DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-26-12
Baltimore, Maryland 21244-1850

December 2, 2022

Tara LeBlanc
Medicaid Director
State of Louisiana, Department of Health
Bienville Building
628 North 4th Street
Baton Rouge, LA 70802

Dear Ms. LeBlanc:

The Centers for Medicare & Medicaid Services (CMS) is approving Louisiana's request to extend the demonstration titled "Healthy Louisiana Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) 1115(a) Demonstration" (Project Number 11-W-00311/6), in accordance with section 1115(a) of the Social Security Act (the Act). This approval is effective January 1, 2023, through December 31, 2027. Approval of this demonstration extension request will enable the state to continue to receive federal financial participation (FFP) for state plan services provided to otherwise-eligible Medicaid beneficiaries who are primarily receiving treatment and withdrawal management services for SUD while residing in institutions for mental diseases (IMD).

CMS' approval of the section 1115(a) demonstration is subject to the limitations specified in the expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this demonstration project. The state may deviate from Medicaid and CHIP state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable to expenditures authorized under the demonstration.

Specifically, the demonstration is expected to maintain the continuum of services to treat addiction to opioids and other substances, including services provided to Medicaid enrollees with SUD who are short-term residents in residential and inpatient treatment facilities that meet the definition of an IMD.

In alignment with the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17-003),[1] the state's goals for this demonstration extension period are to continue providing for its beneficiaries access to high quality, evidence-based SUD treatment services in order to help improve or maintain identification, initiation, engagement, adherence to, and retention in treatment; reduce costlier preventable or medically inappropriate utilization of emergency departments through improved access to other continuum of care services; reduce readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; improve or maintain health outcomes; and reduce overdose deaths particularly those due to opioids.

The state's Interim Evaluation Report for the prior demonstration approval period presented preliminary evidence that the demonstration is having a small but positive impact on SUD beneficiaries related to health care access, utilization, and quality of care.[2] The report evaluated the demonstration from its implementation through the end of 2020, though in the context of the COVID-19 Public Health Emergency (PHE), it was difficult to draw conclusive findings for the effects of the demonstration on several outcomes. Nevertheless, the report showed, for example, that the demonstration resulted in an increase in the use of residential and inpatient services and a discernible increase in the use of Medication-Assisted Treatment (MAT). The distinct improvement in the share of beneficiaries receiving MAT happened at a pace faster than the growth in the number of providers and providers per capita over this duration. This indicates that the demonstration has been effective at educating abstinence-based residential providers on the benefits of MAT and encouraging physicians and other qualified providers to become certified dispensers to increase the use of MAT.

Additionally, inpatient stays for OUD/SUD treatment, which were increasing prior to the intervention, have leveled off post-intervention, though there was no change in the rate of emergency department visits post-intervention, indicating a modest impact on reduction of medically inappropriate care. The relatively limited movement on other measures, particularly care coordination, likely was the result of the relatively short time period post-intervention, taking into consideration the care interruptions due to the COVID-19 pandemic and the 2020 hurricane season, which caused particularly devastating impacts in the western region of the state. Overall, the state's ongoing demonstration monitoring and evaluation efforts indicate that the state is making progress toward achieving its demonstration goals.

Budget Neutrality

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstrations are likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's

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

[2] Consistent with the STCs for the Healthy Louisiana OUD/SUD demonstration, the state submitted its draft Interim Evaluation Report for the prior demonstration approval period on December 2021, which was revised on October, 2022. The Interim Evaluation Report will be posted publicly once approved by CMS.

Medicaid costs in that state likely would have been without the demonstration. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" (WOW) costs).

In this extension of the Louisiana SUD demonstration, CMS is including revised STCs, as applicable, that reflect these efforts to achieve the aforementioned balance between fiscal integrity and state innovation. Specifically, CMS is revising the approach to adjusting the budget neutrality calculation in the middle of a demonstration approval period. Historically, CMS has limited its review of state requests for "mid-course" budget neutrality adjustments to situations that necessitate a corrective action plan, in which projected expenditure data indicate a state is likely to exceed its budget neutrality expenditure limit. CMS has updated its approach to mid-course corrections in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (e.g., expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (e.g., unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (e.g., a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

