clear that CMS remains committed to ensuring state accountability for the health and well-being of Medicaid enrollees and that monitoring and evaluation are important for understanding the outcomes and impacts of approaches to Medicaid SUD demonstrations. For this purpose, CMS is undertaking efforts to help states monitor the elements of these demonstrations, while giving them the flexibility to adapt to changing conditions in their states. States with approved SUD demonstrations are required to develop implementation and monitoring plans, including monitoring metrics, a monitoring protocol, and regular monitoring reports describing their implementation progress.

In addition, the STCs for these section 1115 demonstrations address that states are required to submit in their regular monitoring reports, information on milestones and performance measures that they elected to represent key indicators of progress toward meeting the goals for the demonstrations.

Furthermore, to improve the quality and efficiency of the reporting requirements for SUD demonstrations, CMS in conjunction with state advisory groups developed a set of standardized monitoring tools for states to use for their regular reporting, including:

- The Medicaid section 1115 SUD demonstration monitoring protocol template (this is one-time submission)¹;
- The Medicaid section 1115 SUD demonstration monitoring protocol workbook (this is a one-time submission)¹;
- The Medicaid section 1115 SUD demonstration monitoring report template, and;
- The Medicaid Section 1115 SUD demonstration monitoring report workbook.

As specified in official 1115 policy communications to states:

In accordance with 42 CFR 431.428 states must submit all post-approval deliverables as stipulated by CMS and within the timeframes outlined within the STCs for the specific Medicaid 1115 State Demonstration.

The State Medicaid Director Letter, #17-003, entitled, *Strategies Addressing the Opioid Epidemic*, provides a framework for SUD demonstrations under Medicaid Section 1115 Authority. This letter indicates that a state's application should confirm its commitment to assuring the necessary resources to support robust monitoring protocol and evaluation, and that the state will provide an implementation plan subject to CMS approval. The letter further states that information about the specific measures and reporting will be detailed in a monitoring protocol agreed upon by CMS and the state after approval of the demonstration which will demonstrate progress toward meeting the goals for this demonstration initiative.

In addition, the STCs for the Medicaid section 1115 SUD demonstrations require that approved states submit an SUD implementation plan subject to CMS approval, and an SUD monitoring protocol to be developed in cooperation with CMS and which is subject to CMS approval. The SUD monitoring protocol, reporting templates, and associated monitoring metrics flow down from the OMB-approved SUD implementation plan, which aligns with the goals and objectives of the demonstration as expressed in SMDL #17-003.

The STCs also require approved states to submit three quarterly and one annual monitoring reports consistent with the elements provided in 42 CFR 431.428 and in accordance with a framework to be provided by CMS. The STCs also provide that the monitoring framework be subject to change as monitoring systems are developed and evolve, and that states are required to report in a structured manner that supports federal tracking and analysis.

The SUD implementation plan template is currently approved by OMB under CMS-10398

¹ The SUD demonstration monitoring protocol template and SUD demonstration monitoring protocol workbook are each submitted once per demonstration approval period. Should the state be approved for a SUD demonstration extension it will need to submit an updated monitoring protocol workbook and monitoring protocol template.

#53 (also, OMB 0938-1148).

In this 2022 information collection request, we have revised the following monitoring tools:

- Monitoring protocol tools:
 - Monitoring protocol workbook (updated to Version 6.0)
 - Monitoring protocol template (updated to Version 4.0)
- Monitoring report tools:
 - Monitoring report template (updated to Version 4.0)
 - Monitoring report workbook (updated to Version 6.0)

This 2022 release incorporates updated guidance on reporting metrics, narrative information, and other clarifications. This release also reflects modifications to align with the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics Manual Version 4.0 (released September 2021).

In addition, this release incorporates updated functionality in the Performance Metrics Database & Analytics (PMDA) system aimed to automate aspects of reporting and customize tools to ease state burden. Updated functionality includes:

- Auto-population of certain fields within the monitoring report tools in alignment with the state's CMS-approved monitoring protocol.
- Reporting flagged items early in the process to reduce resubmission and allow CMS to engage with the state faster and on a more detailed level.
- Ensuring the latest version of the monitoring tools are utilized by sending an e-mail notification to all designated demonstration contacts when customized monitoring report tools are available.

A summary of changes to each tool is provided below under *Information Collection Instruments and Instruction/Guidance Documents*. An exhaustive list of changes can be found in the respective "Crosswalk" documents.

