**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**

June 25, 2025

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) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

## Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Healthy Louisiana Opioid Use Disorder/Substance Use Disorder (Project Number 11-W-00311/6) demonstration.

*Reporting Cadence and Due Date*

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section

1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The Healthy Louisiana Opioid Use Disorder/Substance Use Disorder demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on June 29, 2026 which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

*Structured Monitoring Report Template*

As noted in STC 8.6, "Quarterly and Annual Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Some of the metrics currently required for Substance Use Disorder (SUD) and Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) demonstrations will no longer be required.

CMS is also removing the requirement for a Monitoring Protocol deliverable, which has been required under certain types of section 1115 demonstration, including but not limited to the SUD, SMI/SED, Health-Related Social Needs (HRSN), and reentry demonstrations. Removal of the

Monitoring Protocol requirement simplifies and streamlines demonstration monitoring activities for states and CMS.

*Demonstration Monitoring Calls*

As STC 8.10 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Healthy Louisiana Opioid Use Disorder/Substance Use Disorder section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Cecilia Williams, State Monitoring Lead, Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES**
**EXPENDITURE AUTHORITY**

**NUMBER:** **11W00311/6**

**TITLE:** **Healthy Louisiana Substance Use Disorder 1115 Demonstration**

**AWARDEE:** **Louisiana Department of Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Louisiana for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from February 1, 2018 through December 31, 2022, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Louisiana (state) to operate the above-identified section 1115 demonstration.

1. **Residential Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

**CENTERS FOR MEDICARE & MEDICAID SERVICES**
**SPECIAL TERMS AND CONDITIONS (STCs)**

NUMBER: 11W00311/6

TITLE: Healthy Louisiana Opioid Use Disorder/Substance Use Disorder 1115(a) Demonstration

AWARDEE: Louisiana Department of Health

## I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Healthy Louisiana Substance Use Disorder" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Louisiana Department of Health (hereinafter "state"), to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The STCs are effective as of the date of the approval letter, unless otherwise specified.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from February 1, 2018 through December 31, 2022.

The STCs have been arranged into the following subject areas:



Additional attachments have been included to provide supplementary information and guidance for specific STCs.

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: Reserved for Evaluation Design
- Attachment D: Substance Use Disorder (SUD) Implementation Plan Protocol
- Attachment E: Reserved for SUD Monitoring Protocol

## II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for Louisiana to maintain critical access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. This demonstration will provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD). It will also build on the state's existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions and strengthen a continuum of SUD services based on the American Society of Addiction Medicine (ASAM) criteria or other comparable nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

During the demonstration period, Louisiana seeks to achieve the following:

- Increase enrollee access to and utilization of appropriate OUD/SUD treatment services based on the ASAM Criteria;
- Decreased use of medically inappropriate and avoidable high-cost emergency department and hospital services by enrollees with OUD/SUD;
- Increased initiation of follow-up after discharge from emergency department for alcohol or other drug dependence; and
- Reduced readmission rates for OUD/SUD treatment.

## III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

2. **Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program, or the Children's Health Insurance Program (CHIP) for the separate CHIP population, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

   a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.

   b. If mandated changes in the federal law require state legislation, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.

5. **State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid state plan governs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including, but not limited to the failure by the state to submit required reports

and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 15. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

b. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

c. An up-to-date CHIP allotment worksheet, if necessary.

d. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and

e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request demonstration extensions under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, if the state intends to request a demonstration extension under section 1115(a) of the Act, the state must submit the extension application no later than 12 months prior to the expiration date of the demonstration. The Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 10.
9. **Compliance with Transparency Requirements 42 CFR Section 431.412.** As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements 42 CFR Section 431.412 and the public notice and tribal consultation requirements outlined in STC 15, as well as include the following supporting documentation:

a. Demonstration Summary and Objectives: The state must provide a narrative summary of the demonstration project, reiterate the objectives set forth at the time the demonstration was proposed and provide evidence of how these objectives have been met as well as future goals of the program. If changes are requested, a narrative of the changes being requested along with the objective of the change and desired outcomes must be included.

b. Special Terms and Conditions: The state must provide documentation of its compliance with each of the STCs. Where appropriate, a brief explanation may be accompanied by an attachment containing more detailed information. Where the

STCs address any of the following areas, they need not be documented a second time.

c. Waiver and Expenditure Authorities: The state must provide a list along with a programmatic description of the waivers and expenditure authorities that are being requested in the extension.

d. Quality: The state must provide summaries of: External Quality Review Organization (EQRO) reports; managed care organization (MCO) reports; state quality assurance monitoring; and any other documentation that validates the quality of care provided or corrective action taken under the demonstration.

e. Compliance with Budget Neutrality Cap: The state must provide financial data (as set forth in the current STCs) demonstrating the state's detailed and aggregate, historical and projected budget neutrality status for the requested period of the extension as well as cumulatively over the lifetime of the demonstration. CMS will work with the state to ensure that federal expenditures under the extension of this project do not exceed the federal expenditures that would otherwise have been made. In doing so, CMS will take into account the best estimate of current trend rates at the time of the extension. In addition, the state must provide up to date responses to the CMS Financial Management standard questions. If title XXI funding is used in the demonstration, a CHIP Allotment Neutrality worksheet must be included.

f. Evaluation Report: The state must provide an evaluation report reflecting the hypotheses being tested and any results available. For the proposed extension period, the state must provide a narrative summary of the evaluation design, status (including evaluation activities and findings to date), and plans for evaluation activities during the extension period.

g. Documentation of Public Notice 42 CFR section 431.408: The state must provide documentation of the state's compliance with public notice process as specified in 42 CFR section 431.408 including the post-award public input process described in 431.420(c) with a report of the issues raised by the public during the comment period and how the state considered the comments when developing the demonstration extension application.

**10. Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft phase-out plan to CMS, the state must publish on its website the draft phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received the state's response to the comment and how the state incorporated the received comment into a revised phase-out plan.

The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of phase-out activities must be no sooner than 14 calendar days after CMS approval of the phase-out plan.

b. Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

c. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR §431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, State Health Official Letter #10-008.

d. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

**11. CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

**12. Finding of Non-Compliance.** The state does not relinquish its rights to challenge CMS' finding that the state materially failed to comply.

**13. Withdrawal of 1115(a) Authority.** CMS reserves the right to withdraw waiver or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services and administrative costs of disenrolling participants.

**14. Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach,

and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

15. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR section 447.205 for changes in statewide methods and standards for setting payment rates.

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR section 431.408(b), State Medicaid Director Letter #01-024, and contained in the state's approved Medicaid State plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

16. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter, or later date if so identified elsewhere in these STCs or in the list of waiver or expenditure authorities.

17. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

18. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities which may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and which are designed to study, evaluate, or otherwise examine the Medicaid program – including public benefit or service programs; procedures for obtaining Medicaid benefits or services; possible changes in or alternatives to those programs or procedures; or possible changes in methods or level of payment for benefits or services under those programs. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

## IV. ELIGIBILITY AND ENROLLMENT

19. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility. Standards for eligibility remain set forth under the state plan. The demonstration will allow Louisiana Medicaid recipients to receive OUD/SUD treatment services in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. All demonstration services are delivered through a

managed care delivery , with the exception the spend-down medically needy population. All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan. All Medicaid eligibility standards and methodologies for these eligibility groups remain applicable.

## V. DEMONSTRATION PROGRAMS AND BENEFITS

**20. Opioid Use Disorder/Substance Use Disorder Program.** Effective upon CMS' approval of the OUD/SUD Implementation Protocol the demonstration benefit package for Louisiana Medicaid recipients will include OUD/SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Louisiana Medicaid recipients residing in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD and other SUD treatment services ranging from acute withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The coverage of OUD/SUD residential treatment and withdrawal management during short term residential stays in IMDs will expand Louisiana's current OUD/SUD benefit package available to all Louisiana Medicaid recipients as outlined in Table 1. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

**Table 1: Louisiana OUD/SUD Benefits Coverage with Expenditure Authority**

| SUD Benefit | Medicaid Authority | Expenditure Authority |
|---|---|---|
| Outpatient Services | State plan (Individual services covered) | |

| | | |
|---|---|---|
| Ambulatory Withdrawal Management | State plan | |
| Intensive Outpatient Services | State plan (Individual services covered) | |
| Inpatient Services | State plan (Individual services covered) | Services provided to individuals in IMDs |
| Residential Treatment | State plan (Individual services covered) | Services provided to individuals in IMDs |
| Clinically Managed Withdrawal Management | State plan | Services provided to individuals in IMDs |
| Medically Supervised Withdrawal Management | State plan | Services provided to individuals in IMDs |
| Medication-Assisted Treatment (MAT) | State plan | Services provided to individuals in IMDs |

**21. SUD Implementation Protocol.** The state must submit an OUD/SUD Implementation Protocol within 90 calendar days after approval of this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the Implementation Protocol. Once approved, the Implementation Protocol will be incorporated into the STCs, as Attachment D, and once incorporated, may be altered only with CMS approval. After approval of the Implementation Protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Protocol will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the OUD/SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. At a minimum, the OUD/SUD Implementation Protocol must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the SUD component of this demonstration program:

a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;
b. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within

12-24 months of OUD/SUD program demonstration approval;

c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;

d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the Louisiana Administrative Code and the Louisiana Medicaid provider manual. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other comparable, nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD program demonstration approval;

e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;

g. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of SUD program demonstration approval;

h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand access to naloxone;

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 27 ; and

**Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

**22. SUD Monitoring Protocol.** The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of SUD program under this demonstration. The SUD

Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the SUD Monitoring Plan Protocol will include reporting relevant to each of the program implementation areas listed in STC 21. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion. The SUD Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in STC 32 of the demonstration. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the Monitoring Protocol will be reported via the quarterly and annual monitoring reports.

23. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment by November 16, 2020 of the demonstration. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward closing the gap between baseline and target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The mid-point assessment will also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the assessor will provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The assessor will provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. A copy of the report will be provided to CMS. CMS will be briefed on the report.

    For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation Protocol and SUD Monitoring Plan Protocols for ameliorating these risks subject to CMS approval.

24. **Deferral for Insufficient Progress Towards Milestones and Failure to Report Measurement Data.** If the state does not demonstrate sufficient progress on milestones, as specified in the Implementation Protocol, as determined by CMS, or fails to report data as approved in the Monitoring Protocol Monitoring Protocol, CMS will defer funds in the

amounts specified in STC 29 and STC 30 for each incident of insufficient progress or failure to report in each reporting quarter.

**25. SUD Evaluation.** The OUD/SUD Evaluation will be subject to the requirements listed in sections VIII General Reporting Requirements and X Evaluation of the Demonstration of the STCs.

**26. SUD Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

a. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly Reports and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

b. Evaluation Questions and Hypotheses Specific to OUD/SUD Program. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF)

**27. SUD Health Information Technology (Health IT).** The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This "SUD Health IT Plan," or assurance, will be included as a section of the state's "Implementation Plan" (see STC 21) to be approved by CMS, and

must be submitted no later than 90 calendar days after approval of the demonstration. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.

a. The SUD Health IT section of the Implementation plan will include implementation milestones and dates for achieving them.

b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

c. The SUD Health IT Plan will describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP).[1]

d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

e. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

g. In developing the Health IT Plan, states should use the following resources:

    i. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."
    ii. States may also use the CMS 1115 Health IT resources available on

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[2] *Ibid*.

[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

"Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

iii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

d. The state will include in its monitoring Plan (see STC 21) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.

e. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (see STC 32).

f. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

i. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

ii. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest

## VI. COST SHARING

Cost sharing imposed upon individuals under the demonstration is consistent with the provisions of the approved state plan.

## VII. DELIVERY SYSTEM

Louisiana's SUD/OUD Medicaid delivery system is based on an integrated managed care model for physical and behavioral health. It utilizes Managed Care Organizations (MCOs) to deliver integrated physical and behavioral health services, including SUD. Under the demonstration, Healthy Louisiana will continue to operate as approved in Section 1932(a) state plan authority for managed care and concurrent 1915(b) demonstration.

## VIII. GENERAL REPORTING REQUIREMENTS

**28. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

**29. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. Specifically:

a. Thirty (30) calendar days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.
b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).
    i. CMS may decline the extension request.
    ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.
    iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.
f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, what quarter the deferral applies to and how the deferral is released.

**30. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones.** Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Protocol and the required performance measures in the Monitoring protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5M will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

**31. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

## IX. MONITORING

**32. Monitoring Reports.** The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90 calendar days) following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements- Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures

associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 27.

**33. Close Out Report**. Within 120 calendar days prior to the expiration of the demonstration, the state must submit a Draft Close out Report to CMS for comments.

a. The draft report must comply with the most current Guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the Close-Out report.
c. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
d. The Final Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 29.

**34. Monitoring Calls**. CMS will convene periodic conference calls with the state.

a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on evaluation activities.

a. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.

b. The state and CMS will jointly develop the agenda for the calls.

**35. Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

## X. EVALUATION OF THE DEMONSTRATION

**36. Independent Evaluator.** Upon approval of the demonstration, the state must begin arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved, draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

**37. Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

**38. Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

**39. Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

**40. Evaluation Questions and Hypotheses.** Consistent with attachments A and B (Preparing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of

Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

41. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

    a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

    b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

    c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

    d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

    e. The Interim Evaluation Report must comply with Attachment B of these STCs.

42. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, February 1, 2018 –December 31, 2022, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

    a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

    b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

43. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

**44. Public Access**. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.

**45. Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

**46. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 28.

## XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

**47. Reporting Expenditures under the Demonstration.** The following describes the reporting of expenditures subject to the Budget Neutrality agreement:

a. Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the BN expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11-W-00304/0) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered.

b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.

c. Pharmacy Rebates. When claiming these expenditures the state may refer to the July 24, 2014 CMCS Informational Bulletin which contains clarifying information for quarterly reporting of Medicaid Drug Rebates in the Medicaid Budget and Expenditures (MBES) (http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-24-2014.pdf). The state must adhere to the requirement at section 2500.1 of the State Medicaid Manual that all state collections, including drug rebates, must be reported on the CMS-64 at the applicable Federal Medical Assistance Percentage (FMAP) or other matching rate at which related expenditures were originally claimed.

d. Use of Waiver Forms. For each demonstration year, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be completed, using the waiver names listed below. Expenditures should be allocated to these forms based on the guidance which follows.

   i. **SUD IMD:**. All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.

e. Demonstration Years. The demonstration years are as follows:

| | | |
|---|---|---|
| Demonstration Year 1 | February XX, 2018-<br>December 31, 2018 | 11 Months |
| Demonstration Year 2 | January 1, 2019 -<br>December 31, 2019 | 12 Months |
| Demonstration Year 3 | January 1, 2020 -<br>December 31, 2020 | 12 Months |
| Demonstration Year 4 | January 1, 2021 -<br>December 31, 2021 | 12 Months |
| Demonstration Year 5 | January 1, 2022 –<br>December 31, 2022 | 12 Months |

**48. Budget Neutrality Monitoring Tool.** The state and CMS will jointly develop a BN monitoring tool (using a mutually agreeable spreadsheet program) for the state to use for quarterly BN status updates including established baseline and member months data and other in situations when an analysis of BN is required. The tool will incorporate the "C Report" for monitoring actual expenditures subject to BN. A working version of the monitoring tool will be available for the state's first Annual Report.

**49. Quarterly Expenditure Reports:** The state must provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided through this demonstration under the Medicaid program, including those provided through the demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

FFP will be provided for expenditures net of collections in the form of pharmacy rebates, cost sharing, or third party liability.

**50. Expenditures Subject to the Budget Neutrality Agreement.** For the purpose of this section, the term "expenditures subject to the budget neutrality agreement" means expenditures for the EGs outlined in Section XII, Monitoring Budget Neutrality for the Demonstration, except where specifically exempted. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or 64.9P Waiver.

**51. Administrative Costs.** Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using separate CMS-64.10 waiver and 64.10 waiver forms, with waiver name "ADM".

**52. Claiming Period.** All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

**53. Reporting Member Months.** The following describes the reporting of member months for demonstration populations.

a. For the purpose of calculating the BN expenditure limit and for other purposes, the state must provide to CMS, as part of the BN Monitoring Tool required under STC 48, the actual number of eligible member months for the each MEG defined in subparagraph D below. The state must submit a statement accompanying the BN Monitoring Tool, which certifies the accuracy of this information. To permit full recognition of "in-process" eligibility, reported counts of member months may be subject to revision.

b. The term "eligible member/months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member/months.

c. The state must report separate member month totals for individuals enrolled in the Healthy Louisiana OUD/SUD demonstration and the member months must be subtotaled according to the MEGs defined in STC 47(i)(1).

d. The required member month reporting MEG is:

i. **SUD IMD**: SUD IMD Member Months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

**54. Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report those expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both Medical Assistance Payments (MAP) and state and Local Administrative Costs (ADM). As a supplement to the Form CMS-37, the state will provide updated estimates of expenditures subject to the budget neutrality limit. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

**55. Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding. CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the limits described in Section XII:

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

**56. Sources of Non-Federal Share.** The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.

b. Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provision, as well as the approved Medicaid state plan.

**57. State Certification of Funding Conditions.** Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes—including health care provider-related taxes—fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

**58. Program Integrity.** The state must have a process in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

## XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

**59. Limit on Title XIX Funding.** The state will be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STCs 60 and 61, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in section XI. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

**60. Risk.** The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the for all demonstration populations, CMS will not place the state at risk for changing economic conditions. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

**61. Calculation of the Budget Neutrality Limit and How It Is Applied.** For the purpose of calculating the overall budget neutrality limit for the demonstration, annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each EG (shown on the table in STC 63) by the corresponding actual member months total, and summing the results of those calculations. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by Composite Federal Share, which is defined in STC 64 below. The demonstration expenditures subject to the budget neutrality limit are those reported under the following Waiver Names; SUD IMD.

**62. Impermissible DSH, Taxes, or Donations.** CMS reserves the right to adjust the budget neutrality ceiling to be consistent with enforcement of laws and policy statements, including regulations and letters regarding impermissible provider payments, health care related taxes, or other payments (if necessary adjustments must be made). CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

**63. Main Budget Neutrality Test.**

The trend rates and per capita cost estimates for each EG for each year of the demonstration are listed in the table below.

| MEG | TREND | DY 1 - PMPM | DY 2 PMPM | DY 3 PMPM | DY 4 PMPM | DY 5 PMPM |
|---|---|---|---|---|---|---|
| SUD IMD | 5.0% | $687 | $721 | $757 | $795 | $835 |

**64. Hypothetical Model.** As part of the SUD initiative, the state may receive FFP for the continuum of services to treat OUD and other SUDs, provided to Medicaid enrollees in an IMD. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical for the purposes of budget neutrality. Hypothetical services can be treated in budget neutrality in a way that is similar to how Medicaid state plan services are treated, by including them as a "pass through" in both the without-waiver and with-waiver calculations. However, the state will not be allowed to obtain budget neutrality "savings" from these services.

**65. Composite Federal Share Ratios.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by Louisiana on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through

MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method.

**66. Exceeding Budget Neutrality.** The budget neutrality limit calculated in STC 63 will apply to actual expenditures for demonstration services as reported by the state under Section XI of these STCs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

**67. Enforcement of Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration, rather than on an annual basis. However, if the state exceeds the calculated cumulative target limit by the percentage identified below for any of the DYs, the state must submit a corrective action plan to CMS for approval.

| Demonstration Year | Cumulative Target Definition | Percentage |
|---|---|---|
| DY 1 | Cumulative budget neutrality limit | 2.0 percent |
| DY 1 through DY 2 | Cumulative budget neutrality limit | 1.5 percent |
| DY 1 through DY 3 | Cumulative budget neutrality limit | 1.0 percent |
| DY 1 through 4 | Cumulative budget neutrality limit | .5 percent |
| DY 1 through 5 | Cumulative budget neutrality limit | 0 percent |

## XIII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

| Date | Deliverable | STC |
|---|---|---|
| 30 days after approval date | State acceptance of demonstration Waivers, STCs, and Expenditure Authorities | Approval letter |
| 90 days after SUD program approval date | SUD Implementation Protocol | STC 21 |
| 150 days after SUD program approval date | SUD Monitoring Protocol | STC 22 |
| 180 days after approval date | Draft Evaluation Design | STCs 26 and 38 |
| 60 days after receipt of CMS comments | Revised Draft Evaluation Design | STCs 26 and 39 |
| 30 days after CMS Approval | Approved Evaluation Design published to state's website | STCs 25 and 39 |
| November 16, 2020 | Mid-Point Assessment | STC 23 |
| One year prior to the end of the demonstration, or with renewal application | Draft Interim Evaluation Report | STC 41(c) |
| 60 days after receipt of CMS comments | Final Interim Evaluation Report | STC 41(d) |
| 18 months of the end of the demonstration | Draft Summative Evaluation Report | STC 42 |
| 60 calendar days after receipt of CMS comments | Final Summative Evaluation Report | STC 42(a) |
| 30 calendar days of CMS approval | Approved Final Summative Evaluation Report published to state's website | STC 42(b) |
| Monthly Deliverables | Monitoring Calls | STC 34 |
| Quarterly Deliverables<br><br>Due 60 days after end of each quarter, except 4th quarter | Quarterly Monitoring Reports | STC 32 |
| | Quarterly Expenditure Reports | STC 49 |
| Annual Deliverables -<br><br>Due 90 days after end of each 4th quarter | Annual Reports | STC 32 |

| | | |
|---|---|---|
| Within 120 calendar days prior to the expiration of the demonstration | Draft Close-out Operational Report | STC 33 |
| 30 calendar days after receipt of CMS comments | Final Close-out Operational Report | STC 33(d) |

**ATTACHMENT A**
**Developing the Evaluation Design**

## Introduction

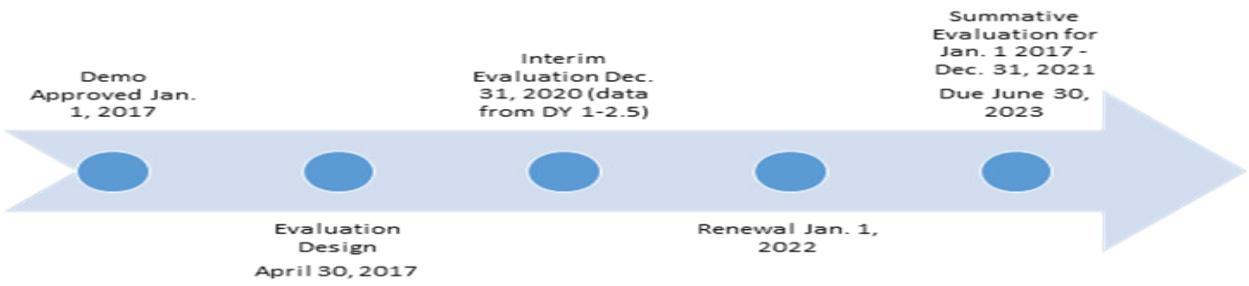
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

## Expectations for Evaluation Designs

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

**The format for the Evaluation Design is as follows:**
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

**Submission Timelines**
There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.




**Required Core Components of All Evaluation Designs**

The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

**A. General Background Information** – In this section, the state should include basic information about the demonstration, such as:

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

**B. Evaluation Questions and Hypotheses** – In this section, the state should:

1. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3. Identify the state's hypotheses about the outcomes of the demonstration:

4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

**C. Methodology**– In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and

submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

**Table A. Example Design Table for the Evaluation of the Demonstration**

| Research Question | Outcome measures used to address the research question | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|---|---|---|---|
| **Hypothesis 1** | | | | |
| Research question 1a | -Measure 1<br>-Measure 2<br>-Measure 3 | -Sample e.g. All attributed Medicaid beneficiaries<br>-Beneficiaries with diabetes diagnosis | -Medicaid fee-for-service and encounter claims records | -Interrupted time series |
| Research question 1b | -Measure 1<br>-Measure 2<br>-Measure 3<br>-Measure 4 | -sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months) | -Patient survey | Descriptive statistics |
| **Hypothesis 2** | | | | |
| Research question 2a | -Measure 1<br>-Measure 2 | -Sample, e.g., PPS administrators | -Key informants | Qualitative analysis of interview material |

**D. Methodological Limitations –** This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

**E. Attachments**

**Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

**A. Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a

breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

**B. Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

## ATTACHMENT B
## Preparing the Interim and Summative Evaluation Reports

### Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

### Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

### Intent of this Guidance

The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

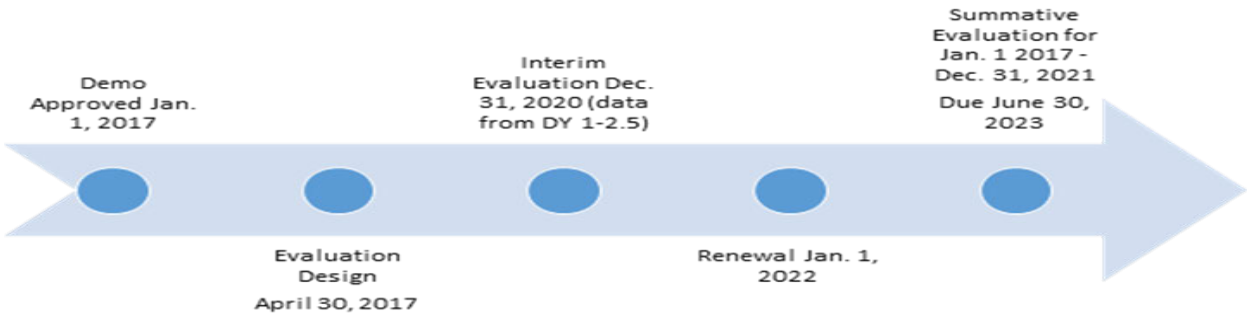
The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;

I. Lessons Learned and Recommendations; and
J. Attachment(s).

**Submission Timelines**

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.




**Required Core Components of Interim and Summative Evaluation Reports**

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

**A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

**B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5) Describe the population groups impacted by the demonstration.

**C. Evaluation Questions and Hypotheses** – In this section, the state should:

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
    a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
    b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
    c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?

2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

**A. Methodological Limitations -** This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

**B. Results** – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

**C. Conclusions** – In this section, the state will present the conclusions about the evaluation results.

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

**D. Interpretations, Policy Implications and Interactions with Other State Initiatives –** In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

**E. Lessons Learned and Recommendations** – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

**F. Attachment**

Evaluation Design: Provide the CMS-approved Evaluation Design

**Attachment C:**
**Reserved for Evaluation Design**

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: May 17, 2019

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Janna Wisniewski, PhD
Charles Stoecker, PhD

## A. General Background and Information

As of 2016, Louisiana had the fifth highest per-capita rate of opioid prescriptions among U.S. states and was above the national average in drug overdose deaths (CDC, 2018). Furthermore, from 2015 to 2016, deaths in Louisiana from opioid overdose increased by 22% (KFF, 2018).

The Treatment Episode Data Set (TEDS) suggests nearly 14 thousand admissions for SUD last year.

**Table 1: Substance Abuse Treatment Admissions by Primary Substance of Abuse, among admissions aged 12 and older: Louisiana 2017**

| Primary Substance | Number | | Primary Substance | Number |
|---|---|---|---|---|
| Alcohol only | 793 | | Other stimulants | 17 |
| Alcohol with secondary drug | 891 | | Tranquilizers | 140 |
| Heroin | 1,129 | | Sedatives | 37 |
| Other opiates | 743 | | Hallucinogens | 28 |
| Cocaine (smoked) | 649 | | PCP | 33 |
| Cocaine (other) | 239 | | Inhalants | 12 |
| Marijuana | 934 | | Other/Unknown | 6,748 |
| Amphetamines | 1,510 | | TOTAL | 13,903 |

https://wwwdasis.samhsa.gov/webt/quicklink/LA17.htm

The National Survey of Substance Abuse Treatment Services (N-SSATS) is an annual survey of facilities providing substance abuse treatment. In Louisiana, 157 substance abuse treatment facilities were included in the 2016 N-SSATS, which reported a total of 9,628 clients in substance abuse treatment on March 31, 2016. (http://www.samhsa.gov/data/2k3/NSSATS/NSSATS.pdf).

Treatment options for patient with SUD include one or more of the following service components:

- Individual and group counseling
- Inpatient and residential treatment
- Intensive outpatient treatment
- Partial hospital programs
- Case or care management
- Medication
- Recovery support services
- 12-Step fellowship
- Peer supports

Source: https://www.samhsa.gov/treatment/substance-use-disorders

Among the treatment options 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 mental diseases at non-residential settings and leave states with the responsibility for funding inpatient psychiatric services (https://lac.org/wp-content/uploads/2014/07/IMD_exclusion_fact_sheet.pdf).

Since 2012, Louisiana has been able to include coverage of IMD provided services under the Louisiana Behavioral Health Partnership (LBHP) and, later, Healthy Louisiana, since coverage was determined to be "cost-effective" and capitated by the Louisiana Department of Health (LDH). In 2016, the Center 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.

In response to the growing concern over rates of opioid use disorders (OUDs) and substance use disorders (SUDs) in general, the Louisiana Department of Health applied for a Section 1115(a) Demonstration in 2017 to allow for the continuation of treatment for OUD/SUD in institutions for mental diseases (IMDs) regardless of the length of stay.[1,2] In addition, the waiver included several other proposed interventions 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 will continue through December 31, 2022. The scope of the demonstration requires no change in Medicaid eligibility, therefore the affected population will be Medicaid beneficiaries in the state of Louisiana who are treated for an OUD/SUD.

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

a. Increase access to evidence-based OUD/SUD care
b. Increase access to and utilization of medication-assisted treatment (MAT) for OUD/SUD
c. Ensure sufficient provider capacity at each level of care for OUD/SUD
d. Decrease use of medically inappropriate care and reduced reliance on emergency department and hospital services for OUD/SUD treatment
e. Reduce readmission rates for OUD/SUD treatment
f. Increase use of evidence-based OUD/SUD patient placement criteria
g. Increase initiation of follow-up after discharge from the emergency department or hospital for OUD/SUD

[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."

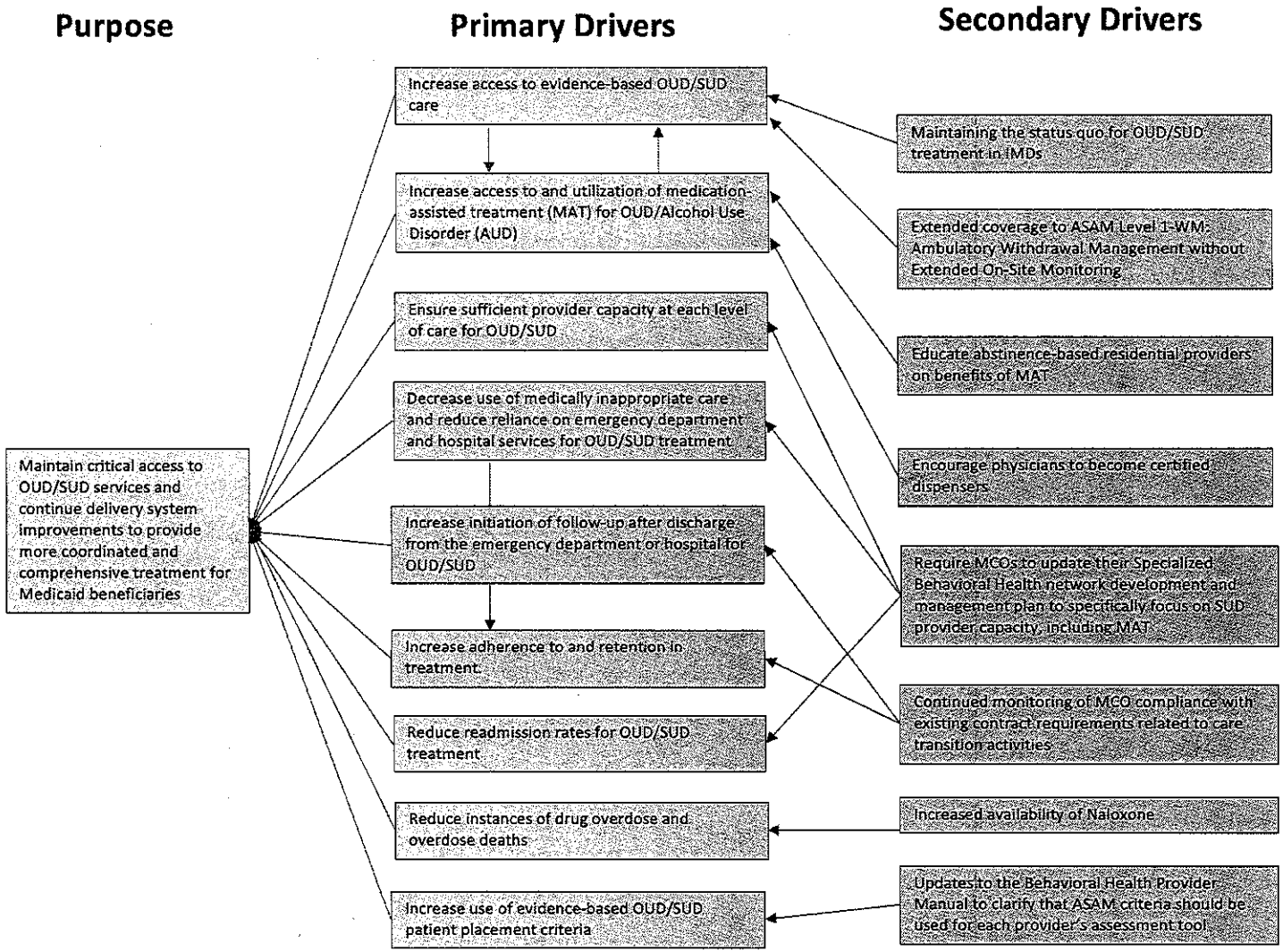
[2] While IMDs have been excluded from federal financial participation since Medicaid's inception, several states have used an "in lieu of" policy to fund IMD care using federal dollars through capitated payments to managed care organizations (Musumeci, 2018). In May 2016, CMS implemented a policy to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

h. Increase adherence to and retention in treatment
i. Reduce instances of drug overdose and overdose deaths

The demonstration implementation plan includes five separate milestones that address various areas of OUD/SUD treatment including access, placement, standards of care, and provider capacity. We develop hypotheses surrounding these milestones and their potential impact on the demonstration goals and describe our proposed methodology for testing these hypotheses below.

## B. Evaluation Questions and Hypotheses

*B.1 Driver Diagram & Model Assumptions*



Model Assumptions:

1. Medicaid beneficiaries cannot afford treatment.
2. Providers will read the Louisiana Medicaid Provider manual.
3. Abstinence-only providers will read or participate in education.
4. Cost is a major barrier to evidence-based treatment for providers.
5. Knowledge is a major barrier preventing providers from engaging in evidence-based treatment.
6. Providers will comply with the requirement.
7. MCOs' contract requirements related to linkages to care are appropriate.
8. There is a process in place by which tracking data for opioids and Naloxone is acted upon.
9. Community-based services are effective.