Monitoring and Evaluation

With this extension of the Healthy Louisiana OUD/SUD demonstration, consistent with CMS requirements for section 1115 demonstrations, and as outlined in the STCs, the state is required to continue conducting systematic monitoring and robust evaluation of the demonstration. The state will continue tracking, using quantitative and qualitative data, its progress toward the demonstration's milestones and goals—taking into account the achievements and challenges from the prior approval period. Additionally, the state will develop an Evaluation Design for this demonstration approval period by reframing and refocusing as needed the evaluation hypotheses and research questions to appropriately factor in where it can reasonably expect continued improvements, and where the demonstration's role might be more to help stabilize outcomes. Likewise, the state must revisit its analytic approaches, compared to those used in the prior approval period evaluation activities, to ensure that the evaluation taps into the longer implementation time span to support understanding the demonstration's impact on beneficiary coverage, access to and quality of care, and health outcomes.

Under the STCs, the state is required to contract with an independent evaluator to conduct the evaluation and develop the demonstration's Interim and Summative Evaluation Reports, in alignment with the approved Evaluation Design. The state will also have an independent entity conduct a mid-point assessment of the extension period. The mid-point assessment will provide the state an opportunity to outline any necessary mitigation strategies.

Finally, the state and CMS will work collaboratively such that the state's demonstration monitoring and evaluation efforts accommodate data collection and analyses stratified by key subpopulations of interest—to the extent feasible—to inform a fuller understanding of existing disparities in access, utilization, and health outcomes, as well as how the demonstration might support bridging any such inequities.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(l) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

Section 1115(d)(2)(A) & (C) of the Act further specifies that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposed no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments. 42 CFR § 431.416(d)(2).

During the federal comment period, which took place from May 26, 2022 to June 24, 2022, CMS received three comments, two in support of and one in opposition to this demonstration extension. One comment was from a professional group that supports granting the state's demonstration extension request. The commenter advocates for the multidisciplinary, comprehensive treatment of SUD before, during, and after pregnancy in order to improve maternal health outcomes and reduce maternal health disparities experienced by women of color. Another commenter supports granting the extension, but recommends promoting education and awareness about the transmission of infectious diseases like the human immunodeficiency virus (HIV) associated with injection drug use, incorporating pre-exposure prophylaxis (PrEP) counseling and prescriptions and HIV testing for all individuals with SUD into all substance use demonstrations in order to prevent the transmission of HIV.

The other commenter opposed the demonstration extension for various reasons, including making an argument that the IMD exclusion cannot be waived. Section 1115(a)(2) of the Act grants the Secretary the authority, in the context of a demonstration project under 1115(a), to provide federal matching of state expenditures that would not otherwise be federally matchable under the terms of 1903 of the Act. Specifically, with respect to state expenditures under a

section 1115 "demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid]," expenditures that would "not otherwise" be matchable under section 1903 may "be regarded as expenditures under the State plan or plans approved under such title, or for administration of such State plan or plans . . . as may be appropriate." This "expenditure authority" has been exercised by the Secretary for decades to conduct demonstration projects that provide coverage to individuals or services that could not otherwise be covered under a Medicaid state plan. This has allowed the Secretary to expand eligibility for benefits to individuals who would not otherwise be eligible, and for services that would not otherwise be covered. This interpretation has been upheld in court as a valid exercise of the Secretary's demonstration authority under section 1115. For example, federal courts have upheld demonstration projects that covered individuals under section 1115(a)(2) who would not otherwise be eligible for coverage, and imposed cost-sharing obligations on these individuals that would not be permissible under the Medicaid statute.[3]

The commenter also expressed concerns that authorizing FFP for services provided in IMDs could risk diverting resources away from community-based services and would undermine community integration efforts for beneficiaries with SUD. Nothing in this demonstration requires that services be provided to any individual in any particular setting, nor does it limit the availability of community-based settings. Findings from the demonstration's prior period interim evaluation indicate that the demonstration resulted in an increase in the use of residential services and MAT, while also facilitating modest improvements in reducing medically inappropriate care. Furthermore, survey data analyses show that the majority of inpatient facilities provided information to patients about, or referred them to, other services at discharge, most frequently, medical and housing services.

