

# Medicaid Section 1115 Substance Use Disorder (SUD) Demonstrations: Federal Meta-Analysis Support (Revision)

Clearance for Medicaid and CHIP State Plan, Waiver, and  
Program Submissions  
(CMS-10398 # 64, OMB 0938-1148)

## Generic Supporting Statement

Prepared for

Michael Trieger  
Center for Medicaid and CHIP Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-25-26  
Baltimore, MD 21244-1850

Prepared by  
Anupa Bir, ScD, MPH  
Susan Haber, ScD  
Heather Kane, PhD  
Kyle Emery, MS  
Jesse Hinde, PhD  
Madeline Britvec, MS  
Anna Sommers, PhD  
Eric Villeneuve  
Amanda Bingaman  
RTI International  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

## 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 as a result 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.

Starting in 2015, in response to the opioid epidemic, CMS offered states the flexibility to test Medicaid coverage of a full substance use disorder (SUD) treatment service array in the context of overall SUD service delivery transformation through the authority of section 1115 demonstrations, provided states met specific requirements (0938-1148 [CMS-10398 #57])<sup>1</sup>. These specific requirements included: (1) comprehensive evidence-based design, (2) appropriate standards of care (e.g., American Society of Addiction Medicine [ASAM] criteria), (3) strong network development, (4) care coordination, (5) integration of physical and SUD treatment, (6) program integrity safeguards, (7) benefit management, (8) community integration, (9) strategies to address prescription drug misuse and opioid use disorder (OUD), (10) services to youth and adolescents with SUD, (11) reporting of quality metrics, and (12) collaboration with the single state agency for substance abuse. A key component of the section 1115 demonstration is that states could apply to receive federal financial participation (FFP) for the continuum of services to treat addiction to opioids or other substances, including institutions for mental disease (IMDs), which are normally ineligible for FFP if the facility has more than 16 beds.

CMS modified the requirements for SUD section 1115 demonstrations in November 2017 to improve access to clinically appropriate treatment for OUD and other SUDs, to better support the development and expansion of comprehensive treatment strategies, and to incorporate improved progress and outcome monitoring. The modifications added the mandatory provision of medication-assisted treatment (MAT). The modifications also added flexibility to the SUD demonstration requirements, including allowing states to implement an alternative or modified set of patient placement criteria that are widely recognized as representing an expert consensus on appropriate treatment.<sup>2</sup> As of October, 2021, 32 states including the District of Columbia have received approval for SUD section 1115 demonstrations.<sup>3</sup>

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<sup>1</sup> Centers for Medicare & Medicaid Services. (2015, July). SMD # 15-003. Retrieved from <https://www.medicaid.gov/federal-policy-guidance/downloads/smd15003.pdf>

<sup>2</sup> Centers for Medicare & Medicaid Services. (2017, November 1). SMD # 17-003: Strategies to address the opioid epidemic. Retrieved from <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf>

<sup>3</sup> Kaiser Family Foundation. (2021, October) Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers

CMS awarded the Federal Meta-Analysis Support contract to RTI International in September 2018. The goal of the Meta-Analysis Support contract is to understand the overall effectiveness of the groups of demonstrations with similar features and how variations in state demonstration features and the context in which they are implemented contribute to differences in effectiveness. Under this contract, RTI will work with CMS to conduct a meta-analysis of Medicaid section 1115 SUD demonstrations.

The meta-analyses of the SUD demonstration will compare experiences of these demonstrations across states and will document and explore variation in state baseline conditions and demonstration design, approach, and implementation to explain differences in outcomes observed across demonstrations. The meta-analyses of the demonstrations will provide CMS and states with a deeper understanding of what levers affect successful outcomes—both implementation and impacts—as well as whether, under what conditions, and how these initiatives would best be replicated in other states.

Meta-analysis incorporates synthesis of qualitative and quantitative data. To support the meta-analyses, RTI is compiling a cross-state database for each group of demonstrations that includes states' applications, implementation and evaluation plans, monitoring reports, and evaluation plans. We will conduct qualitative analysis of primary and secondary data from demonstration states to document demonstration implementation and contextual features that will be used in quantitative analyses (see Supporting Statement Part B). Qualitative data will also be used for targeted case studies that take a deep dive into demonstration design and implementation topics that will be identified in consultation with CMS. Primary data collection will include virtual interviews with leaders in the state Medicaid Agency and/or the single state agency for substance abuse in the states that have approved section 1115 SUD demonstrations. The June 2020 collection of information request was only for approval of the data collection materials that was used for the first round of interviews in SUD demonstration states. This 2022 revision seeks OMB's approval of the data collection material used for the second round of interviews with SUD Section 1115 Demonstration implementors.

