



FEB - 1 2018

Administrator
Washington, DC 20201

Jen Steele
Medicaid Director
State of Louisiana, Department of Health and Hospitals
Bienville Building
628 North 4th Street
Baton Rouge, LA 70802

Dear Ms. Steele:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) has granted Louisiana's request for a new 1115(a) demonstration, Healthy Louisiana Opioid Use Disorder/Substance Use Disorder (SUD) (Project Number 11W00311/6). This approval is effective from February 1, 2018, through December 31, 2022, unless otherwise specified.

This SUD demonstration authorizes Louisiana to receive federal financial participation (FFP) for the continuum of services to treat addiction to opioids or other substances, including services provided to Medicaid enrollees with substance use disorder residing in certain residential treatment facilities that meet the definition of an Institution for Mental Disease (IMD). This is part of a comprehensive strategy to combat prescription drug abuse and opioid use disorders, and provide treatment services, including withdrawal management services. Implementation of the Opioid Use Disorder (OUD)/SUD program advances the purposes of the Medicaid program as it is expected to improve health outcomes for Medicaid beneficiaries, by increasing access to high quality OUD/SUD care and by maintaining the OUD/SUD provider networks available to serve Medicaid populations. At this time, CMS is not able to provide authority for Louisiana to receive FFP for services other than those specified above for enrollees with SUD residing in an IMD. CMS is coordinating input from states to identify strategies to support the provision of comprehensive mental health services.

CMS's approval of this demonstration is conditioned on compliance with the enclosed set of special terms and conditions (STCs) defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to your written acknowledgement of the award and acceptance of the STCs within 30 calendar days of the date of this letter. Please send your written acceptance to your project officer, Ms. Deborah Steinbach. She is available to answer any questions concerning your section 1115 demonstration. Her contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-01-16
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-7404
E-mail: deborah.steinbach@cms.hhs.gov

Official communication regarding official matters should be simultaneously sent to Ms. Steinbach and Mr. Bill Brooks, Associate Regional Administrator for the Division of Medicaid and Children's Health in our Dallas Regional Office. Mr. Brooks' contact information is as follows:

Mr. Bill Brooks
Associate Regional Administrator
Centers for Medicare & Medicaid Services
1301 Young St., Suite 714
Dallas, TX 75202
Telephone: (214) 767-4461
E-mail: bill.brooks@cms.hhs.gov

If you have any questions regarding this approval, please contact Ms. Judith Cash, Acting Director, State Demonstrations Group, Centers for Medicaid and CHIP Services at (410) 786-9686.

Sincerely,

A black rectangular redaction box covers the signature of Seema Verma.

Seema Verma

Enclosure

**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).

Healthy Louisiana SUD Demo

Demonstration Approval Period: February 1, 2018 through December 31, 2022

**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:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Demonstration Programs and Benefits
- VI. Cost Sharing
- VII. Delivery System
- VIII. General Reporting Requirements
- IX. Monitoring
- X. Evaluation of the Demonstration
- XI. General Financial Requirements Under Title XIX
- XII. Monitoring Budget Neutrality for the Demonstration
- XIII. Schedule of Deliverables for the Demonstration Extension Period

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/ODU 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 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.
- 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- December 31, 2018	11 Months
Demonstration Year 2	January 1, 2019 - December 31, 2019	12 Months
Demonstration Year 3	January 1, 2020 - December 31, 2020	12 Months
Demonstration Year 4	January 1, 2021 - December 31, 2021	12 Months
Demonstration Year 5	January 1, 2022 – 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	Quarterly Monitoring Reports	STC 32
Due 60 days after end of each quarter, except 4 th quarter	Quarterly Expenditure Reports	STC 49
Annual Deliverables - Due 90 days after end of each 4 th 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