The commenter expressed concerns that Louisiana has not presented a valid hypothesis that would justify approval. Louisiana's prior approval period Evaluation Design, approved by CMS, included a comprehensive set of evaluation hypotheses and research questions, in alignment with the SUD SMDL #17-003 and CMS's SUD evaluation design guidance.[4,5,6] Per the demonstration STCs, and as is consistent with section 1115 demonstrations, Louisiana is required to submit an Evaluation Design for the demonstration extension period, and the expectations for a rigorous evaluation including robust hypotheses are outlined in the STCs.

The commenter also shared concerns about how long the SUD demonstrations are approved. As explained in the SUD SMDL, CMS has determined that these demonstrations promote the objectives of Medicaid and states, like Louisiana, should have the opportunity to extend the

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[3] *Spry v. Thompson*, 487 F.3d 1272 (9th Cir. 2007); *Wood v. Betlach*, No. CV-12-08098, 2013 WL 3871414 (D. Ariz. July 26, 2013).

[4] Available at: https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf.

[5] CMS's evaluation design guidance for SUD and other policies are available here: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html.

[6] Louisiana's prior approval period Evaluation Design is available here: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/la/oud-sud-demo/la-healthy-oud-sud-sud-eval-dsgn-appvl-ltr-20190619.pdf.

demonstrations, subject to conducting systematic robust monitoring and a comprehensive evaluation of its demonstrations per requirements set in the STCs.

Finally, the commenter also raised concerns about the length of stay (LOS) in IMDs. Any state with a section 1115 SUD demonstration is expected to meet a statewide average length of stay (ALOS) of 30 days or less in residential treatment setting over the duration of the demonstration approval period. Louisiana's ALOS ranged between 14.4 and 16.6 days during the first four years of the prior demonstration approval period.[7] Per the STCs, the state is required to continue monitoring the ALOS in IMDs throughout the course of the demonstration extension approval period, and in the event the metric trend indicates any risks for the state to not meet the ALOS target over the extension approval period, it is required to develop careful mitigation strategies in its mid-point assessment.

After carefully reviewing the demonstration proposal and the public comments submitted during the federal comment period, CMS has concluded that the demonstration is likely to assist in promoting the objectives of Medicaid as it is expected to increase beneficiary access to high-quality SUD care.

Other Information

CMS's approval of this demonstration project is contingent upon compliance with the enclosed expenditure authority and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

The project officer for this demonstration is Ms. Kathleen O'Malley. She is available to answer any questions concerning your section 1115 demonstration. Ms. O'Malley's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Kathleen.OMalley@cms.hhs.gov

[7] Louisiana's SUD Quarterly and Annual Monitoring Reports for demonstration years 1 – 4.

We appreciate your state's commitment to improving the health of people in Louisiana, and we look forward to partnering with you on the Healthy Louisiana Opioid Use Disorder/Substance Use Disorder section 1115(a) demonstration. If you have questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services at (410)786-9686.

Sincerely,

Daniel Tsai
Deputy Administrator and Director

Enclosure

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

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

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

AWARDEE: **Louisiana Department of Health**

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

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

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

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

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

AWARDEE: **Louisiana Department of Health**

1. PREFACE

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

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

The STCs have been arranged into the following subject areas:

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

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

Attachment A: Developing the Evaluation Design

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

2. PROGRAM DESCRIPTION AND OBJECTIVES

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

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

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

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

3. GENERAL PROGRAM REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. ELIGIBILITY AND ENROLLMENT

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

5. DEMONSTRATION PROGRAM AND BENEFITS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUD program demonstration approval.

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

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

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

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

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

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

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

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

[3] *Ibid*.

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

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

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

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

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

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

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

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

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

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

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

6. COST SHARING

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

7. DELIVERY SYSTEM

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

8. MONITORING AND REPORTING REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 1: Master MEG Chart

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject

[5] Per 42 CFR § 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and § 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS' current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

9.16. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. Contents of Request and Process. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 9.16.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b. Types of Allowable Changes. Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:

i. Provider rate increases that are anticipated to further strengthen access to care;

ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;

iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;

iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;

v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;

vi. High cost innovative medical treatments that states are required to cover; or,

vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. Budget Neutrality Update. The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

10. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

10.1. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of one or more Hypothetical Budget Neutrality Tests, as described below. CMS' assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

10.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1, Master MEG Chart and Table 2, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

10.3. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration

expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

10.4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of one Hypothetical Budget Neutrality Test. Any excess spending under the Hypothetical Budget Neutrality Test must be returned to CMS.

