

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850



State Demonstrations Group

April 24, 2024

Kimberly Sullivan
Medicaid Executive Director
Department of Health
628 N 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030

Dear Director Sullivan,

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC #11.3 “Evaluation Design” of the state’s section 1115 demonstration, “Healthy Louisiana Opioid Use Disorder/Substance Use Disorder” (Project No: 11-W-00311/6), effective through December 31, 2027. CMS has determined that the Evaluation Design, which was submitted on May 5th, 2023 and revised on March 8th, 2024, and April 8th, 2024, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state’s Evaluation Design.

CMS has added the approved Evaluation Design to the demonstration’s STCs as Attachment E. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state’s Medicaid website within 30 days. CMS will also post the approved Evaluation Design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an Interim Evaluation Report, consistent with the approved Evaluation Design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the state chooses to extend the demonstration. Likewise, a Summative Evaluation Report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

Page 2 – Kimberly Sullivan

We appreciate our continued partnership with Louisiana on the Healthy Louisiana Opioid Use Disorder/Substance Use Disorder section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Tobias Griffin, State Monitoring Lead, CMS Medicaid and CHIP Operations Group



Tulane
University

SCHOOL OF PUBLIC HEALTH
AND TROPICAL MEDICINE

Department of Health Policy and Management

**Proposed Evaluation of the State of Louisiana Substance
Use Disorder Section 1115 Demonstration**

DRAFT: March 8, 2024

Mark L. Diana, PhD
Kevin Callison, PhD
Janna Wisniewski, PhD
Charles Stoecker, PhD
Brigham Walker, PhD
J. Kevin Massey, MS

A. General Background and Information

A.1 Substance Use Disorder in Louisiana

Louisiana experiences a disproportionately high prevalence of substance use disorders (SUD), both nationally and relative to other states in the south (SAMHSA, 2023). Mirroring national trends, drug overdose deaths in Louisiana accelerated at a rapid pace during the COVID-19 pandemic. Peaking at more than 2,500 deaths from mid-2021 to mid-2022, drug overdose deaths in Louisiana had more than doubled compared to the same period from 2018 to 2019 (CDC, 2023). However, in contrast to national trends, drug overdose deaths in Louisiana have fallen substantially from their mid-2022 peak, down by 12% over the 12-month period that followed (CDC, 2023). At the same time, drug overdose deaths attributable to synthetic opioids (primarily fentanyl) have continued to increase in Louisiana and, by 2021, had surpassed deaths involving heroin or natural and semi-synthetic opioids (Williams, 2023).

Confronted with these challenges, the Louisiana Department of Health is seeking to renew an existing SUD demonstration waiver and build upon ongoing efforts to address the opioid epidemic in Louisiana. These efforts have been met with success. For example, in 2022, rates of initiation and engagement in SUD treatment for Louisiana Medicaid members exceeded the 90th percentile benchmarks established by the National Committee for Quality Assurance (NCQA). And while national initiation and engagement rates for SUD treatment have remained stagnant over the past decade, rates among Louisiana Medicaid members have experienced significant increases (NCQA, 2024). Further by 2023, rates of medication use for opioid use disorder (MOUD) for Louisiana Medicaid members had increased by more than 50% compared to the period preceding the demonstration waiver.

A.2 Healthy Louisiana Substance Use Disorder 1115 Demonstration

Among the treatment options for SUD are Institutions for Mental Diseases (IMD). However, from its inception in 1965, Medicaid has excluded IMD coverage for those between the ages of 21 and 64 (Section 1905(a)(B) of the Social Security Act). The IMD exclusion was intended to focus treatment of psychiatric conditions in outpatient settings and leave states with the responsibility for funding residential and inpatient psychiatric services (Musumeci, 2019).

Since 2012, Louisiana has been able to include coverage of IMD provided services under the Louisiana Behavioral Health Partnership and, later, Healthy Louisiana, because coverage was determined to be “cost-effective” and capitated by the Louisiana Department of Health (LDH) through the managed care in lieu of (ILO) option. In 2016, the Centers for Medicare and Medicaid Services (CMS) revised regulations and changed capitation policies prohibiting coverage (Federal participation in coverage) for IMD stays beyond 15 days per month through the ILO option.

In response, LDH applied for a Section 1115(a) Demonstration in 2017 to allow for the continuation of treatment for OUD/SUD in IMDs regardless of the length of stay.^{1,2} In addition, the waiver included several other provisions aimed at improving outcomes for those with an OUD/SUD in areas such as access to critical levels of care for OUD/SUD, the use of evidence-based SUD patient placement criteria, access to medication-assisted treatment (MAT), and care coordination and transition between levels of OUD/SUD care. The Healthy Louisiana Substance Use Disorder 1115 Demonstration was approved by CMS on February 1, 2018, and continued through December 31, 2022 (Phase 1). The demonstration was approved for renewal from January 1, 2023, through December 31, 2027 (Phase 2). The scope of the demonstration required no change in Medicaid eligibility; therefore, the affected population was Medicaid beneficiaries in the state of Louisiana who are treated for an OUD/SUD.

The purpose of this demonstration is for Louisiana to maintain critical access to OUD and other SUD services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. Phase 2 of the demonstration is designed to achieve the following goals:

- a. Increased rates of identification, initiation, and engagement in treatment.
- b. Increased adherence to and retention in treatment.
- c. Reductions in overdose deaths, particularly those due to opioids.
- d. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.
- e. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate.
- f. Improved access to care for physical health conditions among beneficiaries.

We develop hypotheses surrounding these goals and their potential impact on the demonstration purpose and describe our proposed methodology for testing these hypotheses below.

A.3 Key Findings from the Original Demonstration

Preliminary results from Phase 1 of the Healthy Louisiana Substance Use Disorder 1115 Demonstration waiver indicate that the growth rate of the share of Louisiana Medicaid members with an SUD has slowed since the Phase 1 demonstration's implementation. Consistent with the goals of the Phase 1 demonstration, Louisiana Medicaid has also seen an increase in the share of members with an SUD receiving treatment in an IMD and the share treated with MOUD, the latter increasing by more than 50% since the Phase 1 demonstration period began.