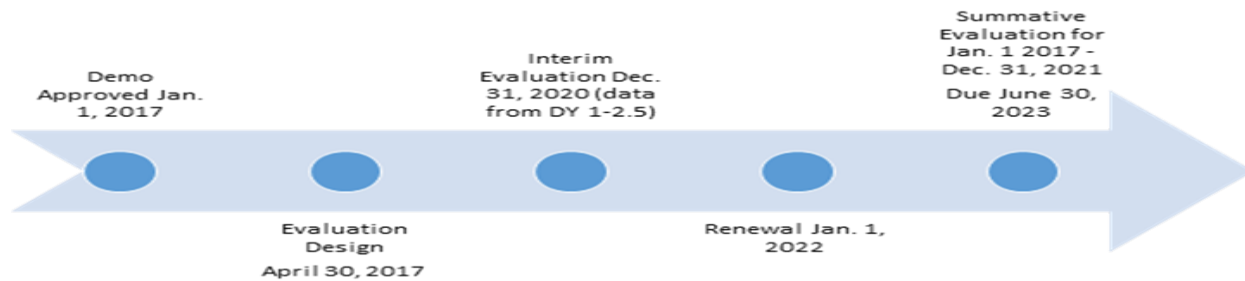
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -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 -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.

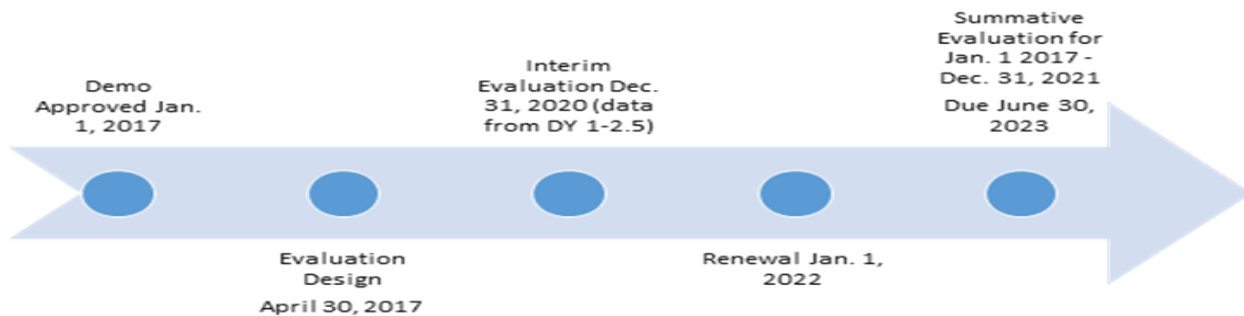
The format for the Interim and Summative Evaluation reports is as follows:

- 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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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://www.dasis.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.”