*B.2 Questions and Hypotheses*

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

| Evaluation Question 1.0: Did access to evidence-based OUD/SUD care increase as a result of the demonstration? | | | | | | |
|---|---|---|---|---|---|---|
| Demonstration Goal 1.1: Increase access to evidence-based OUD/SUD care. | | | | | | |
| Evaluation Hypothesis: The demonstration will increase the share of beneficiaries who are treated for OUD/SUD in ways that are consistent with evidence-based care. | | | | | | |
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Increase access to evidence-based OUD/SUD care) | Share of beneficiaries with an OUD/SUD treated in an IMD | CMS | Extensive Margin: Number of unduplicated beneficiaries enrolled in a reporting month (year) with a claim that uses an SUD diagnosis code as the primary diagnosis from an IMD billing provider | Number of unduplicated Medicaid beneficiaries enrolled in 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 | Louisiana Medicaid Claims Data | DD using IMD patients with no OUD/SUD as controls |
| | Average LOS for beneficiaries with an OUD/SUD treated in an IMD | | Intensive Margin: Average LOS for beneficiaries treated in an IMD | Condition on unduplicated beneficiaries enrolled in a reporting month (year) with a claim that uses an SUD diagnosis code as the primary diagnosis from an IMD billing provider | | |
| Secondary Drivers (Maintaining the status quo for OUD/SUD treatment in IMDs; Extended coverage to ASAM Level 1-WM: Ambulatory Withdrawal Management without Extended On-Site Monitoring) | Share of beneficiaries with an OUD/SUD receiving ASAM care at various levels. | ASAM | Number of unduplicated Medicaid beneficiaries enrolled in reporting month (year) with a paid/accepted ASAM claim at each ASAM level | Number of unduplicated Medicaid beneficiaries enrolled in 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 | Louisiana Medicaid Claims Data | Pre/Post |

| Demonstration Goal 1.2: Increase access to and utilization of medication-assisted treatment (MAT) for OUD/Alcohol Use Disorder (AUD). Evaluation Hypothesis: The demonstration will increase the use of MAT | | | | | | |
|---|---|---|---|---|---|---|
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Increase access to and utilization of medication-assisted treatment (MAT) for OUD/Alcohol Use Disorder (AUD)) | Share of those with an OUD/AUD diagnoses who are treated using MAT | N/A | Number of unduplicated Medicaid beneficiaries enrolled in a reporting month (year) with a claim that uses an OUD/AUD diagnoses code as the primary diagnosis for Buprenorphine, Suboxone, Bunavail, Zubsolv, Probuphine, Naltrexone, Vivitrol, Disulfiram, or Acamprosate. | Number of unduplicated Medicaid beneficiaries enrolled in reporting month (year) with a paid/accepted claim for date of service in reporting month (year) that uses an OUD/AUD diagnosis code as the primary diagnosis | Louisiana Medicaid Claims data | ITS & DD using pre-demonstration exposure to MAT |
| | | | | | Key informant interviews with residential providers | Thematic analysis of qualitative data |
| Secondary Drivers (Educate abstinence-based residential providers on benefits of MAT; Encourage physicians to become certified dispensers) | Number of providers who are certified to prescribe or dispense buprenorphine per 100,000 state residents. | SAMHSA | Number of waivered physicians | State population divided by 100,000. | SAMHSA Buprenorphine Treatment Practitioner Locator; Number of DATA-Certified Physicians | DD comparing LA to other states |
| | | | Number of waivered physicians with paid/accepted MAT prescription claims that use an SUD diagnosis code as the primary diagnosis for more than 2 unduplicated beneficiaries in a reporting month (year) | N/A | SAMHSA and Louisiana Medicaid Claims data | Pre/Post |
| | | | | | Key informant interviews with physicians | Thematic analysis of qualitative data |

| Demonstration Goal 1.3: Ensure sufficient provider capacity at each level of care for OUD/SUD.<br>Evaluation Hypothesis: The demonstration will improve provider capacity. | | | | | | |
|---|---|---|---|---|---|---|
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Ensure sufficient provider capacity at each level of care for OUD/SUD) | Total number of SUD providers | N/A | Number of Unduplicated NPI provider records with active enrollment for SUD services during reporting year | N/A | Louisiana Medicaid Claims data | ITS |
| Secondary Driver (Require MCOs to update their Specialized Behavioral Health network development and management plan to specifically focus on SUD provider capacity, including MAT) | SUD providers per SUD beneficiary | N/A | | Number of unduplicated Medicaid beneficiaries enrolled in 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 | | |
| | SUD providers per SUD beneficiary by ASAM level of care | ASAM | Number of Unduplicated NPI provider records with active enrollment for SUD services during reporting year by ASAM level of care | Number of unduplicated Medicaid beneficiaries enrolled in 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 | | |

| Evaluation Question 2: Did use of medically inappropriate care (including care covered during inpatient stays for OUD/SUD) decrease as a result of the demonstration? | | | | | | |
|---|---|---|---|---|---|---|
| Demonstration Goal 2.1: Decrease use of medically inappropriate care and reduce reliance on emergency department and hospital services for OUD/SUD treatment.<br>Evaluation Hypothesis: The demonstration will reduce visits to the emergency department and the use of hospital services for the treatment of OUD/SUD. | | | | | | |
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Decrease use of medically inappropriate care and reduce reliance on emergency department and hospital services for OUD/SUD treatment) | Emergency department visits for OUD/SUD | N/A | Number of unduplicated beneficiaries enrolled in a reporting month (year) with a claim that uses an SUD diagnosis code as the primary diagnosis with HCPCS/Procedure Codes 99281, 99282, 99283, 99284, 99285 or place of service 23 (ER-Hospital) | N/A | Louisiana Medicaid Claims data | ITS & DD using non-targeted conditions for those with no OUD/SUD |
| Secondary Driver (Require MCOs to update their Specialized Behavioral Health network development and management plan to specifically focus on SUD provider capacity, including MAT) | Inpatient admissions for OUD/SUD | | Number of unduplicated beneficiaries enrolled in a reporting month (year) with admit date for inpatient services billed from a Mental Health Free-Standing Hospital or from a Distinct Part Psych Hospital that uses an SUD diagnosis code as the primary diagnosis, or for inpatient services billed from a General Acute Care Hospital that uses an SUD diagnosis code as the primary diagnosis along with a visit from an LMHP during inpatient stay | | Key informant interviews with primary care/treatment providers and ED managers | Thematic analysis of qualitative data |

| Demonstration Goal 2.2: Reduce readmission rates for OUD/SUD treatment.<br>Evaluation Hypothesis: The demonstration will reduce hospital readmission rates for OUD/SUD. | | | | | | |
|---|---|---|---|---|---|---|
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Reduce readmission rates for OUD/SUD treatment) | Readmissions for OUD/SUD | ASAM | Number of paid/accepted (ASAM 4-WM) claims in a reporting month (year) for inpatient withdrawal management services billed from a Mental Health Free-Standing Hospital or from a Distinct Part Psych Hospital that uses an SUD diagnosis code as the primary diagnosis, or for inpatient withdrawal management services billed from a General Acute Care Hospital that uses an SUD diagnosis code as the primary diagnosis along with a visit from an LMHP during inpatient stay, that follows within 30 days of a previous discharge from an ASAM 4-WM inpatient stay | N/A | Louisiana Medicaid Claims data | ITS & DD using non-targeted conditions for those with no OUD/SUD |
| Secondary Driver (Require MCOs to update their Specialized Behavioral Health network development and management plan to specifically focus on SUD provider capacity, including MAT) | | | | | | |

| Demonstration Goal 2.3: Increase use of evidence-based OUD/SUD patient placement criteria.<br>Evaluation Hypothesis: The demonstration will increase the use of evidence-based OUD/SUD patient placement criteria. | | | | | | |
|---|---|---|---|---|---|---|
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Increase use of evidence-based OUD/SUD patient placement criteria) | Appropriate patient placement for OUD/SUD treatment | LDH | Number of unduplicated Medicaid beneficiaries in a reporting month (year) with a paid/accepted claim that uses an SUD diagnoses code as the primary diagnosis receiving medically appropriate placement | Number of unduplicated Medicaid beneficiaries enrolled in 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 | MCO Monitoring Reports | ITS |
| Secondary Driver (Updates to the Behavioral Health Provider Manual to clarify that ASAM criteria should be used for each provider's assessment tool) | | | | | | |

| Evaluation Questions: Delivery System Improvements Related to Demonstration | | | | | | |
|---|---|---|---|---|---|---|
| Demonstration Goal 3.1: Increase initiation of follow-up after discharge from the emergency department or hospital for OUD/SUD | | | | | | |
| Evaluation Hypothesis: The demonstration will increase initiation of follow-up after discharge from the emergency department or hospital for OUD/SUD | | | | | | |
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Increase initiation of follow-up after discharge from the emergency department or hospital for OUD/SUD) | Follow-up after discharge from the ED for OUD/SUD | NCQA | Number of ED visits for OUD/SUD for which the beneficiary received follow-up within (a) 7 days of discharge or (b) 30 days of discharge | Total number of ED visits for OUD/SUD | Louisiana Medicaid Claims data | ITS |
| Secondary Driver (Continued monitoring of MCO compliance with existing contract requirements related to care transition activities) | Follow-up after discharge from the hospital for OUD/SUD | | Number of hospital inpatient admissions for OUD/SUD for which the beneficiary received follow-up within (a) 7 days of discharge or (b) 30 days of discharge | Total number of hospital inpatient admissions for OUD/SUD | Survey of SUD treatment facilities pre- and post-intervention | Descriptive statistics; chi square tests of significance comparing values before and after the intervention |

| Demonstration Goal 3.2: Increase adherence to and retention in treatment.<br>Evaluation Hypothesis: The demonstration will increase adherence to and retention in treatment. | | | | | | |
|---|---|---|---|---|---|---|
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Increase adherence to and retention in treatment)<br><br>Secondary Driver (Continued monitoring of MCO compliance with existing contract requirements related to care transition activities) | Share of those with an OUD/SUD diagnosis who receive follow-up treatment within 35-60 and 61-90 days after initial episode of care | LDH | Number of unduplicated Medicaid beneficiaries in a reporting month (year) with a paid/accepted claim that uses an SUD diagnoses code as the primary diagnosis who have no prior SUD service claim in the previous 90 days and who have at least one SUD service claim between days 35-60 and days 61-90 following initiation of treatment | Number of unduplicated Medicaid beneficiaries in a reporting month (year) with a paid/accepted claim that uses an SUD diagnoses code as the primary diagnosis who have no prior SUD service claim in the previous 90 days | Louisiana Medicaid claims data | Pre/Post |

| Evaluation Question 4: Did health outcomes for Medicaid beneficiaries with OUD/SUD improve (i.e., decrease rate of drug overdose deaths) as a result of the demonstration? | | | | | | |
|---|---|---|---|---|---|---|
| Demonstration Goal 4.1: Reduce instances of drug overdose and overdose deaths. | | | | | | |
| Evaluation Hypothesis: The demonstration will decrease the rate of drug overdose and the number of drug deaths. | | | | | | |
| **Driver** | **Measure Description** | **Steward** | **Numerator** | **Denominator** | **Data Source** | **Analytic Approach** |
| Primary Driver (Reduce instances of drug overdose and overdose deaths) | Number of non-fatal drug overdoses | N/A | Number of unduplicated Medicaid beneficiaries enrolled in a reporting month (year) with a non-fatal occurrence of drug overdose. Non-fatal overdoses will be tracked using ICD-10 poisoning codes of all intents for medication/drugs/substances commonly abused and cross-referenced with death record data to exclude fatal overdoses. | N/A | Louisiana Medicaid Claims data and Louisiana Office of Public Health Vital Records | ITS |
| | Share of those with an OUD/SUD diagnosis who experience a non-fatal overdose | | | Number of unduplicated Medicaid beneficiaries enrolled in 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 | | |
| Secondary Driver (Increased availability of Naloxone) | Number of overdose deaths | CDC<br>LDH<br>OBH | Total number of deaths in Louisiana attributed to accidental poisoning by and exposure to drugs and other biological substances | N/A | National Vital Statistics System Mortality Multiple Cause-of-Death Restricted Use Files<br><br>Louisiana Medicaid Claims data and data from the Advisory Council on Heroin and Opioid Prevention and Education (HOPE council) | DD |
| | Share of all deaths related to overdose | | | Total number of deaths in Louisiana | Key informant interviews with primary care/treatment providers and local health officials | Thematic analysis of qualitative data |

*B.3 Required Evaluation Topic: Demonstrate patterns and trends in Medicaid costs associated with SUD 1115 demonstration*

Methodology for analyzing costs of the Louisiana SUD waiver to the Medicaid program

*Identify Medicaid beneficiaries with a SUD.* Using files obtained from Louisiana Medicaid data warehouse, including inpatient, outpatient, pharmacy, and long-term care claims, we will identify beneficiaries with a substance use diagnosis or treatment code during the pre- and post-demonstration periods. We will link beneficiaries with a SUD diagnosis or treatment during the specified time periods to Medicaid eligibility data and demographic characteristics, to identify the months a beneficiary was enrolled in Medicaid. The analysis will include the first month where a SUD diagnosis or treatment claim was observed for the beneficiary and for up to eleven additional months that did not include claims for SUD diagnosis or treatment if the beneficiary remained enrolled in Medicaid. Repeated SUD diagnoses or treatment claims will extend the observation period included in the analysis.

*Organize the data to create a file with an observation for each month a beneficiary is Medicaid-eligible, on or after their first observed SUD-related claim during the analysis period.* For each month that an individual is enrolled, the data file will contain an observation with their Medicaid costs in that month, using the ten variables specified in Table 1 and demographic characteristics merged from the eligibility data.

*Develop shadow cost prices.* As Louisiana Medicaid patients are in managed care we will use the published fee-for-service 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.

*Waiver administrative costs.* The costs for administering Louisiana's SUD 1115 waiver program are entirely staffing costs. There are 10 staff members involved in administering the waiver program. We will ask each staff member to estimate the percentage of their effort spent on administering the SUD waiver, percentage of time spent supporting the waiver evaluation efforts, and percentage of time spent on other duties. We will multiply the percentage efforts spent directly on administering the waiver by salaries to obtain administrative costs for the waiver program.

*Calculate and trend average monthly spending.* From the individual month-level data, we will calculate average costs, across the categories presented in Table 3, separated into months before the demonstration and months after. These means will be plotted to show trends visually and to verify that month-to-month variation is within expectations and does not indicate an underlying data error. Depending on variance in costs we may collapse data to the quarterly level to smoothly out monthly variation in costs.

**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 |
| | Non-SUD | Louisiana Medicaid Claims Data |
| Type or source of care cost drivers* | Outpatient costs – non ED | Louisiana Medicaid Claims Data |
| | Outpatient costs – ED | |
| | Inpatient costs | |
| | Pharmacy costs | |
| | Long-term care costs | |

Our model for identifying the impact of the SUD 1114 waiver program on costs will be an interrupted time-series design without a comparison group. This is necessary as there is no geographic or eligibility variation in the Louisiana Medicaid population in who is eligible for these services. For our interrupted time series regression analysis of costs, we will include an indicator equal to 1 for months on or after the start date of the demonstration and equal to 0 for the pre-demonstration period months. Our regression model will also include covariates to control for age, race, gender, and dual eligibility status. We will model costs in a two-part model where the first part is a logit model where the outcome is whether there are any costs in the person-month and in the second part the outcome is log costs as costs are typically not normally distributed.

For each outcome in Table 3 we will run the following model:

$$Costs = \beta 0 + \beta 1 * TIME + \beta 2 * POST + \beta 3 * (TIME * POST) + Bi * CONTROLS + \varepsilon$$

Where:

TIME is a count variable that starts with the first quarter pre-demonstration period data and ends with the last quarter of post-demonstration period data.

POST is the indicator variable that equals 1 if the month occurred on or after demonstration start date.

CONTROLS are covariates, such as age, gender, race, dual Medicare-Medicaid enrollment, and month.

We will report marginal effects and standard errors to assess statistically significant changes in costs. Changes in average costs after the intervention will be captured by $\beta 2$. If this is positive and statistically significant it will indicate costs are higher in the post-demonstration period. Changes in trends in costs will be captured by $\beta 3$. If this is positive and statistically significant it will indicate cost trends have increased in the post period. Together these two coefficients will capture potential program impacts on cost. We will also report regression adjusted means (either monthly or quarterly), as described previously, to make regression results more easily interpretable for lay audiences.

## C. Methodology

### *C.1 Evaluation Methodology*

We will use three methods to evaluate the hypotheses listed in Table 2. When it is possible to designate a control group, our preferred methodology 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.

Use of the DD methodology will not be possible when we are unable to identify an appropriate control group who would be plausibly unaffected by a particular intervention. Instead, we will rely on one of two alternative research designs: interrupted time series analysis or a pre/post analysis. 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 so as 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 milestones 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.

Finally, for a small number of outcomes, both the DD and ITS will be infeasible. This will occur when we are unable to identify an appropriate control group and when time-series data on a particular outcome is limited. For example, since ASAM Level 1-WM treatment was not a covered benefit prior to the demonstration, we cannot model the trend in this treatment over time for Medicaid beneficiaries. In these cases, we will use a simple pre/post analysis to statistically compare changes in outcomes from the pre-intervention period to the post-intervention period.

### *C.2 Target and Comparison Populations*

For most analyses, the target population will consist of the Medicaid population with an OUD/SUD. The inclusion criterion for this group is Medicaid beneficiaries enrolled in a specific reporting period (e.g., month or year) with a paid/accepted claim that uses an OUD/SUD diagnosis code as the primary diagnosis.

When examining changes in physician certified dispensers, the target population will include all waivered physicians in the state of Louisiana listed in the SAMHSA Buprenorphine Treatment Practitioner Locator and the DATA-Certified Physician Totals. In some specifications, we will compare changes in the number of waivered physicians in Louisiana to changes in other states.

In those instances, our population will expand to include physicians from non-SUD demonstration states. In addition, we will use NPI provider records from the Medicaid claims data to measure active physician treatment for SUD services.

Finally, when examining overdose deaths, our target population will be comprised of those whose cause of death is listed as an "accidental poisoning by and exposure to drugs and other biological substances" in both Louisiana and other control states.

*C.3 Evaluation Period*

The evaluation period for analyses using the Medicaid claims data will begin in January 2014 and will be ongoing through the projected end of the demonstration in December 2022. Though the demonstration was approved in February 2018, we will incorporate data from the 2014 through 2017 in order to establish trends and use-rates in the pre-demonstration period. We will then measure changes in these outcomes from the pre-demonstration to post-demonstration periods.

*C.4 Data Sources*

The primary data source for our analysis is the Louisiana Medicaid claims database. We have obtained this data through an agreement with the Louisiana Department of Health. Additional data sources include the Buprenorphine Treatment Practitioner Locator and DATA-Certified Physicians Totals collected by SAMHSA and the National Vital Statistics System Mortality Multiple Cause-of-Death Restricted Use Files. The Buprenorphine Treatment Practitioner Locator and DATA-Certified Physicians data are freely available through SAMHSA's website. We will apply for access to restricted-use versions of the Mortality Multiple Cause-of-Death files, which is necessary in order to obtain geographic identifiers.

The quality of the Medicaid claims data is quite 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 are able to 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.

Similarly, the quality of the Mortality Multiple Cause-of-Death files is generally seen to be high as the data are derived from individual death certificates and are a near census of all deaths in U.S. According to the National Vital Statistics System, the Mortality Multiple Cause-of-Death files are a "fundamental" source of information on cause of death. A potential limitation of these data is underreporting of opioid overdose as a cause of death. For example, Buchanich et al. (2018) suggests that as many as 70,000 opioid overdose deaths from 1999 to 2015 were misclassified as "unspecified overdose deaths". To address this limitation, we plan to analyze both opioid-related overdose deaths and all deaths due to overdose.

SAMHSA maintains two sources of data on physician certification for treating OUD/SUD through MAT: The Buprenorphine Treatment Practitioner Locator and DATA-Certified Physicians database. Data elements on DATA-Certified Physicians is collected from online submission forms that physicians must complete in order to attain waiver certification. The Buprenorphine Treatment Practitioner Locator data is taken from practitioner profiles maintained by SAMHSA. In both cases, the quality of the data depend on the accuracy of the information provided by physicians. Inaccuracies are likely to be minimal for data on the counts of waivered physicians, while information on physician location (including practice address) will be more susceptible to error. We can use the Medicaid Claims Provider files to improve our understanding of physician location.

We have obtained Louisiana Medicaid claims data from January 2014 through February 2018 and will continue to receive updated claims at 6-month intervals. The Mortality Multiple Cause-of-Death files are made available with a 1-year lag (i.e., data for the year 2017 will be made available in December 2018). We will apply for the Mortality Multiple Cause-of-Death files through 2018 and continue to apply for updated data each year as new files are made available. The SAMHSA data is updated annually with some delay.

*C.5 Analytic Methods*

Quantitative 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:

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

Where $Outcome_{ist}$ represents the outcome of interest to be estimated for individual $i$ living in state/region $s$ at time $t$. $Treat$ is an indicator for assignment to the treatment group and $Post$ an indicator for the post-intervention period. The interaction term, $Treat_{is} \times Post_t$, 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 individual characteristics such as age and sex, $Z$ is a vector of state or region characteristics such as unemployment rates, $\delta$ and $\tau$ are state/region and time fixed effects, and $\varepsilon$ 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. Table 2 below lists each outcome that we plan to analyze using the DD technique and the populations assigned to the treatment and control groups.

**Table 4: Outcomes and Treatment/Control Designations for DD Models**

| Outcome | Treatment Group | Control Group |
|---|---|---|
| Share of beneficiaries with an OUD/SUD treated in an IMD | OUD/SUD beneficiaries | Non-OUD/SUD beneficiaries treated at IMDs |
| Average LOS for beneficiaries with an OUD/SUD treated in an IMD | OUD/SUD beneficiaries | Non-OUD/SUD beneficiaries treated at IMDs |
| Share of those with an OUD/SUD diagnoses who are treated using MAT | OUD/SUD beneficiaries in regions with low pre-demonstration MAT use | OUD/SUD beneficiaries in regions with high pre-demonstration MAT use |
| Number of providers who are certified to prescribe or dispense buprenorphine per capita. | Per capita certified dispensers in Louisiana | Per capita certified dispensers in control states |
| Emergency department visits for OUD/SUD | OUD/SUD beneficiaries | Non-OUD/SUD beneficiaries |
| Inpatient admissions for OUD/SUD | OUD/SUD beneficiaries | Non-OUD/SUD beneficiaries |
| Readmissions for OUD/SUD | OUD/SUD beneficiaries | Non-OUD/SUD beneficiaries |
| Number of overdose deaths | Louisiana decedents | Decedents in control states |
| Share of all deaths related to overdose | Louisiana decedents | Decedents in control states |

The inclusion criteria for each of our proposed control groups is as follows:

1. Non-OUD/SUD beneficiaries treated at IMDs: includes Medicaid beneficiaries treated at IMDs who do not have a diagnosis of OUD/SUD and are therefore subject to the IMD exclusion rule. We plan to use a propensity score matching technique to generate a control group of non-OUD/SUD IMD patients with characteristics similar to those with an OUD/SUD diagnosis.

2. OUD/SUD beneficiaries in regions with high pre-demonstration MAT use: MAT use for OUD/SUD varies geographically across the state of Louisiana. For example, Orleans Parish has 182 certified MAT prescribers, while 40 parishes have fewer than 5 MAT prescribers and 9 parishes have 0 prescribers.[3] We propose to create a control group composed of Medicaid OUD/SUD beneficiaries in regions with high pre-demonstration MAT use, as these individuals would be relatively less impacted by the demonstration's efforts to increase MAT use. Geographic regions would likely be delineated at the zip code or parish level depending on the sample size and high/low MAT use will be defined based on quartile of per-capita MAT claims.

3. Certified dispensers in control states: control states will include those states that have expanded Medicaid coverage under the ACA, but have not received approval for an SUD Section 1115 Demonstration Waiver. Additionally, we will confirm whether pre-

[3] See the Louisiana Section 1115 Demonstration Waiver Implementation Plan for a complete count of MAT prescribers by parish.

demonstration trends in outcomes for Louisiana and the control states are similar and may alter the combination of control states based on these trends.

4. Non-OUD/SUD beneficiaries: includes Medicaid beneficiaries without an OUD/SUD diagnosis. We plan to use a propensity score matching technique to generate a control group of non-OUD/SUD beneficiaries with characteristics similar to those with an OUD/SUD diagnosis. We will also compare average resource utilization by diagnosis to eliminate beneficiaries from the control group who visit the ED or are admitted to the hospital with conditions that tend to result in much higher or much lower utilization compared to OUD/SUD treatments.

5. Decedents in control states: control states will include those states that have expanded Medicaid coverage under the ACA, but have not received approval for an SUD Section 1115 Demonstration Waiver. Additionally, we will confirm whether pre-demonstration trends in outcomes for Louisiana and the control states are similar and may alter the combination of control states based on these trends.

For cases where no appropriate control group can be defined, we will instead rely on either an interrupted time series analysis or a simple pre/post analysis. The interrupted time series model can be described as follows:

$$Outcome_{it} = \beta_0 + \beta_1 Time_t + \beta_2 Implement_t + \beta_3 Time_t \times Implement_t + \beta_4 X_{ist} + \beta_5 Z_{st} + \delta_s + \varepsilon_{ist}$$

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 milestone 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 to the slope of the trend that occurred after the intervention. All other variables remain as previously defined.

Finally, in a small number of cases, neither a DD or ITS will be feasible due to a lack of control group and time-series data. In these cases, we will use a simple pre/post comparison of mean changes and test for statistical significance between the pre- and post-period using t-tests or chi-square tests depending on the outcome to be analyzed.

Qualitative methods

**1. Evaluation methodology**

The evaluation will use qualitative methods to examine the reasons why the expected impacts were or were not observed. Qualitative data collection will be informed by findings from a preliminary analysis of quantitative indicators listed in the summary table which will be conducted after the first 12 months of the intervention. The methodology used to assess each research question is as follows:

**a. Does the demonstration increase access to and utilization of SUD treatment centers?**

In-depth interviews will be conducted with inpatient and outpatient treatment providers who began offering evidence-based treatment/MAT after the start of the intervention, and those who did not. The interviews will discuss whether the SUD 1115 waiver impacted the decision to begin offering treatment, and the barriers the offering evidence-based treatment that remain.

**b. Did use of medically-inappropriate care including emergency department and hospital care for OUD/SUD decline as a result of the demonstration?**

Key informant interviews with primary care/treatment providers and ED managers will be conducted. If preliminary data shows that inappropriate care has declined, the interviews will explore the mechanisms by which the SUD 1115 waiver had an impact. If inappropriate care has not declined, interviews will explore the reasons why the SUD 1115 wavier has not had an impact and the barriers to reducing inappropriate care.

**c. Did care-coordination improve as a result of the demonstration?**

A survey will be administered to treatment facilities after the first year of the demonstration (February/March 2019) and repeated annually over the course of the demonstration. The survey will assess the changes in capacity for care coordination of each facility before and after the intervention.

**d. Did health outcomes for Medicaid beneficiaries with OUD/SUD improve as a result of the demonstration?**

Key informant interviews with primary care/treatment providers and local health officials will be conducted. If preliminary data shows that health outcomes are improving, the discussions will focus on the mechanisms by which the SUD 1115 waiver had an impact. If not, the discussions will center on the reasons why this expected impact has not been observed.

**e. Target and comparison populations.**

The types and numbers of respondents, as well as the selection methodology, is detailed in the table below. In most cases, two respondents will be selected from each of Louisiana's nine LDH regions, to ensure regional representation.

**Table 5: Types and numbers of respondents and selection methodology.**

| Research question | Type of respondent | Number | Selection methodology |
|---|---|---|---|
| Does the demonstration increase access to and utilization of SUD treatment centers? | Inpatient treatment providers who started offering MAT after Feb 2018 | 18 | Selected randomly within health regions from Medicaid claims data cross-referenced with SAMHSA survey data |
| | Inpatient treatment providers who continue not to offer MAT after Feb 2018 | 18 | Selected randomly within health regions from Medicaid claims data cross-referenced with SAMHSA survey data |
| | Outpatient providers who received certification to offer MAT after Feb 2018 | 18 | Selected randomly within health regions from Medicaid claims data cross-referenced with SAMHSA survey data |
| | Outpatient providers who continue not to have certification to offer MAT after Feb 2018 | 18 | Selected randomly within health regions from Medicaid claims data cross-referenced with SAMHSA survey data |
| Did use of medically-inappropriate care including emergency department and hospital care for OUD/SUD decline as a result of the demonstration? | Primary care/ treatment providers who care for SUD patients | 18 | Selected randomly within health regions from Medicaid claims data |
| | Emergency department managers | 18 | Selected randomly within health regions from roster of hospitals with ED's |
| Did care-coordination improve as a result of the demonstration? | SUD treatment facilities | All existing | All Louisiana facilities listed on SAMHSA roster |
| Did health outcomes for Medicaid beneficiaries with OUD/SUD improve as a result of the demonstration? | Primary care/ treatment providers who care for SUD patients | 18 | Selected randomly within health regions from Medicaid claims data |
| | Parish and city health officials | 18 | Health departments selected randomly within health regions from NACCHO roster; respondents identified as point people for SUD programming |

**f. Evaluation period**

Qualitative data will be collected during Year 3 of the intervention.

**g. Data sources**

Data will be collected through in-depth and key informant interviews with stakeholders within the health system. 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.

**h. Analytic methods**

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 the 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.

## D. Methodological Limitations

*D.1 Quantitative Limitations*

There are two important limitations of the DD design that we propose to use throughout this evaluation. The first limitation involves simultaneous changes in OUD/SUD policy that overlap with the waiver demonstration. For example, if the state or local municipalities enact policies aimed at curbing opioid overdose that are concurrent with the implementation of the demonstration measures, then it would be difficult to untangle the relative impact of the two interventions on overdose rates. This is a valid concern as several opioid-related policies have taken effect throughout Louisiana recently. In instances where these policies vary geographically, we can leverage this variation to separate demonstration impacts from alternate policy impacts. However, concurrent policy adoption remains a limitation of the DD methodology.

Another necessary assumption for the validity of the DD design is that outcomes for the treatment and control groups would have continued to trend in a similar fashion in the absence of changes associated with the demonstration. This assumption is untestable, as it is impossible to observe the treatment group in the untreated state during the post-treatment period; however, evidence that these two groups followed similar trends in the outcome variable in the pre-demonstration period lends credence to the DD estimation strategy. We will examine evidence of parallel pre-period trends before implementing our DD models.

Both the ITS and pre/post methods suffer from similar limitations. In neither case is a control group employed to account for changes common to both those affected by the demonstration and those who are unaffected. Therefore, these methods are less rigorous than a DD analysis. Because of its reliance on time-series data, the ITS can provide a stronger claim at identifying causal effects than a simple pre/post analysis. However, like the DD, both methods can also be confounded by concurrent policy changes unrelated to the demonstration.

*D.2 Qualitative Limitations*

Though not a limitation, it should be noted that the results of the qualitative analysis will not be statistically representative. However, the findings derived from interviews with multiple subjects across geographic areas will produce information which can be generalized to other settings.

## E. Attachments

*E.1 Independent Evaluator*

Qualifications of the Evaluation Team

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.

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Diana, Mark L.

eRA COMMONS USER NAME (credential, e.g., agency login): mdiana

POSITION TITLE: Associate Professor, Department of Global Health Management & Policy

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| Shenandoah University | BS | 1989 | Respiratory Care |
| Shenandoah University | MBA | 1994 | Health Care Management |
| Virginia Commonwealth University | MSIS | 2003 | Information Systems |
| Virginia Commonwealth University/Medical College of Virginia | PhD | 2006 | Health Services Organizations & Research |

**NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.**

### A. Personal Statement

I am an Associate Professor in the department of Global Health Management & Policy of Tulane University's School of Public Health and Tropical Medicine. My research has focused on the organizational impact of health information systems, primarily in hospitals in the US, and I have recently begun investigating the performance of patient-centered medical homes and accountable care organizations. Most of this work involves the use of large secondary data sets and the conduct of research at the organizational level. I have experience working on the validation of measures of both CPOE and EHR adoption and implementation, which is well suited to this project. I also have experience in funded evaluation work as a co-evaluator of phase II of the Health Information Security and Privacy Collaboration (HISPC) Project, as the principle investigator on the external evaluation of the Louisiana Long-term Care Real Choice Systems Transformation Grant, through the Louisiana Department of Health and Hospitals, as the PI for an evaluation of an electronic health record implementation in Mexico, funded by the

MEASURE Evaluation project of USAID, as the PI for the evaluation of the Louisiana Health Information Exchange, among other projects.

1. Kanger C., Brown L., Mukherjee S., Xin H., **Diana M.L.**, Khurshid A. (2014) Evaluating the Reliability of EHR-Generated Clinical Outcomes Reports: A Case Study. Generating Evidence & Methods to Improve Patient Outcomes. *eGEMS, 2*(3).
2. Kazley, A. S., **Diana, M. L.**, & Menachemi, N. (2011). The Agreement and Internal Consistency of National Hospital EMR Measures. *Health Care Management Science, 14*(4), 303-313.
3. **Diana, M. L.**, Kazley, A. S., & Menachemi, N. (2011). An assessment of Health Care Information and Management Systems Society and Leapfrog data on computerized provider order entry. *Health Services Research, 46*(5), 1575-1591.

## B. Positions and Honors

**Positions and Employment**

1980-1982 Respiratory Therapist, Richmond Memorial Hospital, Richmond, VA
1982-1983 Respiratory Therapy Clinical Coordinator, Humana/St. Luke's Hospital, Richmond, VA
1983-1985 Respiratory Therapist, The Retreat Hospital, Richmond, VA
1985-1986 Supervisor, Respiratory Therapy, Medical College of Virginia Hospitals, Richmond, VA
1986-1987 Respiratory Therapist, Foster Medical Corporation, Richmond, VA
1987-1988 Instructor, Respiratory Therapy, Shenandoah University, Winchester, VA
1988-1995 Director of Clinical Education, Respiratory Therapy, Shenandoah University, Winchester, VA
1995-1999 Director, Respiratory Therapy, Northern Virginia Community College, Annandale, VA
1999-2007 Instructor, Department of Health Administration, VA Commonwealth University, Richmond, VA
2007-2013 Assistant Professor, Department of Health Systems Management and Global Health Systems & Development, Tulane University, New Orleans, LA
2008-2010 MHA Program Director, Health Systems Management, Tulane University, New Orleans, LA
2013-current MHA Program Director, Global Health Systems & Development, Tulane University, New Orleans, LA
2013-current Associate Professor, Drs. W. C. Tsai and P. T. Kung Professor in Health Systems Management, Global Health Systems & Development, Tulane University, New Orleans, LA

**Other Experience and Professional Service**

2002-current AcademyHealth
2001-current American College of Healthcare Executives (ACHE)
2002-current Health Information Management Systems Society (HIMSS)
2007-current Academy of Management

**Honors**

2006 James W. Begun Award for Excellence in Doctoral Studies in Health Administration, Department of Health Administration, Virginia Commonwealth University.