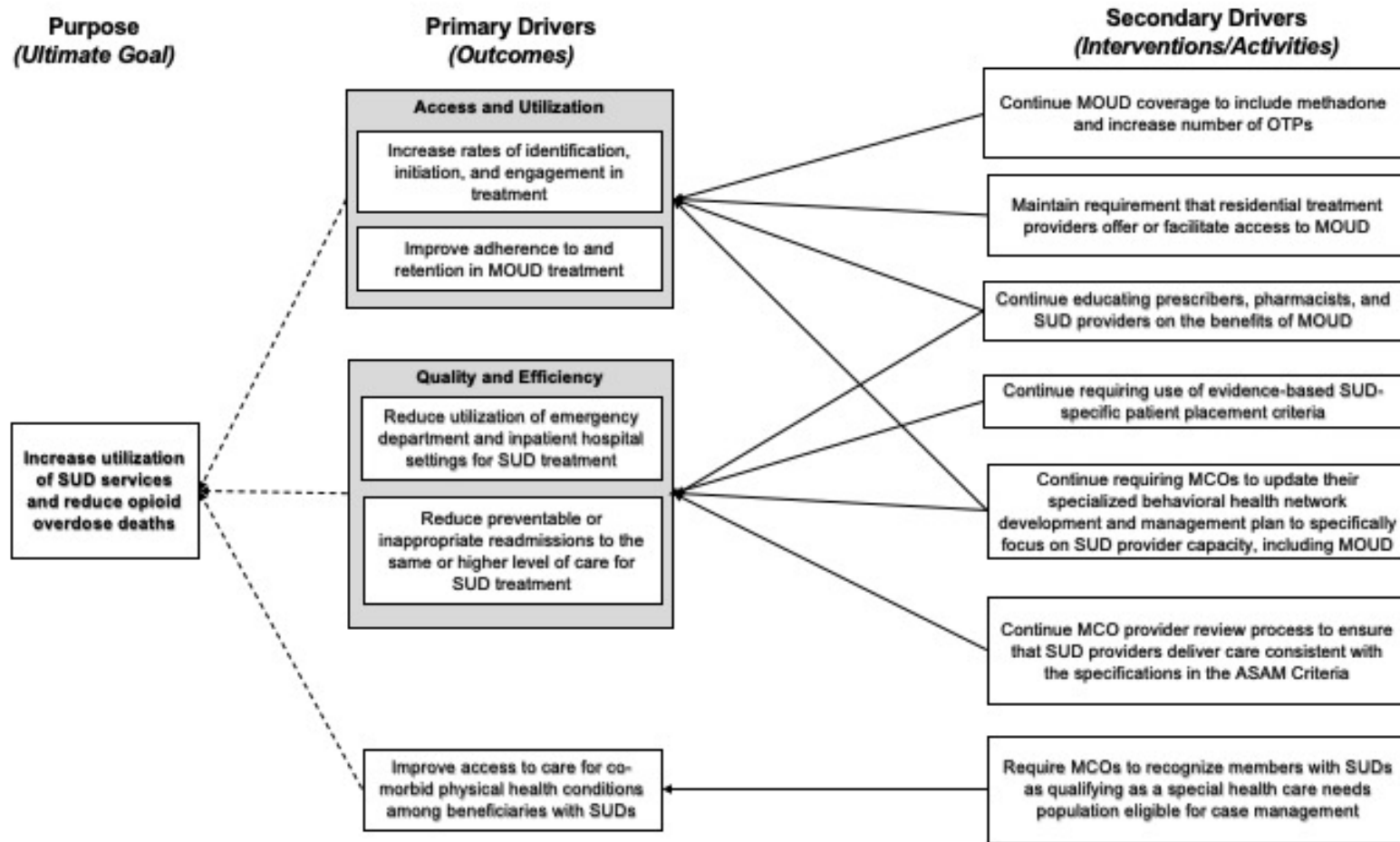
¹ Section 1905 42 of U.S.C. 1396d defines IMDs as “a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.”

² While IMDs have been excluded from federal financial participation since Medicaid's inception, several states have used an “in lieu of” policy to fund IMD care using federal dollars through capitated payments to managed care organizations (Musumeci, 2018). In May 2016, CMS implemented a policy to limit “in lieu of” payments to IMD stays to 15 days in a calendar month (Priest et al., 2017)

The Phase 2 evaluation plan presented in this document seeks to build on the work done during the Phase 1 evaluation and the evaluation team has relied on Phase 1 results to inform aspects of the current plan. For example, the notable rise in MOUD use documented in the Phase 1 evaluation prompted the research team to include “continuity of pharmacotherapy for opioid use disorder” as a Phase 2 evaluation outcome. Similarly, the Phase 2 evaluation places a specific focus on initiation and engagement in SUD treatment because, while Louisiana compares favorably in these metrics to other states, the Phase 1 evaluation indicated the possibility for further improvement in these areas.

B. Evaluation Questions and Hypotheses

B.1 Driver Diagram



This model assumes that Louisiana has sufficient health IT infrastructure “ecosystem” at every appropriate level (i.e., state, delivery system, and individual provider) to achieve the goals of the demonstration.

B.2 New versus Ongoing Demonstration Interventions and Activities

Most of the interventions/activities comprising the secondary drivers in the Driver Diagram are continuations of efforts that were established either before or during the previous demonstration period. Secondary drivers that represent new interventions/activities include “Continue MOUD coverage to include methadone and increase number of OTPs” and “Require MCOs to recognize members with SUDs as qualifying as a special health care needs population eligible for case management”. Louisiana Medicaid began covering methadone at OTPs during the first demonstration period in January 2020, however the number of OTPs in Louisiana increased from 10 to 11 when Behavioral Health Group (BHG) opened an OTP in Houma in August 2023. Also beginning in 2023, new MCO contracts require that any Medicaid member with an SUD qualifies for case management as a special healthcare needs population. While qualification does not ensure actual case management enrollment, it is an important initial step in increasing adherence to appropriate forms of SUD treatment.