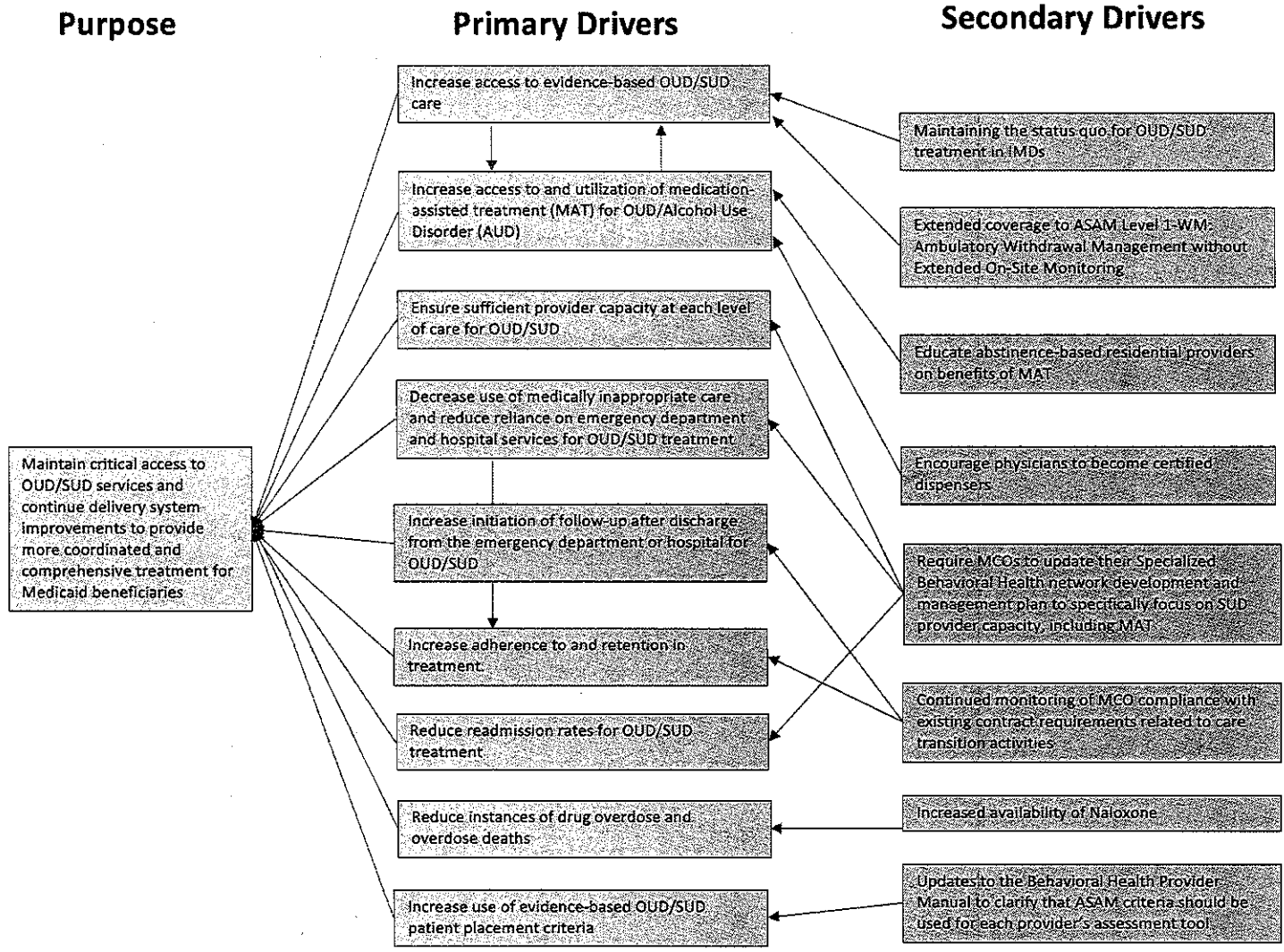
² While IMDs have been excluded from federal financial participation since Medicaid’s inception, several states have used an “in lieu of” policy to fund IMD care using federal dollars through capitated payments to managed care organizations (Musumeci, 2018). In May 2016, CMS implemented a policy to limit “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: Did access to evidence-based OUD/SUD care increase?						
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 waived 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 waived 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						
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 emergency department and hospital care for OUD/SUD decline 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.						
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						
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.						
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 Objectives, Program Description, and Evaluation Hypothesis						
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						
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)	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
Secondary Driver (Continued monitoring of MCO compliance with existing contract requirements related to care transition activities)						

Evaluation Question 4: Do the all outcomes for Medicaid beneficiaries						
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 LDH 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 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:

$$\text{Costs} = \beta_0 + \beta_1 * \text{TIME} + \beta_2 * \text{POST} + \beta_3 * (\text{TIME} * \text{POST}) + B_i * \text{CONTROLS} + \varepsilon$$

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 β_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 β_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 waived 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 waived 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 waived 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, δ and τ are state/region and time fixed effects, and ε is an error term that captures unobserved factors associated with the outcome of interest. Most of the DD models will be estimated using ordinary least squares (OLS), however we may employ nonlinear estimation techniques to account for relatively rare

outcomes. 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-ODU/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-ODU/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 waiver 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 the 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/bibliography/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 <i>(if applicable)</i>	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
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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
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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
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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 4th dose that does 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 \geq 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