## C. Contribution to Science

1. My primary contribution is in the area of health information technology (HIT) adoption and use in hospitals, and the effect of hospital HIT adoption and use on quality, safety, and other performance outcomes. I have developed this stream of research in the context of the two seminal IOM reports on safety and quality—*To Err is Human* and *Crossing he Quality Chasm*—and the incentives programs implemented in the HITECH Act. Key findings from this work indicate that achieving quality and safety gains is not an inherent property of HIT, but that there are other factors that work with the technology to achieve the desired outcomes. Identifying those factors remains a high priority. I believe this work has influenced how other researchers, practitioners, and policy makers think about the role of HIT in improving hospital performance. My role in this work has been as a primary investigator or co-investigator in collaboration with a relatively small group of colleagues.
    a. Burke, D. E., Wang, B., Wan, T. T. H., & **Diana, M. L.** (2002). Exploring hospitals' adoption of information technology. *Journal of Medical Systems, 26*(4), 349-355.
    b. Kazley, A. S., & **Diana, M. L.** (2011). Hospital computerized provider order entry adoption and quality: An examination of the United States. *Health Care Management Review, 36*(1), 86-94.
    c. **Diana M.L.**, Harle C.A., Huerta T.R., Ford E.W., & Menachemi N. (2014) Hospitals Characteristics Associated with Achievement of Meaningful Use. *Journal of Healthcare Management, 59*(4):272-284.
    d. Kazley, A. S., **Diana, M. L.**, & Menachemi, N. (2012). Is EHR Use Associated with Patient Satisfaction in Hospitals? *Health Care Management Review, 37*(1), 23-30.

2. A related contribution to the adoption and use of HIT in hospitals stream of research is on the measurement of HIT adoption and use. My interest in the measurement issue arose from difficulties my colleagues and I encountered in examining the effects of HIT adoption and use. Put simply, the available data sources for examining electronic health record (EHR) adoption and use were rudimentary, and data on components of an EHR, like computerized provider order entry (CPOE) were also, and beyond CPOE virtually non-existent, with the single exception of the Health Information and Management Systems Society (HIMSS) data. I believe the work we did in examining the reliability, validity, and consistency of various measures has contributed to the growing sophistication of measures of HIT adoption and use, but I also believe there is still much work to be done in this area.
    a. Kanger C., Brown L., Mukherjee S., Xin H., **Diana M.L.**, Khurshid A. (2014) Evaluating the Reliability of EHR-Generated Clinical Outcomes Reports: A Case

Study. Generating Evidence & Methods to Improve Patient Outcomes. *eGEMS, 2*(3).

b. Kazley, A. S., **Diana, M. L.**, & Menachemi, N. (2011). The Agreement and Internal Consistency of National Hospital EMR Measures. *Health Care Management Science, 14*(4), 303-313.

c. **Diana, M. L.**, Kazley, A. S., & Menachemi, N. (2011). An assessment of Health Care Information and Management Systems Society and Leapfrog data on computerized provider order entry. *Health Services Research, 46*(5), 1575-1591.

3. A third area of research I am developing in collaboration with doctoral students and junior colleagues is examining the performance of new models of health care delivery, specifically patient-centered medical homes (PCMH) and accountable care organizations (ACO). There is a clear relationship between this line of inquiry and my first area, since both of these care models rely on a robust HIT infrastructure to achieve the proposed performance improvements in terms of improved quality, improved care coordination, greater access, and reduced costs. We are in the early stages of this work, but we already have contributed some significant knowledge to the growing literature in this area. I anticipate this line of research to continue to grow.

   a. Yeager, V., Zhang, Y., & **Diana, M.L.** (2015) Analyzing Determinants of Hospitals' Accountable Care Organizations Participation: A Resource Dependency Theory Perspective. *Medical Care Research & Review.* [Accepted for Publication.]

   b. **Diana, M.L.**, Walker, D.M., Mora, A.M, & Zhang, Y. (2015) Vertical integration strategies in healthcare organizations. *Journal of Health Administration Education.* [Accepted for Publication.]

   c. Cole, E. S., Campbell, C., **Diana, M. L.,** Webber, L., & Culbertson, R. (2015). Patient-centered medical homes in Louisiana had minimal impact on Medicaid population's use of acute care and costs. *Health Aff (Millwood), 34*(1), 87-94.

**Complete List of Published Work in MyBibliography:**
http://www.ncbi.nlm.nih.gov/sites/myncbi/1jK0j1P7alG5C/bibliograpahy/48140102/public/?sort=date&direction=ascending

## D. Research Support

**Ongoing Support**

July 2018 – June 2019
Louisiana State University Center for Healthcare Value & Equity, Louisiana Department of Health Statewide Medicaid Expansion Program Evaluation, $1,370,541. Role: PI.

July 2018 – June 2019
Louisiana State University Center for Healthcare Value & Equity, Louisiana Department of Health, Medicaid 1115 Substance Use Disorder Demonstration Waiver Evaluation, $226,991. Role: PI.

**Completed Research Support**

R03 HS 24637– 01A1(McCoy) 07/01/2017 – 06/30/2018 1.2 calendar
AHRQ $66,154
EHR-Based Measurement of Care Coordination in an Accountable Care Organization
The purpose of this grant is to implement EHR-based care coordination measures, develop a framework illustrating key domains for measuring care coordination in the ACO context, and map each of the EHR-based measures to the framework domains.

September 2017 – June 2018
Louisiana State University Consortium for Health Transformation, Louisiana Department of Health Statewide Medicaid Expansion Program Evaluation, $513,391. Role: PI.

October 2014 – December 2015
USAID MEASURE Evaluation project to develop guidance for evaluating health systems strengthening. $150,000. Role: Investigator (Overall MEASURE Evaluation Project PI: Stacey Gage)

July 2014 – June 2015
Patient Centered Outcomes Research Institute, Louisiana Clinical Research Data Network (LaCDRN). Role: Co-Investigator.

July 2014 – June 2015
Agency for Healthcare Research and Quality (AHRQ), R36 Dissertation Award. Grant Number: 1R36HS023343-01. Hospital Efficiency Changes from Health Information Exchange Participation. $37,448. PI: Daniel M. Walker. Role: Faculty Advisor.

July 2010 – June 2015
Tulane Quality and Cost Effectiveness Team Initiatives, $60,000. Role: PI.

July 2013 – June 2014
Agency for Healthcare Research and Quality (AHRQ). Estimating Costs of Supporting Safety-Net PCMH Transformation in New Orleans. $75,000. Role: Co-investigator.

October 2012 – August 2014
USAID MEASURE Evaluation project to develop metrics for evaluating health systems strengthening. $310,000. Role: PI on the study (Overall MEASURE Evaluation Project PI: Stacey Gage)

September 2012 – March 2014
Louisiana Health Care Quality Forum, Louisiana Health Information Exchange (LaHIE) Program Evaluation, $210,350. Role: PI.

June 2011 – September 2012
USAID MEASURE Evaluation project to evaluate the impact of electronic medical records on physician protocol adherence in Colima, MX, Phase 2. Role: PI on the study (Overall MEASURE Evaluation Project PI: Stacey Gage)

April 2011 – November 2011
USAID MEASURE Evaluation project to evaluate electronic medical records in Colima, MX. $91,035. Role: PI on the study (Overall MEASURE Evaluation Project PI: Stacey Gage)

2008 – 2009 Principal Investigator, "State of Louisiana Long-term Care Transformation," Louisiana Department of Health and Hospitals, Center for Medicare and Medicaid Services, Real Choice Systems Change Grant, $200,000.

2007 – 2008 Co-evaluator—Health Information Security and Privacy Collaboration Phase 2, Department of Health and Hospitals, State of Louisiana, $10,000

2002 – 2004 Consultant, AHRQ, Hospital Finances and Quality of Hospital Care.

**BIOGRAPHICAL SKETCH**

NAME: Kevin Callison

eRA COMMONS USER NAME (credential, e.g., agency login): kcalliso

POSITION TITLE: Assistant Professor of Health Management and Policy

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| Ohio State University | B.A. | 05/2006 | Economics |
| University of Illinois at Chicago | M.A. | 06/2008 | Economics |
| University of Illinois at Chicago | Ph.D. | 06/2013 | Economics |

## A. Personal Statement

## B. Positions and Honors

Positions and Employment

2006 – 2013: Teaching Assistant, Department of Economics, University of Illinois at Chicago, Chicago, IL

2007 – 2013: Research Assistant, Department of Economics, University of Illinois at Chicago, Chicago, IL

2013 - 2017: Assistant Professor, Department of Economics, Grand Valley State University, Grand Rapids, MI

2017 - Present: Assistant Professor, Department of Global Health Management and Policy, Tulane University School of Public Health and Tropical Medicine, New Orleans, LA

Professional Memberships

2013 - Present: Member, American Economic Association
2013 - Present: Member, American Society of Health Economists
2016 - Present: Member, Southern Economic Association
2016 - Present: Member, International Health Economics Association

Honors

2016: W.E. Upjohn Institute for Employment Research Early Career Research Award

## C. Contributions to Science

My contributions to the field are concentrated in three general areas of study:

1. Health policy evaluation – My current research efforts are primarily focused on the analysis of recent policy interventions that aim to improve population health. I have a strong interest in evaluating the effects on health and labor market outcomes of the Affordable Care Act's Medicaid expansion and have documented heterogeneous impacts of the expansion across race and ethnicity. I am currently a Co-Investigator on a project sponsored by the State of Louisiana to document changes in health care access and outcomes associated with the state's Medicaid expansion in 2016. Examining a health insurance expansion in a developing country setting, my coauthors and I found evidence of substitution away from traditional forms of health care and towards the use of modern care. These papers complement and add to a body of research concerning the relationship between insurance expansions and the use of care. In a separate policy evaluation, my coauthor and I presented the first evidence on the effectiveness of donor registry laws and first-person consent legislation on the supply of deceased organ donors. This represents a critical area of study as the demand for transplantable organs has far surpassed the available supply and continues to grow at a steep rate. I am in the process of continuing my work on organ failure by examining the effect of recent legislation that penalizes dialysis facilities for poor patient outcomes. Finally, along with Dr. Pesko, I have recently finished conducting an evaluation of state and local paid sick leave mandates in the U.S. Little is known about the health and labor market effects of paid sick leave mandates in the U.S. setting and, therefore, this work has the potential to provide a significant contribution to an emerging policy debate as well as provide support for the successful completion of the proposed research project.

a. Callison, K. & Levin, A. 2016. Donor Registries, First-Person Consent Legislation, and the Supply of Deceased Organ Donors. Journal of Health Economics, 49: 70-75.

b. Callison, K. & Sicilian, P. Economic Freedom and the Affordable Care Act: Medicaid Expansion and Labor Mobility by Race and Ethnicity. Public Finance Review, forthcoming.

c. Abrokwah, S.O., Callison, K., & Meyer, D.J. 2017. Social Health Insurance and the Use of Modern and Traditional Care in Developing Countries: Evidence from Ghana's National Health Insurance Scheme. Journal of Development Studies (in press).

d. Callison, K. & Pesko, M.F. (2017). The Effect of Paid Sick Leave Mandates on Access to Paid Leave and Work Absences. Upjohn Institute Working Paper No. 16-265. DOI: 10.17848/wp-265.

2. Health determinants and substance abuse – My research in this area initially addressed links between adolescent and adult health and explored factors that contributed to substance abuse early in life. These studies contributed to a growing body of evidence on the role of individual non-cognitive factors and external influences in adolescence on health outcomes later in life. Building on these earlier studies, I have analyzed the relationship between cigarette taxes and tobacco use for adults and conducted an examination of the mechanisms underlying addiction and substance use. These are certainly timely issues and will continue to be an area of focus as I advance in my career.

a. Kaestner, R. & Callison, K. (2011). Adolescent Cognitive and Non-Cognitive Correlates of Adult Health. Journal of Human Capital, 5(1): 29-69.

b. Kaestner, R., Lo Sasso, A., Callison, K., & Yarnoff, B. (2013). Youth Employment and Substance Use. Social Science Research, 42(1): 169-185.

c. Callison, K. & Kaestner, R. (2014). Do Higher Tobacco Taxes Reduce Adult Smoking? New Evidence of the Effect of Recent Cigarette Tax Increases on Adult Smoking. Economic Inquiry, 52(1): 155-172.
d. Kaestner, R. & Callison, K. (2018). An Assessment of the Forward-Looking Hypothesis of the Demand for Cigarettes. Southern Economic Journal (in press).

3. Health care use and the organization of health insurance markets -- My interest in the organizational aspects of health care delivery developed early-on in my research career. My dissertation work considered the implications of geographic variation in health care expenditures and I have continued to investigate this topic. Relatedly, I have explored the interaction between health insurance coverage, reimbursement levels, and the use of health care services. I am particularly interested in the role of private insurance plans in the financing of Medicare benefits, an area of increasing importance as the share of privately enrolled Medicare beneficiaries continues to grow. Finally, my work has extended to interdisciplinary efforts to evaluate care coordination interventions for highly complex hospital patients.

a. Callison, K. (2016). Medicare Managed Care Spillovers and Treatment Intensity. Health Economics, 25(7): 873-887.
b. Hardin, L., Kilian, A., Muller, L., Callison, K., & Olgren, M. (2016). Cross-Continuum Tool is Associated with Reduced Utilization and Cost for Frequent High-Need Users. Western Journal of Emergency Medicine, 18(2).
c. Callison, K. & Nguyen, B.T. (2018). The Effect of Medicaid Physician Fee Increases on Patients' Health Care Access, Utilization, and Expenditures. Health Services Research, 53(2): 690-710.

**Complete List of Published Work in My Bibliography:**
**https://www.ncbi.nlm.nih.gov/sites/myncbi/1hI9pOKfooDQA/bibliography/54023620/public/?sort=date&direction=ascending**

## D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

Carol Lavin Bernick Faculty Grant — Callison (PI)
4/26/2018 – 4/26/2019
*Hospital Competition and Quality of Care*
This is an internal, competitive research grant that is funding a project examining hospital response to the introduction of Medicare's Hospital Readmissions Reduction Program by degree of market concentration.

Louisiana Department of Health — Diana (PI)
9/1/2017 – 6/30/2018
*Evaluation of Louisiana's Medicaid Expansion*
The project will evaluate the initial effects of the expansion of the Louisiana Medicaid program on state residents, the economy, and the Louisiana health care delivery system.
Role: Co-I

Departmental Start-Up Grant, Tulane University — Callison (PI)
7/1/2017 – 7/1/2023
Research Start-Up Funds

This is an internal grant designed to provide financial resources that will aid in the development of an independent research agenda. Funds are designed to be used for data acquisition, conference attendance, and computing resources.

Completed Research Support

W.E. Upjohn Institute Early Career Research Award Callison (PI)
10/7/2016 – 11/7/2017
*The Effect of Paid Sick Leave Mandates on Access to Paid Leave and Work Absences*
Funding to pursue a preliminary evaluation of changes in paid sick leave coverage and worker absences following the enactment of local mandates requiring employers to offer paid sick leave benefits.
Role: PI

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Janna Wisniewski

eRA COMMONS USER NAME (credential, e.g., agency login): jwisnie

POSITION TITLE: Research Assistant Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| Michigan State University | BA | 05/2006 | Linguistics |
| Tulane University | MHA | 12/2009 | Health administration |
| Tulane University | PhD | 08/2016 | Public health |

### A. Personal Statement

My training, expertise, and experience both in health services delivery and qualitative research qualify me to complete this research project. I have a broad background in health services research, particularly in the areas of service quality and health workforce. I have designed, implemented, and published research involving primary qualitative data collection through key informant and in-depth interviews with health service providers and patients. I have experience using qualitative findings to build theory and inform interventions. Examples of my work include a study examining provider satisfaction and motivation in the Democratic Republic of Congo using interviews and focus groups, for which I am the Principle Investigator, an analysis of dissatisfaction in the public health workforce in the United States based on qualitative survey data, and an evaluation of the Louisiana Medicaid expansion involving physician and beneficiary interviews.

### B. Positions and Honors

**Positions**

2008 Operations and Billing Specialist, Tulane Community Health Centers
2009 Administrative Resident, Department of Business Development and Strategic Planning, East Jefferson General Hospital
2010 – 2011 Administrative Fellow, St. Luke's Episcopal Health System
2011 – 2013 Manager of Credentialing Oversight, St. Luke's Episcopal Health System
2013 – 2016 Doctoral Student and Research Assistant, Tulane University, School of Public Health and Tropical Medicine

| | |
|---|---|
| 2016 – present | Research Assistant Professor, Department of Global Health Management and Policy, Tulane University School of Public Health and Tropical Medicine |

**Honors**

| | |
|---|---|
| 2007 | Dean's Grant for Graduate Studies, Tulane University School of Public Health |
| 2013 | Chair's Scholarship for Doctoral Studies, Tulane University School of Public Health |
| 2016 | Best poster in category of "Engaging Power and Politics," Fourth Global Symposium on Health Systems Research, Vancouver, BC |

**C. Contributions to Science**

1. **Identification of Strategies that Increase Health Service Utilization in Post-Conflict Settings.** Through my work in the Democratic Republic in Congo, I am studying ways in which access to quality health services can be promoted in post-conflict settings. I began by ascertaining the importance of quality to these populations; my dissertation focused on the relationship between quality and utilization of maternal health services. I found that patients assess service quality accurately when they are exposed to the aspect of quality and understand its importance, and that higher quality is associated with higher utilization of antenatal care. I am currently evaluating the potential for communities to hold providers accountable for service quality; preliminary findings show success at the local level.

    a. Wisniewski, J.M., Diana, M.L., Yeager, V.A., Hotchkiss, D.R. "Comparison of Objective Measures and Patients' Perceptions of Quality of Services in Government Health Facilities in the Democratic Republic of Congo." International Journal for Quality in Health Care, 2018, 1-8 doi: 10.1093/intqhc/mzy052.

    b. Wisniewski, J.M., Diana, M.L., Yeager, V.A., Hotchkiss, D.R. "The Relationship Between Quality and Utilization of Health Services in the Democratic Republic of Congo," Tulane University Press, 2016.

2. **Discovery of Factors Motivating Retention of Public Health Workforce.** I have published several papers examining the factors that matter in the recruitment and retention of the public health workforce. This work has shown that contrary to conventional thinking, salary level is less important to recruitment and retention than other largely modifiable factors such as having a variety of job tasks and opportunities for training and growth. Findings also indicate that public health workers associate dissatisfying factors such as heavy workloads and a lack of training with their abilities to provide high-quality services.

    a. Wisniewski, J.M., Jacinto, C., Yeager, V.A., Castrucci, B., Chapple-McGruder, T., Gould, E. "Opportunities to Improve Employee Satisfaction within State and Local Public Health Agencies." Journal of Public Health Management and Practice, 2018. Accepted.

b. Yeager, V.A., Wisniewski, J.M., Chapple-McGruder, T., Castrucci, B., Gould, E. "Public Health Workforce Self-Identified Training Needs by Jurisdiction and Job Type." Journal of Public Health Management and Practice, 2018. In press.

c. Yeager, V.A. and Wisniewski, J.M. "Factors That Influence the Recruitment and Retention of Nurses in Public Health Agencies." Public Health Reports, 2017, 132(5):556-562. PMID: 28792856.

d. Yeager, V.A., Wisniewski, J.M., Amos, K., and Bialek, R. "Why Do People Work in Public Health? Exploring recruitment and retention among public health workers." Journal of Public Health Management and Practice, 2016, 22(6):559-556.

e. Yeager, V.A., Wisniewski, J.M., Amos, K., and Bialek, R. "What Matters in Recruiting Public Health Employees: Considerations for Filling Workforce Gaps." American Journal of Public Health, 2015, 105(12), e33-6. PMID: 26469672.

3. **Strengthening of Monitoring and Evaluation Methodology.** Based on interviews with leaders in international development, I developed recommendations to improve the monitoring and evaluation of health systems strengthening approaches.

   a. Wisniewski, J.M., Yeager, V.A., Diana, M.L., Hotchkiss, D. "Exploring the Barriers to Rigorous Monitoring and Evaluation of Health Systems Strengthening Activities: Qualitative Evidence from International Development Partners." *Journal of Health Policy and Planning,* 2016. https://doi.org/10.1002/hpm.2339.

## D. Additional Information: Research Support and/or Scholastic Performance

**Ongoing Research Support**

Carol Lavin-Bernick Faculty Grant — Wisniewski (PI) — 06-2017- present
Racial and ethnic disparities in wait times for medical appointments
The objective of this research is to determine whether racial and ethnic minorities wait longer for medical appointments than non-minorities in an urban area of the United States.
Role: Principle investigator

Louisiana Department of Health — Diana (PI) — 09/2017- present
Evaluation of Louisiana's Medicaid expansion
This project will evaluate the initial effects of the expansion of the Louisiana Medicaid program on state residents, the economy, and the Louisiana health care delivery system.
Role: Co-investigator

Blue Cross Blue Shield Foundation of Louisiana — Wisniewski (PI) — 01/18- present
Evaluation of 504HealthNet's Improving Health Equity in New Orleans through Community Based Care, Outreach, and Education project
The purpose of this work is to evaluate the impact of a behavioral and system-level intervention on access to and utilization of health services among low income communities and people of color in New Orleans.
Role: Principle investigator

UK Department for International Development Keating (PI) 03/2013- present
Assessing the impact of the ASSP project in the Democratic Republic of Congo
The purpose of this study is measure the impact of a broad package health system strengthening intervention on health outcomes, behaviors, and exposure to and use of health interventions, and to assess the impact of the overall project on selected health outcomes, behaviors, and health service utilization.
Role: Co-investigator

UK Department for International Development Wisniewski (PI) 03/2013- present
Impact of a simplified community scorecard approach in the Democratic Republic of Congo
The purposes of this study are to monitor the implementation of the simplified community scorecard intervention and offer recommendations for strengthening the intervention's approach, track changes over time in the participating communities' perceptions of quality of health services, communities' utilization of health services, and real changes in the supplies, equipment, and services available at their health facilities, describe the characteristics of a successful or unsuccessful site, and assess unintended effects of the intervention.
Role: Principle investigator

De Beaumont Foundation Yeager (PI) 04/2016- present
Qualitative study of the public health workforce
The purpose of this work is to document the level of job satisfaction and motivation of the United States public health workforce, describe the factors associated with satisfaction and dissatisfaction, and understand the impacts on productivity and quality.
Role: Co-investigator

United States Agency for International Development Yukich (PI) 04/2017- present
Costs of continuous long lasting insecticide-treated net distribution strategies in sub-Saharan Africa
Tulane is conducting a series of studies related to the cost-effectiveness of various strategies for malaria control using LLIN's. These studies are comprised of 1) a case series of costing for continuous distribution strategies, 2) a review a meta-analysis of existing and new cost effectiveness data, 3) simulations of effects using OpenMalaria, and 4) cost-effectiveness comparisons.
Role: Co-investigator

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Stoecker, Charles

eRA COMMONS USER NAME (credential, e.g., agency login): cfstoecker

POSITION TITLE: Assistant Professor of Health Economics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| Harvard University | B.A. | 05/03 | Economics |
| University of California, Davis | M.A. | 05/08 | Economics |
| University of California, Davis | Ph.D. | 05/11 | Economics |
| Centers for Disease Control and Prevention | Post-doc | 05/13 | Health Economics |

### A. Personal Statement

### B. Positions and Honors

**Positions and Employment**

2003-2004 Research Assistant to Jonathan Gruber for cost projections for National Health Insurance Reform, Massachusetts Institute of Technology, Cambridge, MA
2006-2007 Research Assistant to Jonathan Gruber for cost protections for Health Insurance Reform in CA and CT, National Bureau of Economic Research, Cambridge, MA
2006-2008 Research Assistant to Hilary Hoynes for the impact of Food Stamps on natality and mortality, University of California, Davis, CA
2011-2013 Steven M. Teutsch Prevention Effectiveness Fellow, Centers for Disease Control and Prevention, Atlanta, GA
2013- Assistant Professor, Department of Global Health Systems and Development, Tulane University, New Orleans, LA

**Honors**

2018-present J.P. Morgan Chase Chair in Healthcare Finance
2017 Best Abstract Medicare Section, Academy Health Conference, 2017
2014 Kaffee Billah Award for Excellence in Economic Research, Centers for Disease Control and Prevention, Atlanta, GA

### C. Contributions to Science

#### 1. Natural Experiments used to Evaluate Health Policy Changes

As an applied econometrician I have led or coauthored several studies that exploit natural experiments to examine the health impacts of policy changes. I have exploited variation in playoff success to determine the impacts of National Football League teams on local influenza mortality. I used a differences-in-differences framework to examine this question. I have used contingent choice methods to quantify the financial impacts of policies restricting access to nasal decongestants in pharmacies. I have also used policy-induced variation in economic sanctions induced by the Clean Air Act to examine the impacts of pollution fetal and maternal health. This study used a regression discontinuity design that exploited the fact that the EPA established thresholds for air pollution and imposed sanctions on counties over those thresholds. I have extensive experience applying natural experiments to a variety of questions.

a. Stoecker, C, Sanders, NJ, & Barreca, A. Success *is* Something to Sneeze at: Influenza Mortality in Regions that Send Teams to the Super Bowl. American Journal of Health Economics 2(1) (2016):125-143.
b. Finlay, K, Stoecker, C, & Cunningham, S. "Willingness-To-Accept Pharmaceutical Retail Inconvenience: Evidence from a Contingent Choice Experiment." PLoS ONE 10(5) (2015): e0126790.
c. Sanders, NJ & Stoecker, C. "Where Have all the Young Men Gone? Using Sex Ratios to Measure Fetal Death Rates." Journal of Health Economics 41 (2015): 30-45.
d. Lindo, JM, and Stoecker, C. Drawn into Violence: Evidence on "What Makes a Criminal" from the Vietnam Draft Lotteries. Economic Inquiry 52(1) (2014): 239-258.

2. **Cost-effectiveness of Reducing Vaccine Schedules for Children**

My early publications directly addressed the fact that the United States does not have a cost-effective recommended vaccination schedule for pneumococcal vaccine for children. While many other industrialized countries use a 3 dose schedule, the United States spends approximately $500 million per year on a 4$^{th}$ dose that dose very little to improve outcomes. In order to investigate this I developed a model to calculate pneumococcal disease incidence and costs for children. The model tracked outcomes and QALYs through life expectancy. As the model was developed we realized the key input would be the relative effectiveness of the two dosage schedules against otitis media. As no studies had previously examined this we performed propensity score matching on insurance claims data to get a better estimate of the impact of a reduced dose schedule. This work has sparked numerous policy discussions within CDC and FDA and other regulatory agencies that are currently ongoing. I developed the cost-effectiveness model, performed the propensity score matching, and served as the primary investigator for these studies.

a. Stoecker, C, Hampton, L, Link-Gelles, R, Messonnier, M, Zhou, F, & Moore, M. (2013). Cost-effectiveness of using 2 vs 3 primary doses of 13-valent pneumococcal conjugate vaccine. Pediatrics, 132(2), e324-e332.
b. Stoecker, C, Hampton, L, & Moore, M. (2012). 7-valent pneumococcal conjugate vaccine and otitis media: Effectiveness of a 2-dose versus 3-dose primary series. Vaccine, 30(44), 6256-6262.

3. **Cost-effectiveness of Expanded Vaccination Recommendations for Adults**

Adults experienced large declines in incidence of pneumococcal disease caused by serotypes included in the conjugate vaccine. My next projects investigated the cost-effectiveness of including the conjugate vaccine for adults compared to relying on herd immunity protections conferred to adults by the childhood vaccination program. The first study found introducing the vaccine for a particularly susceptible population of adults was cost-saving. After new data emerged on the effectiveness of the vaccine against

pneumococcal pneumonia emerged, we conducted cost-effectiveness analysis for the general adult population. We found a new recommended vaccine schedule would be cost-effective in the short term, but in the long-term the costs were very high compared to the benefits. Both of these studies led to changes in the recommended vaccine schedule for adults, with the recommendation that the cost-effectiveness of the recommendation for the general population be regularly monitored. I helped develop the cost-effectiveness model for susceptible adults, and developed the model for the general adult population. I served as primary investigator for the study on the general adult population and co-primary investigator on the study of particularly susceptible adults.

a. Cho, B., Stoecker, C, Link-Gelles, R, & Moore, M. (2013) Cost-effectiveness of administering 13-valent pneumococcal conjugate vaccine in addition to 23-valent pneumococcal polysaccharide vaccine to adults with immunocompromising conditions. *Vaccine* 31, 6011-6021.
b. Tomczyk, S, Bennet, NM, Stoecker, C. et al. (2014) "Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged≥ 65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP)." *MMWR Morb Mortal Wkly Rep* 63.37: 822-5.

**Complete List of Published Work in My NCBI:**
https://www.ncbi.nlm.nih.gov/sites/myncbi/1ZCkoZq_75yAz/bibliography/51516730/public/?sort=date&direction=ascending

## D. Additional Information: Research Support and/or Scholastic Performance

### Ongoing Research Support

Centers for Disease Control and Prevention 17IPA1711958 Stoecker (PI) 05/01/17 – 05/10/18
The Impacts of Herd Immunity from the Child Immunization Program on the Need for Universal Adult Pneumococcal Conjugate Vaccination
The goal of this project is to evaluate the health and economic consequences of removing pneumococcal conjugate vaccine from the recommended schedule for adults in the context of herd immunity impacts from the children's immunization schedule.
Role: Principal Investigator

R01 1R01HD086794 Kissinger (PI) 07/01/16 – 06/30/21
A New Approach to Controlling Chlamydia Transmission in Young People
The goal of this project is to evaluate the effectiveness and cost-effectiveness of a strategy to increase Chlamydia treatment in the community.
Role: Co-I

PCORI NEN-1508-32257 Shi (PI) 07/01/16 – 06/30/21
Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications
The goal of this project is to evaluate the impact of care coordination on health outcomes and utilization measures for patients with multiple chronic conditions using a regression discontinuity and differences-in-differences framework.
Role: Co-I

World Food Program WFP/BAN/RFP/15/29 Hutchinson (PI) 09/01/15 – 10/01/19
Strategic and Technical Support to Panel Survey VGD Programme Beneficiaries in Bangladesh

The goal of this project is to evaluate the impact of an income support program in Bangladesh using panel data methods.
Role: Co-PI

Gates Foundation Hutchinson (PI) 11/01/16 – 10/31/18
Impact Assessment of Social Marketing in Ghana
The goal of this project is to use econometric techniques to evaluate the impact of an anti-smoking intervention on teenage girls in Ghana.
Role: Co-I

Gates Foundation Hutchinson (PI) 12/01/16 – 11/30/18
MTV Shuga for Family Planning in Nigeria
The goal of this project is to develop econometric techniques to evaluate the effectiveness of a television campaign on contraceptive use in Nigeria.
Role: Co-I

**Completed Research Support**

Centers for Disease Control and Prevention 16IPA1612239 Stoecker (PI) 05/11/16 – 05/10/17
Cost-effectiveness of RSV
The goal of this project was to evaluate the cost effectiveness and model the health consequences of a potential new vaccine against RSV.
Role: Principal Investigator

Centers for Disease Control and Prevention 15IPA1512583 Stoecker (PI) 05/11/16 – 05/10/17
Cost-effectiveness of Adding a Universal Recommendation of Pneumococcal Conjugate Vaccine for All Adults
The goal of this project was to provide economic modeling for immunization schedule questions regarding pneumococcal disease.
Role: Principal Investigator

*E.2 Evaluation Budget and Project Roles*

*E.3 Timeline and Major Milestones*

**References:**

Buchanich, J., L.C. Balmert, K.E. Williams, and D.S. Burke. (2018). The Effect of Incomplete Death Certificates on Estimates of Unintentional Opioid-Related Overdose Deaths in the United States, 1999-2015. *Public Health Reports*, 133(4): 423-431.

Centers for Disease Control and Prevention (2018). U.S. Opioid Prescribing Rate Maps. https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

Kaiser Family Foundation State Health Facts. (2018). Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted). https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Musumeci, M. (2018). Key Questions about Medicaid Payment for Services in Institutions for Mental Disease. *Kaiser Family Foundation June 2018 Issue Brief.*

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.

**Attachment D:**
**Substance Use Disorder (SUD) Implementation Plan Protocol**

## Introduction

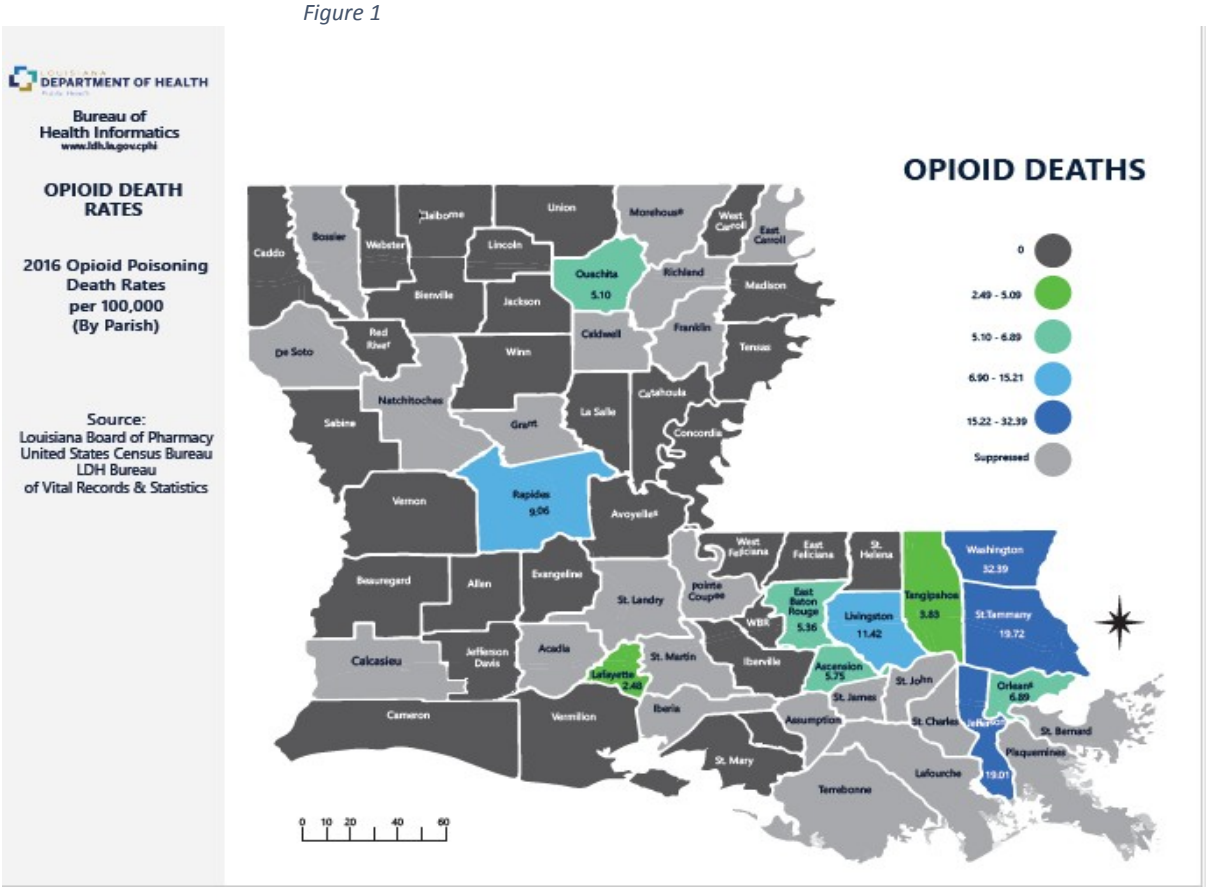
Nationwide, deaths due to opioids continue to increase, are under-reported, and have great variability in the specificity of how they are recorded across the country.[12] Contributing factors to the difficulty of verifying these opioid-related deaths are that a specific drug or cause of death may not be identified or reported, multiple drugs may be listed instead of one, or the primary cause of death may be listed with another diagnosis such as anoxic brain injury or congestive heart failure. From 1999 to 2015, the number of overdose deaths involving opioids in the United States has quadrupled.