B. Description of Information Collection

States will download the latest version of the tools from PMDA for which certain data fields within the tools are auto-populated (as noted in Section A above). States will manually populate the remaining necessary data fields in the tools and upload the completed tools to PMDA. Upon upload, PMDA will display immediate feedback on flagged items allowing states the option to act on the flagged items prior to submitting to CMS. By incorporating the SUD monitoring tools into the PMDA workflow, submissions are parsed and validated, notifying the state of any upfront potential problems with their submissions, reducing downstream communication, and subsequent needs for clarification or modifications to the templates and metrics. PMDA will historically retain all monitoring data and related documents, reducing the number of duplicate

records required and the need for respondents to retain records.

Per each demonstration's STCs, states are required to submit to CMS three quarterly monitoring reports within 60-days of the end of each quarter, as well as an annual report within 90-days of a demonstration year's completion.

To support more efficient, timely and accurate review of states' SUD 1115 demonstrations monitoring reports submissions, CMS has standardized the reporting methodology and together with automation of the reporting submission will support:

- Insight into an approved state's approach to implementation of the SUD requirements included in the Letter #17-003, which crosswalks to SUD requirements in the monitoring metrics and reports, providing a clear basis for assessing the state's implementation of such requirements.
- Consistency of monitoring and evaluation of requirements and other policy approaches that complement SUD requirements.
- Streamlined communication and shorter timeframes for state development and CMS approval of monitoring plans for SUD demonstrations.
- Reduction in timeframes for state reporting and CMS review of monitoring metrics and reports.
- Accuracy in state reporting
- Reduction in timeframes for state reporting and CMS review of monitoring metrics and reports.
- More robust evaluation in so much as it is informed by clear monitoring data.
- Improvements in needed mid-course corrections and the identification and diffusion of best practices under SUD demonstrations.

To achieve these goals, CMS has developed for the Medicaid Section 1115 SUD Demonstrations standardized monitoring reporting templates and performance metrics, as follows:

Medicaid Section 1115 SUD Demonstration Monitoring Protocol Template

The state will use the Medicaid section 1115 SUD monitoring protocol template to develop the monitoring protocol for its SUD demonstration. This protocol describes the state's monitoring plans for the SUD demonstration for submission to CMS as described in the Special Terms and Conditions (STC). It is composed of two components – qualitative and quantitative (metrics) reporting plans. The metrics component of the monitoring protocol is described below under monitoring protocol workbook. The state should use the monitoring protocol template to document its plans to report on demonstration implementation and budget neutrality, as well as any necessary plans for retrospective reporting.

Medicaid Section 1115 SUD Demonstration Monitoring Report Template

The monitoring report template aligns with the monitoring protocol and the state's implementation plan and allows the state to enter narrative information regarding demonstration

progress that the state reports to CMS on a quarterly and annual basis for its SUD demonstration. Performance values on the metrics in the approved monitoring protocol are reported in the monitoring report workbook described below.

Medicaid Section 1115 SUD Demonstration Monitoring Protocol Workbook

The monitoring protocol workbook is an Excel file that contains a set of SUD metrics, which align with the milestones in SMDL #17-003. The monitoring protocol workbook helps the state specify the methods of data collection and timeframes for reporting on the state's progress on required measures and milestones. The state will review the metrics listed in the workbook and the accompanying metrics technical specifications and use the template to identify the metrics it plans to report, including any additional state-specific metrics. The state also identifies annual goals and targets, as well as any deviations from CMS technical specifications. In addition, the monitoring protocol workbook helps states identify the demonstration baseline and performance targets to be achieved by the end of the demonstration. Finally, the monitoring protocol workbook allows the state to document its plans for reporting subpopulations (using the "SUD planned subpops" tab) and outline its anticipated schedule for submitting reports (using the "SUD reporting schedule" tab).

Medicaid Section 1115 SUD Demonstration Monitoring Report Workbook

The monitoring report workbook is an Excel file that contains a set of metrics for the state's SUD demonstration. For the monitoring report, states will report performance on the CMS-approved metrics on a quarterly or annual basis.

C. Deviations from Generic Request

No deviations from the generic PRA request.