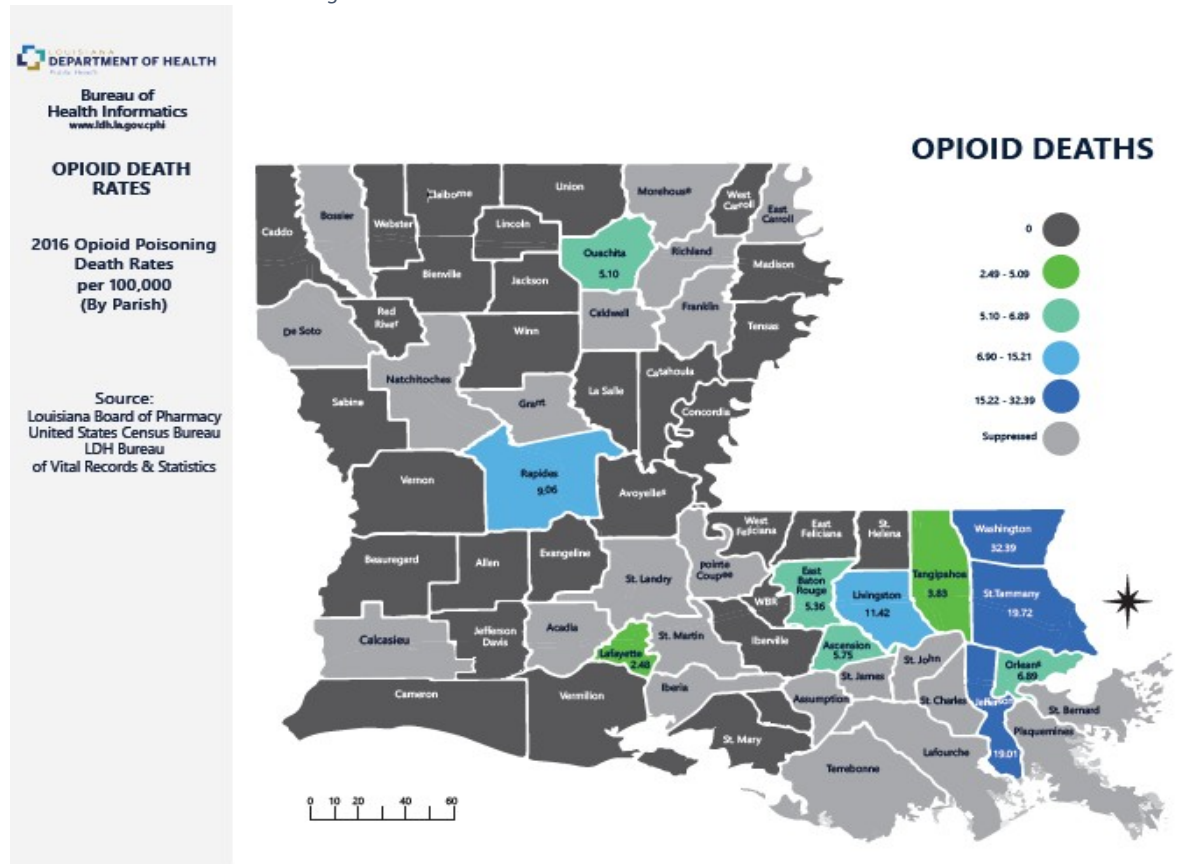
Nationwide, deaths due to opioids continue to increase, are under-reported, and have great variability in the specificity of how they are recorded across the country.¹² Contributing factors to the difficulty of verifying these opioid-related deaths are that a specific drug or cause of death may not be 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.

¹Rudd 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.mm65051e1>

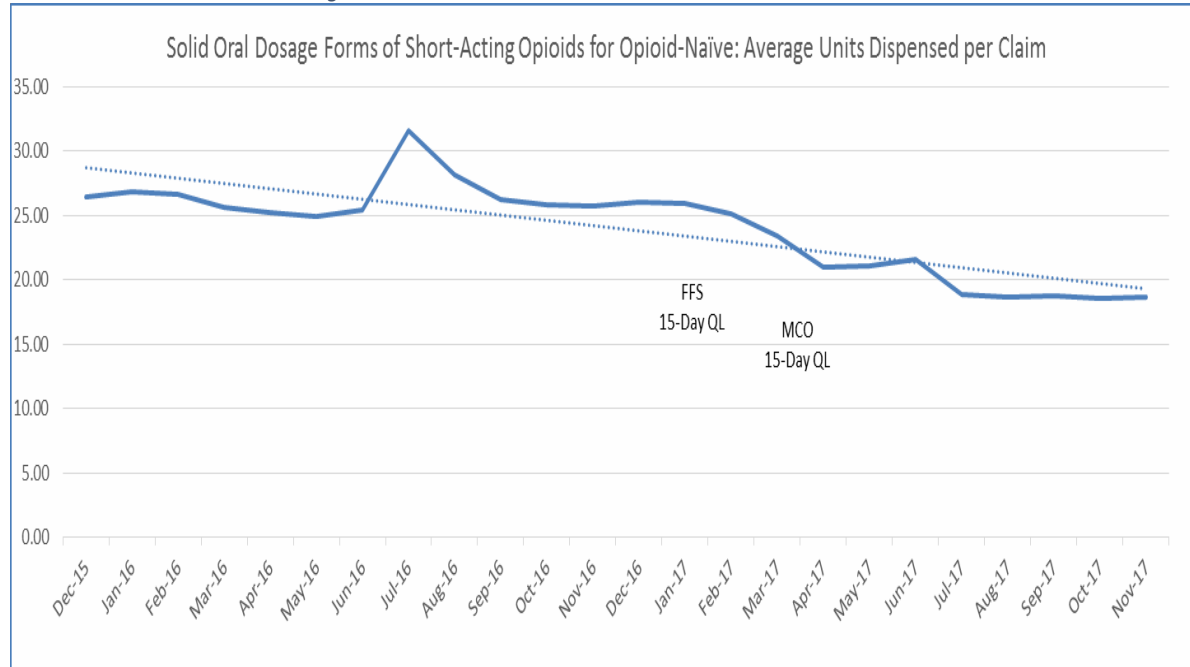
²Ruhm, CJ. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. *American Journal of Preventive Medicine*, Volume 53, Issue 6, 745 - 753