In Louisiana, the Office of Vital Records (OVR) has shown that recorded deaths due to opioids in 2016 (320) has tripled since 2011 (100) and doubled since 2012 (160). Recent OVR internal review estimates that at least 54% of opioid deaths in the state are not being reported as specific opioid-related deaths in their Louisiana Electronic Event Registration System (LEERS). Therefore, Louisiana's Office of Public Health (OPH), through CDC-grant funding, is performing a validation process to improve and maintain systems for an accurate count of opioid-related overdose deaths in order to make accurate data-driven decisions in properly combatting the opioid epidemic in Louisiana. Demographic information is also being evaluated and 2016 data showed that opioid-related death rates occurred most often in men (8.21 rate per 100,000 citizens compared to 4.89 per 100,000 citizens in women) of white descent (8.39 per 100,000 citizens compared to 3.28 per 100,000 citizens in blacks), age 35-44 (rate of 14.43 per 100,000 citizens) in Region 9 of Louisiana, serving Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington parishes (15.87 of 100,000 citizens compared to the state average of 6.51 per 100,000 citizens). See Figure 1 for visualization.

[1] Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1

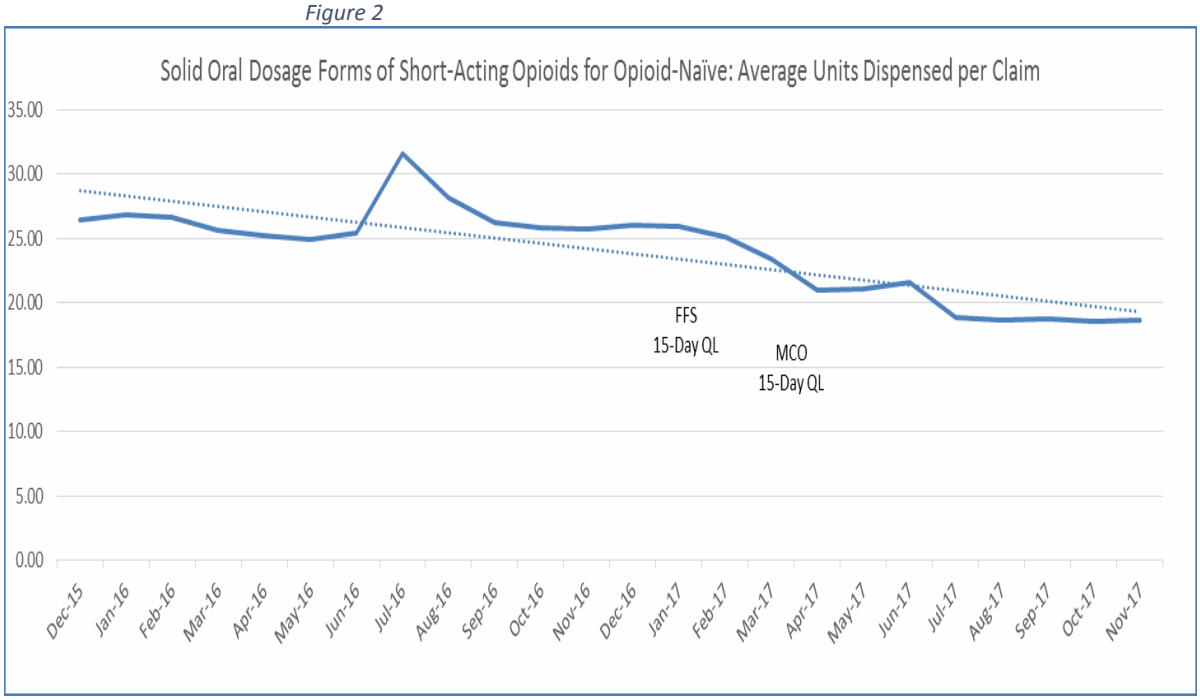
[2] Ruhm, CJ. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. American Journal of Preventive Medicine, Volume 53, Issue 6, 745 - 753

*Figure 1*




The Louisiana Medicaid Program is also active on data-driven strategies on the opioid epidemic. Current efforts include monitoring opioid prescriptions for opioid-naïve patients (patients who have had no opioid prescriptions within the past 90 days) and seeing how statewide opioid legislation and Medicaid opioid policies are effecting claims on opioid prescriptions. Preliminary data has shown that since Medicaid expansion in July 2016, the average units dispensed and average days' supply per claim has decreased. In July 2016, the average units dispensed per claim was 31.64 and in November 2017 it was down to 18.64. See Figure 2. Furthermore, the average days' supply per claim has decreased from an average of 8.9 days in July 2016 to 5.0 days in November 2017. This preliminary analysis of the data has shown roughly a 41% decrease in the amount and 44% decrease in days supplied of opioids per claim with interventions of state legislation and Medicaid policies to ensure better and appropriate practices.

*Figure 2*




## Program Overview

The Bureau of Health Services Financing (BHSF) within the Louisiana Department of Health (LDH) serves as the state Medicaid agency. LDH transitioned delivery of Medicaid services from a fee-for-service model to a managed care model in February 2012 via contracts with health plans to provide physical health and basic behavioral health services. At its outset, the Medicaid managed care program was comprised of two Medicaid-managed care models as defined in federal Medicaid regulations: managed care organizations (MCOs) and primary care case management (PCCM) entities. The five health plans were selected through a competitive procurement in 2011. There were two PCCM plans and three MCOs. Managed care organizations, also called prepaid health plans in Louisiana, are risk-bearing entities that provide a wide array of Medicaid-covered benefits and services to enrolled members in exchange for a monthly capitation payment for each member. The plans contract directly with providers and manage all aspects of service delivery, including reimbursement of providers.

PCCM entities, also called shared savings health plans in Louisiana, were paid a monthly management fee for each enrolled member in exchange for coordinating care for enrolled members. Shared savings health plans only contracted with primary care providers (PCPs) and hospitals. All other services that they coordinated were provided through the Louisiana Medicaid program's provider network. While the plan was responsible for service utilization, actual provider payments were made by LDH. Shared savings health plans were at limited risk for repaying a portion of the monthly management fee in the event savings benchmarks were not achieved. While shared savings health plans were responsible for service utilization for most Medicaid core benefits and services, the fee-for-service legacy Medicaid program continued to authorize durable medical equipment, prosthetics, orthotics, and certain supplies (DMEPOS); pharmacy; and non-emergency medical

transportation (NEMT) to members of these plans.

The Office of Behavioral Health (OBH) is the state program office within LDH responsible for managing the delivery of services and supports necessary to improve the quality of life for citizens with mental illness and substance use or addictive disorders. The mission of OBH is to work collaboratively with partners to develop and implement a comprehensive integrated system of behavioral health and healthcare, social support, and prevention services that promote recovery and resilience for all citizens of Louisiana. OBH assures public behavioral health services are accessible, family-driven, have a positive impact, are culturally and clinically competent, and are delivered in partnership with all stakeholders. OBH was created by Act 384 of the 2009 Regular Session of the Louisiana Legislature which directed the consolidation of the offices of addictive disorders and mental health into the Office of Behavioral Health, effective July 1, 2010, in order to streamline services and better address the needs of people with co- occurring mental illness and substance use or addictive disorders.

The Louisiana Behavioral Health Partnership (LBHP), also implemented in March 2012, was a system of care designed to transform the delivery of and payment for specialized behavioral health services for Medicaid and non-Medicaid adults and children who required specialized behavioral health services, including those children who were at risk for out-of-home placement. LDH contracted with a statewide management organization (SMO), a Prepaid Inpatient Health Plan, to operate the LBHP with the primary goal of improving coordination of services, quality of care, and outcomes. The LBHP served the needs of individuals who comprised one of the following target populations:

1. Children with extensive behavioral health needs either in, or at risk of, out-of-home placement;
2. Medicaid-eligible children with medically necessary behavioral health needs who need coordinated care;
3. Adults with severe mental illness and/or substance use or addictive disorders who are Medicaid eligible; or
4. Non-Medicaid children and adults who have severe mental illness and/or substance use or addictive disorders.

Through better coordination of services, the LBHP enhanced the consumer experience, increased access to a more complete and effective array of behavioral health services and supports, improved quality of care and outcomes, and reduced repeat emergency room visits, hospitalizations, out-of-home placements, and other institutionalizations. The LBHP greatly expanded access to providers.

To continue the significant benefits experienced as a result of development of the managed care delivery system for behavioral health care through the LBHP, LDH developed partnerships with private sector providers to target improved models of care focused on smaller residential settings to deemphasize the role of large, state-run institutions. Residential treatment facilities were also developed for adolescents to provide intensive evidence-based treatment in smaller, more homelike settings.

In February of 2015, LDH implemented its second generation managed care program for physical and basic behavioral health services, including full-risk managed care organizations only. Later that year, the Office of Behavioral Health and Medicaid worked collaboratively to integrate specialized behavioral health services, previously provided separately by the LBHP, into the benefits coordinated by the Healthy Louisiana Managed Care Organizations (MCOs) on December 1, 2015. Children with extensive behavioral health needs either in or at risk of out-of-home placement and enrolled in the Coordinated System of Care (CSoC) waiver program remained managed by the SMO. Integration of behavioral health care services into the Healthy Louisiana program was designed to improve care coordination for enrollees, provide more opportunities for seamless and real-time case management of health services, and better transitioning and use of all resources provided by the system. Medicaid coverage was expanded under the Affordable Care Act on July 1, 2016, and was made available to more than 400,000 Louisianans ages 19 to 64. Within a year, more than 23,000 adults in the Medicaid expansion group received specialized outpatient mental health services and more than 4,500 received inpatient mental health services at a psychiatric facility. Additionally, more than 4,900 adults received specialized substance use outpatient services and more than 5,300 adults received specialized substance use residential services. With the addition of the expansion population, Louisiana Medicaid now covers over 1.6 million members.

## Milestone 1: Access to critical levels of care for OUD and other SUDs

### Specifications:

Coverage of: a) outpatient; b) intensive outpatient services; c) medication-assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet the needs of Medicaid beneficiaries in the state); d) intensive levels of care in residential and inpatient settings; and

e) medically supervised withdrawal management.

### Current State

Louisiana currently covers all of the critical levels of care identified in Milestone 1. For optimum access to substance use disorder (SUD) treatment services for Medicaid beneficiaries, it is important to offer a range of services at varying levels of intensity across a continuum of care as the type of treatment or level of care needed may be more or less effective depending on the individual beneficiary.

Louisiana administers its Medicaid substance use disorder (SUD) services based on the American Society of Addiction Medicine (ASAM) Patient Placement Criteria. Louisiana currently covers a range of outpatient, intensive outpatient, medication-assisted treatment (MAT), residential, inpatient and withdrawal management services. The service definitions, program requirements, eligibility criteria, and detailed provider requirements/qualifications for each level are detailed through the publicly available published provider manual. The below table identifies the ASAM level, brief description, and state plan page number of currently offered services. Because Louisiana has offered ASAM level services since 2012, the levels of services are identified in our authority documents under the old ASAM terminology. LDH can provide a cross walk of former ASAM terminology to current ASAM levels if needed.

| Existing ASAM level of care coverage | Description | Adult/ Adolescent | State Plan Page Number |
|---|---|---|---|
| Level I | Outpatient | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level II.1 | Intensive Outpatient Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level III.1 | Clinically Managed Low Intensity Residential Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.3 | Clinically Managed Medium Intensity Residential Treatment<br>*(Provider manual: Clinically managed population specific high intensity residential)* | Adult only | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.5 | Clinically Managed High Intensity Residential Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 8 |
| | Medically Monitored Intensive Residential Treatment (covered under | Adult | Attachment 3.1 – A, Item 13.d, Page 8 |
| | | Youth | Attachment 3.1 – A, Item 16 |
| Level II-D (2-WM in | Ambulatory Detoxification with Extended Onsite Monitoring | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level III.2D (3.2-WM in | Clinically Managed Residential Social Detoxification (Provider manual: Clinically managed residential | Both | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.7D (3.7-WM in | Medically Monitored Residential Detoxification (Provider manual: Medically monitored inpatient | Adult | Attachment 3.1 – A, Item 13.d, Page 8 |

In addition to these services, Louisiana also covers medically managed inpatient therapies in both inpatient psychiatric hospital and acute care hospital settings (ASAM Level 4-WM) under hospital services in the State Plan. Coverage is also provided for Outpatient Treatment Services (formerly opioid maintenance therapy) through medicated assisted treatment (MAT). Louisiana currently covers MAT, specifically buprenorphine, suboxone, naloxone and naltrexone (Vivitrol). Louisiana covers methadone offered through the Medicaid formulary for the treatment of chronic pain conditions, but not for opioid dependence. The Louisiana Medicaid covered opioid pharmaceutical therapies are listed below. Authorization requirements vary amongst fee-for-service Medicaid and managed care depending on the drug's preferred status or if it is considered a medical-only provided benefit as opposed to being offered in retail pharmacies. Flexibilities are offered within the program for preferred drug list development.

- Buprenorphine
- Buprenorphine-Naloxone [Suboxone]
- Buprenorphine-Naloxone [Bunavail]
- Buprenorphine-Naloxone [Zubsolv]
- Buprenorphine Implant [Probuphine]
- Suboxone Film
- Naloxone Injectable
- Naloxone Nasal Spray [Narcan]

- Naltrexone Tab
- Naltrexone ER Injectable [Vivitrol]

As part of MAT, individuals prescribed one of the opioid pharmaceutical therapies listed above have access to counseling and other behavioral health therapies through the ASAM levels covered under the Medicaid State Plan.

Louisiana provides coverage to all children under the age of 21 for screening, vision, dental, hearing, and other medically necessary health care services to treat, correct, or ameliorate illnesses and conditions discovered, regardless of whether the service is covered in the Medicaid State Plan, as required by Early and Periodic screening, Diagnostic, and Treatment (EPSDT) requirements.

Allowed Provider Types and Specialties through Louisiana's managed care program include:

- Outpatient Services
  - PT 68 Substance Use and Alcohol Use Center PS 70 Clinic / Group
  - PT 74 Mental Health Clinic PS 70 Clinic / Group
  - PT AJ Licensed Addiction Counselor (LAC) PS 8E
- Residential Services
  - PT AZ Substance Use Residential Treatment Facility PS 8U Substance Use or Addiction

Louisiana's MCOs include institutions for mental disease (IMDs) in their provider networks for SUD residential levels of care under the authority for cost-effective "in lieu of" services under managed care rate setting rules.

### Future State

The below table identifies additional coverage Louisiana is considering for a future state plan or 1115 waiver amendment, pending Louisiana legislative budget approval. Louisiana coverage of methadone hinges upon legislative appropriation. Legislative appropriations will determine the scope of services and population coverage.

| ASAM Level of Care proposing to cover | Description |
|---|---|
| Methadone | Medicated Assisted Treatment |
| ASAM Level 1-WM | Ambulatory Withdrawal Management without Extended On-Site Monitoring |

LDH is also researching implementation of the nationally recognized "Hub and Spoke" model, as a mechanism to expand access to MAT and increase accessibility to services. This model would utilize the current ten opioid treatment programs (OTPs) as the "Hubs" and mobilize Drug Addiction Treatment Act (DATA) Waived Physicians as the "Spokes." This model would create an environment that is conducive to partnership development, collaborations and expansion of community resources.

### Summary of Actions Needed:

| Implementation Action Item | Timeline |
|---|---|
| Update State Plan and provider manual to reflect current services array and requirements. | 12 months |

## Milestone 2: Widespread use of evidence-based, SUD-specific patient placement criteria

### Specifications:

1. In addressing patient specific placement criteria, providers must assess treatment needs based on SUD specific, multidimensional assessment tools.
2. Louisiana MCOs must have a utilization management approach such that: a) beneficiaries have access to SUD services at the appropriate level of care; b) interventions are appropriate for the diagnosis and level of care; and c) there is an independent process for reviewing placement in residential treatment settings.

### Current State

The Louisiana MCO contracts incorporate by reference (e.g., at section 7.8.14.2) the requirements detailed in the LDH Behavioral Health Services Provider Manual, which can be found here. These program and service requirements, including assessments for each ASAM Level, are addressed in this Behavioral Health Services Provider Manual and apply to MCO providers. Louisiana does not mandate providers use a specific assessment tool; however, the assessment tool must reflect evidence based clinical treatment guidelines.

MCOs are responsible for implementing a utilization management approach consistent with Milestone
#2. The MCOs perform utilization management for all levels of care. Residential placement undergoes more intensive pre-certification requirements, whereas, outpatient services may be subject to outlier review, practice management, or other less-intensive utilization management strategies. Under the contract, MCOs must currently have utilization management policies and procedures in place that meet National Council on Quality Assurance standards and include medical management criteria and practice guidelines. At minimum, the MCOs' policies must contain the following:

- The methodology utilized to evaluate the medical necessity, appropriateness, efficacy, or efficiency of health care services;
- The data sources and clinical review criteria used in decision making;
- The appropriateness of clinical review shall be fully documented;
- The process for conducting informal reconsiderations for adverse determinations;
- Mechanisms to ensure consistent application of review criteria and compatible decisions;
- Data collection processes and analytical methods used in assessing utilization of health care services;
- Provisions for assuring confidentiality of clinical and proprietary information;
- Service authorization criteria for specialized behavioral health services that are consistent with the Medicaid State Plan;
- Collaborating with child serving agencies and schools to coordinate the discharge and transition of youth in out-of-home placement for the continuance of prescribed medication and other behavioral health services prior to reentry into the community, including necessary provider referrals; and

- Collaborating with hospitals, nursing home facilities, inpatient facilities, and the criminal justice system to coordinate aftercare planning prior to discharge/release and transition of members for the continuance of behavioral health services and medication prior to reentry into the community, including necessary provider referrals.

The State Plan establishes coverage using the ASAM levels of care and as such, service authorization criteria must meet this same standard in each MCO's policies and procedures. These policies are reviewed and approved by LDH, but may warrant additional scrutiny as the program evolves. Additionally, the MCOs are required to take steps to ensure adoption of the clinical practice guidelines by specialized behavioral healthcare providers, and to measure compliance with the guidelines. The MCOs are contractually encouraged to employ substantive provider motivational incentive strategies, such as financial and non-financial incentives, to improve compliance. Additionally, the MCOs are required to perform record reviews. LDH is currently developing an audit tool for record review, including screening and assessments of SUD services, to collect additional data on providers in order to ensure that interventions are appropriate.

For each ASAM level, Section 2.1 of the LDH Behavioral Health Services Provider Manual describes the responsibilities for screening, assessment and treatment plan review, including the requirements to substantiate appropriate patient placement.

Per Section 4.2.24 of the MCO contract, all MCOs are required to have an Addictionologist or an Addiction Services Manager (ASM) who must meet the requirements of a licensed addiction counselor (LAC) or Licensed Mental Health Professional (LMHP) with at least seven (7) years of clinical experience with addiction treatment of adults and children experiencing substance use problems and disorders. The ASM is responsible for oversight and compliance with the addiction principles of care and application of ASAM placement criteria for all addiction program development. The ASM works closely with the Chief Operating Officer, the Behavioral Health Coordinator, the Quality Management Coordinator, and the Behavioral Health Medical Director in assuring quality, appropriate utilization management, and adequacy of the addiction provider network.

Each MCO is also required to have sufficient licensed mental health professionals, including licensed addiction counselors, as well as a board-certified addictionologist included as part of its prior authorization and inpatient concurrent review staff (section 4.3 of the MCO contract).

### Future State

In accordance with this milestone, the state is constantly seeking to improve its review and monitoring of its managed care organizations relative to utilization management. Ongoing review of policies and procedures to ensure they include use of evidence-based practices and SUD-specific criteria will occur to determine if any additional education or changes are warranted.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| The Behavioral Health Provider Manual will be updated to clarify that ASAM criteria and levels of care shall be used for each provider's assessment tool. | 12 months |

## Milestone 3: Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications

### Specifications:

1. Implementation of residential treatment provider qualifications in licensure requirements, program authorities and policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria, or other nationally recognized, evidence- based SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings
2. Implementation of state process for reviewing residential treatment providers to assure compliance with these standards
3. Residential treatment facilities offer MAT on-site or facilitate access off-site

### Current State

Louisiana has established provider qualifications requirements, based on ASAM criteria, for SUD residential treatment providers through licensure standards, managed care contract requirements,

and managed care provider manuals. Providers contracting to provide Medicaid services as part of the MCO

networks are held to certain standards in their individual provider contracts and are required to be credentialed and accredited prior to participating in the network.

LDH has established licensing standards for substance use/addiction treatment facilities located online here; and updates located here.

Louisiana utilizes the ASAM criteria program standards to establish residential treatment provider qualifications in its licensure and authority documents including the types of services, hours of clinical care and credentials of staff for residential treatment settings. These can be found in the addiction treatment section of the provider manual located at this link.

Compliance with licensure, which was developed using ASAM criteria, is administered and monitored by the Health Standards Section of LDH who is responsible for compliance with federal survey and certification requirements. Providers are held compliant by onsite and administrative reviews, which includes reviews of records and observations and interviews with staff and clients, as appropriate to the process. All visits, except for initial licensure surveys, are unannounced. To ensure compliance, reviews are conducted during licensure application, renewal, complaints, onsite, and as administrative reviews. The MCOs also assure compliance with program standards outlined in the provider manuals through monitoring of its provider network via credentialing, monitoring complaints, and during the provider recredentialing cycle.

Currently, most residential providers utilize abstinence-based care models and do not provide MAT onsite or facilitate offsite access to MAT.

Additionally, the Food and Drug Administration (FDA) approved a risk evaluation and mitigation strategy (REMS) on July 9, 2012, for extended release long acting opioid medications. The Collaborative on REMS Education has developed tools, resources, and outcomes to meet the FDA requirements. The Louisiana State Medical Society (LSMS) received an REM grant to facilitate opioid educational offerings throughout the state. LSMS partnered with the in collaboration with the East Baton Rouge Parish Coroner (current head of the Louisiana State Coroner's Association) to perform an opioid educational seminar to physicians, nurses, behavioral health providers and pharmacists. An educational event was held September 21, 2016, and was well received within the healthcare community. The grant facilitated a second educational offering in Shreveport, LA on November 11, 2016. The opioid educational offering solidified a relationship with LSMS which facilitated educating the provider community statewide utilizing national best practices and the CMS guidelines. Additional trainings will be hosted in collaboration with LSMS and providers participating in the Louisiana Opioid STR Initiative will be invited to attend.

### Future State

Over the next 24 months (and possibly longer), Louisiana will be focused on creating a culture change among residential providers to integrate facilitation of MAT into the programmatic requirements and reality. Residential providers will be required to offer or facilitate access to MAT off-site. This is expected to require heavy outreach and education because most of Louisiana's current residential providers practice within strict abstinence-based care models. Additionally, a rate review will be completed when Louisiana determines details for implementation.

The current use of abstinence-based care models will require an increased level of education and guidance necessary to facilitate MAT services in collaboration with those facilities in the future. In

addition to guidance and education by a board certified psychiatrist and addictionologist, Substance Abuse and Mental Health Services Administration (SAMHSA) materials will be utilized to provide education to these

facilities. Examples of these materials include *Methadone Treatment for Pregnant Women; SAMHSA Opioid Overdose Prevention Toolkit;* and *An Introduction to Extended Release Injectable Naltrexone for the Treatment of People with Opioid Dependence*. Board certified psychiatrists and addictionologists will be used to assist with assessment protocols necessary for pregnant women within residential programs.

Louisiana's 10 OTPs have participated in past learning collaboratives, such as the Methadone Educational Initiative, and have volunteered to educate community stakeholders and primary care providers throughout the state. In the implementation of the Opioid State Targeted Response (STR) Grant, the OTPs will be utilized as subject matter experts to educate healthcare providers on their service array and treatment modalities; dispel myths associated with medicated assisted treatment; and provide guidance to ensure providers adhere to culturally competent educational offerings based upon healthcare disparities common with patients in treatment. The purpose of the Louisiana Opioid STR Initiative is also to raise awareness about the dangers of sharing medication; to work with pharmaceutical and medical communities on the risks of overprescribing to young adults; to raise community awareness; and to increase prescription drug abuse education to schools, communities, parents, prescribers and patients.

Educational initiatives will seek to eliminate stereotyping associated with medication-assisted treatment. Educational initiatives will include state and federal guidance associated with medicated assisted treatment and incorporate guidance and approval of the State Opioid Treatment Authority. The treatment guidance for residential treatment providers will include but is not limited to SAMHSA TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction and TIP 43: Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Educate abstinence-based residential providers on benefits of MAT accessibility to begin cultural shift toward acceptance of MAT as a complementary treatment. | 24 months + |
| Review MCO contract language regarding this requirement to determine if changes to the contract to support this milestone are necessary. | 12 months |
| Review provider manual and service description to require access to MAT and any associated provider manual requirements and rate adjustments if needed. | 12 months |

## Milestone 4: Sufficient provider capacity at each level of care, including MAT

### Specifications:

Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT.

### Current State

LDH currently monitors provider sufficiency through MCO reporting. MCOs submit network adequacy reports to LDH on a quarterly basis inclusive of counts of available network providers by levels of care and by provider type. Current ASAM levels of care as reported by the Healthy

Louisiana Managed Care Organizations (MCOs) via quarterly network provider reports indicate an average of the following numbers of providers by Louisiana Department of Health (LDH) administrative region.

*Table 1*

| ASAM Level of Care | MHSD | CAHSD | SCLHSA | AAHSD | ImCal | CLHSD | NLHSD | NDHSA | FPHSA | JPHSA |
|---|---|---|---|---|---|---|---|---|---|---|
| ASAM Level I | 15 | 17 | 8 | 12 | 6 | 13 | 13 | 17 | 10 | 10 |
| ASAM Level II.1 | 17 | 22 | 8 | 13 | 8 | 15 | 14 | 19 | 9 | 13 |
| ASAM Level II.D | 2 | 2 | 1 | 2 | 0 | 1 | 2 | 2 | 3 | 2 |
| ASAM Level III.1 | 3 | 2 | 1 | 1 | 1 | 3 | 3 | 1 | 0 | 1 |
| ASAM Level III.1 | 5 | 4 | 1 | 3 | 1 | 5 | 3 | 3 | 0 | 4 |
| ASAM Level III.2D | 3 | 3 | 1 | 2 | 2 | 3 | 2 | 2 | 1 | 2 |
| ASAM Level III.2D | 2 | 4 | 1 | 4 | 2 | 4 | 2 | 2 | 0 | 2 |
| ASAM Level III.3 | 7 | 10 | 3 | 4 | 3 | 6 | 4 | 5 | 2 | 6 |
| ASAM Level III.5 | 4 | 7 | 2 | 3 | 2 | 6 | 4 | 3 | 1 | 3 |
| ASAM Level III.5 | 8 | 10 | 2 | 5 | 3 | 7 | 4 | 7 | 1 | 4 |
| Psychiatric Residential Treatment Facility (ASAM Level III.7 – Adolescent)* | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 |
| ASAM Level III.7 – Adult | 3 | 5 | 1 | 4 | 2 | 3 | 2 | 3 | 0 | 1 |
| ASAM Level III.7D – Adult | 3 | 4 | 1 | 3 | 1 | 3 | 2 | 2 | 0 | 1 |
| ASAM Level IV.D | 1 | 3 | 1 | 3 | 1 | 2 | 2 | 1 | 0 | 2 |

** Louisiana currently has four licensed Psychiatric Residential Treatment Facilities (PRTFs) for youth that provide medically necessary residential levels of care meeting required criteria.*

MAT Prescriber Count by Parish for December 1, 2016, through November 30, 2017, is included in Table 2 below. This information was extracted using claims and encounter data indicating the number of unduplicated providers that billed for an MAT service.

*Table 2*

| Parish | Prescriber Count |
|---|---|
| ACADIA | 7 |
| ALLEN | 2 |
| ASCENSION | 13 |
| ASSUMPTION | 0 |
| AVOYELLES | 6 |
| BEAUREGARD | 3 |
| BIENVILLE | 0 |
| BOSSIER | 9 |
| CADDO | 40 |
| CALCASIEU | 53 |
| CALDWELL | 0 |
| CAMERON | 1 |

| | |
|---|---|
| CATAHOULA | 0 |
| CLAIBORNE | 2 |
| CONCORDIA | 3 |
| DESOTO | 1 |
| EAST BATON ROUGE | 72 |
| EAST CARROLL | 3 |
| EAST FELICIANA | 3 |
| EVANGELINE | 6 |
| FRANKLIN | 2 |
| GRANT | 1 |
| IBERIA | 16 |
| IBERVILLE | 4 |
| JACKSON | 1 |
| JEFFERSON | 95 |
| JEFFERSON DAVIS | 0 |
| LAFAYETTE | 57 |
| LAFOURCHE | 17 |
| LASALLE | 2 |
| LINCOLN | 6 |
| LIVINGSTON | 4 |
| MADISON | 1 |
| MOREHOUSE | 2 |
| NATCHITOCHES | 2 |
| ORLEANS | 182 |
| OUACHITA | 27 |
| Out of State | 28 |
| PLAQUEMINES | 4 |

| | |
|---|---|
| POINTE COUPE | 1 |
| RAPIDES | 27 |
| RED RIVER | 1 |
| RICHLAND | 2 |
| SABINE | 2 |
| ST. BERNARD | 3 |
| ST. CHARLES | 6 |
| ST. HELENA | 0 |
| ST. JAMES | 0 |
| ST. JOHN | 3 |
| ST. LANDRY | 12 |
| ST. MARTIN | 2 |
| ST. MARY | 4 |
| ST. TAMMANY | 45 |
| TANGIPAHOA | 26 |
| TENSAS | 0 |
| TERREBONNE | 20 |
| UNION | 4 |
| VERMILION | 3 |
| VERNON | 2 |
| WASHINGTON | 13 |
| WEBSTER | 7 |
| WEST BATON ROUGE | 0 |
| WEST CARROLL | 5 |
| WEST FELICIANA | 1 |
| WINN | 1 |

The quarterly network report package additionally includes GeoAccess mapping for all network providers. Should gaps in access or adequacy be identified, the MCOs are required to submit gap analyses and ad hoc network development plans with their quarterly report package. In addition, LDH is currently in the process of procuring a provider management contract which will include a credentialing verification function under a single, statewide vendor. It is intended that this will achieve a single, reliable provider registry. This new provider enrollment and credentialing system is anticipated to activate in 2018. MCOs will then be limited to choosing providers from the state's single source for provider enrollment, allowing LDH to appropriately identify providers in encounter data.

The managed care organizations are tasked with monitoring provider capacity of their networks. Each MCO develops and maintains a provider Network Development and Management Plan which ensures that the provision of core benefits and services will occur. It includes the MCO's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services. The plan demonstrates access to behavioral health services, identifies gaps in network and describes the process to assure services are delivered. The plans provide GEO mapping of providers to geographically demonstrate network

capacity. The MCOs have

policies detailing how the MCO will provide or arrange for medically necessary covered services should the network become temporarily insufficient and will monitor the adequacy, accessibility and availability of its provider network to meet the needs of its members. MCO Network Development and Management Plans are updated at least annually or more often as needed to reflect material changes in network status.

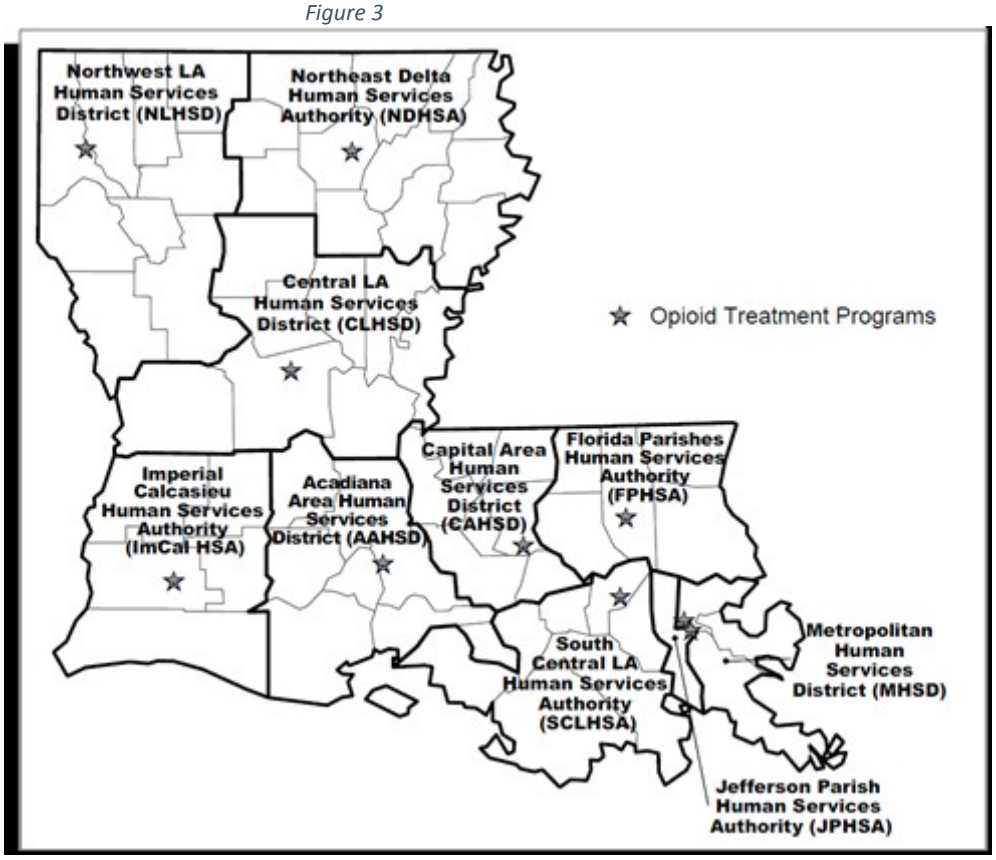
The MCO contract currently specifies geographic access requirements for maximum travel time and /or distance requirements as outlined below:

- Travel distance to behavioral health specialists [i.e., psychologists, medical psychologists, advanced practice registered nurses (APRN) practicing as a Clinical Nurse Specialist (CNS) in mental health, or Licensed Clinical Social Workers (LCSWs)] and to psychiatrists for members living in rural parishes shall not exceed 30 miles for 90% of such members.
- Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN CNS in mental health, or LCSWs) and to psychiatrists for members living in urban parishes shall not exceed 15 miles for 90% of such members.
- Travel distance to Level III.3/5 Clinically Managed High Intensity Residential shall not exceed 30 miles for 90% of adult members, and shall not exceed 60 miles for adolescent members.
- Travel distance to Level III.7 Medically Monitored Intensive Residential co-occurring treatment shall not exceed 60 miles for 90% of adult members.
- Travel distance to Level III.7D Medically Monitored Residential Detoxification shall not exceed 60 miles for 90% of adult members.
- Travel distance to Psychiatric Residential Treatment Facilities (PRTF) shall not exceed 200 miles for 90% of members.
- Request for exceptions as a result of prevailing community standards for time and distance accessibility standards must be submitted in writing to LDH for approval.