B.3 Questions and Hypotheses using Quantitative Data

Table 2: Evaluation Questions, Demonstration Goals, and Evaluation Hypotheses

Evaluation Question 1: Does the demonstration increase access to and utilization of SUD treatment services?						
Demonstration Goal 1.1: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.						
Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
<p><u>Primary Driver</u> <i>Increase the rates of identification, initiation, and engagement in treatment.</i></p> <p><u>Secondary Drivers</u></p> <ul style="list-style-type: none"> Continue MOUD coverage to include methadone and increase number of OTPs. Maintain requirement that residential 	<p>Medicaid Beneficiaries with SUD Diagnosis (monthly)</p> <p>Monitoring Metric #3.</p>	None	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period.	N/A	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>

<p>treatment providers offer or facilitate access to MOUD.</p> <ul style="list-style-type: none"> • Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD. • Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD provider capacity, including MOUD. 						
	Medicaid Beneficiaries with SUD Diagnosis (monthly) (Rate)	None	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period.	All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Any SUD Treatment Monitoring Metric #6.	None	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

			pharmacy claim during the measurement period.			
	Any SUD Treatment (rate)	None	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period.	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid Beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Medicaid Beneficiaries Treated in an IMD for SUD Monitoring Metric #5	None	Number of unduplicated beneficiaries enrolled in a reporting month/year with a paid/accepted claim for date of service in reporting month/year that uses an SUD diagnosis code as the primary diagnosis from an IMD provider.	N/A	Louisiana Medicaid Claims Data	Primary: ITS
	Medicaid Beneficiaries Treated in an IMD for SUD (rate)	None	Number of unduplicated beneficiaries enrolled in a reporting month/year with a paid/accepted claim for date of service in reporting month/year that uses an SUD diagnosis code as the primary diagnosis from an IMD provider.	Medicaid Beneficiaries with an SUD diagnosis.	Louisiana Medicaid Claims Data	Primary: ITS
	Average Length of Stay in IMDs Monitoring Metric #36	None	The average length of stay for beneficiaries discharged from IMD inpatient/residential treatment for SUD	N/A	Louisiana Medicaid Claims Data	Primary: ITS
	Outpatient Services	None	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

	Monitoring Metric #8.		motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period. (ASAM Level 1)			
	Outpatient Services (Rate)	None	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period. (ASAM Level 1)	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Intensive Outpatient and Partial Hospitalization Services Monitoring Metric #9.	None	Number of beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period. (ASAM Level 2)	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Intensive Outpatient and Partial Hospitalization Services (Rate)	None	Number of beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period. (ASAM Level 2)	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

Residential and Inpatient Services Monitoring Metric #10.	None	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period. (ASAM Level 3)	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
Residential and Inpatient Services (Rate)	None	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period. (ASAM Level 3)	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
Withdrawal Management Monitoring Metric #11.	None	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period. (ASAM Level 1-WM)	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
Withdrawal Management (Rate)	None	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period. (ASAM Level 1-WM)	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment. Monitoring Metric #15.	NCQA	Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following:	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

			<ul style="list-style-type: none"> • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit <p>The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.</p>			
	SUD Provider Availability	None	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

	Monitoring Metric #13.		during the measurement period.			
	SUD Provider Availability (Rate)	None	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period.	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence. Monitoring Metric #17(1).	NCQA	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of AOD abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported: - Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). - Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

Demonstration Goal 1.2: Increase adherence to and retention in treatment for OUD and other SUDs. Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries who adhere to treatment of OUD and other SUDs.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
<p><u>Primary Driver</u> <i>Improve adherence to and retention in MOUD treatment.</i></p> <p><u>Secondary Drivers</u></p> <ul style="list-style-type: none"> • Continue MOUD coverage to include methadone and increase number of OTPs. • Maintain requirement that residential treatment providers offer or facilitate access to MOUD. • Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD. • Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD 	<p>Medication-Assisted Treatment</p> <p>Monitoring Metric #12.</p>	None	Number of beneficiaries who have a claim for MAT for SUD during the measurement period.	N/A	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>

provider capacity, including MOUD.						
	Medication-Assisted Treatment (Rate)	None	Number of beneficiaries who have a claim for MAT for SUD during the measurement period.	<p>Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.</p> <p>Alternate: Medicaid beneficiaries with an SUD diagnosis.</p>	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>
	<p>Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.</p> <p>Monitoring Metric #15.</p>		<p>Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following:</p> <ul style="list-style-type: none"> • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment 	N/A	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>

			within 34 days of the initiation visit			
	SUD Provider Availability - MAT Monitoring Metric #14.	None	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT.	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	SUD Provider Availability - MAT (Rate)	None	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT.	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence. Monitoring Metric #17(1).	NCQA	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of AOD abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported: - Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). - Percentage of ED visits for which the	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

			beneficiary received follow-up within 7 days of the ED visit (8 total days).			
--	--	--	--	--	--	--

Evaluation Question 2: Does the demonstration improve quality and efficiency?						
Demonstration Goal 2.1: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.						
Evaluation Hypothesis: The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
<p><u>Primary Driver</u> <i>Reduce utilization of emergency department and inpatient hospital settings for SUD treatment.</i></p> <p><u>Secondary Drivers</u></p> <ul style="list-style-type: none"> Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD. Continue requiring use of evidence-based SUD-specific patient placement criteria. Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD provider capacity, including MOUD. 	<p>Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries.</p> <p>Monitoring Metric #23.</p>	None	The number of ED visits for SUD during the measurement period.	<p>Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.</p> <p>Alternate: Medicaid beneficiaries with an SUD diagnosis.</p>	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>
	<p>The rate of inpatient stays for SUD per 1,000 beneficiaries in the measurement period.</p> <p>Monitoring Metric #24.</p>	None	Total number of inpatient discharges related to a SUD stay per 1,000 beneficiaries in the measurement period.	<p>Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.</p> <p>Alternate: Medicaid beneficiaries with an SUD diagnosis.</p>	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>

<ul style="list-style-type: none">• Continue MCO provider review process to ensure that SUD providers deliver care consistent with the specifications in the ASAM Criteria.						
---	--	--	--	--	--	--

Demonstration Goal 2.2: Reduce preventable or inappropriate readmissions to the same or higher level of care for SUD treatment. Evaluation Hypothesis: The demonstration will decrease the rate of preventable or inappropriate readmissions to the same or higher level of care for SUD treatment.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
<p><u>Primary Driver</u> <i>Reduce preventable or inappropriate readmissions to the same or higher level of care for SUD treatment.</i></p> <p><u>Secondary Drivers</u></p> <ul style="list-style-type: none"> • Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD. • Continue requiring use of evidence-based SUD-specific patient placement criteria. • Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD provider capacity, including MOUD. 	Readmissions Among Beneficiaries with SUD Monitoring Metric #25.	None	The count of all-cause 30-day readmissions during the measurement period among beneficiaries with SUD.	The count of index hospital stays among all beneficiaries with full benefits enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS

