

Generic Supporting Statement (May 2019)

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

Generic Information Collection # 57 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.

In addition, the special terms and conditions (STC) for these 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 1115 SUD monitoring protocol (this one-time submission);
- The 1115 SUD monitoring report template, and;
- The 1115 SUD metrics template 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*, which provides a framework for SUD demonstrations under Medicaid Section 1115 Authority, provides 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 is being finalized by CMS with state input and 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 Special Terms and Conditions (STCs) for the Medicaid 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 and reporting templates, as well as the metrics flow down from OMB approved SUD implementation plan, which aligns with the goals and objectives of the demonstration as expressed in the 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.

While the SUD implementation plan template is already approved under this generic package, SUD Gen IC (specifically, CMS-10398 #53) this May 2019 iteration adds the following under new GenIC #57:

- The 1115 SUD monitoring protocol (this one-time submission only);
- The 1115 SUD monitoring report template, and;
- The 1115 SUD metrics template workbook.

Concerning these documents, The SUD monitoring protocol and reporting templates, as well as the metrics flow down from the OMB-approved SUD implementation plan that aligns with the goals and objectives of the demonstration as expressed in the SMDL #17-003.

They are also consistent with the requirements of the STCs to which approved states have agreed. In addition, CMS convened a State Advisory Group to review and provide comments on these templates, their content and the metrics, and CMS made adjustments in consideration of those comments.

Further, given the urgent nature of addressing the opioid crisis, and the need for states to set up performance measurement strategies and systems to support those strategies, as states have been developing their SUD applications and monitoring plans they have requested that CMS share the draft documents, and they have welcomed the technical assistance that CMS has made available.

CMS believes that these documents are noncontroversial and does not anticipate any adverse reaction from interested parties.

B. Description of Information Collection

Respondents (State Medicaid Agencies) will manually populate the necessary data fields in the templates and submit to CMS project officer and monitoring lead electronically via the Performance Metrics Database & Analytics (PMDA). By incorporating these SUD 1115 demonstration-monitoring documents into the Medicaid 1115 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.

The PMDA application, which issued for submission, will historically retain all monitoring data and related documents, reducing the number of duplicate records required and the need for respondents to retain records.

The characteristics of the monitoring and evaluation requirements for each Medicaid 1115 State Demonstration project are determined as part of CMS and state negotiations that culminate the demonstration's STCs. These STCs include a section describing the monitoring, evaluation requirements and corrective actions. Together, these STCs describe the process by which states should submit these required reports.

Per each demonstration's STCs, states are required to submit to CMS 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.

Currently, there are inconsistencies in the manner in which states submit their required monitoring reports, in significant part due to minimal standardization of the collection instrument. This causes time-consuming reviews and does not support easy monitoring and assessment across the 1115 demonstration portfolio.

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:

- Consistency of monitoring and evaluation of SUD 1115 Demonstrations,
- A streamlined communication methodology between states and CMS,
- Increase in reporting accuracy,
- Reduced timeframes required for monitoring and evaluation.

To achieve these goals, CMS has developed for SUD 1115 Demonstrations a standardized monitoring reporting template, a monitoring protocol and performance metrics, as follows:

SUD 1115 Demonstration Monitoring Protocol Template

The state should use the SUD 1115 Demonstration Monitoring Protocol template to develop its SUD Monitoring Protocol, which should describe the state's monitoring plans for the SUD demonstration for submission to CMS as described in the Special Terms and Conditions (STC).

The SUD Monitoring Protocol template helps the state specify the methods of data collection and timeframes for reporting on the state's progress on required measures and milestones. In addition, the SUD Monitoring Protocol template helps states identify a baseline, a target to be achieved by the end of the demonstration.

SUD 1115 Demonstration Monitoring Report Template

The monitoring report template provides a framework for the state to use as it collate the quantitative and qualitative information for quarterly and annual monitoring reports.

SUD 1115 Demonstration Monitoring Metrics Template

The monitoring metrics template is an Excel file that contains a set of SUD metrics, which align with the milestones in the State Medicaid Director Letter. The state should review the metrics listed in the Monitoring Protocol tab of the SUD Metrics Workbook and the accompanying metrics technical specifications, and use the template to identify the metrics it plans to report, including any additional state-identified metrics.

C. Deviations from Generic Request

No deviations from the generic PRA request.

D. Burden Hour Deduction

The total approved burden ceiling of the generic ICR is 154,104 hours, and CMS previously requested to use 59,141 hours, leaving our burden ceiling at 94,963 hours.