In December of 2017, the Louisiana legislature approved a 23 month contract extension of the current managed care contracts that changes these adequacy standards from 90% to 100% and includes time requirements.

There is one Opioid Treatment Program (OTP) located in each Louisiana Department of Health region, called Local Governing Entity (LGE) regions (see Figure 3). All ten OTPs are privately owned and have historically received no state or federal funding to support MAT, with the exception of Behavioral Health Group (BHG) located in New Orleans, which is currently receiving funds through the recent award of the Medication-Assisted Treatment Prescription Drug and Opioid Addiction (MAT-PDOA) grant. Through the Louisiana Opioid State Targeted Response (STR) grant, funding was recently allocated to the remaining nine OTPs who are not receiving funding to support MAT for under- and uninsured individuals diagnosed with OUD. Current capacity of the 10 OTP sites is approximately 5,000. However, OTP sites have flexibility and capacity, and census is a moving target. Capacity is based upon the current census and LA regulations which indicate 75:1 patient/counselor ratio. Most of the clinics utilize 50:1 ratio and if they receive additional admits they would hire additional counselors to provide services. LDH has observed that at any single point in time over the last two years, no OTP site was at full capacity and total census averaged approximately 3800 to 4000 patients. However, it is anticipated that use of OTPs will expand if methadone becomes a Medicaid covered service.

*Figure 3*




## Future State

Going forward, LDH will establish new reporting requirements for the MCOs for their Specialized Behavioral Health network development and management plans to specifically focus on SUD provider capacity, including MAT. Geo mapping will also be expanded to monitor access to MAT inclusive of a reporting mechanism for how many providers are accepting new patients.

As an additional treatment strategy, physicians will be encouraged to become certified dispensers. According to the Drug Addiction Treatment Act of 2000 (DATA 2000), which expands the clinical context of medication-assisted treatment for persons with Opioid Use Disorder (OUD), certified physicians are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications such as buprenorphine, suboxone, and subutex in settings other than an opioid treatment program (OTP). DATA 2000 reduces the regulatory burden on physicians who choose to practice OUD treatment by permitting qualified physicians to apply for and receive waivers of the special registration requirements defined in the Controlled Substances Act.

In order to become a certified prescriber or dispenser, a physician must qualify for a physician waiver. The physician must complete eight hours of required training and then apply for the waiver. This can be done online at SAMHSA Center for Substance Abuse Treatment's (CSAT's) Buprenorphine Information Center at 866-BUP-CSAT (866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov (link sends e- mail).

Physicians are also required to complete buprenorphine training to receive their training certificate after completing the Waiver Notification Form. These waiver applications are forwarded to the

DEA, which assigns the physician a special identification number. DEA regulations require this number to be included

on all buprenorphine prescriptions for opioid dependency treatment, along with the physician's regular DEA registration number. SAMHSA reviews waiver applications within 45 days of receipt. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number. A list of buprenorphine providers can be assessed through SAMHSA website treatment locator.

Physicians must apply to SAMHSA to treat more than 30 patients as well as meet the following conditions:

- Be currently authorized under DATA 2000 to prescribe buprenorphine products.
- Complete the Online Notification Form to Increase Patient Limit at least one year after initial waiver was approved.

In addition, if a physician has prescribed buprenorphine to 100 patients for at least one year, he/she has the opportunity to apply for an increase to their patient limits up to 275 under new federal regulations. Modifying the number of patients a physician may treat under the DATA 2000 is authorized under the Office of National Drug Control Policy Reauthorization Act of 2006.

SAMHSA is currently tracking the number of certified physicians across the nation. There are identified federal record keeping requirements that must be adhered to by physicians. DEA record keeping requirements for buprenorphine treatment go beyond the Schedule III record keeping requirements. Under the Persons Required to Keep Records in the Code of Federal Regulations, physicians are required to keep records and inventories of all controlled substances dispensed, including approved buprenorphine products.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Require MCOs to update their Specialized Behavioral Health network development and management plan to specifically focus on SUD provider capacity, including MAT. | 12 months |
| Add an indicator if providers are accepting new patients to the quarterly network adequacy reports. | 12 months |
| LDH to assess MAT capacity based MCO data or independent review. | 12 months |

## Milestone 5: Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD

### Specifications

1. Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse
2. Expanded coverage of, and access to, naloxone for overdose reversal
3. Implementation of strategies to increase utilization and improve functionality, of prescription drug monitoring programs

### Current State

The Louisiana Department of Health is currently implementing opioid-related initiatives under nine federal grants. With the common goal to decrease opioid deaths in Louisiana, these initiatives use the following strategies: better data, prevention, rescue, treatment and recovery.

LDH's Office of Public Health has established the Louisiana Opioid Surveillance Initiative identifying, validating, and aligning sources of data, in order to enhance our understanding of the opioid epidemic in Louisiana. Current goals and initiatives of this system include:

- Reporting rapid surveillance data on overdoses and deaths
- Create and maintain an online surveillance system
- Disseminate results of internal analyses to stakeholders and the public
- Use data to measure outcomes of programs and policies

LDH's Office of Behavioral Health is currently addressing capacity and integration of prevention, intervention, treatment, and recovery support services. Current goals and initiatives include:

- Prevention: Each LGE is hiring an Educational Outreach Consultant to provide education and awareness activities, dependent upon local needs and targets. A statewide campaign is currently in development to ensure consistent messaging across the state.
- Intervention: OBH is providing distribution of Naloxone to communities and providers. Each LGE is required to submit a distribution plan with strategies of how they will use and track the kits (nasal sprays).
- Treatment: Each Opioid Treatment Program (OTP) has been provided STR funds to enhance accessibility to treatment services. In addition, each OTP has funding to hire a Resource Coordinator who will work with the region to provide referral services and to ensure peer support specialists have a seamless system of referral to the OTP. Lessons learned about recruitment and retention of consumers in treatment from the MAT-PDOA grant implementation in the New Orleans area will be shared statewide.
- Recovery Supports: Each LGE is also given funding through the STR grant to hire peer support specialists, who are trained and receive credentials through OBH to provide peer services. Peer support services outreach can be done in emergency rooms, one-stop centers, or wherever locally the need is to reach those consumers who are in need of treatment.

Louisiana's Prescription Monitoring Program (PMP) was implemented in August 2008 by the Board of Pharmacy. The PMP is an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed within the state or dispensed by a licensed pharmacy outside the state to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs of concern in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes. Since implementation, the Louisiana Legislature has adopted several measures to improve the program:

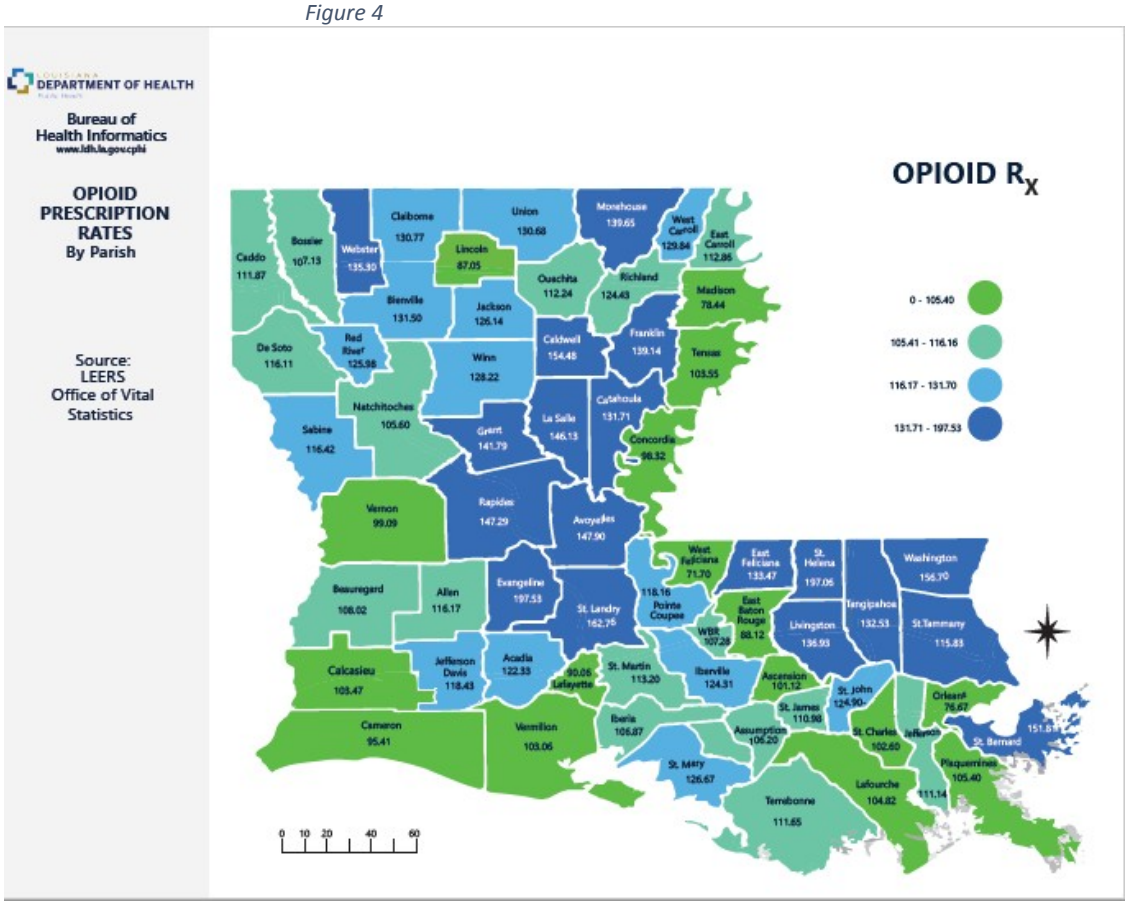
- Pharmacies and other dispensers are required to report their eligible prescription transactions to the program database no later than the next business day following the date of dispensing, instead of the previous seven day allowance.
- Authorized prescribers and dispensers are allowed to appoint delegates for the purpose of retrieving data from the program's database.
- Prescribers of certain controlled substances for the treatment of certain conditions to access the patient's history in the program database prior to initiating such treatment. The same measure will require pharmacists dispensing certain controlled substances to certain patients to access the patient's history in the program database prior to dispensing such

medications.

- The state's controlled substance law was amended to require the automatic issuance of PMP access privileges to all practitioners with prescriptive authority for controlled substances except veterinarians. Another measure amended the PMP law to enable additional categories of authorized users, e.g., medical examiners, substance abuse counselors, and probation and parole officers, as well as judicially supervised specialty courts.

As a result of CDC grants around data surveillance on opioids, the Louisiana Office of Public Health (OPH) has been working in collaboration with the Board of Pharmacy and the PMP to provide data on opioid prescriptions. In 2016, it was found that there were 110 prescriptions per 100 citizens in Louisiana. The national average for opioid prescriptions is 66.5 prescriptions per 100 citizens. Efforts are underway to see how such collaborations and data can be used to ensure appropriate prescribing of opioids and reduce the inappropriate number of prescriptions in Louisiana. Current prescription rate patterns per Louisiana parish can be seen in Figure 4:

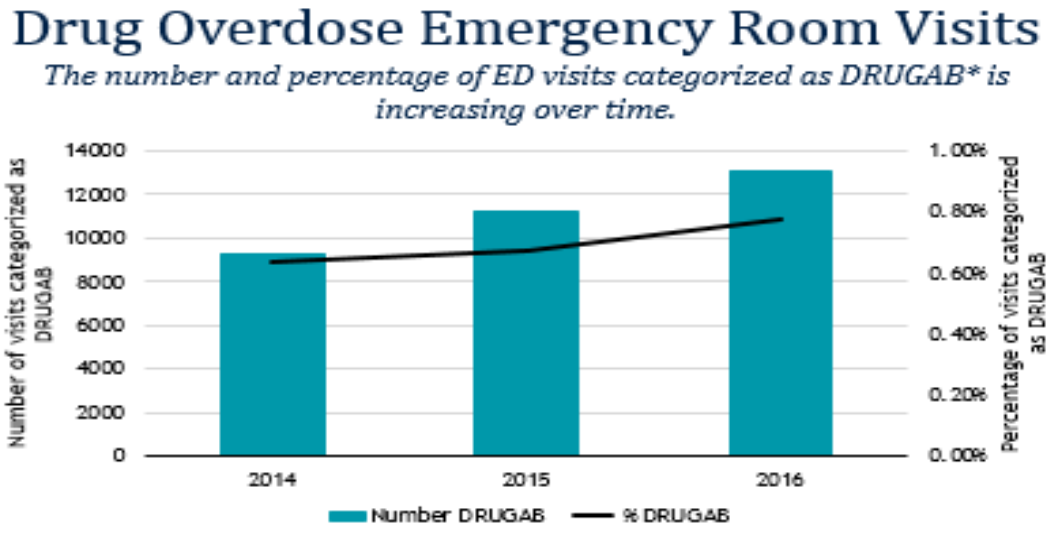
*Figure 4*




In collaboration with partners across the state, OPH is evaluating all data in relation to opioids in Louisiana. Fact sheets on opioid prescription practices and opioid-related deaths are broken down by parish and provided for the public on the LDH website. Furthermore, OPH is collecting and organizing opioid-related data from Emergency Room, Hospital Inpatient, Emergency Medical Systems, and various other databases and systems to build a dashboard in early 2018 to understand the extent of opioid-related hospitalizations including overdoses, deaths, naloxone administration, and neonatal abstinence syndrome (NAS). The goal of such information is to provide data-driven

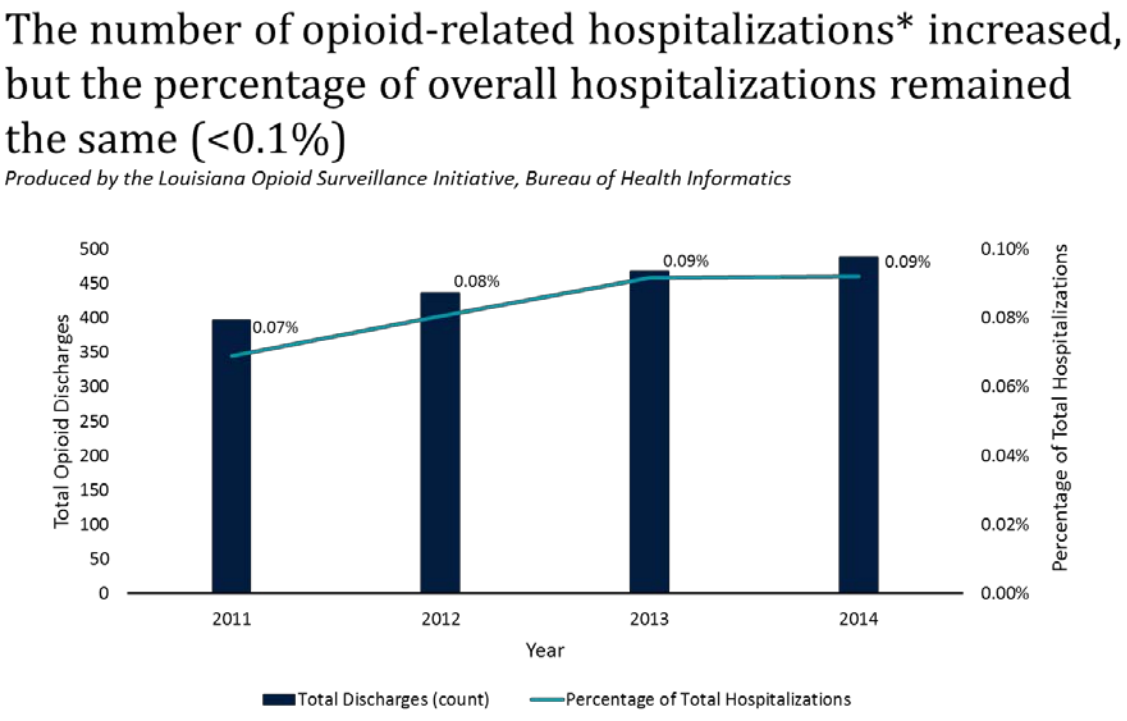
opioid surveillance for better understanding of the extent of the opioid epidemic in Louisiana and to drive data-driven solutions.

*Figure 5*




*Source: Louisiana Early Event Detection System, 2014-2016***
*The syndrome that captures drug overdose visits is called DRUGAB (for "Drug Abuse")
**Emergency Departments (EDs) reporting to LEEDS represent approximately 61% of all EDs in the state of Louisiana. This 61% of EDs cover all 9 Public Health Regions.

*Figure 6*




*Source: Louisiana Hospital Inpatient Discharge Database, 2011-2014*

*Opioid-related hospitalizations were defined as any presence of the following ICD-9-CM codes: 965.00, 965.01, 965.02, 965.09, E850.0, E850.1, E850.2

In 2017, several pieces of legislation were enacted to strengthen the state's efforts against the opioid epidemic:

- Act 76 (SB 55 by Sen. Fred Mills)
  - Requires prescribers to check the PMP system before prescribing an opioid to a patient and to check it every 90 days.
  - Requires prescribers to obtain three continuing education credit hours related to drug diversion training, best practice prescribing of controlled substances, and appropriate treatment for addiction prior to license renewal in 2018.
- Act 82 (HB 192 by Rep. Helena Moreno)
  - Implements a seven-day limit on first-time prescriptions of opioids for acute pain, with exemptions for patients with cancer, chronic pain or those receiving palliative care. It also gives doctors the ability to override the limit when medically necessary, with a notation in the patient's medical record.
  - These opioid prescription limits were implemented in Medicaid in 2017. The implementation timeline along with resources for providers was published on the LDH Opioid FAQ Fact Sheet.
- Act 88 (HB 490 by Rep. Walt Leger)
  - Creates the Advisory Council on Heroin and Opioid Prevention and Education, a 13-member council tasked with coordinating resources and expertise for a statewide response to combat opioid abuse.
- Act 241 (SB 96 by Sen. Ronnie Johns)
  - Provides for access to prescription monitoring information, including medical examiners, coroners, licensed substance abuse or addiction counselors, and probation and parole officers to those who may access prescription monitoring program information in certain circumstances.

In 2017, Naloxone was also made available to treat opioid overdose via standing order issued by the Secretary of LDH. This allows for participating pharmacists to dispense naloxone to laypeople including caregivers, family and friends of an opioid user. This standing order also includes directions on how to administer naloxone to someone who has overdosed. The standing order was recently reissued for another year on January 8, 2018. Information regarding the standing order was disseminated to the MCOs via Informational Bulletin 17-1.

### Future State

LDH is proposing legislative changes to the Prescription Monitoring Program that would allow Medicaid access to the system's audit trail in order to better monitor prescribing practices of Medicaid providers to identify overuse and/or abuse. Any action will require Louisiana Board of Pharmacy approval. Additionally, the Board of Pharmacy is working to make Naloxone a listed "drug of concern" for tracking through the PMP. This will allow the Board and LDH to identify distribution under the standing order and other mechanisms. LDH also has long-term plans to work with provider and stakeholder groups such as hospitals, safety officers, and first responders on tracking Naloxone administration through required reporting.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Coordinate with stakeholders on establishing required reporting for Naloxone administration. | 24 months |
| Coordinate with Board of Pharmacy to create Medicaid access to monitor prescribing practices of opioids under the PMP. | 24 months |

| | |
|---|---|
| Work with Board of Pharmacy to track Naloxone distribution under the | 6 months |

## Milestone 6: Improved care coordination and transitions between levels of care

### Specification:

Implementation of policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

### Current State

Louisiana licensing standards emphasize the importance of transitions of care by outlining certain transfer and discharge requirements specifically addressing discharge, transition to another level of care and transfer to another provider. It requires discharge planning to begin at admission and outlines discharge plan components to provide reasonable protection of continuity of services and agreements between the current transferring provider and the receiving provider. See page 1703 of the Behavioral Health Provider licensing regulations here.

The MCOs are required to develop and maintain effective care coordination, continuity of care, and care transition activities to ensure a continuum of care approach to providing health care services to MCO members. The MCO contracts have explicit language around continuity of care and care transition. Requirements include collaborating with hospitals, nursing home facilities, and inpatient facilities to coordinate aftercare planning prior to discharge and transition of members for the continuance of behavioral health services and medication prior to reentry into the community, including referral to community providers. They are required to coordinate hospital and/or institutional discharge planning that includes post-discharge care as appropriate, including aftercare appointments, following an inpatient, PRTF, or other out-of-home stay and assure that prior authorization for prescription coverage is addressed and or initiated before patient discharge. The MCO must have policies and procedures requiring and assuring that:

- Behavioral health pharmacy prior authorization decisions are rendered before a member is discharged from a behavioral health facility (including, but not limited to, inpatient psychiatric facilities, PRTFs, and residential substance use disorder settings).
- Care managers follow up with members with a behavioral health-related diagnosis within 72 hours following discharge.
- Coordination with LDH and other state agencies following an inpatient, PRTF, or other residential stay for members with a primary behavioral health diagnosis occurs timely when the member is not to return home.

### Future State

OBH/LDH will continue to monitor MCO compliance with existing contract requirements in effort to assure beneficiary needs are met relative to linkage with community-based services.

### Summary of Actions Needed

There are no anticipated actions needed by Louisiana for fulfillment of this milestone.

**Attachment E:**
**Reserved for SUD Monitoring Protocol**

**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.

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 -S

Digitally signed by Danielle Daly -S
Date: 2024.04.24 05:15:36 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

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

**CENTERS FOR MEDICARE & MEDICAID SERVICES**
**EXPENDITURE AUTHORITY**

**NUMBER:** **11-W-00311/6**

**TITLE:** **Healthy Louisiana Opioid Use Disorder/Substance Use Disorder 1115(a) Demonstration**

**AWARDEE:** **Louisiana Department of Health**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Louisiana for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 1, 2023 through December 31, 2027, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The following expenditure authority may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Louisiana (state) to operate the above-identified section 1115 demonstration.

- **Residential Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**SPECIAL TERMS AND CONDITIONS**

**NUMBER:** **11-W-00311/6**

**TITLE:** **Healthy Louisiana Opioid Use Disorder/Substance Use Disorder 1115(a) Demonstration**

**AWARDEE:** **Louisiana Department of Health**

## 1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Healthy Louisiana Opioid Use Disorder/Substance Use Disorder" (hereinafter "Healthy Louisiana") section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Louisiana Department of Health (hereinafter "state"), to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The STCs are effective as of the date of the approval letter, unless otherwise specified.

The STCs related to the programs for those state plan populations affected by the demonstration are effective beginning January 1, 2023 through December 31, 2027.

The STCs have been arranged into the following subject areas:

1. Preface
2. Program Description and Objectives
3. General Program Requirements
4. Eligibility and Enrollment
5. Demonstration Programs and Benefits
6. Cost Sharing
7. Delivery System
8. Monitoring and Reporting Requirements
9. General Financial Requirements
10. Monitoring Budget Neutrality for the Demonstration
11. Evaluation of the Demonstration
12. Schedule of Deliverables

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A: Developing the Evaluation Design

| | |
|---|---|
| Attachment B: | Preparing the Interim and Summative Evaluation Reports |
| Attachment C: | Substance Use Disorder (SUD) Implementation Plan (Approved) |
| Attachment D: | Substance Use Disorder (SUD) Monitoring Protocol (Reserved) |
| Attachment E: | Evaluation Design (Reserved) |

## 2. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration, originally approved on February 1, 2018, enables Louisiana to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD).

The goal of this demonstration is for Louisiana to maintain critical access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. This demonstration will provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an IMD. It will also build on the state's existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions and strengthen a continuum of SUD services based on the American Society of Addiction Medicine (ASAM) criteria or other comparable nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

During the demonstration extension period, Louisiana seeks to achieve—or continue sustaining the progress from achievements during the previous demonstration approval period on—the following objectives, which are in alignment with the six goals described in the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17-003)[1]:

- Increased rates of identification, initiation, and engagement in treatment;
- Increased adherence to and retention in treatment;
- Reductions in overdose deaths, particularly those due to opioids;
- 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; and
- Improve access to care for physical health conditions among beneficiaries.

## 3. GENERAL PROGRAM REQUIREMENTS

3.1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with

[1] SMDL #17-003 Strategies to Address the Opioid Epidemic. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

3.2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program, or the Children's Health Insurance Program (CHIP) for the separate CHIP population, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3.3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

3.4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.

b. If mandated changes in the federal law require state legislation, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.

3.5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid state plan governs.

3.6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 3.7 below.

3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including, but not limited to the failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

b. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

c. An up-to-date CHIP allotment worksheet, if necessary.

d. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and

e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

3.8. **Extension of the Demonstration.** States that intend to request demonstration extensions under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, if the state intends to request a demonstration extension under section 1115(a) of the Act, the state must submit the extension application no later than 12 months prior to the expiration date of the demonstration. The Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at CFR Section 431.412(c) or a phase-out plan consistent with the requirements of STC 3.9.

3.9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period.

In addition, the state must conduct tribal consultation in accordance with STC 3.12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR § 35.916(f)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR § 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR § 431.230.

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR § 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.



Healthy Louisiana OUD/SUD 1115(a) Demonstration Page 6 of 81
Approval Period: January 1, 2023 through December 31, 2027

3.10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

3.11. **Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

3.12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR § 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR § 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 3.7 or extension, are proposed by the state.

3.13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

3.14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the

requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR § 46.104(b)(5).

## 4. ELIGIBILITY AND ENROLLMENT

4.1. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility. Standards for eligibility remain set forth under the state plan. The demonstration will allow Louisiana Medicaid recipients to receive OUD/SUD treatment services in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. All demonstration services are delivered through a managed care delivery, with the exception the spend-down medically needy population. All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan. All Medicaid eligibility standards and methodologies for these eligibility groups remain applicable.

## 5. DEMONSTRATION PROGRAM AND BENEFITS

5.1. **Substance Use Disorder Program Benefits.** Effective upon CMS' approval of the SUD Implementation the demonstration benefit package for Louisiana Medicaid recipients will include OUD/SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Louisiana Medicaid recipients residing in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 8.5, to ensure short-term residential stays.

Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD/ SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to on-going chronic care for these conditions in cost-effective settings.

5.2. **SUD Implementation Plan and Health IT Plan.** The state's SUD Implementation Plan, initially approved for the period from February 1, 2018-December 31, 2022, remains in effect for the approval period from January 1, 2023 through December 31, 2027, and is affixed to the STCs as Attachment D. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will results in a funding deferral. The approved SUD Implementation Plan describes the strategic approach and a detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

a. Access to Critical Levels of Care for OUD and other SUDs: Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;

b. Use of Evidence-based SUD-specific Patient Placement Criteria: Establishment of a requirement

that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;

c. Patient Placement: Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;

d. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities: Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the Louisiana Administrative Code and the Louisiana Medicaid provider manual. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other comparable, nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD program demonstration approval;

e. Standards of Care: Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

f. Standards of Care: Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;

g. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD: An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of SUD program demonstration approval;

h. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD: Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand access to naloxone;

i. SUD Health IT Plan: Implementation of the milestones and metrics as detailed in STC 5.2; and

j. Improved Care Coordination and Transitions between Levels of Care: Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of

SUD program demonstration approval.

5.3 **SUD Health Information Technology (Health IT).** The state has provided CMS with an assurance that is has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities.

This "SUD Health IT Plan," or assurance, will be included as a section of the state's "Implementation Plan" (see STC 5.2), which remain in effect for the approval period from January 1, 2023 through December 31, 2027, and is affixed to the STCs as Attachment D. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.

a. The SUD Health IT section of the Implementation plan will include implementation milestones and dates for achieving them.

b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

c. The SUD Health IT Plan will describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP).[2]

d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[3] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

e. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

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[2] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[3] *Ibid*.

f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[4]

g. In developing the Health IT Plan, states should use the following resources:

    i. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."

    ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans, found at https://www.healthit.gov/topic/advancing-interoperability-medicaid.

    iii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans, and more generally, to meet the goals of the demonstration.

h. The state will include in its SUD Monitoring Protocol (see Attachment D) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.

i. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (see STC 8.6).

j. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

k. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR § 170 Subpart B, the state should use the federally recognized standards, barring another compelling state interest.

l. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR § 170 but included in the ISA, the state should use the federally recognized ISA standards, barring no other compelling state interest.

[4] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

## 6. COST SHARING

6.1. **Cost Sharing.** Cost sharing imposed upon individuals under the demonstration is consistent with the provisions of the approved state plan.

## 7. DELIVERY SYSTEM

7.1. **Delivery System.** Louisiana's SUD/OUD Medicaid delivery system is based on an integrated managed care model for physical and behavioral health. It utilizes Managed Care Organizations (MCOs) to deliver integrated physical and behavioral health services, including SUD. Under the demonstration, Healthy Louisiana will continue to operate as approved in Section 1932(a) state plan authority for managed care and concurrent 1915(b) demonstration.

## 8. MONITORING AND REPORTING REQUIREMENTS

8.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outline in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

8.2. **Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones.** Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

8.3. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

8.4. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional section 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b. Ensure all section 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and

c. Submit deliverables to the appropriate system as directed by CMS.

8.5. **SUD Monitoring Protocol.** The state must submit an updated Monitoring Protocol for the SUD programs authorized by this demonstration within one hundred fifty (150) calendar days after approval of the demonstration. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS' comments. Once approved, the SUD Monitoring Protocol will be incorporated in the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 5.2 and reporting relevant information to the state's Health IT plan described in STC 5.3;

b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section 12 of the demonstration; and

c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

8.6. **Quarterly and Annual Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) compiled Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) days following the end of each demonstration quarter. The compiled Annual Monitoring Report (including the fourth quarter information) is due no later than ninety (90) days following the end of the DY. The state must submit a revised Monitoring Report within sixty (60) calendar days after receipt of CMS' comments, if any. The reports will include all required elements as per 42 CFR § 431.428. and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. Per 42 CFR § 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key operational and other challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics. Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress toward meeting the demonstration's annual goals and overall targets as will be identified in the approved SUD Monitoring Protocol, and will cover key policies under this demonstration.

Additionally, per 42 CFR § 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR § 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.

d. Evaluation Activities and Interim Findings. Per 42 CFR § 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 5.3.

8.7. **SUD Mid-Point Assessment Report.** The state must contract with an independent entity to conduct a mid-point assessment report by December 31, 2025. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of the demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the mid-point assessment report in light of the data from any such prior approval period(s). In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: SUD treatment providers, beneficiaries, and other key partners.

The state must require the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than sixty (60) days after December 31, 2025. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS' comments, if any.

For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation Plan and SUD Monitoring Protocol for ameliorating these risks subject to CMS approval. Elements of the Mid-Point Assessment Report include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol,

b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date,

c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets,

d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement, and

e. An assessment of whether the state is on track to meet the budget neutrality requirements.

8.8. **Corrective Action Plan Related to Demonstration Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8.9. **Close-Out Report.** Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.

a. The Close-Out Report must comply with the most current guidance from CMS.

b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STC 11.8.

c. The state will present to and participate in a discussion with CMS on the Close-Out report.

d. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.

e. A revised Close-Out Report is due to CMS no later than 30 days after receipt of CMS' comments.

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

8.10. **Monitoring Calls.** CMS will convene periodic conference calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

8.11. **Post Award Forum.** Pursuant to 42 CFR § 431.420(c), within 6 months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR § 431.420(c), the state must include a summary of the public comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

## 9. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

9.1. **Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

9.2. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

9.3. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.

b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS' concerns within the time frames allotted by CMS.

c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

9.4. **State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR § 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR § 433.51(c).

c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR § 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.

d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

9.5. **Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR §§ 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

9.6. **Requirements for Health Care-Related Taxes and Provider Donations.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR § 433.55 are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR § 433.68(c).

b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR § 433.68(d).

c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR § 433.72.

d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR § 433.68(f).

e. All provider-related donations as defined by 42 CFR § 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR § 433.66, and 42 CFR § 433.54.

9.7. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 8.1. This report must include:

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;

b. Number of providers in each locality of the taxing entities for each locality tax;

c. Whether or not all providers in the locality will be paying the assessment for each locality tax;

d. The assessment rate that the providers will be paying for each locality tax;

e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;

f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR § 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

9.8. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 10:

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.

9.9. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

9.10. **Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

**Table 1: Master MEG Chart**

| MEG | Which BN Test Applies? | WOW Per Capita | WOW Aggregate | WW | Brief Description |
|---|---|---|---|---|---|
| SUD IMD | Hypo 1 | X | | X | All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment described in Section 5. |

| Table 1: Master MEG Chart | | | | | |
|---|---|---|---|---|---|
| **MEG** | **Which BN Test Applies?** | **WOW Per Capita** | **WOW Aggregate** | **WW** | **Brief Description** |
| ADM | N/A | | | | All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality. |

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

9.11. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS 11-W-00311/6. Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b (in lieu of lines 9 or 10c), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget.

c. Pharmacy Rebates. Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes

to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the MEG Charts and in the STCs in section 9, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section 8.6, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

| Table 2: MEG Detail for Expenditure and Member Month Reporting | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **MEG (Waiver Name)** | **Detailed Description** | **Exclusions** | **CMS-64.9 or 64.10 Line(s) To Use** | **How Expend. Are Assigned to DY** | **MAP or ADM** | **Report Member Months (Y/N)** | **MEG Start Date** | **MEG End Date** |
| **SUD IMD** | Report all medical assistance expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment described in Section 5. | | Follow standard CMS 64.9 Category of Service Definitions | Date of service | MAP | Y | 2/1/18 | 12/31/27 |
| **ADM** | Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality | | Follow standard CMS 64.10 Category of Service Definitions | Date of payment | ADM | N | 1/1/23 | 12/31/27 |

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group;

9.12. **Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the table below.

| Table 3: Demonstration Years | | |
|---|---|---|
| Demonstration Year 6 | January 1, 2023 to December 31, 2023 | 12 months |
| Demonstration Year 7 | January 1, 2024 to December 31, 2024 | 12 months |
| Demonstration Year 8 | January 1, 2025 to December 31, 2025 | 12 months |
| Demonstration Year 9 | January 1, 2026 to December 31, 2026 | 12 months |
| Demonstration Year 10 | January 1, 2027 to December 31, 2027 | 12 months |

9.13. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the

budget neutrality expenditure limits described in section 10. CMS will provide technical assistance, upon request.[5]

9.14. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

9.15. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject

[5] Per 42 CFR § 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and § 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS' current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

9.16. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. Contents of Request and Process. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 9.16.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b. Types of Allowable Changes. Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:

i. Provider rate increases that are anticipated to further strengthen access to care;

ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;

iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;

iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;

v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;

vi. High cost innovative medical treatments that states are required to cover; or,

vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. Budget Neutrality Update. The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

## 10. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

10.1. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of one or more Hypothetical Budget Neutrality Tests, as described below. CMS' assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

10.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1, Master MEG Chart and Table 2, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

10.3. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration

expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

10.4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of one Hypothetical Budget Neutrality Test. Any excess spending under the Hypothetical Budget Neutrality Test must be returned to CMS.