<ul style="list-style-type: none"> Continue MCO provider review process to ensure that SUD providers deliver care consistent with the specifications in the ASAM Criteria. 						
---	--	--	--	--	--	--

Evaluation Question 3: Do enrollees receiving SUD services experience improved health outcomes?						
Demonstration Goal 3.1: Improved access to care for physical health conditions among beneficiaries.						
Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries with SUD who experience care for comorbid conditions.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
<p><u>Primary Driver</u> <i>Improve access to care for co-morbid physical health conditions among beneficiaries with SUDs.</i></p> <p><u>Secondary Drivers</u></p> <ul style="list-style-type: none"> Require MCOs to recognize members with SUDs as qualifying as a special health care needs population eligible for case management. 	<p>Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD</p> <p>Monitoring Metric #32.</p>	NCQA	Percentage of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period	N/A	T-MSIS/Louisiana Medicaid Claims Data	<p>Primary: DD</p> <p>Secondary: ITS</p>

Evaluation Question 4. Are rates of opioid-related overdose deaths impacted by the demonstration?						
Demonstration Goal 4.1: Reduction in overdose deaths, particularly those due to opioids.						
Evaluation Hypothesis: The demonstration will decrease the rate of overdose deaths due to opioids.						
Purpose	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
Reduce opioid-related overdose deaths.	Medication-Assisted Treatment Monitoring Metric #12.	None	Number of beneficiaries who have a claim for MAT for SUD during the measurement period.	N/A	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Continuity of Pharmacotherapy for Opioid Use Disorder. Monitoring Metric #22.	USC; NQF #3175	Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment.	Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Alternate: Medicaid beneficiaries with an SUD diagnosis.	T-MSIS/Louisiana Medicaid Claims Data	Primary: DD Secondary: ITS
	Drug Overdose Deaths (count) Monitoring Metric #26	None	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration.	N/A	OPH Vital Records and Louisiana Medicaid eligibility	ITS

	Drug Overdose Deaths (rate) Monitoring Metric #27	None	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration.	All beneficiaries with full benefits enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period or the 30 days prior to the beginning of the measurement period.	OPH Vital Records and Louisiana Medicaid eligibility	ITS
--	--	------	--	---	--	-----

B.4 Questions using Qualitative Data

The qualitative component of the evaluation will focus on several of the State’s goals for the Demonstration (i.e., outcomes of interest):

- *Increased rates of identification, initiation, and engagement in treatment*
- *Increased adherence to and retention in treatment*
- *Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.*
- *Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate.*

The impact of the Demonstration on *improved access to care for physical health conditions among beneficiaries*, and *reductions in overdose deaths, particularly those due to opioids*, as well as health equity, will be cross-cutting themes throughout the qualitative work.

The evaluation will use qualitative methods to understand the following questions/issues as they relate to each outcome of interest:

- a. How is Louisiana currently performing on this outcome?
- b. What have been the trends in this outcome?
- c. What are the barriers and facilitators to continued improvement or stable high-performance in this outcome?
- d. Are there disparities in this outcome among subpopulations, and if so, what are the reasons?
- e. What policy recommendations do stakeholders have for the Louisiana Department of Health and the State Medicaid program?

Further, the evaluation will explore access to SUD services for three subpopulations: pregnant people and people involved in the criminal justice system. Qualitative data collection will be informed by the ongoing analysis of quantitative indicators listed in the summary table (Table 2).

C. Quantitative Approach

C.1 Methodology

Our preferred methodology for evaluating the hypotheses and tracking changes in the outcome measures listed in Table 2 will be a differences-in-differences (DD) design. DD is a quasi-experimental research technique that compares changes over time for a group that is impacted by an intervention (treatment group) to a group that is unaffected by the intervention (control group). The inclusion of a control group enhances the rigor of the research design and reduces the concern over potential confounders as estimates from the DD model are unaffected by changes common to both the treatment and control groups. We discuss the specifics of the DD models we plan to implement in our evaluation in Section C.5 below and describe limitations of the DD method in Section D.

If an alternative to the DD strategy is required, perhaps due to data replication issues (see Section C.2) or challenges meeting the requirements for valid DD inference (e.g., the parallel trends assumption), we will instead implement an interrupted time design. The interrupted-time series (ITS) method examines changes over time in an outcome for a treatment group. The evaluation period spans the periods before and after the intervention to capture changes that correspond to the timing of the intervention. An ITS analysis does not require a control group, but instead compares changes within the treatment group over time. As an example, suppose we track rates of ED admissions for OUD/SUD in Louisiana in the periods before and after enactment of the secondary drivers described in the state's implementation plan. The ITS works by statistically modeling the trend over time in OUD/SUD ED use and determines whether the level or slope of the trend changes at a point in time that corresponds to the intervention. The level change identifies any immediate effect of the intervention, while the change in slope (or trend) will capture changes over time. ITS will likely serve as our primary analysis method when examining outcome measures related to IMD use due to challenges identifying IMDs in states other than Louisiana.

C.2 Data Sources

The primary data sources for our analyses will include state Medicaid claims data from the Transformed Medicaid Statistical Information System (T-MSIS) and the Louisiana Medicaid claims database. We will access T-MSIS data through the Research Data Assistance Center (ResDAC) housed at the University of Minnesota. We have obtained Louisiana Medicaid claims data beginning in July 2016 through an agreement with the Louisiana Department of Health and will continue to receive updated claims at 6-month intervals. Data on overdose deaths will be supplied by the LDH Office of the State Registrar and Vital Records.

T-MSIS is a standardized, comprehensive data source that includes Medicaid and CHIP claims data from all 50 states. Eligibility and enrollment data are organized at the member level, while data on service utilization are organized at the claim level. The T-MSIS data are routinely used by researchers to generate cross-state comparisons of Medicaid initiatives and are used by CMS to conduct program administration and oversight. We plan to use T-MSIS data for Louisiana and at least one control state that has *not* implemented a Section 1115 SUD Demonstration Waiver similar to the one in effect in Louisiana. We will designate this state(s) as the control unit in our DD analyses.