The first round included two sets of interviews—a demonstration characteristics interview and an implementation interview (**Sections B.1 and B.2**). We conducted the demonstration characteristics interview with the state Medicaid director or their designated staff and the implementation interview with both the state Medicaid director and the director of the single state agency for substance abuse, or their designated staff. A protocol was created for each set of interviews.

The demonstration characteristic interviews were no more than 60 minutes in length. Prior to the interview, states were asked to review and update a pre-populated grid with information on the state's SUD program created by RTI based on secondary data sources. These interviews expanded our understanding of SUD coverage policies and treatment services pre- and post-demonstration. Demonstration characteristic interviews started no earlier than three weeks after receiving PRA clearance and CMS approval (subject to states' availability given the COVID-19 pandemic).

The implementation interviews were conducted with the same stakeholders. These interviews built on the information collected during the first set of interviews and included an in-depth discussion of implementation experiences, challenges, and programmatic changes.

Information from these two sets of interviews are being incorporated in Rapid Cycle Reports (RCRs) on the SUD demonstrations that RTI will prepare for CMS. These reports are targeted case studies of selected demonstration design and implementation topics. Qualitative case comparison was used to explore potential causal pathways between demonstration features and demonstration implementation effectiveness and outcomes.

Three initial RCRs use information collected during the demonstration characteristics and implementation interviews with section 1115 SUD demonstration states. One RCR provides an analysis of implementation challenges, describe states' early experiences in implementing their demonstrations, and offer CMS lessons about challenges that could impact demonstration objectives. A second RCR is an analysis of state programmatic changes that are the result of states' varying approaches to meeting demonstration requirements. Information from the implementation interviews with the section 1115 SUD demonstration states is incorporated into a third RCR on medication assisted treatment (MAT). Information from these interviews may also be incorporated later RCRs on the SUD demonstrations. The Summative Evaluation Report for the SUD demonstrations will incorporate data collected from the two sets of interviews in addition to other data analyses. This report will summarize the demonstrations' accomplishments, challenges, lessons learned, findings and conclusions, and recommendations where applicable.

The second round of interviews will include two sets of respondents for SUD demonstrations – managed care organization (MCO) leaders and behavioral health service providers – and each interview will last approximately 60 minutes. These interviews will expand our understanding of SUD implementation experience. MCO and behavioral health provider stakeholder interviews will start approximately 2 weeks after receiving PRA clearance and CMS approval (subject to states' availability).

The use of statistical methods does not apply for purposes of this collection. We will not be using a statistical methodology for stratification and sample selection. Instead, we will collect data from a purposively selected subset of SUD demonstration states.

## **B. Description of Information Collection**

RTI's meta-analysis includes multiple rounds of qualitative data collection. We previously received approval and implemented the first round of interviews. At this time, we are submitting a request for documents related to our second rounds of data collection activities, which are detailed below in section B3.

B.1 SUD Demonstration Characteristics Interviews (Completed)

B.2 SUD Demonstration Implementation Interviews (Completed)

### B3. State-level stakeholder Virtual Interviews (New)

RTI will conduct a second round of qualitative data collection for the SUD demonstration to learn about the perspectives of other types of stakeholders important to implementing the demonstration. RTI will conduct qualitative data collection from stakeholders with differing perspectives, including leadership of behavioral health service providers and leadership of MCOs or third-party administrators in states with fee-for-service SUD treatment services. Interviews will be conducted in 10 selected SUD demonstration states.