10.5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

10.6. **Hypothetical Budget Neutrality Test 1: SUD IMD.** The table below identifies the MEG that is used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit.

Table 4: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg	WOW Only, WW Only, or Both	Base Year	Trend Rate	DY 6	DY 7	DY 8	DY 9	DY 10
SUD IMD	PC	Both	2020	5.5%	$810.70	$855.29	$902.33	$951.96	$1,004.32

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

reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

10.8. **Corrective Action Plan.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 5: Budget Neutrality Test Corrective Action Plan Calculation		
Demonstration Year	**Cumulative Target Definition**	**Percentage**
DY 6	Cumulative budget neutrality limit plus:	2.0 percent
DY 6 through DY 7	Cumulative budget neutrality limit plus:	1.5 percent
DY 6 through DY 8	Cumulative budget neutrality limit plus:	1.0 percent
DY 6 through DY 9	Cumulative budget neutrality limit plus:	0.5 percent
DY 6 through DY 10	Cumulative budget neutrality limit plus:	0.0 percent

11. EVALUATION OF THE DEMONSTRATION

11.1. **Cooperation with Federal Evaluators.** As required under 42 CFR § 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they will make such data available for the federal evaluation as is required under 42 CFR § 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.1.

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

11.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these

STCs, CMS' evaluation design guidance for SUD, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration evaluations. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 8.6.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS' approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

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

11.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or geography)—to the extent feasible—to

inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

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

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

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

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

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.

d. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.

e. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs.

11.8. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs, and in alignment with the approved Evaluation Design.

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

b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

11.9. **Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

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

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

11.12. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

12. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date	Deliverable	STC
No later than 30 calendar days of approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
No later than 150 calendar days of approval date	SUD Monitoring Protocol	STC 8.5
No later than 60 days after receipt of CMS approval	Revised Monitoring Protocol	STC 8.5
No later than 180 calendar days after approval date	Draft Evaluation Design	STC 11.3
No later than 60 calendar days after receipt of CMS comments	Revised Draft Evaluation Design	STC 11.4
No later than 30 calendar days after CMS approval	Approved Evaluation Design published to state's website	STC 11.4
No later than 60 calendar days after the end of the third demonstration year of the extension (March 1, 2026)	Mid-Point Assessment Report	STC 8.7
No later than December 31, 2026, or with extension application	Draft Interim Evaluation Report	STC 11.7
No later than 60 calendar days after receipt of CMS comments	Final Interim Evaluation Report	STC 11.7.d
No later than 18 months after the end of the demonstration (June 30, 2029)	Draft Summative Evaluation Report	STC 11.8
No later than 60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 11.8.b
No later than 120 days after the end of the demonstration	Draft Close-Out Report	STC 8.9
No later than 30 days after receipt of CMS comments	Revised Close-Out Report	STC 8.9.e
Monthly		
Monthly Deliverables	Monitoring Calls	STC 8.10

Quarterly		
Quarterly Deliverables Due no later than 60 days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 8.6
	Quarterly (CMS-64) Expenditure Reports	STC 9.2
	Quarterly Budget Neutrality Reports	STC 9.13
Annually		
Annual Deliverables - Due 90 days after end of each 4th quarter	Annual Monitoring Reports (including Q4 Expenditure Report and Budget Neutrality Report)	STC 8.6
No later than 6 months after the demonstration's implementation and annually thereafter	Post Award Forum	STC 8.11

