

Federal Meta-Analysis Support: Section 1115 Substance Use Disorder Demonstrations

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

Generic Supporting Statement

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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])¹. 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

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

on appropriate treatment.² As of February 5, 2020, 26 states and the District of Columbia have received approval for SUD section 1115 demonstrations.³

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 SUD demonstrations and how variations in state demonstration features and the context in which they are implemented contribute to differences in effectiveness. The meta-analysis of SUD demonstrations will compare experiences with 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.

Under this contract, RTI will work with CMS to conduct a meta-analysis of Medicaid section 1115 SUD demonstrations. The meta-analysis of the SUD 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-analysis, RTI is compiling a cross-state database 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 (**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 two rounds of 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. This [INSERT MONTH OF SUBMISSION] 2020 collection of information request is only for approval of the data collection materials that will be used for the first round of interviews. We are not requesting approval of the materials for the second round of interviews because the focus will not be determined until closer to the data collection period. Another collection of information request will be submitted before RTI conducts the second round of interviews.

The first round will include two sets of interviews— a demonstration characteristics interview and an implementation interview (**Sections B.1 and B.2**). We will conduct the demonstration

² 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>

³ Kaiser Family Foundation. (2020, February) Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers

characteristics interview with the state Medicaid director or their designated staff and conduct 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 has been created for each set of interviews.

The demonstration characteristic interviews will be no more than 60-minutes in length. Prior to the interview, states will be 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 will expand our understanding of SUD coverage policies and treatment services pre- and post-demonstration. Demonstration characteristic interviews will start no earlier than three weeks after receiving PRA clearance and CMS approval (subject to states' availability given the current COVID-19 pandemic).

The implementation interviews will be conducted with the same stakeholders and will be 90-minutes in length. These interviews will build on the information collected during the first set of interviews and will include an in-depth discussion of implementation experiences, challenges, and programmatic changes. It is anticipated that the implementation interviews will begin three weeks after receiving PRA clearance and CMS approval.

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

Three initial RCRs will use information collected during the demonstration characteristics and implementation interviews with section 1115 SUD demonstration states. One RCR will provide 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 will be 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 will be incorporated into a third RCR on medication assisted treatment (MAT). Information from these interviews may also be incorporated later RCRs. 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 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 the universe of SUD demonstration states.

B. Description of Information Collection

RTI's meta-analysis includes multiple rounds of qualitative data collection. At this time, we are submitting a request for documents related to our initial data collection activities, which are detailed below.

B.1 Demonstration Characteristics Virtual Interview

RTI intends to interview 27 Medicaid directors, or their state staff designees, for the demonstration characteristics interview. CMS will send an introductory email, prepared by RTI, to the Medicaid director in the 27 SUD demonstration states requesting the state's participation in the demonstration characteristics interview (**Attachment 1.a.**). While participation in the interview is voluntary, states that receive a section 1115 demonstration are expected to cooperate with CMS's federal independent evaluator, as noted in each state's special terms and conditions of the section 1115 demonstration award. Recognizing that states are facing a COVID-19 health crisis, RTI will provide ample notice and flexibility for states to respond to requests for interviews, with the understanding that states are prioritizing the COVID-19 response and may want to postpone the interview. RTI will delay sending emails if directed by CMS. After CMS emails the participating states, RTI will send a follow-up email, which will include a pre-populated grid showing the state's pre- and post-demonstration characteristics and a request for a 60-minute virtual interview to review and discuss the grid. (**Attachment 1.b.** for interview email request and program characteristics grid, and **Attachment 1.c** for Demonstration Characteristics Interview questions). Respondents will be asked to review the grid prior to the interview, make corrections and additions, and return the revised grid via email to RTI within 2 weeks. This is expected to take approximately 30 minutes and includes the time for states to respond with their availability for the 60-minute interview.