The T-MSIS data are subject to a stringent quality assessment process overseen by CMS and Mathematica. However, despite this process, there are known data quality issues in some states that pose potential challenges when creating a control group using the T-MSIS data. We propose two methods to ensure data quality and reliability for the evaluation's quantitative analyses. First, we will use Louisiana T-MSIS data to construct claims-based outcome measures in Table 2 and directly compare these measures to the metric results calculated by LDH's Office of Behavioral Health (OBH). If this comparison yields promising results, then we will proceed with the proposed DD research design. If the comparison indicates significant disparities between the T-MSIS and OBH calculated metrics, then we will revert to an ITS strategy using the Louisiana claims data and OBH metrics. We do not anticipate encountering significant disparities in

outcome metric calculations between the T-MSIS and Louisiana claims data, but have included an ITS design as a contingency plan. Second, we will minimize known T-MSIS data quality issues by relying on the information provided by the T-MSIS Data Quality Atlas. The Atlas grades each T-MSIS data table provided by each state in every year on a scale of low- to high-concern. We propose to only include a comparison state(s) that has received grades of “low concern” on all relevant data tables. See section E.3 for a series of tables that include all states that have yet to implement an SUD demonstration waiver along with DQ Atlas data quality scores for each T-MSIS data table.

Limitations associated with using T-MSIS data primarily involve concerns regarding data quality. However, we believe that these concerns can be minimized through the quality control methods we have proposed. Additionally, there is a lag in T-MSIS data availability; validated data through 2021 are currently available as are preliminary data for 2022.

The quality of the Louisiana Medicaid claims data is high and the data have few limitations for our purposes. We have access to the universe of Medicaid claims data, including prescription drug files, so that we can construct a nearly complete picture of beneficiary care for OUD/SUD. Limitations of these data would include coding inconsistencies across MCOs in Louisiana and our inability to observe any patient care obtained that is not financed through the Medicaid system. However, these limitations are not expected to be significant causes of concern for our evaluation as coding for OUD/SUD treatment is standardized and relatively few Medicaid beneficiaries are expected to receive care for which a claim was not processed through the Medicaid program.

C.3 Target Populations

For most analyses, the primary target population will consist of all Medicaid beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period. Additionally, for several metrics, we will analyze outcomes for an alternate population consisting of Medicaid beneficiaries with an SUD diagnosis. The inclusion criterion for this group is Medicaid beneficiaries enrolled in a specific reporting period (e.g., month or year) with a qualifying claim that uses an OUD/SUD diagnosis code as the primary diagnosis. When feasible, we will use the same preferred analytic method (i.e., difference-in-differences) to estimate effects for both the primary and alternate target populations and resort to our secondary analytic method (i.e., interrupted time series) when necessary (see section C.5 for a detailed discussion of the proposed analytic methods).

The cleaning process for both the T-MSIS and Louisiana Medicaid claims data will involve filtering out individuals with only partial Medicaid benefits, based on Medicaid enrollment Aid Categories, so those individuals are not part of the claim/encounter data pull population when the individual is not eligible to receive services defined in the metric numerator. The cleaning process will also exclude individuals with services covered by private insurance based on records of Medicaid claim payment from other payers. Claim/encounter records with a denied status in the state’s adjudication system will also be excluded from the data pull.

When an original accepted claim/encounter is later adjusted or voided, the state’s database still

includes the original and the replacement record; the cleaning process includes accessing a cross-reference table to remove the originals for records that have been adjusted or voided.

To ensure proper inclusion for the reporting period, the process includes searching claim/encounter records for an additional future month beyond the reporting period to account for ongoing stays that actually discharge in the month following the reporting period; records that discharge in the reporting period are included in the report data, and records that discharge before or after the reporting period are not included in the report data.

The state's database is organized in monthly tables for both Medicaid eligibility and claim/encounter records, the data pull logic gathers records for metric reporting one month at a time; Medicaid beneficiaries and their associated claim/encounter records are included in reporting when we see at least one month of eligibility enrollment and/or claim/encounter records, as specified per metric definition, during the reporting period.

C.4 Evaluation Period

The evaluation period for analyses using the Medicaid claims data will begin in July 2016 and is ongoing through the projected end of the demonstration in December 2027. Though the demonstration was approved in February 2018, we incorporate data from 2016 to establish trends and use-rates in the pre-demonstration period. We then measure changes in these outcomes from the pre-demonstration to post-demonstration periods. The decision to begin the analysis period in July 2016 was motivated by the fact that Louisiana expanded Medicaid eligibility under the ACA at that time. This expansion resulted in a compositional change in Louisiana's Medicaid population that would render pre-to-post expansion comparisons problematic. As such, we propose to avoid the pre-expansion period and establish a pre-demonstration period that begins in July 2016.

C.5 Analytic Methods

Our preferred methodology for evaluating the hypotheses listed above is a quasi-experimental research design known as difference-in-differences (DD). The term quasi-experimental refers to approaches like DD that attempt to mimic a randomized controlled trial by assigning individuals to a treatment group or a control group and then measuring changes between the two groups over time. The treatment group is defined by exposure to an intervention, while the control group should ideally be similar to the treatment group but remain unexposed. Under standard assumptions for the DD methodology (listed in section D), changes in outcomes for the treatment group relative to the control group can be interpreted as causal impacts of the intervention.

The DD model can be formally represented as follows:

$$Outcome_{st} = \beta_0 + \beta_1 LA_s + \beta_2 Post_t + \beta_3 LA_s \times Post_t + \beta_4 X_{st} + \beta_5 Z_{st} + \delta_s + \tau_t + \varepsilon_{st}$$

Where $Outcome_{st}$ represents the outcome of interest to be estimated for individuals living in state s at time t . LA is an indicator for Louisiana (i.e., the treatment group in the DD analysis) and $Post$ is an indicator for the post-intervention period. The interaction term, $LA_s \times Post_t$, is the

coefficient of interest and represents the effect of the intervention on the treatment group relative to the control group. Finally, X is a vector of Medicaid population characteristics such as age and sex ratios, Z is a vector of state characteristics such as unemployment rates, δ and τ are state/region and time fixed effects, and ε is an error term that captures unobserved factors associated with the outcome of interest. Most of the DD models will be estimated using ordinary least squares (OLS), however we may employ nonlinear estimation techniques to account for relatively rare outcomes.