10.5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

10.6. **Hypothetical Budget Neutrality Test 1: SUD IMD.** The table below identifies the MEG that is used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit.

**Table 4: Hypothetical Budget Neutrality Test 1**

| MEG | PC or Agg | WOW Only, WW Only, or Both | Base Year | Trend Rate | DY 6 | DY 7 | DY 8 | DY 9 | DY 10 |
|---|---|---|---|---|---|---|---|---|---|
| SUD IMD | PC | Both | 2020 | 5.5% | $810.70 | $855.29 | $902.33 | $951.96 | $1,004.32 |

10.7. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as

reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

10.8. **Corrective Action Plan.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

| Table 5: Budget Neutrality Test Corrective Action Plan Calculation | | |
|---|---|---|
| **Demonstration Year** | **Cumulative Target Definition** | **Percentage** |
| DY 6 | Cumulative budget neutrality limit plus: | 2.0 percent |
| DY 6 through DY 7 | Cumulative budget neutrality limit plus: | 1.5 percent |
| DY 6 through DY 8 | Cumulative budget neutrality limit plus: | 1.0 percent |
| DY 6 through DY 9 | Cumulative budget neutrality limit plus: | 0.5 percent |
| DY 6 through DY 10 | Cumulative budget neutrality limit plus: | 0.0 percent |

## 11. EVALUATION OF THE DEMONSTRATION

11.1. **Cooperation with Federal Evaluators.** As required under 42 CFR § 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they will make such data available for the federal evaluation as is required under 42 CFR § 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.1.

11.2. **Independent Evaluator.** Upon approval of the demonstration, the state must use an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

11.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these

STCs, CMS' evaluation design guidance for SUD, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration evaluations. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 8.6.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS' approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

11.4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR § 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.

11.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or geography)—to the extent feasible—to

inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

11.6. **Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

11.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR § 431.412(c)(2)(vi). When submitting an application for extension of the demonstration, the Interim Evaluation Report should be posted to the state's website with the application for public comment.

a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.

d. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.

e. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs.

11.8. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs, and in alignment with the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

11.9. **Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

11.10. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

11.11. **Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close-Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.

11.12. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

## 12. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

| Date | Deliverable | STC |
|---|---|---|
| No later than 30 calendar days of approval date | State acceptance of demonstration Waivers, STCs, and Expenditure Authorities | Approval letter |
| No later than 150 calendar days of approval date | SUD Monitoring Protocol | STC 8.5 |
| No later than 60 days after receipt of CMS approval | Revised Monitoring Protocol | STC 8.5 |
| No later than 180 calendar days after approval date | Draft Evaluation Design | STC 11.3 |
| No later than 60 calendar days after receipt of CMS comments | Revised Draft Evaluation Design | STC 11.4 |
| No later than 30 calendar days after CMS approval | Approved Evaluation Design published to state's website | STC 11.4 |
| No later than 60 calendar days after the end of the third demonstration year of the extension (March 1, 2026) | Mid-Point Assessment Report | STC 8.7 |
| No later than December 31, 2026, or with extension application | Draft Interim Evaluation Report | STC 11.7 |
| No later than 60 calendar days after receipt of CMS comments | Final Interim Evaluation Report | STC 11.7.d |
| No later than 18 months after the end of the demonstration (June 30, 2029) | Draft Summative Evaluation Report | STC 11.8 |
| No later than 60 calendar days after receipt of CMS comments | Final Summative Evaluation Report | STC 11.8.b |
| No later than 120 days after the end of the demonstration | Draft Close-Out Report | STC 8.9 |
| No later than 30 days after receipt of CMS comments | Revised Close-Out Report | STC 8.9.e |
| *Monthly* | | |
| Monthly Deliverables | Monitoring Calls | STC 8.10 |

| | | |
|---|---|---|
| *Quarterly* | | |
| Quarterly Deliverables<br>Due no later than 60 days after end of each quarter, except 4th quarter | Quarterly Monitoring Reports | STC 8.6 |
| | Quarterly (CMS-64) Expenditure Reports | STC 9.2 |
| | Quarterly Budget Neutrality Reports | STC 9.13 |
| *Annually* | | |
| Annual Deliverables -<br>Due 90 days after end of each 4th quarter | Annual Monitoring Reports (including Q4 Expenditure Report and Budget Neutrality Report) | STC 8.6 |
| No later than 6 months after the demonstration's implementation and annually thereafter | Post Award Forum | STC 8.11 |

**Attachment A**
**Developing the Evaluation**
**Design**

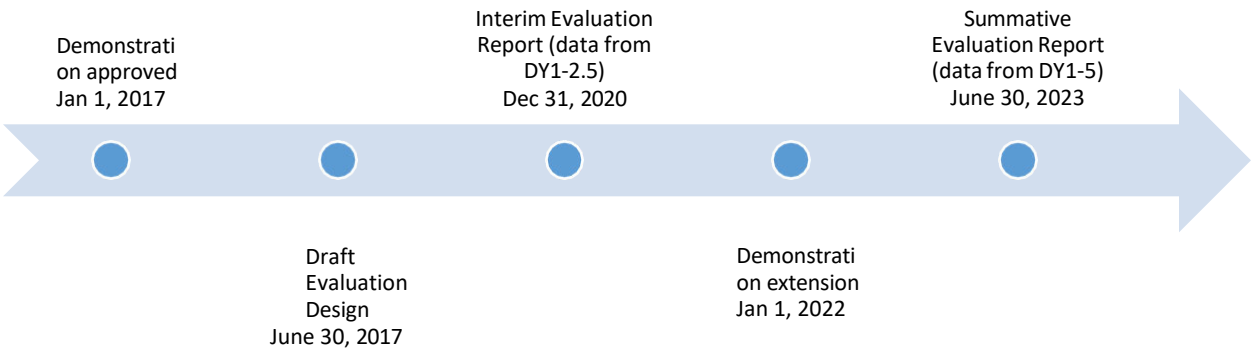
## Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future.

While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

## Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 30 calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



**Expectations for Evaluation Designs**

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration- monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

The state should attempt to involve partners who understand the cultural context in developing an evaluation approach and interpreting findings. Such partners may include community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration. For example, the state's Request for Proposal for an independent evaluator could encourage research teams to partner with impacted groups.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. The roadmap begins with the stated goals for the demonstration, followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

**A.** General Background Information;
**B.** Evaluation Questions and Hypotheses;
**C.** Methodology;
**D.** Methodological Limitations;
**E.** Attachments.

**A. General Background Information** – In this section, the state should include basic information about the demonstration, such as:

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.

4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

**B. Evaluation Questions and Hypotheses** – In this section, the state should:

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.
4. Include a Logic Model or Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the goal, the primary drivers that contribute directly to achieving the goal, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.
5. Include implementation evaluation questions to inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

**C. Methodology –** In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate. The evaluation approach should also consider principles of equitable evaluations, and involve partners—such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the

cultural context—in developing an evaluation approach.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure.

Specifically, this section establishes:

1. *Methodological Design* – Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.

2. *Focus and Comparison Populations* – Describe the characteristics of the focus and comparison populations, incorporating the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally, discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3. *Evaluation Period* – Describe the time periods for which data will be included.

4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

   Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality

Forum. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

5. *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.

6. *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative analysis measures that will adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
    b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
    c. Include a discussion of how propensity score matching and difference-in- differences designs may be used to adjust for differences in comparison populations over time, if applicable.
    d. Consider the application of sensitivity analyses, as appropriate.

7. *Other Additions* – The state may provide any other information pertinent to the Evaluation Design for the demonstration.

**Table A. Example Design Table for the Evaluation of the Demonstration**

| Research Question | Outcome measures used to address the research question | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|---|---|---|---|
| **Hypothesis 1** | | | | |
| Research question 1a | -Measure 1<br>-Measure 2<br>-Measure 3 | -Sample e.g. All attributed Medicaid beneficiaries<br>-Beneficiaries with diabetes diagnosis | -Medicaid fee-for-service and encounter claims records | -Interrupted time series |
| Research question 1b | -Measure 1<br>-Measure 2<br>-Measure 3<br>-Measure 4 | -Sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months) | -Patient survey | Descriptive statistics |
| **Hypothesis 2** | | | | |
| Research question 2a | -Measure 1<br>-Measure 2 | -Sample, e.g., PPS administrators | -Key informants | Qualitative analysis of interview material |

**D. Methodological Limitations** – This section provides more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review.

CMS also recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

1. When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).

2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
   a. Operating smoothly without administrative changes;
   b. No or minimal appeals and grievances;
   c. No state issues with CMS-64 reporting or budget neutrality; and
   d. No Corrective Action Plans for the demonstration.

## E. Attachments

1. **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement signed by the independent evaluator.

2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated costs, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.

3. **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The final Evaluation Design shall incorporate milestones for the development and submission of the Interim and Summative Evaluation Reports. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation Report is due.

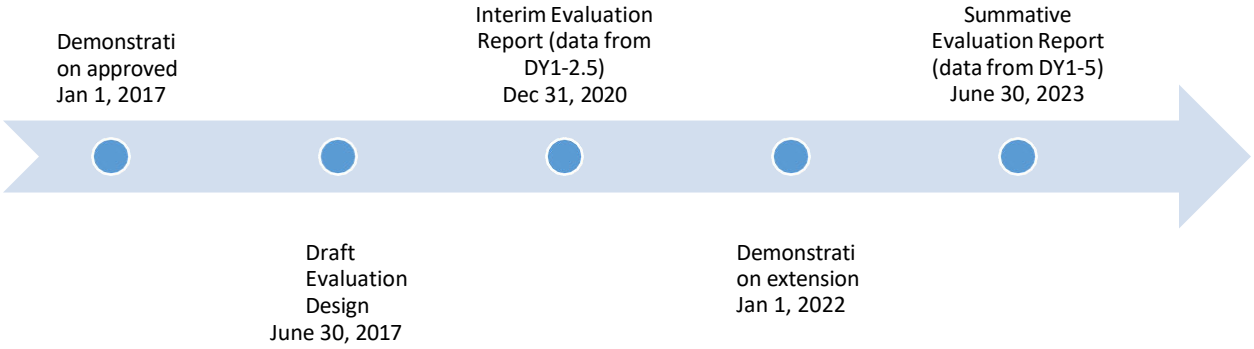
**Attachment B**
**Preparing the Interim and Summative Evaluation Reports**

## Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

## Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



### Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). The already-approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When submitting an application for extension, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115- demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state- monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

### Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's evaluation report submissions must provide comprehensive written presentations of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

### Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

**A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

**B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

**C. Evaluation Questions and Hypotheses** – In this section, the state should:

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.
3. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
4. The inclusion of a Logic Model or Driver Diagram in the Evaluation Report is highly

encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration, consistent with the approved Evaluation Design. The Evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An Interim Evaluation Report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an Interim Evaluation Report.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what was measured and how, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Methodological Design* – Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
2. *Focus and Comparison Populations* – Describe the focus and comparison populations, describing inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected.
4. *Evaluation Measures* – List the measures used to evaluate the demonstration and their respective measure stewards.
5. *Data Sources* – Explain from where the data were obtained, and efforts to validate and clean the data.
6. *Analytic Methods* – Identify specific statistical testing which was undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

**E. Methodological Limitations** – This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

**F. Results** – In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include

findings from the statistical tests conducted.

**G. Conclusions** – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
    a. If the state did not fully achieve its intended goals, why not?
    b. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

**H. Interpretations, Policy Implications and Interactions with Other State Initiatives –** In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long-range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

**I. Lessons Learned and Recommendations** – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

**Attachment C:**
**Substance Use Disorder (SUD) Implementation Plan**
**Originally Approved on February 1, 2018**

## Introduction

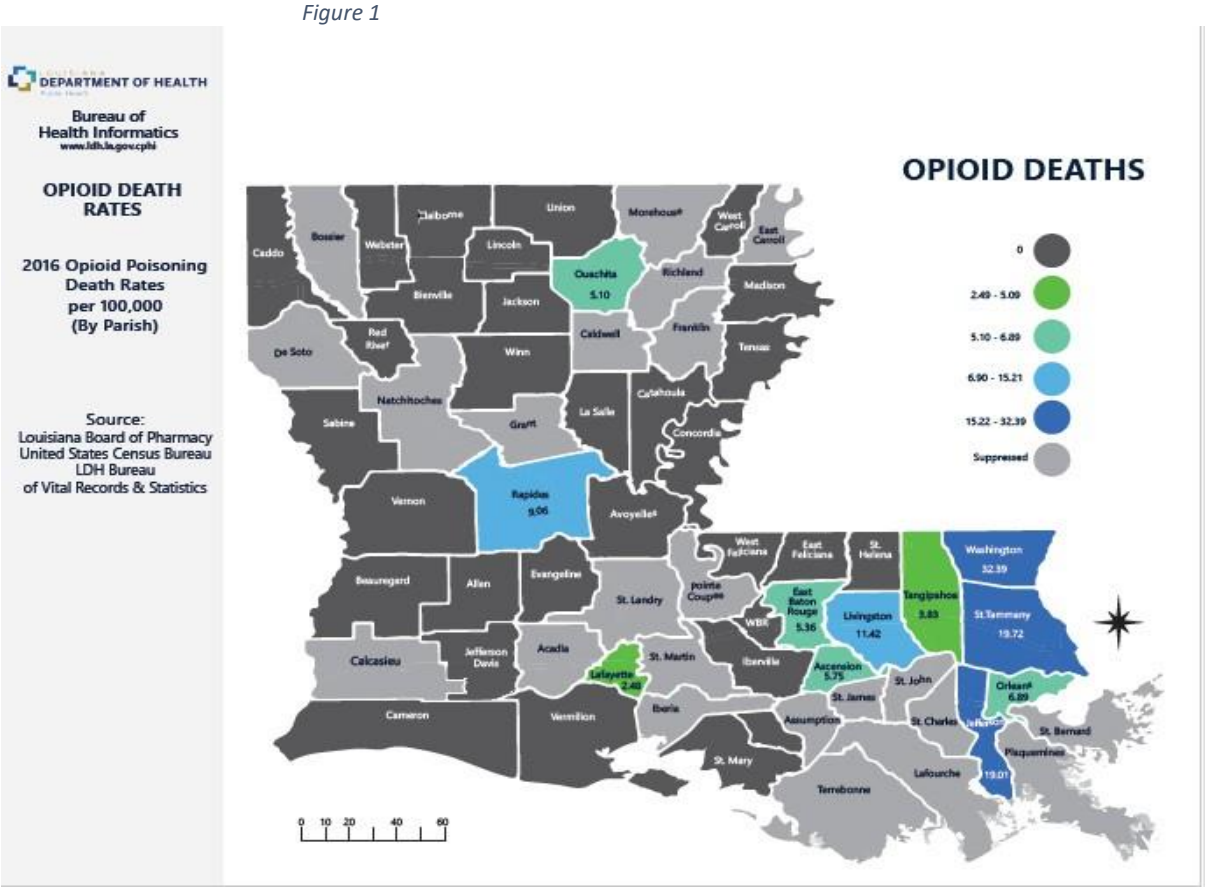
Nationwide, deaths due to opioids continue to increase, are under-reported, and have great variability in the specificity of how they are recorded across the country.[1][2] Contributing factors to the difficulty of verifying these opioid-related deaths are that a specific drug or cause of death may not be identified or reported, multiple drugs may be listed instead of one, or the primary cause of death may be listed with another diagnosis such as anoxic brain injury or congestive heart failure. From 1999 to 2015, the number of overdose deaths involving opioids in the United States has quadrupled.

In Louisiana, the Office of Vital Records (OVR) has shown that recorded deaths due to opioids in 2016 (320) has tripled since 2011 (100) and doubled since 2012 (160). Recent OVR internal review estimates that at least 54% of opioid deaths in the state are not being reported as specific opioid-related deaths in their Louisiana Electronic Event Registration System (LEERS). Therefore, Louisiana's Office of Public Health (OPH), through CDC-grant funding, is performing a validation process to improve and maintain systems for an accurate count of opioid-related overdose deaths in order to make accurate data-driven decisions in properly combatting the opioid epidemic in Louisiana. Demographic information is also being evaluated and 2016 data showed that opioid-related death rates occurred most often in men (8.21 rate per 100,000 citizens compared to 4.89 per 100,000 citizens in women) of white descent (8.39 per 100,000 citizens compared to 3.28 per 100,000 citizens in blacks), age 35-44 (rate of 14.43 per 100,000 citizens) in Region 9 of Louisiana, serving Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington parishes (15.87 of 100,000 citizens compared to the state average of 6.51 per 100,000 citizens). See Figure 1 for visualization.

[1] Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016; 65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1

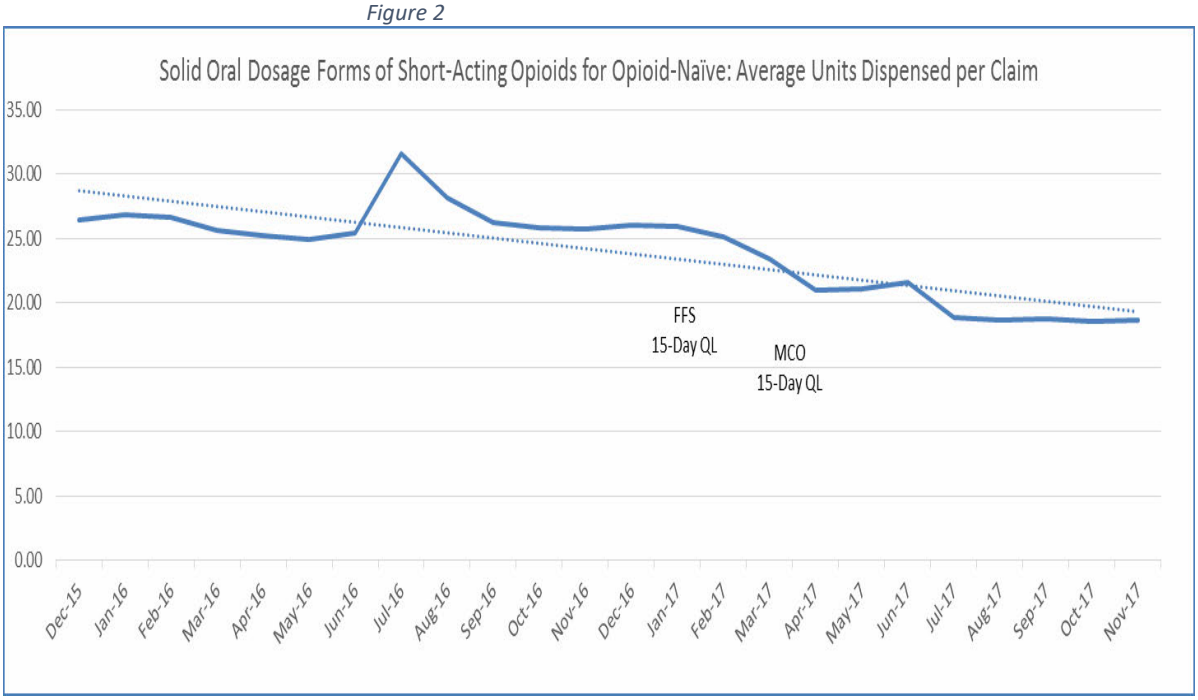
[2] Ruhm, CJ. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. American Journal of Preventive Medicine, Volume 53, Issue 6, 745 - 753

*Figure 1*




The Louisiana Medicaid Program is also active on data-driven strategies on the opioid epidemic. Current efforts include monitoring opioid prescriptions for opioid-naïve patients (patients who have had no opioid prescriptions within the past 90 days) and seeing how statewide opioid legislation and Medicaid opioid policies are effecting claims on opioid prescriptions. Preliminary data has shown that since Medicaid expansion in July 2016, the average units dispensed and average days' supply per claim has decreased. In July 2016, the average units dispensed per claim was 31.64 and in November 2017 it was down to 18.64. See Figure 2. Furthermore, the average days' supply per claim has decreased from an average of 8.9 days in July 2016 to 5.0 days in November 2017. This preliminary analysis of the data has shown roughly a 41% decrease in the amount and 44% decrease in days supplied of opioids per claim with interventions of state legislation and Medicaid policies to ensure better and appropriate practices.

*Figure 2*




## Program Overview

The Bureau of Health Services Financing (BHSF) within the Louisiana Department of Health (LDH) serves as the state Medicaid agency. LDH transitioned delivery of Medicaid services from a fee-for-service model to a managed care model in February 2012 via contracts with health plans to provide physical health and basic behavioral health services. At its outset, the Medicaid managed care program was comprised of two Medicaid-managed care models as defined in federal Medicaid regulations: managed care organizations (MCOs) and primary care case management (PCCM) entities. The five health plans were selected through a competitive procurement in 2011. There were two PCCM plans and three MCOs. Managed care organizations, also called prepaid health plans in Louisiana, are risk-bearing entities that provide a wide array of Medicaid-covered benefits and services to enrolled members in exchange for a monthly capitation payment for each member. The plans contract directly with providers and manage all aspects of service delivery, including reimbursement of providers.

PCCM entities, also called shared savings health plans in Louisiana, were paid a monthly management fee for each enrolled member in exchange for coordinating care for enrolled members. Shared savings health plans only contracted with primary care providers (PCPs) and hospitals. All other services that they coordinated were provided through the Louisiana Medicaid program's provider network. While the plan was responsible for service utilization, actual provider payments were made by LDH. Shared savings health plans were at limited risk for repaying a portion of the monthly management fee in the event savings benchmarks were not achieved. While shared savings health plans were responsible for service utilization for most Medicaid core benefits and services, the fee-for-service legacy Medicaid program continued to authorize durable medical equipment, prosthetics, orthotics, and certain supplies (DMEPOS); pharmacy; and non-emergency medical transportation (NEMT) to members of these plans.

The Office of Behavioral Health (OBH) is the state program office within LDH responsible for managing the delivery of services and supports necessary to improve the quality of life for citizens with mental illness and substance use or addictive disorders. The mission of OBH is to work collaboratively with partners to develop and implement a comprehensive integrated system of behavioral health and healthcare, social support, and prevention services that promote recovery and resilience for all citizens of Louisiana. OBH assures public behavioral health services are accessible, family-driven, have a positive impact, are culturally and clinically competent, and are delivered in partnership with all stakeholders. OBH was created by Act 384 of the 2009 Regular Session of the Louisiana Legislature which directed the consolidation of the offices of addictive disorders and mental health into the Office of Behavioral Health, effective July 1, 2010, in order to streamline services and better address the needs of people with co- occurring mental illness and substance use or addictive disorders.

The Louisiana Behavioral Health Partnership (LBHP), also implemented in March 2012, was a system of care designed to transform the delivery of and payment for specialized behavioral health services for Medicaid and non-Medicaid adults and children who required specialized behavioral health services, including those children who were at risk for out-of-home placement. LDH contracted with a statewide management organization (SMO), a Prepaid Inpatient Health Plan, to operate the LBHP with the primary goal of improving coordination of services, quality of care, and outcomes. The LBHP served the needs of individuals who comprised one of the following target populations:

1. Children with extensive behavioral health needs either in, or at risk of, out-of-home placement;
2. Medicaid-eligible children with medically necessary behavioral health needs who need coordinated care;
3. Adults with severe mental illness and/or substance use or addictive disorders who are Medicaid eligible; or
4. Non-Medicaid children and adults who have severe mental illness and/or substance use or addictive disorders.

Through better coordination of services, the LBHP enhanced the consumer experience, increased access to a more complete and effective array of behavioral health services and supports, improved quality of care and outcomes, and reduced repeat emergency room visits, hospitalizations, out-of-home placements, and other institutionalizations. The LBHP greatly expanded access to providers.

To continue the significant benefits experienced as a result of development of the managed care delivery system for behavioral health care through the LBHP, LDH developed partnerships with private sector providers to target improved models of care focused on smaller residential settings to deemphasize the role of large, state-run institutions. Residential treatment facilities were also developed for adolescents to provide intensive evidence-based treatment in smaller, more homelike settings.

In February of 2015, LDH implemented its second-generation managed care program for physical and basic behavioral health services, including full-risk managed care organizations only. Later that year, the Office of Behavioral Health and Medicaid worked collaboratively to integrate specialized behavioral health services, previously provided separately by the LBHP, into the benefits coordinated by the Healthy Louisiana Managed

Care Organizations (MCOs) on December 1, 2015. Children with extensive behavioral health needs either in or at risk of out-of-home placement and enrolled in the Coordinated System of Care (CSoC) waiver program remained managed by the SMO. Integration of behavioral health care services into the Healthy Louisiana program was designed to improve care coordination for enrollees, provide more opportunities for seamless and real-time case management of health services, and better transitioning and use of all resources provided by the system. Medicaid coverage was expanded under the Affordable Care Act on July 1, 2016, and was made available to more than 400,000 Louisianans ages 19 to 64. Within a year, more than 23,000 adults in the Medicaid expansion group received specialized outpatient mental health services and more than 4,500 received inpatient mental health services at a psychiatric facility. Additionally, more than 4,900 adults received specialized substance use outpatient services and more than 5,300 adults received specialized substance use residential services. With the addition of the expansion population, Louisiana Medicaid now covers over 1.6 million members.

## Milestone 1: Access to critical levels of care for OUD and other SUDs

### Specifications:

Coverage of: a) outpatient; b) intensive outpatient services; c) medication-assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet the needs of Medicaid beneficiaries in the state); d) intensive levels of care in residential and inpatient settings; and
e) medically supervised withdrawal management.

### Current State

Louisiana currently covers all of the critical levels of care identified in Milestone 1. For optimum access to substance use disorder (SUD) treatment services for Medicaid beneficiaries, it is important to offer a range of services at varying levels of intensity across a continuum of care as the type of treatment or level of care needed may be more or less effective depending on the individual beneficiary.

Louisiana administers its Medicaid substance use disorder (SUD) services based on the American Society of Addiction Medicine (ASAM) Patient Placement Criteria. Louisiana currently covers a range of outpatient, intensive outpatient, medication-assisted treatment (MAT), residential, inpatient and withdrawal management services. The service definitions, program requirements, eligibility criteria, and detailed provider requirements/qualifications for each level are detailed through the publicly available published provider manual. The below table identifies the ASAM level, brief description, and state plan page number of currently offered services. Because Louisiana has offered ASAM level services since 2012, the levels of services are identified in our authority documents under the old ASAM terminology. LDH can provide a cross walk of former ASAM terminology to current ASAM levels if needed.

| Existing ASAM level of care coverage | Description | Adult/ Adolescent | State Plan Page Number |
|---|---|---|---|
| Level I | Outpatient | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level II.1 | Intensive Outpatient Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level III.1 | Clinically Managed Low Intensity Residential Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.3 | Clinically Managed Medium Intensity Residential Treatment *(Provider manual: Clinically managed population specific high intensity residential)* | Adult only | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.5 | Clinically Managed High Intensity Residential Treatment | Both | Attachment 3.1 – A, Item 13.d, Page 8 |
| | Medically Monitored Intensive Residential Treatment (covered under | Adult | Attachment 3.1 – A, Item 13.d, Page 8 |
| | | Youth | Attachment 3.1 – A, Item 16 |
| Level II-D (2-WM in | Ambulatory Detoxification with Extended Onsite Monitoring | Both | Attachment 3.1 – A, Item 13.d, Page 6 |
| Level III.2D (3.2-WM in | Clinically Managed Residential Social Detoxification (Provider manual: Clinically managed residential | Both | Attachment 3.1 – A, Item 13.d, Page 7 |
| Level III.7D (3.7-WM in | Medically Monitored Residential Detoxification (Provider manual: Medically monitored inpatient | Adult | Attachment 3.1 – A, Item 13.d, Page 8 |

In addition to these services, Louisiana also covers medically managed inpatient therapies in both inpatient psychiatric hospital and acute care hospital settings (ASAM Level 4-WM) under hospital services in the State Plan. Coverage is also provided for Outpatient Treatment Services (formerly opioid maintenance therapy) through medicated assisted treatment (MAT). Louisiana currently covers MAT, specifically buprenorphine, suboxone, naloxone and naltrexone (Vivitrol). Louisiana covers methadone offered through the Medicaid formulary for the treatment of chronic pain conditions, but not for opioid dependence. The Louisiana Medicaid covered opioid pharmaceutical therapies are listed below. Authorization requirements vary amongst fee-for-service Medicaid and managed care depending on the drug's preferred status or if it is considered a medical-only provided benefit as opposed to being offered in retail pharmacies. Flexibilities are offered within the program for preferred drug list development.

- Buprenorphine
- Buprenorphine-Naloxone [Suboxone]
- Buprenorphine-Naloxone [Bunavail]
- Buprenorphine-Naloxone [Zubsolv]
- Buprenorphine Implant [Probuphine]
- Suboxone Film

- Naloxone Injectable
- Naloxone Nasal Spray [Narcan]
- Naltrexone Tab
- Naltrexone ER Injectable [Vivitrol]

As part of MAT, individuals prescribed one of the opioid pharmaceutical therapies listed above have access to counseling and other behavioral health therapies through the ASAM levels covered under the Medicaid State Plan.

Louisiana provides coverage to all children under the age of 21 for screening, vision, dental, hearing, and other medically necessary health care services to treat, correct, or ameliorate illnesses and conditions discovered, regardless of whether the service is covered in the Medicaid State Plan, as required by Early and Periodic screening, Diagnostic, and Treatment (EPSDT) requirements.

Allowed Provider Types and Specialties through Louisiana's managed care program include:

- Outpatient Services
  - PT 68 Substance Use and Alcohol Use Center PS 70 Clinic / Group
  - PT 74 Mental Health Clinic PS 70 Clinic / Group
  - PT AJ Licensed Addiction Counselor (LAC) PS 8E
- Residential Services
  - PT AZ Substance Use Residential Treatment Facility PS 8U Substance Use or Addiction

Louisiana's MCOs include institutions for mental disease (IMDs) in their provider networks for SUD residential levels of care under the authority for cost-effective "in lieu of" services under managed care rate setting rules.

### Future State

The below table identifies additional coverage Louisiana is considering for a future state plan or 1115 waiver amendment, pending Louisiana legislative budget approval. Louisiana coverage of methadone hinges upon legislative appropriation. Legislative appropriations will determine the scope of services and population coverage.

| ASAM Level of Care proposing to cover | Description |
|---|---|
| Methadone | Medicated Assisted Treatment |
| ASAM Level 1-WM | Ambulatory Withdrawal Management without Extended On-Site Monitoring |

LDH is also researching implementation of the nationally recognized "Hub and Spoke" model, as a mechanism to expand access to MAT and increase accessibility to services. This model would utilize the current ten opioid treatment programs (OTPs) as the "Hubs" and mobilize Drug Addiction Treatment Act (DATA) Waived Physicians as the "Spokes." This model would create an environment that is conducive to partnership development, collaborations and expansion of community resources.

Summary of Actions Needed:

| Implementation Action Item | Timeline |
|---|---|
| Update State Plan and provider manual to reflect current services array and requirements. | 12 months |

## Milestone 2: Widespread use of evidence-based, SUD-specific patient placement criteria

### Specifications:

1. In addressing patient specific placement criteria, providers must assess treatment needs based on SUD specific, multidimensional assessment tools.
2. Louisiana MCOs must have a utilization management approach such that: a) beneficiaries have access to SUD services at the appropriate level of care; b) interventions are appropriate for the diagnosis and level of care; and c) there is an independent process for reviewing placement in residential treatment settings.

### Current State

The Louisiana MCO contracts incorporate by reference (e.g., at section 7.8.14.2) the requirements detailed in the LDH Behavioral Health Services Provider Manual, which can be found here. These program and service requirements, including assessments for each ASAM Level, are addressed in this Behavioral Health Services Provider Manual and apply to MCO providers. Louisiana does not mandate providers use a specific assessment tool; however, the assessment tool must reflect evidence based clinical treatment guidelines.

MCOs are responsible for implementing a utilization management approach consistent with Milestone #2. The MCOs perform utilization management for all levels of care. Residential placement undergoes more intensive pre-certification requirements, whereas, outpatient services may be subject to outlier review, practice management, or other less-intensive utilization management strategies. Under the contract, MCOs must currently have utilization management policies and procedures in place that meet National Council on Quality Assurance standards and include medical management criteria and practice guidelines. At minimum, the MCOs' policies must contain the following:

- The methodology utilized to evaluate the medical necessity, appropriateness, efficacy, or efficiency of health care services;
- The data sources and clinical review criteria used in decision making;
- The appropriateness of clinical review shall be fully documented;
- The process for conducting informal reconsiderations for adverse determinations;
- Mechanisms to ensure consistent application of review criteria and compatible decisions;
- Data collection processes and analytical methods used in assessing utilization of health care services;
- Provisions for assuring confidentiality of clinical and proprietary information;
- Service authorization criteria for specialized behavioral health services that are consistent with the Medicaid State Plan;
- Collaborating with child serving agencies and schools to coordinate the discharge and transition of youth in out-of-home placement for the continuance of prescribed medication and other behavioral health services prior to reentry into the community, including necessary provider referrals; and
- Collaborating with hospitals, nursing home facilities, inpatient facilities, and the criminal justice system to coordinate aftercare planning prior to discharge/release and transition of members for the continuance of behavioral health services and medication prior to reentry into the community, including necessary provider referrals.

The State Plan establishes coverage using the ASAM levels of care and as such, service authorization criteria must meet this same standard in each MCO's policies and procedures. These policies are reviewed and

approved by LDH, but may warrant additional scrutiny as the program evolves. Additionally, the MCOs are required to take steps to ensure adoption of the clinical practice guidelines by specialized behavioral healthcare providers, and to measure compliance with the guidelines. The MCOs are contractually encouraged to employ substantive provider motivational incentive strategies, such as financial and non-financial incentives, to improve compliance. Additionally, the MCOs are required to perform record reviews. LDH is currently developing an audit tool for record review, including screening and assessments of SUD services, to collect additional data on providers in order to ensure that interventions are appropriate.

For each ASAM level, Section 2.1 of the LDH Behavioral Health Services Provider Manual describes the responsibilities for screening, assessment and treatment plan review, including the requirements to substantiate appropriate patient placement.

Per Section 4.2.24 of the MCO contract, all MCOs are required to have an Addictionologist or an Addiction Services Manager (ASM) who must meet the requirements of a licensed addiction counselor (LAC) or Licensed Mental Health Professional (LMHP) with at least seven (7) years of clinical experience with addiction treatment of adults and children experiencing substance use problems and disorders. The ASM is responsible for oversight and compliance with the addiction principles of care and application of ASAM placement criteria for all addiction program development. The ASM works closely with the Chief Operating Officer, the Behavioral Health Coordinator, the Quality Management Coordinator, and the Behavioral Health Medical Director in assuring quality, appropriate utilization management, and adequacy of the addiction provider network.