Once RTI and the state agree upon an interview time, RTI will send an interview confirmation email to the respondents (**Attachment 1.d.**) and a Microsoft Outlook meeting invitation (**Attachment 1.e.**). 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. RTI will also send a reminder email to the interviewee two days prior to the interview call (**Attachment 1.f.**)

At the start of each interview, RTI will inform the interviewee of the interview's purpose, explain that participation is voluntary, and request permission to record the interview solely for note-taking purposes (**Attachment 1.c.**). The interview introduction will also let respondents

know that RTI will not attribute answers directly to an individual in any reports. RTI will refer to individuals anonymously as “state informants.” The interview discussion will focus on clarifying SUD demonstration states’ pre- and post-demonstration characteristics for purposes of completing the grid. Data gathered and information gleaned from these interviews will set the context for the future implementation interviews and provide baseline information for the first three RCRs, inform RCRs in subsequent contract years, as well as the Final Summative Evaluation Report.

B.2 Implementation Virtual Interview

In addition to the demonstration characteristics interview, RTI plans to conduct an in-depth interview with the Medicaid director and the single state substance abuse agency director, or their designees, to discuss implementation experiences, challenges, and programmatic changes associated with the section 1115 SUD demonstration. Appropriate participants for the implementation interview will be identified during the demonstration characteristics interview. CMS will send a second introductory email, prepared by RTI, to the Medicaid director in the 27 SUD demonstration states and to Medicaid directors and single state substance abuse agency directors requesting the state’s participation in the implementation interview (**Attachment 2.a.**). RTI will send an interview invitation via email (**Attachment 2.b.**) and schedule a 90-minute interview with respondents. As described above, 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 reminder email will be sent to the interviewee 2 days prior to the interview call (**Attachment 2.e.**). As with the demonstration characteristics interviews, RTI will begin the interview (**Attachment 2.f.**) 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 purposes. The interview introduction will also let respondents 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.

C. Deviations from Generic Request

None.

D. Burden Hour Deduction

The total approved burden ceiling of the generic ICR is 154,104 hours, and CMS previously requested to use 78,685 hours, leaving our burden ceiling at 75,419 hours.

Wage Estimates

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' May 2019 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 median hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. We are using the Bureau of Labor Statistics' category of Social and Community Service Managers, as it most closely fits with state Medicaid Administrator/state designee and Administrator of single state agency for substance abuse/state designee, which are the two categories of interviewees that will be participating in these data collection efforts.

Occupation Title	Occupation Code	Median Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wage
Social and Community Service Managers	11-9151	\$35.05/hr	\$35.05/hr	\$70.10/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.

Collection of Information Requirements and Associated Burden Estimates

D.2.1 Demonstration Characteristics Virtual Interview

RTI will interview up to two individuals in the 26 states and the District of Columbia that have an approved section 1115 SUD demonstration. The interviews will be conducted with state Medicaid directors or their designee and will be conducted once, during the first year of data collection. To facilitate the data collection and interview, RTI will pre-populate a SUD state grid with program characteristics, based on available state information abstracted from state waiver applications, state special terms and conditions, and state implementation plans. The grid will be copied into an email and sent to interviewees in advance of the virtual interview. Interviewees will be asked to review it, make any updates, and return it via email to RTI.

We expect that delivering a pre-populated grid delineating RTI's understanding of each state's SUD program features will reduce the burden on state officials to perform additional data collection activities. Once the grid has been returned, the interview will be scheduled and conducted with the state administrator.

This is a one-time data collection activity for each approved state and we anticipate the amount of time associated with this data collection activity to be 1.5 hours per person per state consisting of 0.5 hour to review, edit, and update the pre-populated grid and 1.0 hour to participate in the interview. We assume that up to 2 people may need to be involved in this data collection effort. The estimated burden is shown in the following table. In total, the estimated burden is 81 hours (27 responses x 3 hr/response) at a cost of \$5,678 (81 hr x \$70.10/hr).

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 Rate	Total Cost
State Medicaid director (and /or state staff designee)	Demonstration Characteristics Interview (see Attachment 1.c.)	27	27	3.0 (1.5 x 2 FTEs)	81	\$70.10/hr.	\$5,678

D.2.2 Implementation Virtual Interview

RTI will interview up to two individuals in the 26 states and the District of Columbia that have approved section 1115 SUD demonstrations. These interviews will be conducted with state Medicaid directors or their designee and single state substance abuse directors and will be 1.5 hours in duration.