D. Burden Hour Deduction

High-level Assumptions

- Each state submits three quarterly and one annual report per year. Annual reports require somewhat higher level of effort than quarterly reports due to additional metrics reported.
- Each state's first report will require some additional effort for programming/calculating the metrics; all subsequent reports will require a lower level of effort.
- Estimates are provided by average state burden each year; CMS generally approves demonstrations for a 5-year period.
- All templates are completed by a health services manager and/or a computer programmer.

Wage Estimates

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates

(http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer programmer	15-1251	45.98	45.98	91.96
Health services manager	11-9111	57.12	57.12	114.24

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Collection of Information Requirements and Associated Burden Estimates

We estimate approximately thirty-five (35) states with an approved Medicaid section 1115 SUD demonstration.

1. Medicaid Section 1115 SUD Demonstration Monitoring Protocol (Revised)

Monitoring protocol consists of a one-time submission for year one of the demonstration.¹ This estimate includes the labor involved in completing both the protocol template and the protocol workbook, and time-savings provided by the automations in the PMDA system. The protocol would be developed by a health services manager and a computer programmer.

We estimate it would take 18.5 hours (per state) consisting of 8 hours at \$91.96/hr for a computer programmer to review technical specifications and 10.5 hours at \$114.24/hr for a health services manager to: complete monitoring protocol workbook (3.75 hr), complete the monitoring protocol template by reviewing the monitoring report template and budget neutrality materials for attestations (2.75 hr), and QA the monitoring protocol (4 hr). To date, 23 of the 32 currently approved states have met this requirement. Therefore, this estimate is based on 9 states needing to complete the requirement.

In aggregate, we estimate a one-time burden of 167 hours (9 states x 18.5 hr) at a cost of \$17,417 (9 x ([8 hr x \$91.96/hr] + [10.5 hr x \$114.24/hr])).

This is a change of minus 1.5 hours per response (20 currently approved hr – 18.5 proposed hr). Overall, this represents a change of minus 533 total hours (from 700 currently approved hours to 167 proposed hours).

2. Medicaid Section 1115 SUD Demonstration Monitoring Report Template (Revised)

We aimed to streamline reporting by allowing states to check a box if it has no updates/changes to report for a particular item. We assumed that for approximately 1/4 of the prompts included in the reports, the average state would elect not to report updates. In addition, states will not need to provide basic information about their demonstrations as this will be populated by PMDA.

For the annual report, we estimate it would take 9.75 hours at \$114.24/hr for a health services manager to prepare and submit the report per state per demonstration year. This is a change of minus 2.25 hours per response (12 currently approved hr – 9.75 proposed hr). The change is due to the user-friendly modifications made to the monitoring template which help streamline the submission. In aggregate, we estimate an annual burden of 341 hours (1 report x 9.75 hr x 35 states) at a cost of \$38,956 (341 hr x \$114.24/hr) per year. Overall, this represents a change of minus 79 total hours (from 420 currently approved hours to 341 proposed hours).

For each quarterly report, we estimate it would take 6.75 hours at \$114.24/hr for a health services manager to prepare and submit each report per state per demonstration year. In aggregate, we estimate a quarterly report burden of 709 hours (3 reports x 6.75 hr x 35 states) at a cost of \$80,997 (709 hr x \$114.24/hr) per year. This is a change of minus 1.25 hours per response (8 currently approved hr – 6.75 proposed hr). Overall, this represents a change of minus 131 total hours (from 840 currently approved hours to 709 proposed hours).

Consequently, we estimate a total annual burden of 1,050 hours (341 hr + 709 hr) at a cost of \$119,953 (\$38,956 + \$80,997).

3. Medicaid Section 1115 SUD Demonstration Monitoring Report Workbook (Revised)

We assume a computer programmer will calculate the required metrics and populate the monitoring report workbook. Groups of closely related metrics will be calculated simultaneously, rather than sequentially. Initial calculations require an upfront investment, but recalculations for subsequent reports will require significantly less time. In addition, PMDA will automatically populate the template for each quarterly and annual monitoring report with certain state-specific information pulled from the state's approved monitoring protocol. In the past, the state would have to enter this information for every monitoring report.