If a DD design is infeasible, either due to data quality issues or the lack of a valid control group, we will rely on an interrupted time series analysis. The interrupted time series model can be described as follows:

$$Outcome_{it} = \beta_0 + \beta_1 Time_t + \beta_2 Implement_t + \beta_3 Time_t \times Implement_t + \varepsilon_{ist}$$

Where *Time* is a continuous measure of time denoted in either year, year-quarter, or month depending on sample sizes. *Implement* is an indicator for the implementation of a demonstration secondary driver meant to impact the outcome in question and measures any break in trend associated with the intervention. The interaction term, $Time_t \times Implement_t$ captures any change in the slope of the trend that occurred after the intervention. We will focus primarily on the $Time_t \times Implement_t$ term when interpreting results of the model as this term will indicate whether outcome trends have changed concurrently with secondary driver implementation.

C.6 Addressing the Impact of the COVID-19 Public Health Emergency

The COVID-19 Public Health Emergency disrupted all aspects of SUD treatment for Medicaid populations and the associated Continuous Coverage Requirement greatly expanded Medicaid enrollment through mid-2023 when Medicaid redeterminations resumed. We plan to address the potential impacts of COVID-19 in two ways. First, our inclusion of a control state(s) that experienced similar COVID-19-related service restrictions and enrollment patterns should allow us to better isolate outcome changes that were due to the demonstration waiver and not the result of COVID-19. Second, rather than reporting only count outcome metrics, we also include rates using the Medicaid population or Medicaid population with an SUD diagnosis as the denominator. As a result, we will mitigate the potential for distortions in outcome counts caused by enrollment fluctuations and can provide a clearer assessment of waiver impacts.

D. Cost Analysis

D.1 Methodology for Analyzing Costs of the Louisiana SUD Demonstration to the Medicaid Program

Develop shadow cost prices. As Louisiana Medicaid patients are in managed care, we use the published specialized behavioral health fee schedule for Louisiana's Medicaid program. This list maps Current Procedural Terminology (CPT) codes and provider types onto dollar costs. Additionally, there are Healthcare Common Procedure Coding System (HCPCS) codes that

define daily charges for SUD IMD stays and these rates are specific to SUD patients. Per guidance from CMS, we exclude room and board from these shadow prices.

Waiver administrative costs. The costs for administering Louisiana’s SUD 1115 waiver program are attributed to LDH staffing costs and Independent Evaluator costs. LDH staff report time spent each week administering the SUD waiver, supporting waiver evaluation efforts, and other duties associated with the waiver. Staff report this time into the state’s LaGOV system which allows an accurate accounting of each staff’s effort spent working on the waiver to be fed onto the quarterly CMS-64 form for federal expenditure reporting. Independent Evaluator costs are reported to capture any costs associated with completing the assessment and evaluation deliverables included in the waiver’s Special Terms and Conditions. These costs are tracked through the collection and approval of invoices for each completed deliverable from the Independent Evaluator and also reported on the CMS-64.

Table 3: Types of costs and data sources

Level of analysis	Type of costs	Data source
Total costs	Total costs	Louisiana Medicaid Claims Data, IMD costs, administrative costs
	Total federal costs	Total Medicaid costs * federal medical assistance percentage [FMAP] for the state
SUD cost drivers*	SUD-IMD	IMD costs reported by Louisiana Medicaid Claims Data
	SUD-other	Louisiana Medicaid Claims Data
Type or source of care cost drivers*	Non-SUD	Louisiana Medicaid Claims Data
	Outpatient costs – non ED	Louisiana Medicaid Claims Data
	Outpatient costs – ED	
	Inpatient costs	
	Pharmacy costs	
	Long-term care costs	

As we will not have cost information for other states, we will use an ITS model to identify the impact of the SUD 1115 waiver program on costs. The interrupted time series model that we propose for the cost analysis is identical to the model described in section C.5 with the exception that outcome measures for the cost model will be those identified in Table 3. The model can be described as follows:

$$Outcome_{it} = \beta_0 + \beta_1 Time_t + \beta_2 Implement_t + \beta_3 Time_t \times Implement_t + \varepsilon_{ist}$$

Where *Time* is a continuous measure of time denoted in either year, year-quarter, or month depending on sample sizes. *Implement* is an indicator for the implementation of a demonstration secondary driver meant to impact the outcome in question and measures any break in trend associated with the intervention. The interaction term, $Time_t \times Implement_t$ captures any change in the slope of the trend that occurred after the intervention. We will focus primarily on the $Time_t \times Implement_t$ term when interpreting results of the model as this term

will indicate whether outcome trends have changed concurrently with secondary driver implementation.

E. Qualitative Approach

E.1 Evaluation Period

Outcomes related to treatment (*increased rates of identification, initiation, and engagement in treatment and increased adherence to and retention in treatment*) will be studied in Years 6 and 7 of the Demonstration. Data collection in Year 6 will be conducted in urban/suburban areas, and in rural areas in Year 7. Case studies documenting the experience of one patient in an urban area and one patient in a rural area will also be developed in Years 6 and 7.

In Years 7-10, the researchers will collect on equity in outcomes related to treatment for two subpopulations. During this timeframe, they will also develop a case study documenting the experience of one patient who had an SUD diagnosis during pregnancy and one patient who had an SUD diagnosis while involved in the criminal justice system. The midpoint assessment will be conducted in Year 9.

Years 9 and 10 will be dedicated to outcomes related to avoidable use of the emergency department (*reduced utilization of emergency departments through improved access to other continuum of care services*). Data collection in Year 9 will be conducted in urban/suburban areas, and in rural areas in Year 10. A timeline for qualitative data collection is shown in Table 8.

Table 8: Timeline of qualitative data collection

Outcome/Group	Y6	Y7	Y8	Y9	Y10
Treatment: Urban	X				
Treatment: Rural		X			
Pregnant people		X	X		
Criminally involved			X	X	
Midpoint assessment			X		
Avoidable use: Urban				X	
Avoidable use: Rural					X

E.2 Data Collection

Data will be collected through in-depth and key informant interviews with stakeholders (see Table 9 for an illustrative list of stakeholders). Interviews will be audio recorded with the respondent's permission. If no permission is given, the interviewer and a research assistant will take detailed notes. Audio recordings will be transcribed.