The estimated burden is shown in the following table. In total, the estimated burden is 81 hours (27 responses x 3 hr/response) at a cost of \$5,678 (81 hr x \$70.10/hr).

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 Rate	Total Cost
State Medicaid director & director single state agency for substance abuse	Implementation Interview (see Attachment 2.f.)	27	27	3.0 (1.5 x 2 FTEs)	81	\$70.10/hr.	\$5,678

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 Rate (\$/hr)	Total Cost (\$)
State Medicaid director (and /or state staff designee)	Demonstration Characteristics Interview (see Attachment 1.c.)	27	27	3	81	70.10	5,678
State Medicaid director & director single state agency for substance abuse	Implementation Interview (see Attachment 2.f.)	27	27	3	81	70.10	5,678
TOTAL		27	54	3	162	70.10	11,356

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.

D.3.1 Documents Associated with the Demonstration Characteristics Virtual Interview

- Demonstration Characteristics Interview Introductory Email from CMS to State Medicaid Director - CMS will send an email, prepared by RTI, to the Medicaid directors in all states with a SUD demonstration to introduce RTI and request the state's participation in this data collection (**Attachment 1.a.**).
- Demonstration Characteristics Interview Email Invitation with program characteristics grid - RTI will follow up CMS's email with an email to respondents that will include an invitation for a 60-minute interview and the Program Characteristics Grid. The Program Characteristics Grid is a table within the email that RTI has filled out with information describing the state's pre- and post-demonstration characteristics. This PRA clearance package contains a sample grid that has been filled out for a hypothetical state. Respondents will be asked via the email invitation to review the grid prior to the

interview, make corrections and updates, and return the revised grid via email to the RTI staff member identified in the email within 2 weeks (**Attachment 1.b.**).

- Demonstration Characteristics Interview Questions – A comprehensive list of interview questions (**Attachment 1.c.**) will be used in conjunction with the program characteristics grid (**Attachment 1.b.**) to guide the conversation with the respondent. RTI will only include questions from this list that pertain to topics in need of additional information.
- Demonstration Characteristics Interview Confirmation Email – This email will be sent immediately upon scheduling a date and time for the interview, providing instructions for connecting to the interview using telephone and/or Zoom videoconferencing technology. (**Attachment 1.d.**)
- Demonstration Characteristics Interview Outlook Invitation – RTI will send an interview invitation after receiving a date and time from the respondent. The invitation includes instructions on how to join the call using a telephone or computer, and the Zoom conference call information (**Attachment 1.e.**).
- Demonstration Characteristics Interview Reminder Email – This is a follow-up email to the respondent to remind them of the interview and to return the program characteristics grid (**Attachment 1.f.**).

D.3.2 Documents Associated with the Implementation Virtual Interview

- Implementation Interview Introductory Email from CMS to State Medicaid Director and single state substance abuse agency director - CMS will send an email, prepared by RTI, to the Medicaid directors and directors of the single state agency for substance abuse in all states with a SUD demonstration to introduce RTI and request the state's participation in this data collection (**Attachment 2.a.**).
- Implementation Interview Email Invitation - RTI will send an interview invitation via email and schedule a 90-minute interview with respondents (**Attachment 2.b.**).
- Implementation 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 2.c.**).
- Implementation 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 2.d.**).
- Implementation Interview Reminder Email – A reminder email will be sent to the interviewee prior to the interview call (**Attachment 2.e.**).
- Implementation Interview 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. The Implementation Interview protocol builds upon data from the previous Demonstration Characteristics Interview and includes an in-depth discussion of implementation experiences, challenges,

and programmatic changes. Interviewer’s instructions, prompts, and indications of important questions are indicated in this document (**Attachment 2.f.**).

E. Timeline

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 and the Implementation Interviews and 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 in this Request for PRA Clearance

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

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