- Low LOE metrics (for 15 metrics total: 4 annual metrics, 8 quarterly metrics, and 3 health IT metrics):
 - 24 hours for initial report per state for the *1st year of the demonstration only* (assume it is annual and includes all required metrics)
 - 7.75 hours for each *subsequent annual report* per state. This is a change of minus 0.25 hours (from 8 hr/response) as currently approved by OMB. This change is due to the user-friendly modifications made to the monitoring workbook which help streamline the submission.
 - 7.75 hours for each *subsequent quarterly report* per state. This is a change of minus 0.25 hours (from 8 hr/response) as currently approved by OMB. This change is due to the user-friendly modifications made to the monitoring workbook which help streamline the submission.
- Medium LOE metrics (6 metrics total: 4 annual metrics, 2 quarterly metrics):

- 48 hours for initial report per state for the *1st year of the demonstration only* (assume it is annual and includes all required metrics)
- 20 hours for each *subsequent annual report* per state
- 4 hours for each *subsequent quarterly report*
- High LOE metrics (5 annual metrics):
 - 56 hours for initial report per state *1st year of the demonstration only* (assume it is annual and includes all required metrics)
 - 4 hours for each *subsequent annual report* per state
 - 0 hours for each *subsequent quarterly report* per state (no quarterly high-LOE metrics) This is a change of minus 4 hours as currently approved by OMB.
- Metric Summary
 - Initial Report: 1,152 hours (9 states x [24 hr Low + 48 hr Medium + 56 hr Low]) at a cost of \$105,938 (1,152 hr x \$91.96/hr) for a computer programmer.
 - Subsequent Annual Report: 1,111 hours (35 states x [7.75 hr Low + 20 hr Medium + 4 hr Low]) at a cost of \$102,167 (1,111 hr x \$91.96/hr) for a computer programmer.
 - Subsequent Quarterly Report: 2,914 hours ([35 states x 3 reports] x [7.75 hr Low + 20 hr Medium + 0 hr Low]) at a cost of \$267,971 (2,914 hr x \$91.96/hr) for a computer programmer.
 - TOTAL: 5,177 hours (1,152 hr + 1,111 hr + 2,914 hr) at a cost of \$476,076 (\$105,938 + \$102,167 + \$267,971).

Overall, this represents a change of minus 2,943 total hours (from 8,120 currently approved hours to 5,177 proposed hours).

3. PMDA and Instruction Videos (Revised)

We expect states to submit via PMDA their respective Medicaid Section 1115 SUD monitoring protocol and quarterly and annual reports (here forward referred to as “monitoring documents”). The 4th quarter report may be included in the annual report. We expect to maintain the same number of reports. No statistical methods are employed in information collection and in addition, the quarterly and annual reporting data fields are not duplicating any other collections.

We expect the time for each state to complete the submission of the Medicaid Section 1115 SUD monitoring documents via PMDA to be the same or similar to the time it takes today for states to submit other deliverables and each state may approximately spend 3 to 5 minutes per submission.

Each state/territory with an approved Medicaid Section 1115 SUD demonstration will be required to complete and submit via PMDA the monitoring documents established by CMS, aimed to support more efficient, timely and accurate review of states’ Medicaid Section 1115 SUD demonstrations monitoring document submissions. The burden is associated with submitting the Medicaid Section 1115 SUD monitoring report protocol/templates/ metrics provided to states/territories by CMS to assist in this effort, as well as the burden related to states viewing as necessary any instructions.

We estimate approximately thirty-five (35) states with an approved Medicaid Section 1115 SUD demonstration. As mentioned above, each demonstration is estimated to need approximately 3 to 5 minutes quarterly/annually at \$114.24/hr for a Health Services Manager to submit via PMDA the necessary Medicaid Section 1115 SUD monitoring documents. The burden is subsumed within the preceding estimates along with the time (30 min) to review the “instructions” and watch the respective video.

Summary of Collection of Information Requirements and Burden Estimates

Burden Summary

Requirement	No. Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost (\$/hr)	Total Annual Cost (\$)
Monitoring Protocol	35	9	18.5	167	Varies	17,417
Monitoring Report Template (Annual)	35	35	9.75	341	114.24	38,956
Monitoring Report Template (Quarterly)	35	105	6.75	709	114.24	80,997
Monitoring Report Workbook	35	447	Varies	5,177	91.96	476,076
TOTAL	35	596	Varies	6,394	Varies	613,446

Burden Reconciliation

Requirement	Respondents	Total Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost (\$/hr)	Total Annual Cost (\$)
Currently Approved by OMB	35	455	Varies	10,080	Varies	840,286
Proposed	35	596	Varies	6,394	Varies	613,446
CHANGE	no change	+ 141	Varies	- 3,686	Varies	- 226,840

Given that this February 2022 collection of information request proposes to reduce our active total time estimate by minus 3,686 hours, we are adding 5 hours of burden to account for the limitations of ROCIS which does not allow the submission of negative burden for the collection’s GenICs . We will address this limitation when the umbrella package is submitted for renewal. The current expiration date is April 30, 2024.