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 (<i>Provider manual: Clinically managed population specific high intensity residential</i>)	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
Section 1115 Waiver Implementation Plan - REVISED | January 26, 2018

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	CAHS D	SCLHS A	AAHS D	ImCal	CLHS D	NLHS D	NDHS A	FPHS A	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		
		BEAUREGARD	3
		BIENVILLE	0
ACADIA	7	BOSSIER	9
ALLEN	2	CADDO	40
ASCENSION	13	CALCASIEU	53
ASSUMPTION	0	CALDWELL	0
AVOYELLES	6	CAMERON	1

CATAHOULA	0	POINTE COUPE	1
CLAIBORNE	2	RAPIDES	27
CONCORDIA	3	RED RIVER	1
DESOTO	1	RICHLAND	2
EAST BATON ROUGE	72	SABINE	2
EAST CARROLL	3	ST. BERNARD	3
EAST FELICIANA	3	ST. CHARLES	6
EVANGELINE	6	ST. HELENA	0
FRANKLIN	2	ST. JAMES	0
GRANT	1	ST. JOHN	3
IBERIA	16	ST. LANDRY	12
IBERVILLE	4	ST. MARTIN	2
JACKSON	1	ST. MARY	4
JEFFERSON	95	ST. TAMMANY	45
JEFFERSON DAVIS	0	TANGIPAHOA	26
LAFAYETTE	57	TENSAS	0
LAFOURCHE	17	TERREBONNE	20
LASALLE	2	UNION	4
LINCOLN	6	VERMILION	3
LIVINGSTON	4	VERNON	2
MADISON	1	WASHINGTON	13
MOREHOUSE	2	WEBSTER	7
NATCHITOCHE	2	WEST BATON ROUGE	0
ORLEANS	182	WEST CARROLL	5
OUACHITA	27	WEST FELICIANA	1
Out of State	28	WINN	1
PLAQUEMINES	4		

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.