Each MCO is also required to have sufficient licensed mental health professionals, including licensed addiction counselors, as well as a board-certified addictionologist included as part of its prior authorization and inpatient concurrent review staff (section 4.3 of the MCO contract).

### Future State

In accordance with this milestone, the state is constantly seeking to improve its review and monitoring of its managed care organizations relative to utilization management. Ongoing review of policies and procedures to ensure they include use of evidence-based practices and SUD-specific criteria will occur to determine if any additional education or changes are warranted.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| The Behavioral Health Provider Manual will be updated to clarify that ASAM criteria and levels of care shall be used for each provider's assessment tool. | 12 months |

## Milestone 3: Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications

### Specifications:

1. Implementation of residential treatment provider qualifications in licensure requirements, program authorities and policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria, or other nationally recognized, evidence- based SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings
2. Implementation of state process for reviewing residential treatment providers to assure compliance with these standards
3. Residential treatment facilities offer MAT on-site or facilitate access off-site

### Current State

Louisiana has established provider qualifications requirements, based on ASAM criteria, for SUD residential treatment providers through licensure standards, managed care contract requirements, and managed care provider manuals. Providers contracting to provide Medicaid services as part of the MCO networks are held to certain standards in their individual provider contracts and are required to be credentialed and accredited prior to participating in the network.

LDH has established licensing standards for substance use/addiction treatment facilities located online here; and updates located here.

Louisiana utilizes the ASAM criteria program standards to establish residential treatment provider qualifications in its licensure and authority documents including the types of services, hours of clinical care and credentials of staff for residential treatment settings. These can be found in the addiction treatment section of the provider manual located at this link.

Compliance with licensure, which was developed using ASAM criteria, is administered and monitored by the Health Standards Section of LDH who is responsible for compliance with federal survey and certification requirements. Providers are held compliant by onsite and administrative reviews, which includes reviews of records and observations and interviews with staff and clients, as appropriate to the process. All visits, except for initial licensure surveys, are unannounced. To ensure compliance, reviews are conducted during licensure application, renewal, complaints, onsite, and as administrative reviews. The MCOs also assure compliance with program standards outlined in the provider manuals through monitoring of its provider network via credentialing, monitoring complaints, and during the provider recredentialing cycle.

Currently, most residential providers utilize abstinence-based care models and do not provide MAT onsite or facilitate offsite access to MAT.

Additionally, the Food and Drug Administration (FDA) approved a risk evaluation and mitigation strategy (REMS) on July 9, 2012, for extended release long acting opioid medications. The Collaborative on REMS Education has developed tools, resources, and outcomes to meet the FDA requirements. The Louisiana State

Medical Society (LSMS) received a REM grant to facilitate opioid educational offerings throughout the state. LSMS partnered with the in collaboration with the East Baton Rouge Parish Coroner (current head of the Louisiana State Coroner's Association) to perform an opioid educational seminar to physicians, nurses, behavioral health providers and pharmacists. An educational event was held September 21, 2016, and was well received within the healthcare community. The grant facilitated a second educational offering in Shreveport, LA on November 11, 2016. The opioid educational offering solidified a relationship with LSMS which facilitated educating the provider community statewide utilizing national best practices and the CMS guidelines. Additional trainings will be hosted in collaboration with LSMS and providers participating in the Louisiana Opioid STR Initiative will be invited to attend.

### Future State

Over the next 24 months (and possibly longer), Louisiana will be focused on creating a culture change among residential providers to integrate facilitation of MAT into the programmatic requirements and reality. Residential providers will be required to offer or facilitate access to MAT off-site. This is expected to require heavy outreach and education because most of Louisiana's current residential providers practice within strict abstinence-based care models. Additionally, a rate review will be completed when Louisiana determines details for implementation.

The current use of abstinence-based care models will require an increased level of education and guidance necessary to facilitate MAT services in collaboration with those facilities in the future. In addition to guidance and education by a board-certified psychiatrist and addictionologist, Substance Abuse and Mental Health Services Administration (SAMHSA) materials will be utilized to provide education to these facilities. Examples of these materials include *Methadone Treatment for Pregnant Women; SAMHSA Opioid Overdose Prevention Toolkit;* and *An Introduction to Extended Release Injectable Naltrexone for the Treatment of People with Opioid Dependence*. Board certified psychiatrists and addictionologists will be used to assist with assessment protocols necessary for pregnant women within residential programs.

Louisiana's 10 OTPs have participated in past learning collaboratives, such as the Methadone Educational Initiative, and have volunteered to educate community stakeholders and primary care providers throughout the state. In the implementation of the Opioid State Targeted Response (STR) Grant, the OTPs will be utilized as subject matter experts to educate healthcare providers on their service array and treatment modalities; dispel myths associated with medicated assisted treatment; and provide guidance to ensure providers adhere to culturally competent educational offerings based upon healthcare disparities common with patients in treatment. The purpose of the Louisiana Opioid STR Initiative is also to raise awareness about the dangers of sharing medication; to work with pharmaceutical and medical communities on the risks of overprescribing to young adults; to raise community awareness; and to increase prescription drug abuse education to schools, communities, parents, prescribers and patients.

Educational initiatives will seek to eliminate stereotyping associated with medication-assisted treatment. Educational initiatives will include state and federal guidance associated with medicated assisted treatment and incorporate guidance and approval of the State Opioid Treatment Authority. The treatment guidance for residential treatment providers will include but is not limited to SAMHSA TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction and TIP 43: Medication Assisted Treatment

for Opioid Addiction in Opioid Treatment Programs.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Educate abstinence-based residential providers on benefits of MAT accessibility to begin cultural shift toward acceptance of MAT as a complementary treatment. | 24 months + |
| Review MCO contract language regarding this requirement to determine if changes to the contract to support this milestone are necessary. | 12 months |
| Review provider manual and service description to require access to MAT and any associated provider manual requirements and rate adjustments if needed. | 12 months |

## Milestone 4: Sufficient provider capacity at each level of care, including MAT

### Specifications:

Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT.

### Current State

LDH currently monitors provider sufficiency through MCO reporting. MCOs submit network adequacy reports to LDH on a quarterly basis inclusive of counts of available network providers by levels of care and by provider type. Current ASAM levels of care as reported by the Healthy Louisiana Managed Care Organizations (MCOs) via quarterly network provider reports indicate an average of the following numbers of providers by Louisiana Department of Health (LDH) administrative region.

*Table 1*

| ASAM Level of Care | MHSD | CAHSD | SCLHSA | AAHSD | ImCal | CLHSD | NLHSD | NDHSA | FPHSA | JPHSA |
|---|---|---|---|---|---|---|---|---|---|---|
| ASAM Level I | 15 | 17 | 8 | 12 | 6 | 13 | 13 | 17 | 10 | 10 |
| ASAM Level II.1 | 17 | 22 | 8 | 13 | 8 | 15 | 14 | 19 | 9 | 13 |
| ASAM Level II.D | 2 | 2 | 1 | 2 | 0 | 1 | 2 | 2 | 3 | 2 |
| ASAM Level III.1 | 3 | 2 | 1 | 1 | 1 | 3 | 3 | 1 | 0 | 1 |
| ASAM Level III.1 | 5 | 4 | 1 | 3 | 1 | 5 | 3 | 3 | 0 | 4 |
| ASAM Level III.2D | 3 | 3 | 1 | 2 | 2 | 3 | 2 | 2 | 1 | 2 |
| ASAM Level III.2D | 2 | 4 | 1 | 4 | 2 | 4 | 2 | 2 | 0 | 2 |
| ASAM Level III.3 | 7 | 10 | 3 | 4 | 3 | 6 | 4 | 5 | 2 | 6 |
| ASAM Level III.5 | 4 | 7 | 2 | 3 | 2 | 6 | 4 | 3 | 1 | 3 |
| ASAM Level III.5 | 8 | 10 | 2 | 5 | 3 | 7 | 4 | 7 | 1 | 4 |
| Psychiatric Residential Treatment Facility (ASAM Level III.7 – Adolescent)* | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 |
| ASAM Level III.7 – Adult | 3 | 5 | 1 | 4 | 2 | 3 | 2 | 3 | 0 | 1 |
| ASAM Level III.7D – Adult | 3 | 4 | 1 | 3 | 1 | 3 | 2 | 2 | 0 | 1 |
| ASAM Level IV.D | 1 | 3 | 1 | 3 | 1 | 2 | 2 | 1 | 0 | 2 |

** Louisiana currently has four licensed Psychiatric Residential Treatment Facilities (PRTFs) for youth that provide medically necessary residential levels of care meeting required criteria.*

MAT Prescriber Count by Parish for December 1, 2016, through November 30, 2017, is included in Table 2 below. This information was extracted using claims and encounter data indicating the number of unduplicated providers that billed for a MAT service.

*Table 2*

| Parish | Prescriber Count |
|---|---|
| ACADIA | 7 |
| ALLEN | 2 |
| ASCENSION | 13 |
| ASSUMPTION | 0 |
| AVOYELLES | 6 |
| BEAUREGARD | 3 |
| BIENVILLE | 0 |
| BOSSIER | 9 |
| CADDO | 40 |
| CALCASIEU | 53 |
| CALDWELL | 0 |
| CAMERON | 1 |

| | |
|---|---|
| CATAHOULA | 0 |
| CLAIBORNE | 2 |
| CONCORDIA | 3 |
| DESOTO | 1 |
| EAST BATON ROUGE | 72 |
| EAST CARROLL | 3 |
| EAST FELICIANA | 3 |
| EVANGELINE | 6 |
| FRANKLIN | 2 |
| GRANT | 1 |
| IBERIA | 16 |
| IBERVILLE | 4 |
| JACKSON | 1 |
| JEFFERSON | 95 |
| JEFFERSON DAVIS | 0 |
| LAFAYETTE | 57 |
| LAFOURCHE | 17 |
| LASALLE | 2 |
| LINCOLN | 6 |
| LIVINGSTON | 4 |
| MADISON | 1 |
| MOREHOUSE | 2 |
| NATCHITOCHES | 2 |
| ORLEANS | 182 |
| OUACHITA | 27 |
| Out of State | 28 |
| PLAQUEMINES | 4 |

| | |
|---|---|
| POINTE COUPE | 1 |
| RAPIDES | 27 |
| RED RIVER | 1 |
| RICHLAND | 2 |
| SABINE | 2 |
| ST. BERNARD | 3 |
| ST. CHARLES | 6 |
| ST. HELENA | 0 |
| ST. JAMES | 0 |
| ST. JOHN | 3 |
| ST. LANDRY | 12 |
| ST. MARTIN | 2 |
| ST. MARY | 4 |
| ST. TAMMANY | 45 |
| TANGIPAHOA | 26 |
| TENSAS | 0 |
| TERREBONNE | 20 |
| UNION | 4 |
| VERMILION | 3 |
| VERNON | 2 |
| WASHINGTON | 13 |
| WEBSTER | 7 |
| WEST BATON ROUGE | 0 |
| WEST CARROLL | 5 |
| WEST FELICIANA | 1 |
| WINN | 1 |

The quarterly network report package additionally includes GeoAccess mapping for all network providers. Should gaps in access or adequacy be identified, the MCOs are required to submit gap analyses and ad hoc network development plans with their quarterly report package. In addition, LDH is currently in the process of procuring a provider management contract which will include a credentialing verification function under a single, statewide vendor. It is intended that this will achieve a single, reliable provider registry. This new provider enrollment and credentialing system is anticipated to activate in 2018. MCOs will then be limited to choosing providers from the state's single source for provider enrollment, allowing LDH to appropriately identify providers in encounter data.

The managed care organizations are tasked with monitoring provider capacity of their networks. Each MCO develops and maintains a provider Network Development and Management Plan which ensures that the provision of core benefits and services will occur. It includes the MCO's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services. The plan

demonstrates access to behavioral health services, identifies gaps in network and describes the process to assure services are delivered. The plans provide GEO mapping of providers to geographically demonstrate network capacity. The MCOs have policies detailing how the MCO will provide or arrange for medically necessary covered services should the network become temporarily insufficient and will monitor the adequacy, accessibility and availability of its provider network to meet the needs of its members. MCO Network Development and Management Plans are updated at least annually or more often as needed to reflect material changes in network status.

The MCO contract currently specifies geographic access requirements for maximum travel time and /or distance requirements as outlined below:

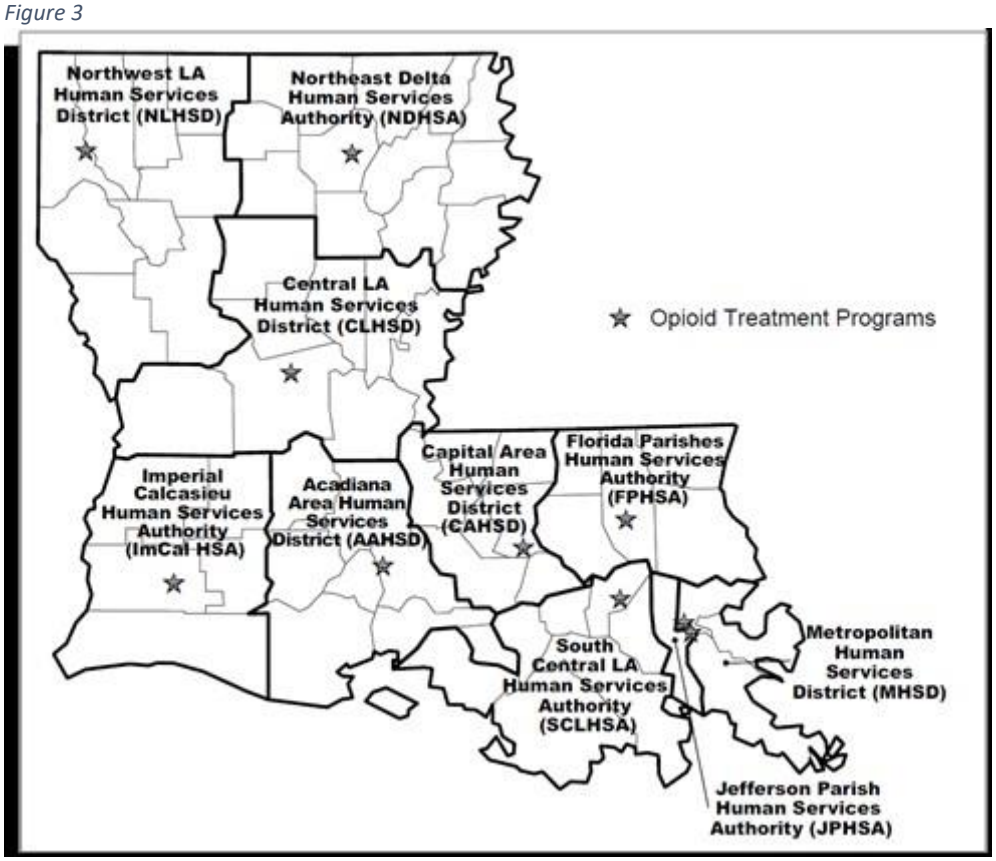
- Travel distance to behavioral health specialists [i.e., psychologists, medical psychologists, advanced practice registered nurses (APRN) practicing as a Clinical Nurse Specialist (CNS) in mental health, or Licensed Clinical Social Workers (LCSWs)] and to psychiatrists for members living in rural parishes shall not exceed 30 miles for 90% of such members.
- Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN CNS in mental health, or LCSWs) and to psychiatrists for members living in urban parishes shall not exceed 15 miles for 90% of such members.
- Travel distance to Level III.3/5 Clinically Managed High Intensity Residential shall not exceed 30 miles for 90% of adult members, and shall not exceed 60 miles for adolescent members.
- Travel distance to Level III.7 Medically Monitored Intensive Residential co-occurring treatment shall not exceed 60 miles for 90% of adult members.
- Travel distance to Level III.7D Medically Monitored Residential Detoxification shall not exceed 60 miles for 90% of adult members.
- Travel distance to Psychiatric Residential Treatment Facilities (PRTF) shall not exceed 200 miles for 90% of members.
- Request for exceptions as a result of prevailing community standards for time and distance accessibility standards must be submitted in writing to LDH for approval.

In December of 2017, the Louisiana legislature approved a 23-month contract extension of the current managed care contracts that changes these adequacy standards from 90% to 100% and includes time requirements.

There is one Opioid Treatment Program (OTP) located in each Louisiana Department of Health region, called Local Governing Entity (LGE) regions (see Figure 3). All ten OTPs are privately owned and have historically received no state or federal funding to support MAT, with the exception of Behavioral Health Group (BHG) located in New Orleans, which is currently receiving funds through the recent award of the Medication-Assisted Treatment Prescription Drug and Opioid Addiction (MAT-PDOA) grant. Through the Louisiana Opioid State Targeted Response (STR) grant, funding was recently allocated to the remaining nine OTPs who are not receiving funding to support MAT for under- and uninsured individuals diagnosed with OUD. Current capacity of the 10 OTP sites is approximately 5,000. However, OTP sites have flexibility and capacity, and census is a

moving target. Capacity is based upon the current census and LA regulations which indicate 75:1 patient/counselor ratio. Most of the clinics utilize 50:1 ratio and if they receive additional admits they would hire additional counselors to provide services. LDH has observed that at any single point in time over the last two years, no OTP site was at full capacity and total census averaged approximately 3800 to 4000 patients. However, it is anticipated that use of OTPs will expand if methadone becomes a Medicaid covered service.

*Figure 3*




## Future State

Going forward, LDH will establish new reporting requirements for the MCOs for their Specialized Behavioral Health network development and management plans to specifically focus on SUD provider capacity, including MAT. Geo mapping will also be expanded to monitor access to MAT inclusive of a reporting mechanism for how many providers are accepting new patients.

As an additional treatment strategy, physicians will be encouraged to become certified dispensers. According to the Drug Addiction Treatment Act of 2000 (DATA 2000), which expands the clinical context of medication-assisted treatment for persons with Opioid Use Disorder (OUD), certified physicians are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications such as buprenorphine, suboxone, and subutex in settings other than an opioid treatment program (OTP). DATA 2000 reduces the regulatory burden on physicians who choose to practice OUD treatment by permitting qualified physicians to apply for and receive waivers of the

special registration requirements defined in the Controlled Substances Act.

In order to become a certified prescriber or dispenser, a physician must qualify for a physician waiver. The physician must complete eight hours of required training and then apply for the waiver. This can be done online at SAMHSA Center for Substance Abuse Treatment's (CSAT's) Buprenorphine Information Center at 866-BUP-CSAT (866-287-2728) or send an email to infobuprenorphine@samhsa.hhs.gov (link sends e- mail).

Physicians are also required to complete buprenorphine training to receive their training certificate after completing the Waiver Notification Form. These waiver applications are forwarded to the DEA, which assigns the physician a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the physician's regular DEA registration number. SAMHSA reviews waiver applications within 45 days of receipt. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number. A list of buprenorphine providers can be assessed through SAMHSA website treatment locator.

Physicians must apply to SAMHSA to treat more than 30 patients as well as meet the following conditions:

- Be currently authorized under DATA 2000 to prescribe buprenorphine products.
- Complete the Online Notification Form to Increase Patient Limit at least one year after initial waiver was approved.

In addition, if a physician has prescribed buprenorphine to 100 patients for at least one year, he/she has the opportunity to apply for an increase to their patient limits up to 275 under new federal regulations. Modifying the number of patients a physician may treat under the DATA 2000 is authorized under the Office of National Drug Control Policy Reauthorization Act of 2006.

SAMHSA is currently tracking the number of certified physicians across the nation. There are identified federal record keeping requirements that must be adhered to by physicians. DEA record keeping requirements for buprenorphine treatment go beyond the Schedule III record keeping requirements. Under the Persons Required to Keep Records in the Code of Federal Regulations, physicians are required to keep records and inventories of all controlled substances dispensed, including approved buprenorphine products.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Require MCOs to update their Specialized Behavioral Health network development and management plan to specifically focus on SUD provider capacity, including MAT. | 12 months |
| Add an indicator if providers are accepting new patients to the quarterly network adequacy reports. | 12 months |
| LDH to assess MAT capacity based MCO data or independent review. | 12 months |

## Milestone 5: Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD

### Specifications

1. Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse
2. Expanded coverage of, and access to, naloxone for overdose reversal
3. Implementation of strategies to increase utilization and improve functionality, of prescription drug monitoring programs

### Current State

The Louisiana Department of Health is currently implementing opioid-related initiatives under nine federal grants. With the common goal to decrease opioid deaths in Louisiana, these initiatives use the following strategies: better data, prevention, rescue, treatment and recovery.

LDH's Office of Public Health has established the Louisiana Opioid Surveillance Initiative identifying, validating, and aligning sources of data, in order to enhance our understanding of the opioid epidemic in Louisiana. Current goals and initiatives of this system include:

- Reporting rapid surveillance data on overdoses and deaths
- Create and maintain an online surveillance system
- Disseminate results of internal analyses to stakeholders and the public
- Use data to measure outcomes of programs and policies

LDH's Office of Behavioral Health is currently addressing capacity and integration of prevention, intervention, treatment, and recovery support services. Current goals and initiatives include:

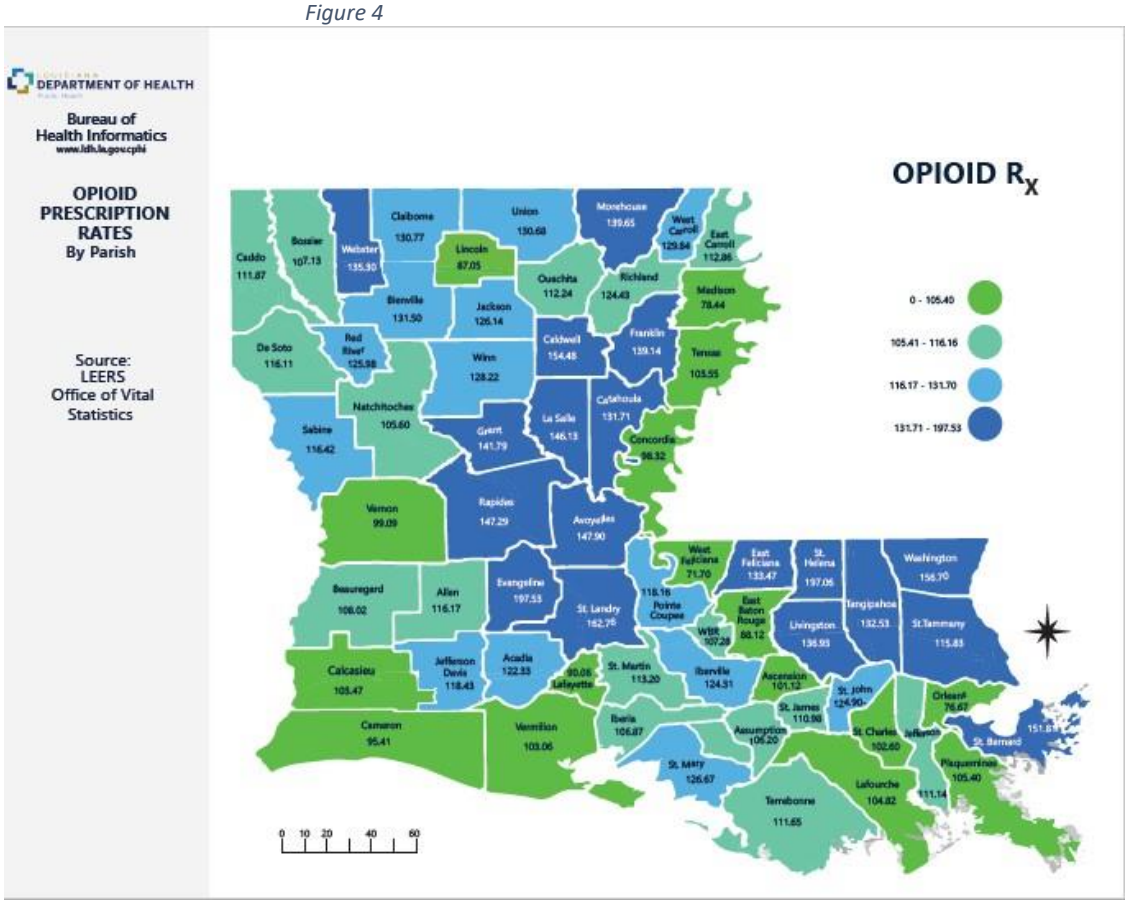
- Prevention: Each LGE is hiring an Educational Outreach Consultant to provide education and awareness activities, dependent upon local needs and targets. A statewide campaign is currently in development to ensure consistent messaging across the state.
- Intervention: OBH is providing distribution of Naloxone to communities and providers. Each LGE is required to submit a distribution plan with strategies of how they will use and track the kits (nasal sprays).
- Treatment: Each Opioid Treatment Program (OTP) has been provided STR funds to enhance accessibility to treatment services. In addition, each OTP has funding to hire a Resource Coordinator who will work with the region to provide referral services and to ensure peer support specialists have a seamless system of referral to the OTP. Lessons learned about recruitment and retention of consumers in treatment from the MAT-PDOA grant implementation in the New Orleans area will be shared statewide.
- Recovery Supports: Each LGE is also given funding through the STR grant to hire peer support specialists, who are trained and receive credentials through OBH to provide peer services. Peer support services outreach can be done in emergency rooms, one-stop centers, or wherever locally the need is to reach those consumers who are in need of treatment.

Louisiana's Prescription Monitoring Program (PMP) was implemented in August 2008 by the Board of Pharmacy. The PMP is an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed within the state or dispensed by a licensed pharmacy outside the state to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs of concern in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes. Since implementation, the Louisiana Legislature has adopted several measures to improve the program:

- Pharmacies and other dispensers are required to report their eligible prescription transactions to the program database no later than the next business day following the date of dispensing, instead of the previous seven day allowance.
- Authorized prescribers and dispensers are allowed to appoint delegates for the purpose of retrieving data from the program's database.
- Prescribers of certain controlled substances for the treatment of certain conditions to access the patient's history in the program database prior to initiating such treatment. The same measure will require pharmacists dispensing certain controlled substances to certain patients to access the patient's history in the program database prior to dispensing such medications.
- The state's controlled substance law was amended to require the automatic issuance of PMP access privileges to all practitioners with prescriptive authority for controlled substances except veterinarians. Another measure amended the PMP law to enable additional categories of authorized users, e.g., medical examiners, substance abuse counselors, and probation and parole officers, as well as judicially supervised specialty courts.

As a result of CDC grants around data surveillance on opioids, the Louisiana Office of Public Health (OPH) has been working in collaboration with the Board of Pharmacy and the PMP to provide data on opioid prescriptions. In 2016, it was found that there were 110 prescriptions per 100 citizens in Louisiana. The national average for opioid prescriptions is 66.5 prescriptions per 100 citizens. Efforts are underway to see how such collaborations and data can be used to ensure appropriate prescribing of opioids and reduce the inappropriate number of prescriptions in Louisiana. Current prescription rate patterns per Louisiana parish can be seen in Figure 4:

*Figure 4*

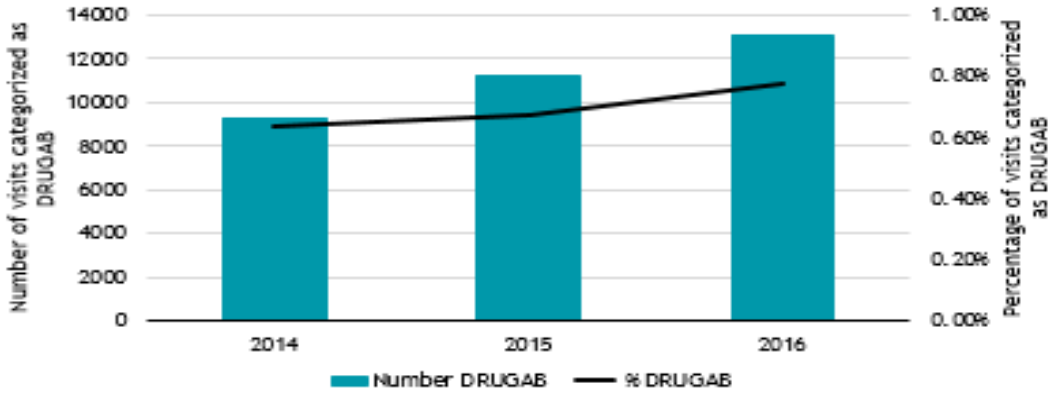



In collaboration with partners across the state, OPH is evaluating all data in relation to opioids in Louisiana. Fact sheets on opioid prescription practices and opioid-related deaths are broken down by parish and provided for the public on the LDH website. Furthermore, OPH is collecting and organizing opioid-related data from Emergency Room, Hospital Inpatient, Emergency Medical Systems, and various other databases and systems to build a dashboard in early 2018 to understand the extent of opioid-related hospitalizations including overdoses, deaths, naloxone administration, and neonatal abstinence syndrome (NAS). The goal of such information is to provide data-driven opioid surveillance for better understanding of the extent of the opioid epidemic in Louisiana and to drive data-driven solutions.

*Figure 5*

# Drug Overdose Emergency Room Visits

*The number and percentage of ED visits categorized as DRUGAB* is increasing over time.*




*Source: Louisiana Early Event Detection System, 2014-2016***

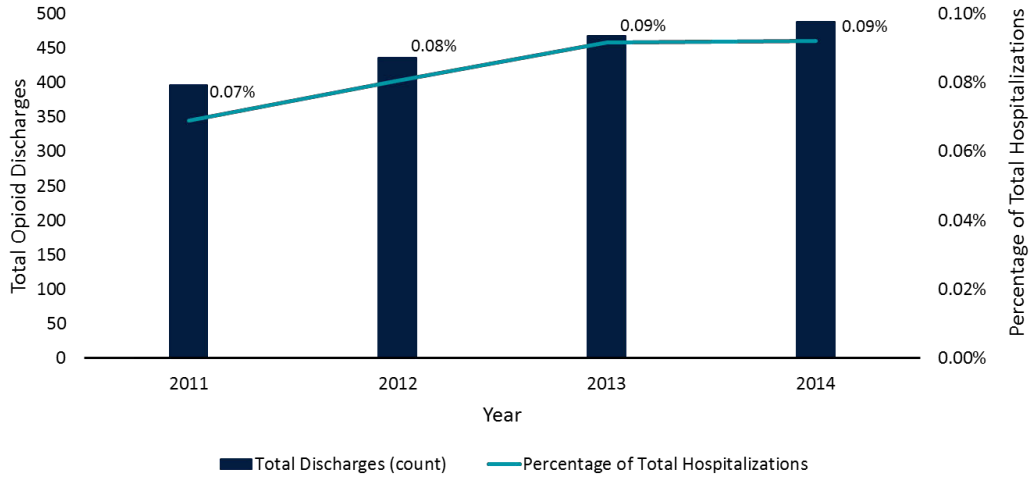
*The syndrome that captures drug overdose visits is called DRUGAB (for "Drug Abuse")

**Emergency Departments (EDs) reporting to LEEDS represent approximately 61% of all EDs in the state of Louisiana. This 61% of EDs cover all 9 Public Health Regions.

*Figure 6*

## The number of opioid-related hospitalizations* increased, but the percentage of overall hospitalizations remained the same (<0.1%)

*Produced by the Louisiana Opioid Surveillance Initiative, Bureau of Health Informatics*




*Source: Louisiana Hospital Inpatient Discharge Database, 2011-2014*

*Opioid-related hospitalizations were defined as any presence of the following ICD-9-CM codes: 965.00, 965.01, 965.02, 965.09, E850.0, E850.1, E850.2

In 2017, several pieces of legislation were enacted to strengthen the state's efforts against the opioid epidemic:

- Act 76 (SB 55 by Sen. Fred Mills)
  - Requires prescribers to check the PMP system before prescribing an opioid to a patient and to check it every 90 days.
  - Requires prescribers to obtain three continuing education credit hours related to drug diversion training, best practice prescribing of controlled substances, and appropriate treatment for addiction prior to license renewal in 2018.
- Act 82 (HB 192 by Rep. Helena Moreno)
  - Implements a seven-day limit on first-time prescriptions of opioids for acute pain, with exemptions for patients with cancer, chronic pain or those receiving palliative care. It also gives doctors the ability to override the limit when medically necessary, with a notation in the patient's medical record.
  - These opioid prescription limits were implemented in Medicaid in 2017. The implementation timeline along with resources for providers was published on the LDH Opioid FAQ Fact Sheet.
- Act 88 (HB 490 by Rep. Walt Leger)
  - Creates the Advisory Council on Heroin and Opioid Prevention and Education, a 13-member council tasked with coordinating resources and expertise for a statewide

response to combat opioid abuse.

- Act 241 (SB 96 by Sen. Ronnie Johns)
  - Provides for access to prescription monitoring information, including medical examiners, coroners, licensed substance abuse or addiction counselors, and probation and parole officers to those who may access prescription monitoring program information in certain circumstances.

In 2017, Naloxone was also made available to treat opioid overdose via standing order issued by the Secretary of LDH. This allows for participating pharmacists to dispense naloxone to laypeople including caregivers, family and friends of an opioid user. This standing order also includes directions on how to administer naloxone to someone who has overdosed. The standing order was recently reissued for another year on January 8, 2018. Information regarding the standing order was disseminated to the MCOs via Informational Bulletin 17-1.

### Future State

LDH is proposing legislative changes to the Prescription Monitoring Program that would allow Medicaid access to the system's audit trail in order to better monitor prescribing practices of Medicaid providers to identify overuse and/or abuse. Any action will require Louisiana Board of Pharmacy approval. Additionally, the Board of Pharmacy is working to make Naloxone a listed "drug of concern" for tracking through the PMP. This will allow the Board and LDH to identify distribution under the standing order and other mechanisms. LDH also has long-term plans to work with provider and stakeholder groups such as hospitals, safety officers, and first responders on tracking Naloxone administration through required reporting.

### Summary of Actions Needed

| Implementation Action Item | Timeline |
|---|---|
| Coordinate with stakeholders on establishing required reporting for Naloxone administration. | 24 months |
| Coordinate with Board of Pharmacy to create Medicaid access to monitor prescribing practices of opioids under the PMP. | 24 months |
| Work with Board of Pharmacy to track Naloxone distribution under the | 6 months |

### Milestone 6: Improved care coordination and transitions between levels of care

#### Specification:

Implementation of policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

#### Current State

Louisiana licensing standards emphasize the importance of transitions of care by outlining certain transfer and discharge requirements specifically addressing discharge, transition to another level of care and transfer to another provider. It requires discharge planning to begin at admission and outlines discharge plan components to provide reasonable protection of continuity of services and agreements between the current transferring provider and the receiving provider. See page 1703 of the Behavioral Health Provider licensing regulations here.

The MCOs are required to develop and maintain effective care coordination, continuity of care, and care transition activities to ensure a continuum of care approach to providing health care services to MCO members. The MCO contracts have explicit language around continuity of care and care transition. Requirements include collaborating with hospitals, nursing home facilities, and inpatient facilities to coordinate aftercare planning prior to discharge and transition of members for the continuance of behavioral health services and medication prior to reentry into the community, including referral to community providers. They are required to coordinate hospital and/or institutional discharge planning that includes post-discharge care as appropriate, including aftercare appointments, following an inpatient, PRTF, or other out-of-home stay and assure that prior authorization for prescription coverage is addressed and or initiated before patient discharge. The MCO must have policies and procedures requiring and assuring that:

- Behavioral health pharmacy prior authorization decisions are rendered before a member is discharged from a behavioral health facility (including, but not limited to, inpatient psychiatric facilities, PRTFs, and residential substance use disorder settings).
- Care managers follow up with members with a behavioral health-related diagnosis within 72 hours following discharge.
- Coordination with LDH and other state agencies following an inpatient, PRTF, or other residential stay for members with a primary behavioral health diagnosis occurs timely when the member is not to return home.