CMS will send an introductory email, prepared by RTI, to the Medicaid director in the 10 SUD demonstration states (**Attachment 3.a.**) asking the Medicaid director's help to identify and send an email to selected MCO and behavioral health service provider leaders, providing a warm hand-off. After sending the introductory email, RTI will follow up with an email confirming the Medicaid director is willing to help identify and directly connect RTI with MCO and behavioral health provider stakeholders (**Attachment 3.b.**) with an email template attached (**Attachment 3.c.**) to be used by the Medicaid director to connect RTI with the MCO and behavioral health provider stakeholders. RTI will send a follow-up email, inviting the MCO and behavioral health provider stakeholders to participate in the interview and select a date and time for the interview (**Attachment 3.d.**) After confirming the interview date and time, RTI will send a Microsoft Outlook meeting invitation (**Attachment 3.e.**) scheduling a 60-minute interview with respondents. The email and invitation will include: 1) the agreed upon date and time, 2) Zoom meeting call-in information and instructions on how to join by telephone or computer, and 3) contact information for the project director and interviewer. A confirmation email will be sent to the interviewee 2 days prior to the interview call (**Attachment 3.f.**). RTI will begin the interview (**Attachment 3.g., Attachment 3.h., Attachment 3.i.**) with an introduction informing interviewees of the purpose of the interview, communicate that their participation is voluntary, and request their permission to record the interview solely for note-taking and transcription purposes. The interview introduction will also let interviewees know that RTI will not attribute answers directly to an individual in any reports. RTI will refer to individuals anonymously as "state informants." Information obtained during these interviews will be incorporated in RCRs that will be prepared for CMS and will also provide input for a Summative Evaluation Report. Following the interviews, RTI will send a thank you email (**Attachment 3.j.**) to the participating stakeholders.

Information from MCO and behavioral health provider interviews will be incorporated in Rapid Cycle Reports (RCRs) that RTI will prepare for CMS. The RCR topics will be selected in consultation with CMS and will focus on emerging demonstration design and implementation issues. Report schedules will depend on when data required for the report is expected to be available. RTI and CMS will review the planned report topics periodically during the year in the event different priorities emerge.

### C. Deviations from Generic Request

While the meta-analysis incorporates a synthesis of qualitative and quantitative data, the use of statistical methods does not apply since we will not be using a statistical methodology for stratification and sample selection. Instead, we will collect data from a purposively selected

subset of SUD demonstration states. In this regard we are not requesting OMB’s approval of any statistical deviations from the generic PRA process.

We are, however, surveying MCO/behavioral health provider leaders which is outside the scope (and therefore deviates from) the effort of state governments. We request OMB’s approval of this deviation since the state/non-state surveys are a combined effort that fulfill the same purpose. We believe that separating them into different collections of information processes (generic vs non-generic) or packages (state and non-state) would be impractical and would not serve the public’s interest.

**D. Burden Hour Deduction**

*D.1. 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](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.

<b>Occupation Title</b>	<b>Occupation Code</b>	<b>Mean Hourly Wage</b>	<b>Fringe Benefits and Overhead</b>	<b>Adjusted Hourly Wage</b>
Healthcare Practitioners and Technical Occupations	29-0000	\$41.30/hr	\$41.30/hr	\$82.60/hr
Social and Community Service Managers	11-9151	\$36.13/hr	\$36.13/hr	\$72.26/hr

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.

*D.2. Collection of Information Requirements and Associated Burden Estimates*

D.2.1 SUD Demonstration Characteristics Interviews (Completed)

### SUD Demonstration Characteristics Interview Burden

Type of Respondent	Form Name	Number of Respondents	Total Number of Responses	Average Time per Response (hr)	Total Time (hr)	Average Hourly Wage	Total Cost
State Medicaid director (and /or state staff designee)	Demonstration Characteristics Interview (see Attachment 1.c.)	-27	-54	-1.5	-81	\$72.26/hr	-\$5,853

### D.2.2 SUD Demonstration Implementation Interviews (Completed)

#### SUD Demonstration Implementation Interview Burden

Type of Respondent	Form Name	Number of Respondents	Total Number of Responses	Average Time per Response (hr)	Total Time (hr)	Average Hourly Wage	Total Cost
State Medicaid director & director single state agency for substance abuse	Implementation Interview (see Attachment 2.f.)	-27	-54	-1.5	-81	\$72.26/hr	-\$5,853

### D.2.3 SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interviews (New)

RTI will interview up to 8 individuals in each of the 10 states selected. States will be selected based on RCR topics, willingness to participate in round 1 interviews, and those with at least two years of demonstration implementation. State staff will connect RTI to the MCO and behavioral health service provider leaders via email, which is estimated to take 0.25 hours. The interviews are a one-time data collection and will be conducted with MCO and behavioral health service provider leaders and will be 1.0 hours in duration.