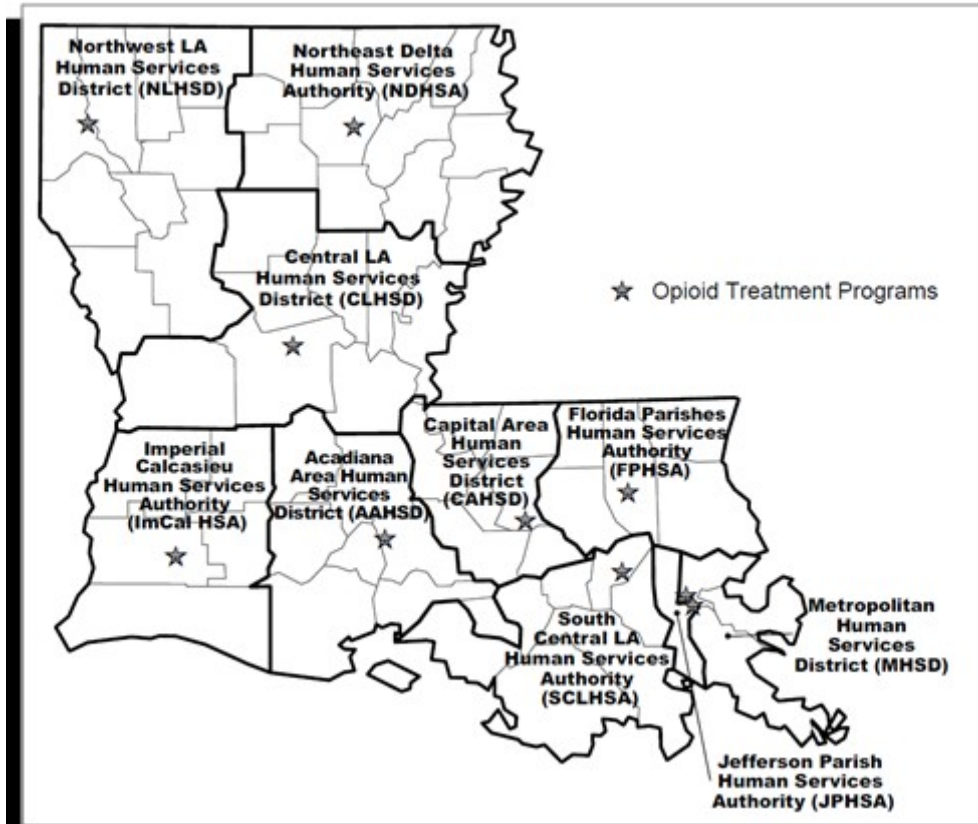
The MCO contract currently specifies geographic access requirements for maximum travel time and /or distance requirements as outlined below:

- 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:

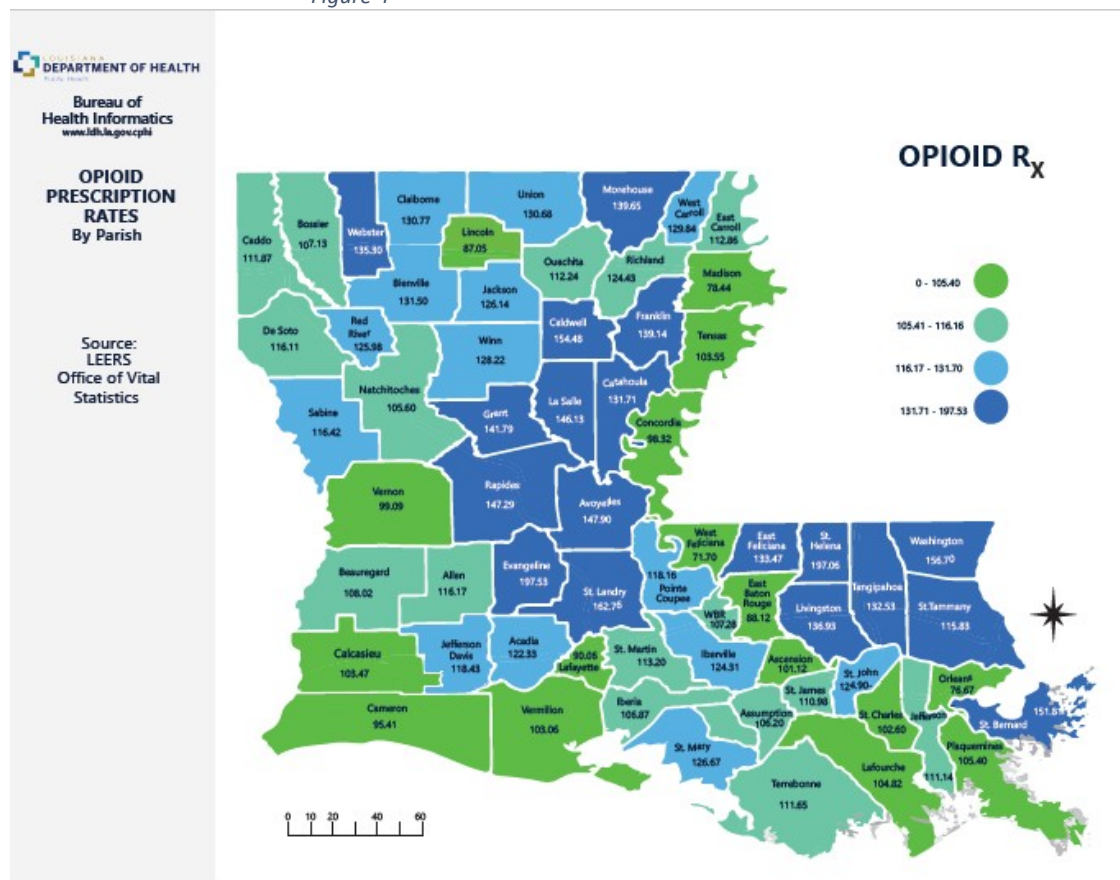
- Pharmacies and other dispensers are required to report their eligible prescription transactions to the program database no later than the next business day following the date of dispensing, instead of the previous seven day allowance.
- Authorized prescribers and dispensers are allowed to appoint delegates 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



