

Generic Supporting Statement
Federal Meta-Analysis Support:
Section 1115 Substance Use Disorder Demonstrations (Revision)

CMS–10398 #64, OMB 0938–1148

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 (approved by OMB under control number: 0938-1148 [CMS-10398 #57, entitled: “Medicaid Section 1115 Substance Use Disorder (SUD) Demonstration: Monitoring Reports Documents and Templates”]¹). The 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

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

set of patient placement criteria that are widely recognized as representing an expert consensus on appropriate treatment.²

CMS also conducts a federal meta-evaluation of the SUD section 1115 demonstrations. 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 (metrics) 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 (metrics) analyses. 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 Meta-Evaluation includes two rounds of interviews. States with demonstrations approved prior to 2021 have completed these interviews, thus this is completed for many states. The first round included two sets of interviews— a demonstration characteristics interview and an implementation interview (see Section D.2 of this Supporting Statement for the respective burden and section D.4 for a list of the reporting instruments and supplemental documents). 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.

Prior to the demonstration characteristic 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. This has been completed for many states. The interviews expanded

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

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

our understanding of SUD coverage policies and treatment services pre- and post-demonstration. 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.

The second round of interviews included two sets of respondents for SUD demonstrations – managed care organization (MCO) leaders and behavioral health service providers (see Section D.2 of this Supporting Statement for our burden estimates and section D.4 for a list of the reporting instruments and supplemental documents). The interviews expanded our understanding of SUD implementation experience.

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.

This 2023 iteration revises our currently approved collection of information request. The revisions propose to: (1) adjust the number of states that have received approval for SUD section 1115 demonstrations by 13 (from 27 to 40), (2) increase the number of potential key informants (Medicaid directors or their state staff designees) by 26 to align with the maximum number of potential for the demonstration characteristics interviews, and (3) RTI will interview behavioral health providers and managed care organizations from 20 states (from 80 providers to 160 providers).

We are not making any changes to our currently approved interview documents. Nor are we adding any new interview documents.

B. Description of Information Collection

RTI's meta-analysis includes two rounds of qualitative data collection which consists of Round 1 (a demonstration characteristics interview and an implementation interview) and Round 2 (interview of managed care organization (MCO) leaders and behavioral health service providers).

The 2023 changes that are identified above in the Background section are reflected in the following table. The changes are necessary because more states have applied for and been approved for section 1115 SUD demonstrations.

Form Name	Number of Respondents			Total Number of Responses			Total Time (hours)		
	Currently Approved	Proposed	Change	Currently Approved	Proposed	Change	Currently Approved	Proposed	Change
Characteristics Interview	27 States	40 States	13 States	54	80	26	81	120	3
Implementation Interview	27 States	40 States	13 States	54	80	26	81	120	3
MCO and Behavioral Health Provider Stakeholder Interview and Resource Submission	10 states	20 providers	10 providers	80	160	80	80	160	8
MCO and Behavioral Health Provider Introductory Email	10 states	20 providers	10 providers	10	20	10	2.5	5	2
TOTAL	47 (27 unique states)	60 (40 States + 20 providers)	23 (13 States + 10 providers)	198	340	142	245	405	13

Consistent with our currently approved collection of information request, information from the interviews will be incorporated in Rapid Cycle Reports (RCRs) that RTI will prepare for CMS. The RCR topics are 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

Consistent with our currently approved collection of information request, the use of statistical methods does not apply; in this regard we are not requesting approval of any statistical deviations from the generic PRA process.

We are, however, surveying MCO/behavioral health provider leaders which is outside the scope of (and therefore deviates from) the effort of state governments. We continue to request approval of this deviation under this collection request 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 2022 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2022/may/oes_nat.htm). In this regard, the following table presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Healthcare Practitioners and Technical Occupations	29-0000	46.52	46.52	93.04
Social and Community Managers	11-9151	38.13	38.13	76.26

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 other indirect 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 for states approved prior to 2021)

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	40	80	1.5	120	\$76.26/hr	\$9,151.2

D.2.2 SUD Demonstration Implementation Interviews (Completed for states approved prior to 2021)

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.)	40	80	1.5	120	\$76.26/hr	\$9,151.2

D.2.3 SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interviews (Completed for states approved prior to 2021)

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 160 hours (1600 responses x 1 hr/response) at a cost of \$13,216 (160 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 \$180.65 (2.5 hr x \$72.26/hr). Therefore, the total burden estimate is 82.50 hours at a cost of \$6788.65.

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	160	160	1.0	160	\$93.04/hr	\$14,886.4
State staff connecting RTI via email to MCO/Behavioral health provider leaders	MCO and Behavioral Health Provider Introductory Email	20	20	.25	5	\$76.26/hr	\$381.30

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 (attachments 1.a-f)	40 States	80	1.5	120	76.26	9,151
State Medicaid director & director single state agency for substance abuse	Implementation Interview (attachments 2.a-f)	40 States	80	1.5	120	76.26	9,151
<i>Subtotal: States</i>		<i>40 States</i>	<i>160</i>	<i>1.5</i>	<i>240</i>	<i>76.26</i>	<i>18,302</i>
MCO/behavioral health provider leaders	MCO and Behavioral Health Provider Stakeholder Interview (attachments 3a-b, d-j)	20 providers	160	1	160	93.04	14,886
State staff connecting RTI via email to MCO/Behavioral health provider leaders	MCO and Behavioral Health Provider Introductory Email (attachment 3.c)	20 providers	20	0.25	5	76.26	381
<i>Subtotal: Providers</i>		<i>20 providers</i>	<i>180</i>	<i>1.25</i>	<i>165</i>	<i>Varies</i>	<i>15,268</i>
TOTAL		60 (40 States + 20 providers)	340	Varies	405	Varies	33,570

D.4. Information Collection Instruments and Instructions/Guidance Documents

Documents Associated with the SUD Demonstration Characteristics Interview (Completed for states approved prior to 2021)

- 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.**).

Documents Associated with the SUD Demonstration Implementation Interview (Completed for states approved prior to 2021)

- 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.**).

Documents Associated with the SUD Demonstration MCO and Behavioral Health Provider Stakeholder Interview (Completed for states approved prior to 2021)

- 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.a.**).
- 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.b.**).
- 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.c.**).
- 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.d.**).
- 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.e.**).
- 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.f.**)

- 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.g.**).
- 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.h.**).
- 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.i.**).
- MCO and Behavioral Health Provider Stakeholder Interview Thank You Email – A thank you email will be sent to the interviewee following the interview call (**Attachment 3.j.**).

E. Timeline

The 14-day notice published in the Federal Register on June 20, 2023 (88 FR 39853). While comments were due by July 5, 2023, none were received.

As the Federal Meta-Evaluation contract ends on September 30, 2023, CMS requests OMB's approved as soon as possible but no later than July 15, 2023, so we can conduct this collection's interviews this summer. Several states have been approved for section 1115 SUD demonstrations thus far in 2023, which delayed the submission of this package.