In the assessments of treatment and avoidable use outcomes, the evaluation team will work with health department staff to identify and recruit interview subjects. The research team will identify the cities or rural parishes (i.e., sites) in which data will be collected. Sites will be purposively selected to emphasize geographic coverage and demographic/socioeconomic diversity.

The researchers will ask the Louisiana Department of Health to introduce them to an appropriate local health official at the site who will be their liaison. The researchers and local health official will then work together on a landscaping activity, identifying the key players (individuals and institutions) in the SUD/ODD system at that site. They will then identify potential interview subjects and, when appropriate, the local health official will make introductions.

For the assessments of SUD services for subgroups, the research team will partner with a researcher or practitioner with subject-matter expertise and connections in the field or community. This partner will participate in a landscaping exercise to identify potential subjects and assist with recruitment. The researchers may ask the Louisiana Department of Health for assistance in identifying partners.

Potential subjects will be invited via mail or email to participate, with follow-up by phone if needed. In some cases, the liaison will assist with recruitment and scheduling interviews. The research team will make every effort to visit sites in-person, and to collect data from subjects at a location convenient to them. When that is not possible, interviews will be conducted virtually. Subjects who are not civil servants will receive a gift card following their participation. The value of the gift card will be set based on the subject type at rates deemed not to be coercive.

Table 4: Types of subjects, numbers of sites and selection methodology (illustrative)

Outcomes	Types of subjects	Number of sites (urban/suburban)	Number of sites (rural)
Treatment	Social workers Outreach workers Treatment providers Local health officials Local leaders	4	4
	Patients (for case study)	1	1
Avoidable use of the emergency department services	Outpatient SUD treatment providers Residential SUD treatment providers Emergency physicians Emergency department managers Discharge planners Social workers	4	4
Subgroup: Pregnant people	Community health center-based PCPs and ObGyns Outpatient SUD treatment providers Midwives/Doulas Maternal health equity/advocacy organizations based in LA	Statewide	Statewide
	Patient (for case study)	1	
Subgroup: Criminally involved people	Outpatient SUD treatment providers Community health center-based PCPs Social workers “Drug court” judges Public defenders	Statewide	Statewide
	Patient (for case study)	1	

Note: Subjects will be identified during the landscaping exercises.

E.3 Analysis

Two members of the research staff will code a subset of the data, then develop a common set of codes. Each research staff member will code the full data set and inter-rater reliability will be calculated. Major discrepancies in coding will be resolved between research staff members.

Data will be coded for themes based on the research questions and triangulated with findings from the quantitative analysis. The analysis will describe areas of consensus among respondents, as well as areas in which there were differing viewpoints. Findings will be presented with illustrative quotations. Table 10 shows the primary drivers examined in the qualitative component, mapped to the supporting themes and informants.

Table 5. Primary drivers examined in qualitative component, with themes, informant types, and methods.

Primary driver	Themes examined	Informant type(s)	Method(s)
Increased rates of identification, initiation, and engagement in treatment	Identification of people needing care	Social workers, outreach workers Community health center-based PCPs and ObGyns Outpatient SUD treatment providers Midwives/Doulas “Drug court” judges Public defenders	Interviews
	Referral for treatment	Treatment providers Community health center-based PCPs and ObGyns Outpatient SUD treatment providers Midwives/Doulas “Drug court” judges Public defenders	Interviews
	Relevant policies and programs	Local health officials, local leaders Maternal health equity/advocacy organizations based in LA “Drug court” judges Public defenders	Interviews
	Personal experience with initiating treatment	Patients	Case studies
Increased adherence to and retention in treatment	Retention in treatment	Social workers, treatment providers Community health center-based PCPs and ObGyns Outpatient SUD treatment providers Midwives/Doulas “Drug court” judges Public defenders	Interviews
	Personal experience in receiving treatment	Patients	Case studies
	Trends in avoidable use	Outpatient SUD treatment providers Residential SUD treatment providers	Interviews

Reduced utilization of emergency departments for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.		Emergency physicians Emergency department managers	
	Strategies for and barriers to avoiding ED	Outpatient SUD treatment providers Intensive Outpatient Program treatment providers Residential SUD treatment providers	Interviews
Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate.	Referral after ED: processes, barriers	Emergency physicians Emergency department managers Discharge planners Social workers	Interviews

F. Methodological Limitations

F.1 Quantitative Limitations

We plan to estimate demonstration-related changes to outcome measures using a difference-in-difference (DD) design. However, if this proves to be infeasible due to data or methodological challenges, we will revert to an interrupted time series (ITS) design. The primary limitation of an ITS design, in comparison to the DD model, is the lack of a control group to account for changes common to both those affected by the demonstration and those who are unaffected. As a result, the ITS framework is prone to confounding from concurrent policy changes or events unrelated to the demonstration.

There are known limitations to the monitoring metrics used to measure inpatient stays, ED utilization, and readmissions. The measure specifications for metrics 23 through 25 as written do not provide for the level of SUD attribution implied by the titles of metrics 23 through 25 and, as a result, have limited predictive utility for directly associating ED visits or hospitalizations with substance use disorders. An SUD diagnosis at any position on a claim does not definitively correlate to an ED visit or hospitalization being caused by, or perhaps even being related to, a substance use disorder. Consequently, ED visits and hospitalizations in the numerators for metrics 23 and 24 as currently written may, or may not, be due to a substance use disorder. Metric 25 has the identical significant attribution limitation as metrics 23 and 24, with the level of attribution error being compounded since the numerator is nearly all-cause readmissions, which include most reasons for hospitalization.

There are also limitations associated with the calculation of metrics 8 through 10, designating different ASAM levels for care. For each of these metrics, only the highest level of care is reported regardless of whether an individual experienced multiple levels of care. As such, those receiving residential and inpatient services (metric #10) will not be recorded as having received outpatient (metric #8) or intensive outpatient and partial hospitalization services (metric #9). The same holds true for those receiving both outpatient and intensive outpatient and partial hospitalization services.