Information Collection Instruments and Instruction/Guidance Documents

- (1) Video: [Overview of the Standardized Monitoring Report Process](#) (8:59 minutes)
(Deleted)

The video is being deleted because it describes an out-dated process that CMS does not use anymore. The process is significantly different and will warrant a new video (rather than updates) if CMS determines a video will be helpful.

- (2) Video: [Populating and Submitting Monitoring Templates](#) (8:24 minutes)
(Deleted)

This video is being deleted because it describes how to populate and submit an old version of the monitoring templates. The submission process is significantly different and will warrant a new video (rather than updates) if CMS determines a video will be helpful.

- (3) Video: [Uploading and Submitting Monitoring Protocol Templates](#) (2:47 minutes)
(Deleted)

This video is being deleted because it describes an out-dated process for how to upload a Monitoring Protocol. The process is significantly different and will warrant a new video (rather than updates) if CMS determines a video will be helpful.

- (4) Video: [Uploading and Submitting Monitoring Report Templates](#) (3:11 minutes) (Deleted)

This video is being deleted because it describes an out-dated process for how to upload a Monitoring Report. The process is significantly different and will warrant a new video (rather than updates) if CMS determines a video will be helpful.

- (5) Video: [Downloading 1115 Demonstration Monitoring Report Templates](#) (3:00 minutes)
(Nonsubstantive Changes)

The changes describe the new location where states can find a monitoring report template specifically for their demonstration and state.

- (6) Medicaid Section 1115 SUD Demonstration Monitoring Protocol Workbook (Version 6.0) (Revised)

Summary of Changes (see the attached Crosswalk for more detailed information)

- Deleted the “SUD version notes” tab
- Added PMDA functionality to the workbook to automatically populate header rows
- Minor formatting changes, such as clarifying column, row, and tab names, adding/removing rows and columns, adding footnotes, and adding standard drop-down options for a number of columns

- (7) Medicaid Section 1115 SUD Demonstration Monitoring Report Workbook (Version 6.0)

(Revised)

Summary of Changes (see the attached Crosswalk for more detailed information)

- Deleted the “SUD version notes” tab
- Added PMDA functionality to the workbook to automatically populate some rows in the header (*State* and *Demonstration name*) for “SUD metrics” and “SUD reporting issues” tabs
- Minor formatting changes, such as clarifying column, row, and tab names, adding/removing rows and columns, adding footnotes, and adding standard drop-down options for a number of columns

(8) Medicaid Section 1115 SUD Monitoring Protocol Template (Version 4.0) (Revised)

Summary of Changes (see the attached Crosswalk for more detailed information)

- Included additional information on the definition of a state’s SUD demonstration implementation date
- Added PMDA functionality to the template to automatically populate some of the header information and title page rows
- Included additional information on the state’s reporting requirements for retrospective reporting in Section 4 (“Retrospective reporting”)

(9) Medicaid Section 1115 SUD Monitoring Report Template (Version 4.0) (Revised)

Summary of Changes (see the attached Crosswalk for more detailed information)

- Included a PRA placeholder cover page
- Added PMDA functionality to the template to automatically populate some of the header information and title page rows
- Included additional information on the definition of a state’s SUD demonstration implementation date
- Included additional row for the state to provide beneficiary satisfaction survey, as well as grievances and appeals updates

(10) Medicaid Section 1115 SUD Monitoring Protocol Instructions
(Revised)

The changes include revisions to information about how the monitoring protocol interacts with the PMDA system, such as which features will auto-populate.

(11) Medicaid Section 1115 SUD Monitoring Report Instructions
(Revised)

The changes include revisions to information about how the monitoring report interacts with the PMDA system, such as errors that are automatically identified through the submission process.

(12) November 1, 2017 – State Medicaid Directors letter #17-003
(No Changes)

E. Timeline

The 14-day notice published in the Federal Register on February 24, 2022 (87 FR 10367). Comments are due on/by March 10, 2022.