The estimated burden is shown in the following table. In total, the estimated burden for the interviews is 80 hours (80 responses x 1 hr/response) at a cost of \$6,608 (80 hr x \$82.60/hr). The estimated burden for the state coordination to introduce RTI to MCO and Behavioral Health Providers is 2.5 hours (10 responses x 0.25hr/response) at a cost of \$181 (2.5 hr x \$72.26/hr). Therefore, the total burden estimate is 82.50 hours at a cost of \$6,789.

#### SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interview Burden

Type of Respondent	Form Name	Number of Respondents	Total Number of Responses	Average Time per Response (hr)	Total Time (hr)	Average Hourly Wage	Total Cost
MCO/behavioral health provider leaders	MCO and Behavioral Health Provider Stakeholder Interview (see Attachment 3.g., Attachment 3.h., & Attachment 3.i.)	80	80	1.0	80	\$82.60/hr	\$6,608
State staff connecting RTI via email to MCO/Behavioral health provider leaders	MCO and Behavioral Health Provider Introductory Email	10	10	0.25	2.5	\$72.26/hr	\$181
<b>TOTAL</b>		90	90	Varies	83	Varies	\$6,789

*D.3. Burden Summary*

Type of Respondent	Form Name	Number of Respondents	Total Number of Responses	Average Time per Response (hr)	Total Time (hr)	Average Hourly Wage (\$/hr)	Total Cost (\$)
State Medicaid director (and /or state staff designee)	Demonstration Characteristics Interview (see Attachment 1.c.)	-27	-54	-1.5	-81	-72.26	-5,853
State Medicaid director & director single state agency for substance abuse	Implementation Interview (see Attachment 2.f.)	-27	-54	-1.5	-81	-72.26	-5,853
<i>Subtotal</i>		-27	-108	-1.5	-162	-72.26	-11,706
MCO/ behavioral health provider leaders	MCO and Behavioral Health Provider Stakeholder Interview (see Attachment 3.g., 3.h, & 3.i.) and Resource Submission (see Attachment 3.j)	80	80	1	80	82.60	6,608
State staff connecting RTI via email to MCO/Behavioral health provider leaders	MCO and Behavioral Health Provider Introductory Email	10	10	0.25	2.50	76.26	181
<i>Subtotal</i>		90	90	<i>Varies</i>	83	<i>Varies</i>	6,789
<b>BALANCE</b>		<b>+36</b>	<b>-18</b>	<b>Varies</b>	<b>-80</b>	<b>Varies</b>	<b>-4,917</b>

Given that this collection of information request proposes to reduce our active total time estimate we are adding 5 hours of burden to account for the limitations of ROCIS which does not allow the submission of negative total time estimates for generic collections such as this. The reduction will be addressed when this collection of information’s control number is extended. The current expiration date is April 30, 2024.

*D.3. Information Collection Instruments and Instructions/Guidance Documents*

All relevant documents for data collection are provided as attachments and listed below along with a short description of each.

- Documents Associated with the SUD Demonstration Characteristics Interview (Removed)

Attachments 1.a. through 1.f. are removed since the task has been completed.

- Documents Associated with the SUD Demonstration Implementation Interview (Removed)

Attachments 2.a. through 2.f. are removed since the task has been completed.

- Documents Associated with the SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interview (New)

Attachments 3.a. through 3.j. are new documents.

- **Attachment 3.a.** MCO and Behavioral Health Stakeholder Interview Introductory Email from CMS to State Medicaid Director - CMS will send an email, prepared by RTI, to the Medicaid directors in 10 selected states with a SUD demonstration to introduce RTI and request the state's help providing a warm hand-off to MCO and behavioral health provider stakeholders (MCOs and behavioral health service provider leadership)
- **Attachment 3.b.** MCO and Behavioral Health Provider Stakeholder Interview Introductory Email from RTI to State Medicaid Director – RTI will send a follow up email to Medicaid directors in 10 selected states with a SUD demonstration to request the state's help identifying four MCOs and four behavioral health service providers and provide a warm hand-off to the MCO and behavioral health provider stakeholders identified. The email will also provide selection criteria for both MCOs and behavioral health service providers.
- **Attachment 3.c.** MCO and Behavioral Health Provider Stakeholder Interview Introductory Email from State Medicaid Director – The State Medicaid Director will send an email, prepared by RTI, to the MCO and behavioral health provider stakeholders in 10 states with a SUD demonstration to introduce RTI and request the stakeholder's participation in this data collection.
- **Attachment 3.d.** MCO and Behavioral Health Provider Stakeholder Interview Email Invitation - RTI will send an interview invitation via email and schedule a 60 minute interview with respondents.
- **Attachment 3.e.** MCO and Behavioral Health Provider Stakeholder Interview Outlook Invitation – RTI will send an interview invitation after receiving a date and time from the respondent. The invitation includes the agreed upon date and time of the interviews, instructions on how to join the call using a telephone or computer, and the Zoom conference call information.
- **Attachment 3.f.** MCO and Behavioral Health Provider Stakeholder Interview Confirmation Email – This email will be sent immediately upon scheduling a date and time for the interview, thanking the respondent for agreeing to be interviewed and