F.2 Qualitative Limitations

It should be noted that the results of the qualitative analysis will not be statistically representative. However, data will be collected until data saturation is achieved, and so the findings derived from interviews with multiple subjects across geographic areas and levels of care will produce information generalizable to many providers.

G. Attachments

G.1 Independent Evaluator

The State attests that the relationship between the Contracting Party, Tulane University, shall be, and only be, that of an independent contractor and the Contracting Party shall not be construed to be an employee, agent, or in joint venture with, the State and/or agency. Furthermore, it is a requirement of all publicly funded contracts and agreements to be subject to audit and inspection by the Legislative Auditor of the State of Louisiana, and/or the Office of the Governor, Division of Administration auditors.

We have provided standard NIH-style biosketches for the Tulane University School of Public Health and Tropical Medicine team. The members of the team certify that they do not have any conflict of interest in conducting this evaluation and that they will conduct a fair and impartial evaluation and prepare an objective Evaluation Report.

G.2 Evaluation Budget and Timeline

The evaluation budget consists of both staffing and contractor costs. There are 10 Louisiana Department of Health (LDH) staff members involved in administering the waiver program. Each staff reports their time spent on administering the waiver, which totals approximately \$225,000 annually of which 30% of this time is estimated to be spent on supporting evaluation efforts, totaling \$67,500 annually. Additionally, the LDH Bureau of Health Services Financing (BHSF) signed a Cooperative Endeavor Agreement with Tulane University to serve as the independent evaluator. The agreement's effective date is July 1, 2023 and runs through June 30, 2028. Tulane also served as the independent evaluator for the first five years of the demonstration. The total estimated cost of the evaluation activities for demonstration years six through ten is approximately \$1.7 million. The following table lists key evaluation deliverables and timelines:

Table 6: Evaluation Timeline

Deliverable	Completion Date <i>(future dates projected)</i>
Draft Evaluation Design (work completed under previous agreement)	3/6/2023
Final Evaluation Design (work completed under previous agreement)	5/27/2023
Draft Summative Evaluation Report (DY1-5)	1/9/2024
Final Summative Evaluation Report (DY1-5)	5/1/2024
Draft Mid-Point Assessment Report	6/30/2025
Final Mid-Point Assessment Report	12/1/2025
Draft Interim Evaluation Report	6/30/2026
Final Interim Evaluation Report	12/1/2026

The total evaluation costs including LDH staffing and contractor costs for demonstration years six through ten is approximately \$2M.

G.3 Potential Control States for Difference-in-Differences Design and DQ Atlas Concern Levels

Tables 7 through 9 include T-MSIS data quality indicators for each potential control state (i.e., states that have not yet implemented SUD Demonstration waivers).

Table 7: TMSIS Data Quality Indicator Concern Levels, Inpatient Claims

State	Indicators	2017	2018	2019	2020	2021
Arizona	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Arkansas	Volume	Low	Low	Low	Low	Low
	Users	Medium	Low	Low	Low	Low
Missouri	Volume	Low	Low	Medium	Medium	Medium
	Users	Low	Low	Low	Medium	Low
Mississippi	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
North Dakota	Volume	Medium	Medium	Medium	Medium	Medium
	Users	Low	Low	Low	Low	Low
South Carolina	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
South Dakota	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Tennessee	Volume	Medium	Medium	Medium	Low	Low
	Users	Medium	Medium	Low	Low	Low
Texas	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Wyoming	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low

Table 8: TMSIS Data Quality Indicator Concern Levels, Outpatient Claims

State	Indicators	2017	2018	2019	2020	2021
Arizona	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Arkansas	Volume	Low	Low	Low	Low	Low
	Users	Medium	Low	Low	Low	Low
Missouri	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Mississippi	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
North Dakota	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
South Carolina	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
South Dakota	Volume	Low	Low	Low	Low	Low

	Users	Low	Low	Low	Low	Low
Tennessee	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Texas	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Wyoming	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low

Table 9: TMSIS Data Quality Indicator Concern Levels, Prescription Drug Claims

State	Indicators	2017	2018	2019	2020	2021
Arizona	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Arkansas	Volume	Medium	Medium	Medium	Medium	Medium
	Users	Medium	Low	Low	Low	Medium
Missouri	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Mississippi	Volume	Low	Low	Low	Medium	Low
	Users	Low	Low	Low	Low	Low
North Dakota	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
South Carolina	Volume	Medium	Medium	Medium	Medium	Medium
	Users	Low	Low	Low	Low	Low
South Dakota	Volume	Medium	Medium	Medium	Medium	Low
	Users	Low	Low	Low	Low	Low
Tennessee	Volume	Low	Low	Low	Low	Low
	Users	Low	Low	Low	Low	Low
Texas	Volume	Low	Low	Low	Medium	Medium
	Users	Low	Low	Low	Low	Low
Wyoming	Volume	Low	Low	Medium	Medium	Medium
	Users	Low	Low	Low	Low	Low

References

- Centers for Disease Control and Prevention (2023). *Provisional Drug Overdose Death Counts*: <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.
- Musumeci, M. (2018). *Key Questions about Medicaid Payment for Services in Institutions for Mental Disease*. Kaiser Family Foundation June 2018 Issue Brief. San Francisco, CA: Kaiser Family Foundation.
- Musumeci, M., Chidambaram, P., & Orgera, K. (2019). (rep.). *State Options for Medicaid Coverage of Inpatient Behavioral Health Services*. San Francisco, CA: Kaiser Family Foundation.
- National Committee for Quality Assurance (NCQA) (2024). *Initiation and Engagement of Substance Use Disorder Treatment*: <https://www.ncqa.org/hedis/measures/initiation-and-engagement-of-substance-use-disorder-treatment/>.
- Priest, K.C., A.W. Leof, D. McCarty, and V. King. (2017). *Medicaid Coverage for Residential Substance Use Disorder Treatment: Addressing the Institution for Mental Disease Exclusion Policy*. Health Affairs. DOI: 10.1377/hblog20170831.061745.
- Substance Abuse and Mental Health Services Administration (SAMHSA) (2023). *2022 NSDUH Detailed Tables*: <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.
- Williams, T. (2023). *Opioid Deaths in Louisiana: 2021 Annual Fact Sheet*. Baton Rouge, Louisiana Department of Health. https://ldh.la.gov/assets/opioid/2021_Annual_Drug_Death_Report.pdf