#### Future State

OBH/LDH will continue to monitor MCO compliance with existing contract requirements in effort to assure beneficiary needs are met relative to linkage with community-based services.

#### Summary of Actions Needed

There are no anticipated actions needed by Louisiana for fulfillment of this milestone.

**Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) – Planned Metrics (Version 7.0)**
State: Louisiana
Demonstration Name: Healthy Louisiana Opioid Use Disorder/Substance Use Disorder (OUD/SUD) Demonstration

**Table: Substance Use Disorder Demonstration Planned Metrics**

| Standard information on CMS-provided metrics | | | | | | | | | | | Baseline, annual goals, and demonstration target | | | Alignment with CMS-provided technical specifications manual | | Phased-in metrics reporting | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Metric name | Metric description | Milestone or reporting metric* | Metric type | Reporting frequency | Data source | Measurement period | Reporting frequency | Reporting priority | State will report (Y/N) | Baseline period (MM/DD/YYYY-MM/DD/YYYY) | Annual goal | Overall demonstration target | Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N) | Explanation of any deviations from the CMS-provided technical specifications manual or other considerations (different data source, definition, codes, target population, etc.)** | State plans to phase in (mm/dd/yyyy) (Y/N) | SUD monitoring report in which metric will be phased in (Format: DY#Q#, e.g., DY1Q2) | Explanation of any plans to phase in meantime over time |
| *EXAMPLE: 1 (Do not delete or edit this row)* | *EXAMPLE: Assessed for SUD Treatment Needs Using a Standardized Screening Tool* | *EXAMPLE: Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period* | *EXAMPLE: Assessment of need and qualification for SUD treatment services* | *EXAMPLE: CMS-constructed* | *EXAMPLE: Other monthly and quarterly metrics* | *EXAMPLE: Medical record review or claims* | *EXAMPLE: Month* | *EXAMPLE: Quarterly* | *EXAMPLE: Recommended* | *EXAMPLE: Y* | *EXAMPLE: 07/01/2018-06/30/2019* | *EXAMPLE: Increase* | *EXAMPLE: Increase* | *EXAMPLE: N* | *EXAMPLE: The Department will use state-defined procedure codes (list specific codes) to calculate this metric.* | *EXAMPLE: Y* | *EXAMPLE: DY2Q3* | *EXAMPLE: This measure requires an update to the Adult Needs and Strengths Assessment tool that reflects an ASAM level of treatment. The work is in the testing phase with anticipated go-live in mid to late 2021.* |
| 1 | Assessed for SUD Treatment Needs Using a Standardized Screening Tool | Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period | Assessment of need and qualification for SUD treatment services | CMS-constructed | Other monthly and quarterly metrics | Medical record review or claims | Month | Quarterly | Recommended | N | | | | | | | | |
| 2 | Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis | Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period but not in the three months before the measurement period | Assessment of need and qualification for SUD treatment services | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Recommended | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 3 | Medicaid Beneficiaries with SUD Diagnosis (monthly) | 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 | Assessment of need and qualification for SUD treatment services | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 4 | Medicaid Beneficiaries with SUD Diagnosis (annually) | 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 12 months before the measurement period | Assessment of need and qualification for SUD treatment services | CMS-constructed | Other annual metrics | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 5 | Medicaid Beneficiaries Treated in an IMD for SUD | Number of beneficiaries with a claim for inpatient/residential treatment for SUD in an IMD during the measurement period. | Milestone 2 | CMS-constructed | Other annual metrics | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | To ensure all SUD Residential Treatment services available through Louisiana Medicaid are captured in this metric, the following (5) Residential SUD Treatment service HCPCS codes (H0011, H0012, H2033, H2034, H2036) were added to the HCPCS Codes list in step 1b. To address an issue with the use of incorrect POS codes on SUD Outpatient Treatment claims, modification was made to step 1a to require SUD Residential Treatment HCPCS codes H0011, H0012, H0019, H2033, H2034, H2036 on claims using POS 55.<br><br>The state creates a list of provider NPI for facilities that qualify as an IMD. The IMD qualification criteria is based on the "institution for mental diseases" term as defined in 42 U.S.C. Sec. 1905(i). The state uses a combination of facility licensure and provider enrollment information, which specifically identifies free standing psychiatric and residential facilities, to determine which entities qualify as an IMD. This list of IMD NPI is not published, but it is shared with our actuaries for utilization in the development of our annual data book related to rate setting. It is also used as part of the criteria to determine which claim records to include in the calculations for metric #7; when the claim record's Billing Provider NPI is one of the IMD NPI, then the services from that claim record were from an IMD.<br><br>LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 6 | Any SUD Treatment | Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | To ensure all SUD Residential Treatment services available through Louisiana Medicaid are captured in this metric, the following (5) Residential SUD Treatment service HCPCS codes (H0011, H0012, H2033, H2034, H2036) were added to the HCPCS Codes list in step 1b. To address an issue with the use of incorrect POS codes on SUD Outpatient Treatment claims, modification was made to step 1a to require SUD Residential Treatment HCPCS codes H0011, H0012, H0019, H2033, H2034, H2036 on claims using POS 55.<br><br>LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 7 | Early Intervention | Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | Y | | N | | |
| 8 | Outpatient Services | 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 | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Increase | Consistent or Increase | Y | | N | | |
| 9 | Intensive Outpatient and Partial Hospitalization Services | 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 | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Increase | Consistent or Increase | Y | | N | | |
| 10 | Residential and Inpatient Services | Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | To ensure all SUD Residential Treatment services available through Louisiana Medicaid are captured in this metric, the following (5) Residential SUD Treatment service HCPCS codes (H0011, H0012, H2033, H2034, H2036) were added to the HCPCS Codes list in step 1b. To address an issue with the use of incorrect POS codes on SUD Outpatient Treatment claims, modification was made to step 1a to require SUD Residential Treatment HCPCS codes H0011, H0012, H0019, H2033, H2034, H2036 on claims using POS 55.<br><br>LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 11 | Withdrawal Management | Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | N | LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 12 | Medication-Assisted Treatment | Number of beneficiaries who have a claim for MAT for SUD during the measurement period | Milestone 1 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Increase | Increase | Y | | N | | |
| 13 | SUD Provider Availability | The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period | Milestone 4 | CMS-constructed | Other annual metrics | Provider enrollment database; Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | Y | The number of SUD providers is determined by counting the number of unique Rendering provider (individual) NPI that were listed on the results claim records from metric #6 (Any SUD Treatment). There were no limits on the types of providers counted for metric #13, all types of Rendering providers listed on metric #6 claim records were included. The count of unique SUD providers was based on metric #6 claim records that have a date of service in the reporting year. | N | | |
| 14 | SUD Provider Availability - MAT | 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 | Milestone 4 | CMS-constructed | Other annual metrics | Provider enrollment database; Claims; SAMHSA datasets | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | Y | The number of MAT SUD providers is determined by counting the number of unique Rendering provider (individual) NPI that were listed on results claim records from metric #12 (Medication-Assisted Treatment). There were no limits on the types of providers counted for metric #14, all types of Rendering providers listed on metric #12 claim records were included. The count of unique MAT SUD providers was based on metric #12 claim records that have a date of service in the reporting year. | N | | |
| 15 | Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD)<br><br>[NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure] | Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following:<br><br>• 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<br>• 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<br><br>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. | Milestone 6 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | Y | | N | | |
| 16 | SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission] | SUB-3: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addiction treatment.<br><br>SUB-3a: Patients who are identified with alcohol or drug disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addiction treatment. | Milestone 6 | Established quality measure | Annual metrics that are established quality measures | Medical record review or claims | Year | Annually | Recommended | N | | | | | | | | |
| 17(1) | Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence (FUA-AD) [NCQA; NQF #3400; Medicaid Adult Core Set; Adjusted HEDIS measure]d | 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:<br><br>- Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days).<br>- Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). | Milestone 6 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Increase | Increase | Y | | N | | |
| 17(2) | Follow-up after Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF #3489; Medicaid Adult Core Set; Adjusted HEDIS measure]e | Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported:<br><br>- Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days)<br>- Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). | Milestone 6 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Increase | Increase | Y | | N | | |
| 18 | Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) [PQA; NQF #2940; Medicaid Adult Core Set] | Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded. | Milestone 5 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent | Consistent or Decrease | Y | | N | | |
| 19 | Use of Opioids from Multiple Providers in Persons without Cancer (OMP) [PQA; NQF #2950] | The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days. | Milestone 5 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Recommended | N | | | | | | | | |

**Table: Substance Use Disorder Demonstration Planned Metrics**

| Standard information on CMS-provided metrics | | | | | | | | | | | Baseline, annual goals, and demonstration target | | | Alignment with CMS-provided technical specifications manual | | Phased-in metrics rationale | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 20 | Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) [PQA, NQF #2951] | The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies. | Milestone 5 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Recommended | N | | | | | | | | |
| 21 | Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA, NQF #3389; Medicaid Adult Core Set] | Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded. | Milestone 5 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | Y | | N | | |
| 22 | Continuity of Pharmacotherapy for Opioid Use Disorder [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 | Milestone 1 | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2017-12/31/2018 | Consistent or Increase | Increase or Consistent | Y | | N | | |
| 23 | Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries | Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period | Milestone 5 | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | Y | | N | | |
| 24 | Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries | Total number of inpatient stays per 1,000 beneficiaries in the measurement period | Other SUD-related metrics | CMS-constructed | Other monthly and quarterly metrics | Claims | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | N | LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| 25 | Readmissions Among Beneficiaries with SUD | The rate of all-cause readmissions during the measurement period among beneficiaries with SUD | Milestone 6 | CMS-constructed | Other annual metrics | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | Y | | N | | |
| 26 | Overdose Deaths (count) | Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid). | Other SUD-related metrics | CMS-constructed | Other annual metrics | State data on cause of death | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | Y | | N | | |
| 27 | Overdose Deaths (rate) | Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid). | Milestone 5 | CMS-constructed | Other annual metrics | State data on cause of death | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Decrease | Y | | N | | |
| 28 | SUD Spending | Total Medicaid SUD spending during the measurement period. | Other SUD-related metrics | CMS-constructed | Other annual metrics | Claims | Year | Annually | Recommended | N | | | | | | | | |
| 29 | SUD Spending Within IMDs | Total Medicaid SUD spending on inpatient/residential treatment within IMDs during the measurement period. | Other SUD-related metrics | CMS-constructed | Other annual metrics | Claims | Year | Annually | Recommended | N | | | | | | | | |
| 30 | Per Capita SUD Spending | Per capita SUD spending during the measurement period | Other SUD-related metrics | CMS-constructed | Other annual metrics | Claims | Year | Annually | Recommended | N | | | | | | | | |
| 31 | Per Capita SUD Spending Within IMDs | Per capita SUD spending within IMDs during the measurement period | Other SUD-related metrics | CMS-constructed | Other annual metrics | Claims | Year | Annually | Recommended | N | | | | | | | | |
| 32 | Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD [Adjusted HEDIS measure] | The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period. | Other SUD-related metrics | Established quality measure | Annual metrics that are established quality measures | Claims | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | Y | | N | | |
| 33 | Grievances Related to SUD Treatment Services | Number of grievances filed during the measurement period that are related to SUD treatment services | Other SUD-related metrics | CMS-constructed | Grievances and appeals | Administrative records | Quarter | Quarterly | Recommended | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Consistent or Decrease | Y | | N | | |
| 34 | Appeals Related to SUD Treatment Services | Number of appeals filed during the measurement period that are related to SUD treatment services | Other SUD-related metrics | CMS-constructed | Grievances and appeals | Administrative records | Quarter | Quarterly | Recommended | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Consistent or Decrease | Y | | N | | |
| 35 | Critical Incidents Related to SUD Treatment Services | Number of critical incidents filed during the measurement period that are related to SUD treatment services | Other SUD-related metrics | CMS-constructed | Grievances and appeals | Administrative records | Quarter | Quarterly | Recommended | Y | 01/01/2018-12/31/2018 | Consistent or Decrease | Consistent or Decrease | Y | | N | | |
| 36 | Average Length of Stay in IMDs | The average length of stay for beneficiaries discharged from IMD inpatient/residential treatment for SUD. | Milestone 2 | CMS-constructed | Other annual metrics | Claims; State-specific IMD database | Year | Annually | Required | Y | 01/01/2018-12/31/2018 | Consistent | No More than 30 days | N | To ensure all SUD Residential Treatment services available through Louisiana Medicaid are captured in this metric, the following (5) Residential SUD Treatment service HCPCS codes (H0001, H0012, H2033, H2034, H2036) were added to the HCPCS Codes list in step 1b.<br><br>To address an issue with the use of incorrect POS codes on SUD Outpatient Treatment claims, modification was made to step 1a to require SUD Residential Treatment HCPCS codes H0001, H0012, H0019, H2033, H2034, H2036 on claims using POS 55.<br><br>The state creates a list of provider NPI for facilities that qualify as an IMD. The IMD qualification criteria is based on the "institution for mental diseases" term as defined in 42 U.S.C. Sec. 1905(i). The state uses a combination of facility licensure and provider enrollment information, which specifically identifies free standing psychiatric and residential facilities, to determine which entities qualify as an IMD. This list of IMD NPI is not published, but it is shared with our actuaries for utilization in the development of our annual data book related to rate setting. It is also used as part of the criteria to determine which claim records to include in the calculations for metric #5; when the claim record's Billing Provider NPI is one of the IMD NPI, then the services from that claim record were from an IMD.<br><br>LA will not include the "same provider" in the criteria to determine these residential and inpatient stays. This deviation will result in LA calculating the stays based on residential and inpatient claims having less than a one-day break for the same beneficiary. | N | | |
| Q1 | *Percentage of eligible physicians with access to the PMP* | Percentage of eligible physicians with active accoss privileges to the PMP | Health IT | State-specific | Other monthly and quarterly metrics | LA Board of Ph | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent | Consistent | | | N | | |
| Q2 | *Emergency department admit, discharge, transfer (ADT) data sharing* | Number of EDs providing ADT information to the state | Health IT | State-specific | Other monthly and quarterly metrics | LaEDIE | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent | Consistent | | | N | | |
| Q3 | *Corrections and care delivery systems* | Number of incarcerated individuals who are Medicaid eligible that are enrolled with a MCO prior | Health IT | State-specific | Other monthly and quarterly metrics | Enrollment Brid | Month | Quarterly | Required | Y | 01/01/2018-12/31/2018 | Consistent | Consistent | | | N | | |
| **State-specific metrics** | | | | | | | | | | | | | | | | | | |
| *S1* | PMP utilization by physicians | Number of inquiries to the AWARxE™ system made by physicians with active accoss privileges | Health IT | State-specific | Other monthly and quarterly metrics | LA Board of Pharmacy | Month | Quarterly | State-specific | Y | 01/01/2018-12/31/2018 | Consistent or Increase | Consistent or Increase | | | N | | |

[a] There are no CMS-provided metrics related to milestone 3

[b] If the state is not reporting a required metric (i.e., column K = "N"), enter explanation in corresponding row in column P.

[c] The state should use column P to outline calculation methods for specific metrics as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions.

[d] Rates 1 and 2 reported for Metric #17(1) correspond to rates 2 and 3 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics

[e] Rates 1 and 2 reported for Metric #17(2) correspond to rates 1 and 2 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics

[f] While grievances and appeals metrics are recommended for reporting, the state is required, per 42 CFR 431.428(a)5, to provide updates on the results of beneficiary satisfaction surveys, if conducted during the reporting year, including updates on grievances and appeals from beneficiaries, in its annual (Q4) monitoring report.

**Medicaid Section 1115 SUD Demonstrations Protocol (Part A) - Planned Subpopulations (Version 7.0)**

State: Louisiana

Demonstration Name: Healthy Louisiana Opioid Use Disorder/Substance Use Disorder (OUD/SUD) Demonstration

**Table: Substance Use Disorder Demonstration Planned Subpopulations**

| Planned subpopulation reporting | | | | | | Alignment with CMS-provided technical specifications manual | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Subpopulations | | Relevant metrics | |
| Subpopulation category | Subpopulations | Reporting priority | Relevant metrics | Subpopulation type | State will report (Y/N) | Attest that planned subpopulation reporting within each category matches the description in the CMS-provided technical specifications manual (Y/N) | If the planned reporting of subpopulations does not match (i.e., column G = "N"), list the subpopulations state plans to report (Format comma separated)[a,b,c] | Attest that metrics reporting for subpopulation category matches CMS-provided technical specifications manual (Y/N) | If the planned reporting of relevant metrics does not match (i.e., column I = "N"), list the metrics for which state plans to report for each subpopulation category (Format metric number, comma separated) |
| *EXAMPLE: Age group* ***(Do not delete or edit this row)*** | *EXAMPLE: Children <18, adults 18–64, and older adults 65+* | *EXAMPLE: Required* | *EXAMPLE: Metrics #1-3, 6-12, 23, 24, 26, 27* | *EXAMPLE: CMS-provided* | *EXAMPLE: Y* | *EXAMPLE: N* | *EXAMPLE: Children/Young adults 12-21, Adults 21-65* | *EXAMPLE: N* | *EXAMPLE: 1, 2, 3* |
| Age group | Children <18, adults 18–64, and older adults 65+ | Required | Metrics #1-3, 6-12, 23, 24, 26, 27 | CMS-provided | Y | Y | | Y | |
| Dual–eligible status | Dual-eligible (Medicare-Medicaid eligible), Medicaid only | Required | Metrics #1-3, 6-12 | CMS-provided | Y | Y | Individuals are determined to be part of the dual-eligible subpopulation based on Medicaid's Medicare enrollment data where the type of Medicare coverage is either Part A, Part B, Buy-In Part A or Buy-In Part B, and where the Medicare coverage is effective for the reporting period of the metric. If the individual is not determined to be dual-eligible, then the individual is placed in the Medicaid-only subpopulation. 11/5/21 Update: In the database table that we use to find Part-A and Part-B individuals, the Part-C (Medicare Advantage) individuals are listed as having Part-A and/or Part-B; so yes we can confirm our method of determining dual eligible for 1115 SUD reporting does automatically include Part-C individuals including D-SNP and regular Medicare Advantage. | Y | |
| Pregnancy status | Pregnant, Not pregnant | Required | Metrics #1-3, 6-12 | CMS-provided | Y | Y | Individuals are determined to be part of the pregnant subpopulation based on Medicaid enrollment data having female as the gender and having age greater than 9 and having a HEDIS Pregnancy value set ICD10CM diagnosis, during the metric reporting period. If the individual is not determined to be pregnant, then the individual is placed in the Not pregnant subpopulation. | Y | |
| Criminal justice status | Criminally involved, Not criminally involved | Required | Metrics #1-3, 6-12 | CMS-provided | Y | Y | Individuals are determined to be part of the Criminally involved subpopulation based on Medicaid's records from the Louisiana Department of Corrections where the incarceration dates include any date within the metric reporting period. If the individual is not determined to be Criminally involved, then the individual is placed in the Not criminally involved subpopulation. | Y | |
| OUD population | Opioid diagnosis | Recommended | Metrics #2-12, 23, 24, 26, 27, 36 | CMS-provided | Y | Y | Individuals are determined to be part of the OUD subpopulation based on the individual having a HEDIS Opioid Abuse and Dependence value set ICD10CM diagnosis during the metric reporting period. | Y | |
| *[Insert row(s) for any state-specific subpopulation(s)]* | | | | | | | | | |

[a] If the state is not reporting a required subpopulation category (i.e., column F = "N"), enter explanation in corresponding row in column H.

[b] If the state is reporting on the Dual-eligible status, Pregnancy status, Criminal justice status, and OUD population subpopulation categories, the state should use column H to outline its subpopulation identification approach as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions.

[c] If the state is planning to phase in the reporting of any of the subpopulation categories, the state should (1) select N in column G and (2) provide an explanation and the

**Medicaid Section 1115 Substance Use Disorder Demonstrations**
**Monitoring Protocol Template**

*Note: PRA Disclosure Statement to be added here*

## 1. Title page for the state's substance use disorder (SUD) demonstration or the SUD component of the broader demonstration

*The state should complete this title page as part of its SUD monitoring protocol. Definitions for certain rows are provided below the table. The Performance Metrics Database and Analytics (PMDA) system will populate some rows of the table. The state should complete the rest of the table. The state can revise the demonstration goals and objectives if needed. PMDA will use this information to populate part of the title page of the state's monitoring reports.*

| | |
|---|---|
| **State** | Louisiana |
| **Demonstration name** | Healthy Louisiana Opioid Use Disorder Substance Use Disorder (OUD SUD) |
| **Approval period for section 1115 demonstration** | *Enter the current approval period for the section 1115 demonstration as listed in the current special terms and conditions (STC), including the start date and end date (MM/DD/YYYY – MM/DD/YYYY).*<br>*Start Date:* 01/01/2023 *End Date:* 12/31/2027 |
| **SUD demonstration start date**[a] | *Enter the start date for the section 1115 SUD demonstration or SUD component if part of a broader demonstration (MM/DD/YYYY).*<br>01/01/2023 |
| **Implementation date of SUD demonstration, if different from SUD demonstration start date**[b] | *Enter SUD demonstration implementation date (MM/DD/YYYY).*<br>02/01/2018 |
| **SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives** | *Enter summary of the SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives.*<br>The goal of this demonstration is for Louisiana to maintain critical access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. This demonstration will provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD). It will also build on the state's existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions and strengthen a continuum of SUD services based on the American Societv of Addiction Medicine |

[a] **SUD demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval note that the SUD demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the SUD demonstration. Note that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2020, with an effective date of January 1, 2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

[b] **Implementation date of SUD demonstration:** The date the state began claiming or will begin claiming federal financial participation for services provided to individuals in institutions for mental disease.

**2. Acknowledgement of narrative reporting requirements**

☒ The state has reviewed the narrative questions in the Monitoring Report Template provided by CMS and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested narrative information (with no modifications).

**3. Acknowledgement of budget neutrality reporting requirements**

☒ The state has reviewed the Budget Neutrality Workbook (which can be accessed via PMDA – see Monitoring Protocol Instructions for more details) and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (with no modifications).

**4. Retrospective reporting**

The state is not expected to submit metrics data until after monitoring protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to monitoring protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

For a state that has monitoring protocols approved after one or more initial quarterly monitoring report submissions, it should report metrics data to CMS retrospectively for any prior quarters (Qs) of the section 1115 SUD demonstration that precede the monitoring protocol approval date. A state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data— in its second monitoring report submission that contains metrics. The retrospective monitoring report for a state with a first SUD demonstration year (DY) of less than 12 months, should include data for any baseline period Qs preceding the demonstration, as described in Part A of the state's monitoring protocols. (See Appendix B of the Monitoring Protocol Instructions for further instructions on determining baseline periods for first SUD DYs that are less than 12 months.) If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its section 1115 SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its monitoring report submission (Section 3: Narrative information on implementation, by milestone and reporting topic). This general assessment is not intended to be a comprehensive description of every trend observed in the metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metric changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for a state to provide context on its retrospective metrics

data and to support CMS's review and interpretation of these data. For example, consider a state that submits data showing an increase in the number of medication-assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. This state may decide to highlight this trend for CMS in Part B of its monitoring report (under Milestone 4) by briefly summarizing the trend and explaining that during this period, a grant supporting training for new MAT providers throughout its state was implemented.

For further information on how to compile and submit a retrospective monitoring report, the state should review Section B of the Monitoring Report Instructions document.

☐ The state will report retrospectively for any Qs prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after monitoring protocol approval.

☒ The state proposes an alternative plan to report retrospectively for any Qs prior to monitoring protocol approval: *Insert narrative description of proposed alternative plan for retrospective reporting. Regardless of the proposed plan, retrospective reporting should include retrospective metrics data and a general assessment of metric trends for the period. The state should provide justification for its proposed alternative plan.*

Not applicable; monitoring protocol applies to a demonstration extension period

**Attachment E:**
**Evaluation Design**

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

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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 90$^{th}$ 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*

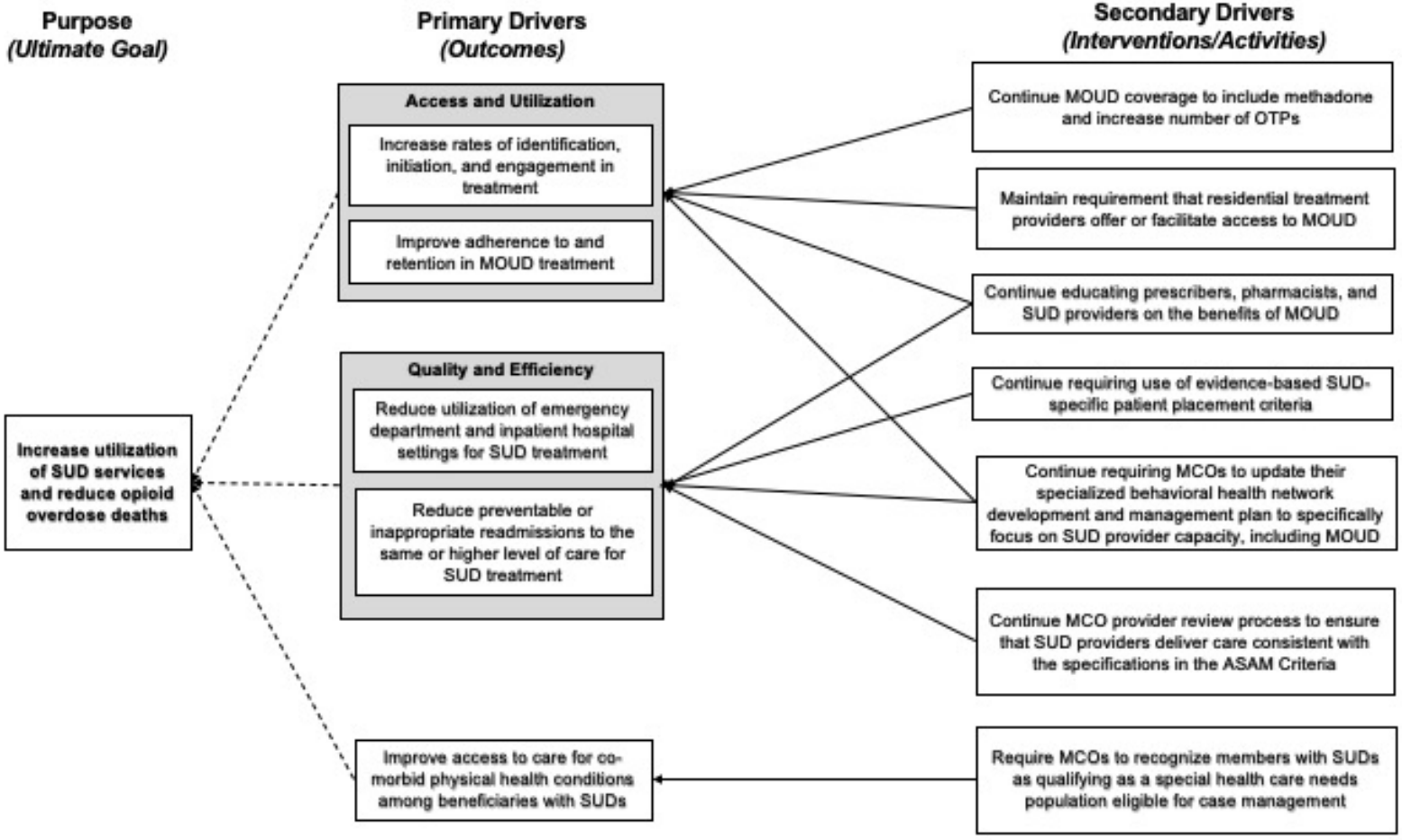
Preliminary results from Phase 1 of the Healthy Louisiana Substance Use Disorder 1115 Demonstration waiver indicate that the growth rate of the share of Louisiana Medicaid members with an SUD has slowed since the Phase 1 demonstration's implementation. Consistent with the goals of the Phase 1 demonstration, 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.<br>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** |
| Primary Driver<br>*Increase the rates of identification, initiation, and engagement in treatment.*<br><br>Secondary Drivers<br>• Continue MOUD coverage to include methadone and increase number of OTPs.<br>• Maintain requirement that residential | Medicaid Beneficiaries with SUD Diagnosis (monthly)<br><br>Monitoring Metric #3. | 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 | Primary: DD<br><br>Secondary: ITS |

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| treatment providers offer or facilitate access to MOUD.<br>• Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD.<br>• 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<br><br>Secondary: ITS |
| | Any SUD Treatment<br><br>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<br><br>Secondary: ITS |

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| | | | 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.<br><br>Alternate: Medicaid Beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Medicaid Beneficiaries Treated in an IMD for SUD<br><br>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<br><br>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<br><br>Secondary: ITS |

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| | 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.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Intensive Outpatient and Partial Hospitalization Services<br><br>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<br><br>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.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |

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| | Residential and Inpatient Services<br><br>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<br><br>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.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Withdrawal Management<br><br>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<br><br>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.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.<br><br>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<br><br>Secondary: ITS |

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| | | | • 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<br><br>• 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<br><br>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. | | | |
| | 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<br><br>Secondary: ITS |

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| | 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<br><br>Secondary: ITS |
| | Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence.<br><br>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.<br><br>Two rates are reported:<br>- Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days).<br>- 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<br><br>Secondary: ITS |

| Demonstration Goal 1.2: Increase adherence to and retention in treatment for OUD and other SUDs.<br>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** |
| Primary Driver<br>*Improve adherence to and retention in MOUD treatment.*<br><br>Secondary Drivers<br>• Continue MOUD coverage to include methadone and increase number of OTPs.<br>• Maintain requirement that residential treatment providers offer or facilitate access to MOUD.<br>• Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD.<br>• Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD | Medication-Assisted Treatment<br><br>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<br><br>Secondary: ITS |

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| provider capacity, including MOUD. | | | | | | |
| | Medication-Assisted Treatment (Rate) | None | Number of beneficiaries who have a claim for MAT for SUD during the measurement period. | Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.<br><br>Monitoring Metric #15. | | Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following:<br><br>• 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<br><br>• 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 | Primary: DD<br><br>Secondary: ITS |

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| | | | within 34 days of the initiation visit | | | |
| | SUD Provider Availability - MAT<br><br>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<br><br>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<br><br>Secondary: ITS |
| | Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence.<br><br>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.<br><br>Two rates are reported:<br>- Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days).<br>- Percentage of ED visits for which the | N/A | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |

| | | | | | | |
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| | | | 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.<br>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** |
| Primary Driver<br>*Reduce utilization of emergency department and inpatient hospital settings for SUD treatment.*<br><br>Secondary Drivers<br>• Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD.<br>• Continue requiring use of evidence-based SUD-specific patient placement criteria.<br>• Continue requiring MCOs to update their specialized behavioral health network development and management plan to specifically focus on SUD provider capacity, including MOUD. | Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries.<br><br>Monitoring Metric #23. | None | The number of ED visits for SUD during the measurement period. | Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | The rate of inpatient stays for SUD per 1,000 beneficiaries in the measurement period.<br><br>Monitoring Metric #24. | None | Total number of inpatient discharges related to a SUD stay per 1,000 beneficiaries in the measurement period. | Primary: All beneficiaries with full benefits enrolled in Medicaid for any amount of time during the measurement period.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |

| | | | | | | |
|---|---|---|---|---|---|---|
| • 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.<br>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** |
| Primary Driver<br>*Reduce preventable or inappropriate readmissions to the same or higher level of care for SUD treatment.*<br><br>Secondary Drivers<br>• Continue educating prescribers, pharmacists, and SUD providers on the benefits of MOUD.<br>• Continue requiring use of evidence-based SUD-specific patient placement criteria.<br>• 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<br><br>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<br><br>Secondary: ITS |

| | | | | | | |
|---|---|---|---|---|---|---|
| • 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.<br>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** |
| Primary Driver<br>*Improve access to care for co-morbid physical health conditions among beneficiaries with SUDs.*<br><br>Secondary Drivers<br>• Require MCOs to recognize members with SUDs as qualifying as a special health care needs population eligible for case management. | Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD<br><br>Monitoring Metric #32. | 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 | Primary: DD<br><br>Secondary: ITS |

| 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.<br>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<br><br>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<br><br>Secondary: ITS |
| | Continuity of Pharmacotherapy for Opioid Use Disorder.<br><br>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.<br><br>Alternate: Medicaid beneficiaries with an SUD diagnosis. | T-MSIS/Louisiana Medicaid Claims Data | Primary: DD<br><br>Secondary: ITS |
| | Drug Overdose Deaths (count)<br><br>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)<br><br>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 waver 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, $\delta$ and $\tau$ are state/region and time fixed effects, and $\varepsilon$ 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 |
| | Non-SUD | Louisiana Medicaid Claims Data |
| Type or source of care cost drivers* | 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 on 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/OUD 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<br>Outreach workers<br>Treatment providers<br>Local health officials<br>Local leaders | 4 | 4 |
| | Patients (for case study) | 1 | 1 |
| Avoidable use of the emergency department services | Outpatient SUD treatment providers<br>Residential SUD treatment providers<br>Emergency physicians<br>Emergency department managers<br>Discharge planners<br>Social workers | 4 | 4 |
| Subgroup: Pregnant people | Community health center-based PCPs and ObGyns<br>Outpatient SUD treatment providers<br>Midwives/Doulas<br>Maternal health equity/advocacy organizations based in LA | Statewide | Statewide |
| | Patient (for case study) | 1 | |
| Subgroup: Criminally involved people | Outpatient SUD treatment providers<br>Community health center-based PCPs<br>Social workers<br>"Drug court" judges<br>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<br>Community health center-based<br>PCPs and ObGyns<br>Outpatient SUD treatment providers<br>Midwives/Doulas<br>"Drug court" judges<br>Public defenders | Interviews |
| | Referral for treatment | Treatment providers<br>Community health center-based<br>PCPs and ObGyns<br>Outpatient SUD treatment providers<br>Midwives/Doulas<br>"Drug court" judges<br>Public defenders | Interviews |
| | Relevant policies and programs | Local health officials, local leaders<br>Maternal health equity/advocacy organizations based in LA<br>"Drug court" judges<br>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<br>Community health center-based<br>PCPs and ObGyns<br>Outpatient SUD treatment providers<br>Midwives/Doulas<br>"Drug court" judges<br>Public defenders | Interviews |
| | Personal experience in receiving treatment | Patients | Case studies |
| | Trends in avoidable use | Outpatient SUD treatment providers<br>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<br>Emergency department managers | |
| | Strategies for and barriers to avoiding ED | Outpatient SUD treatment providers<br>Intensive Outpatient Program treatment providers<br>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<br>Emergency department managers<br>Discharge planners<br>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 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** *(future dates projected)* |
|---|---|
| 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 |

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