providing instructions for connecting to the interview using telephone and/or Zoom videoconferencing technology.

- **Attachment 3.g.** MCO Protocol with Instructions - The Interview protocol starts with an introduction that informs the interviewee that participation in the interview is voluntary and confidential and the participant can refuse to respond to questions they do not want to answer. It also requests permission to record the call. Interviewer’s instructions, prompts, and indications of important questions are indicated in this document.
- **Attachment 3.h.** Behavioral Health Stakeholder Interview Protocol with Instructions (Residential Providers) - The Interview protocol starts with an introduction that informs the interviewee that participation in the interview is voluntary and confidential and the participant can refuse to respond to questions they do not want to answer. It also requests permission to record the call. Interviewer’s instructions, prompts, and indications of important questions are indicated in this document.
- **Attachment 3.i.** Behavioral Health Stakeholder Interview Protocol with Instructions (Non-Residential Providers)- The Interview protocol starts with an introduction that informs the interviewee that participation in the interview is voluntary and confidential and the participant can refuse to respond to questions they do not want to answer. It also requests permission to record the call. Interviewer’s instructions, prompts, and indications of important questions are indicated in this document.
- **Attachment 3.j.** MCO and Behavioral Health Provider Stakeholder Interview Thank You Email – A thank you email will be sent to the interviewee following the interview call.

**E. Timeline (Federal Register/Program)**

*Federal Register*

The 14-day notice published in the Federal Register on March 3, 2022 (87 FR 12170). Comments were due by March 17, 2022, but none were received.

*Program*

The Federal Meta-Analysis Support contract for Section 1115 Demonstrations was awarded by CMS to RTI on September 24, 2018, and consists of a base year and four options years, terminating on September 23, 2023. Primary data collection activities are planned to begin in contract year 2 and will extend through contract year 5. The planned schedule for data collection activities for which PRA clearance is requested in this package are those related to the Demonstration Characteristics Interviews, the Implementation Interviews, and SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interviews is provided in the following chart. Considering the current COVID-19 pandemic, states will not be contacted until CMS approves moving forward and interviews may be delayed based on states’ availability. Dates in the timeline are all shown relative to PRA clearance and CMS approval to contact states.

Timeline for Use of Data Collection Instruments

Data Collection Activity	Dates
<i>SUD Demonstration Characteristics Interviews with State Administrators</i>	<i>Week following PRA Clearance and CMS Approval</i>

	<b>for Interviews (COMPLETED)</b>
CMS to send introductory emails to state administrators	Week 2
RTI to send email invitations with pre-populated grids to states	Week 2
Reminder emails sent to state administrators	Weeks 2 – 5
Demonstration Characteristics Interviews*	Weeks 3 – 10
RTI send draft RCR on programmatic changes to CMS	Week 16
<b>SUD Demonstration Implementation Interviews with State Administrators</b>	<b>(COMPLETED)</b>
RTI to send email invitations to states	Week 3
Implementation Interviews – 1st wave of 9 state interviews*	Weeks 4 - 6
Implementation Interviews – remaining 18 state interviews*	Week 8
RTI send draft RCR on implementation challenges and MAT Access to CMS	Week 12 – 13
<b>SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interviews</b>	<b>Week following PRA Clearance and CMS Approval for Interviews (NEW)</b>
CMS to send introductory emails to state Medicaid director	Week 2
State Medicaid director to send introductory emails to MCO and behavioral health service provider leaders	Week 2
RTI to send email invitations to MCOs and behavioral health service providers.	Week 3
Reminder emails sent to MCOs and behavioral health service providers.	Weeks 3 - 10
MCO and Behavioral Health Service Provider Interviews*	Weeks 4 – 12
RTI send draft RCRs	Week 24

*\*Potential COVID-19 related delays, interviews are dependent on state staff availability*