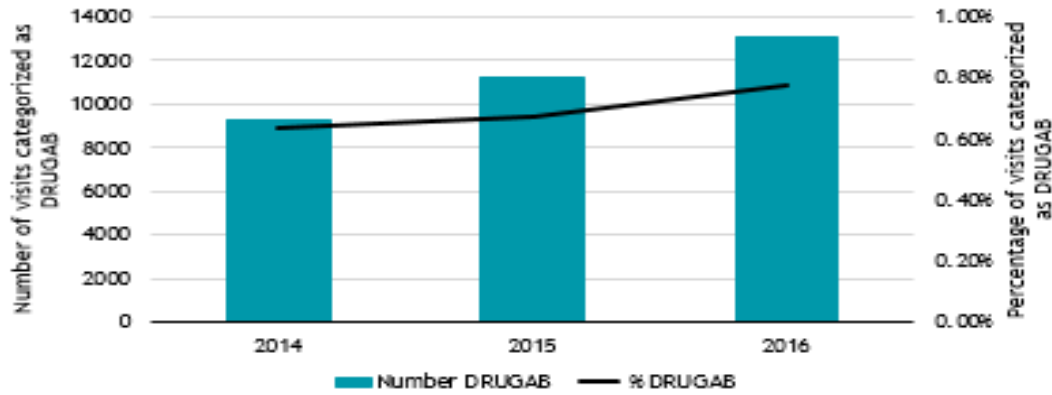
In collaboration with partners across the state, OPH is evaluating all data in relation to opioids in Louisiana. Fact sheets on opioid prescription practices and opioid-related deaths are broken down by parish and provided for the public on the LDH website. Furthermore, OPH is collecting and organizing 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**

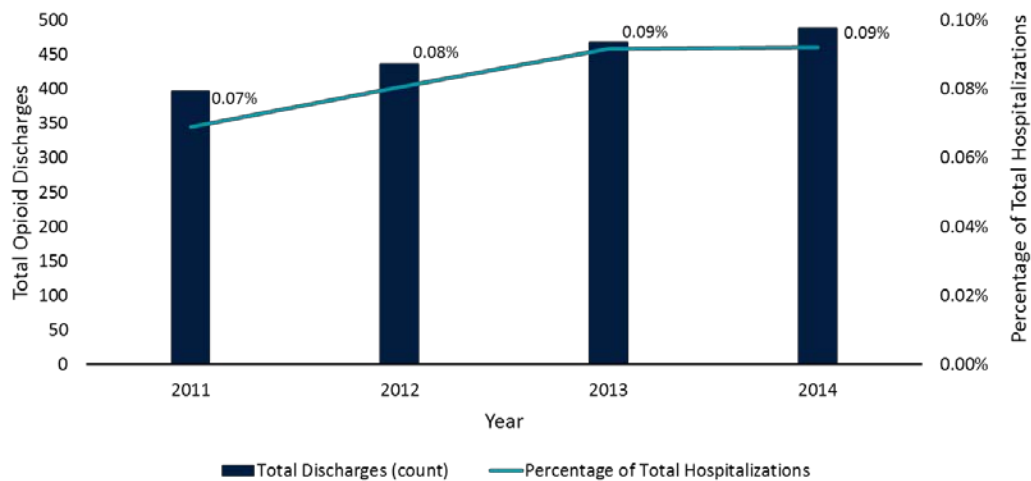
*The syndrome that captures drug overdose visits is called DRUGAB (for "Drug Abuse")

**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
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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**