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 state by year, given that CMS can approve demonstrations for varying lengths of time.
- 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 2018 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 the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer programmer	15-1131	43.07	43.07	86.14
Health services manager	11-9111	54.68	54.68	109.36

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

1. 1115 SUD Monitoring Protocol

Monitoring protocol consists of a one-time submission for year-one of the demonstration. The protocol would be developed by a health services manager and a computer programmer:

We estimate it would take 20 hours (per state) consisting of 8 hours at \$86.14/hr for a computer programmer to review technical specifications and 12 hours at \$109.36/hr for a health services manager to: complete metrics workbook (4 hr), complete the narrative portion by reviewing the monitoring report template and budget neutrality materials for attestations (4 hr), and QA the monitoring protocol (4 hr).

In aggregate, we estimate a burden of 700 hours (35 states x 20 hr) at a cost of \$3,035.12 ([20 hr x \$86.14/hr] + [12 hr x \$109.36/hr]).

2. 1115 SUD Monitoring Report Templates

We aimed to streamline reporting by allowing states to check a box if it has no updates/changes to report. We assumed that for approximately 1/4 of the reports, the average state would elect not to report updates.

For the annual report, we estimate it would take 12 hours at \$109.36/hr for a health services manager to prepare and submit the report per state per demonstration year. In aggregate, we

estimate an annual report burden of 420 hours (1 report x 12 hr x 35 states) at a cost of \$45,931.20 (420 hr x \$109.36/hr).

For each quarterly report, we estimate it would take 8 hours at \$109.36/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 840 hours (3 reports x 8 hr x 35 states) at a cost of \$91,862.40 (840 hr x \$109.36/hr).

Consequently, we estimate a total burden of 1,260 hours (420 hr + 840 hr) at a cost of \$183,724.8 (\$45,931.20 + \$91,862.40).

3. 1115 SUD Monitoring Metrics Template

Outside of the 4 hours burden estimated above for the monitoring protocol portion of the metrics workbook, we assume a computer programmer will calculate the metrics and populate the metrics template. Groups of metrics will be calculated simultaneously, rather than sequentially. Initial calculations require an upfront investment, but recalculations for subsequent reports will require significantly less time.

- 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's annual and includes all metrics)
 - 8 hours for each **subsequent annual report** per state
 - 8 hours for each **subsequent quarterly report** per state
- 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's annual and includes all 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's annual and includes all metrics)
 - 4 hours for each **subsequent annual report** per state
 - 4 hours for each **subsequent quarterly report** per state.

 - 164 hours per state for first demonstration year = ((128 hr per state for initial report including all metrics) + [12 hr per state x 3 subsequent quarterly reports]) at a cost of \$14,126.96 (164 hr x \$86.14/hr)
 - **68 hours** for a computer programmer per state for subsequent years = ((32 hr per state for subsequent annual reports) + [12 hr per state x 3 subsequent quarterly reports]) at a cost of \$5,857.52 (68 hr x \$86.14/hr)

4. PMDA and Instruction Videos

We expect states to submit via PMDA their respective 1115 SUD quarterly and annual reports, and 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 SUD 1115 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 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’ SUD 1115 demonstrations monitoring reports submissions. The burden is associated with submitting the 1115 SUD monitoring report protocol/templates/ and 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 1115 SUD demonstration reporting, however, we anticipate this number to grow in the upcoming years. As mentioned above, each demonstration is estimated to need approximately 3 to 5 minutes quarterly/annually at \$109.36/hr for a Health Services Manager to submit via PMDA the necessary 1115 SUD monitoring reports and metrics. The burden is subsumed within the preceding estimates along with the time (30 min) to review the “instructions” and watch the respective videos.

Summary of Collection of Information Requirements and Burden Estimates

Requirement	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor cost of Reporting (\$/hr)	Total Cost (\$)
Monitoring Protocol	35	35	20	700	Varies	3,035.12
Reporting Template: Annual	35	35	12	420	109.36	45,931.20
Reporting Template: Quarterly	35	105	8	840	109.36	91,862.40
Metrics Workbook: Year 1	35	140	41 (164/4)	5,740	86.14	494,443.60
Metrics Workbook: Subsequent Years	35	140	17 (68/4)	2,380	86.14	205,013.20
TOTAL	35	455	Varies	10,080	Varies	840,285.52

Information Collection Instruments and Instruction/Guidance Documents

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

- (2) Video: [Populating and Submitting Monitoring Templates](#) (8:24 minutes)
- (3) Video: [Downloading 1115 Monitoring Report Templates](#) (2:59 minutes)
- (4) 1115 SUD Monitoring Report Template – *attached*
- (5) 1115 SUD Monitoring Report Protocol – *attached*
- (6) 1115 SUD Metrics Template – *attached*
- (7) 1115 SUD Monitoring Report Template Instructions – *attached*
- (8) 1115 SUD Monitoring Report Protocol Instructions – *attached*
- (9) November 1, 2017 – State Medicaid Directors letter #17-003

E. Timeline

Approval is requested by May 17, 2019, given the urgent nature of addressing the opioid crisis, and the need for states to set up performance measurement strategies and systems to support those strategies.