Attachment A
Developing the Evaluation Design

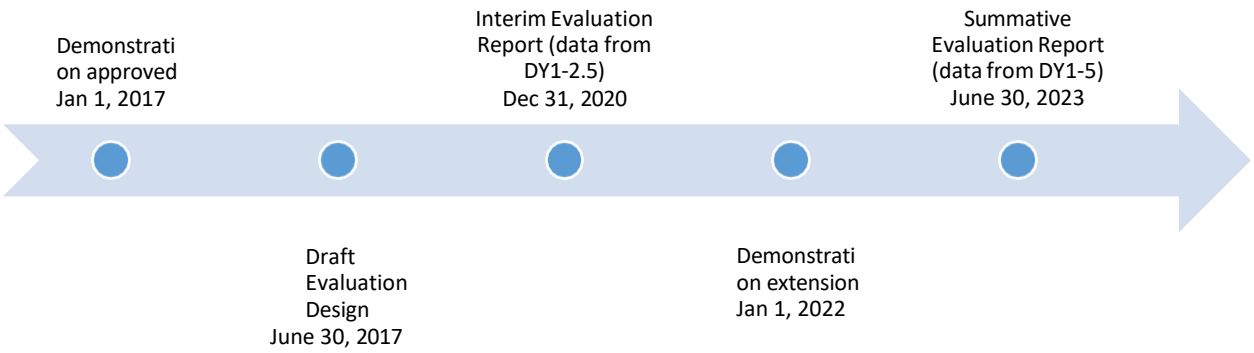
Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future.

While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 30 calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration- monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

The state should attempt to involve partners who understand the cultural context in developing an evaluation approach and interpreting findings. Such partners may include community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration. For example, the state's Request for Proposal for an independent evaluator could encourage research teams to partner with impacted groups.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. The roadmap begins with the stated goals for the demonstration, followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

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

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.

4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.
4. Include a Logic Model or Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the goal, the primary drivers that contribute directly to achieving the goal, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.
5. Include implementation evaluation questions to inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate. The evaluation approach should also consider principles of equitable evaluations, and involve partners—such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the

cultural context—in developing an evaluation approach.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure.

Specifically, this section establishes:

1. *Methodological Design* – Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.

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

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

4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

   Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality

Forum. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

5. *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.

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

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
    b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
    c. Include a discussion of how propensity score matching and difference-in- differences designs may be used to adjust for differences in comparison populations over time, if applicable.
    d. Consider the application of sensitivity analyses, as appropriate.

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

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -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 more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review.

CMS also recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

1. When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).

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

E. Attachments

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

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

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

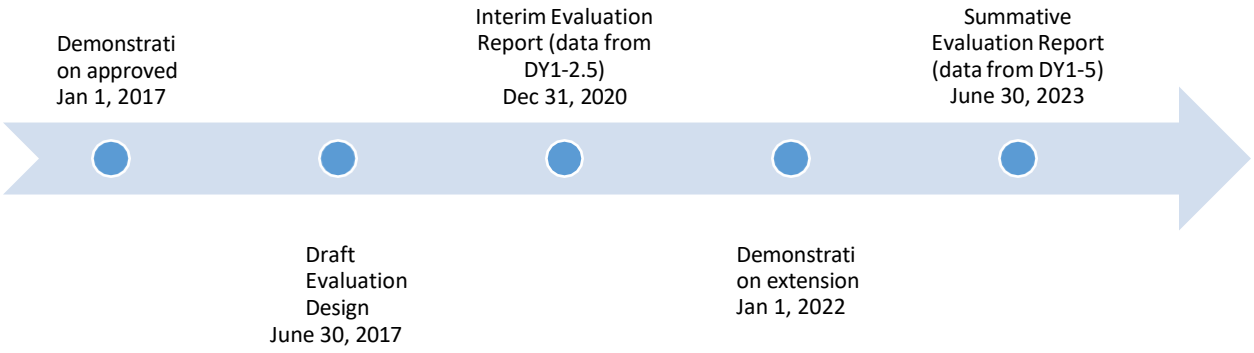
Attachment B
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). The already-approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When submitting an application for extension, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115- demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state- monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

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

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

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.
3. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
4. The inclusion of a Logic Model or Driver Diagram in the Evaluation Report is highly

encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

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

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what was measured and how, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Methodological Design* – Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
2. *Focus and Comparison Populations* – Describe the focus and comparison populations, describing inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected.
4. *Evaluation Measures* – List the measures used to evaluate the demonstration and their respective measure stewards.
5. *Data Sources* – Explain from where the data were obtained, and efforts to validate and clean the data.
6. *Analytic Methods* – Identify specific statistical testing which was undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

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

F. Results – In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include

findings from the statistical tests conducted.

G. Conclusions – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
    a. If the state did not fully achieve its intended goals, why not?
    b. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long-range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

I. Lessons Learned and Recommendations – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:

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

Attachment C:
Substance Use Disorder (SUD) Implementation Plan
Originally Approved on February 1, 2018

Introduction

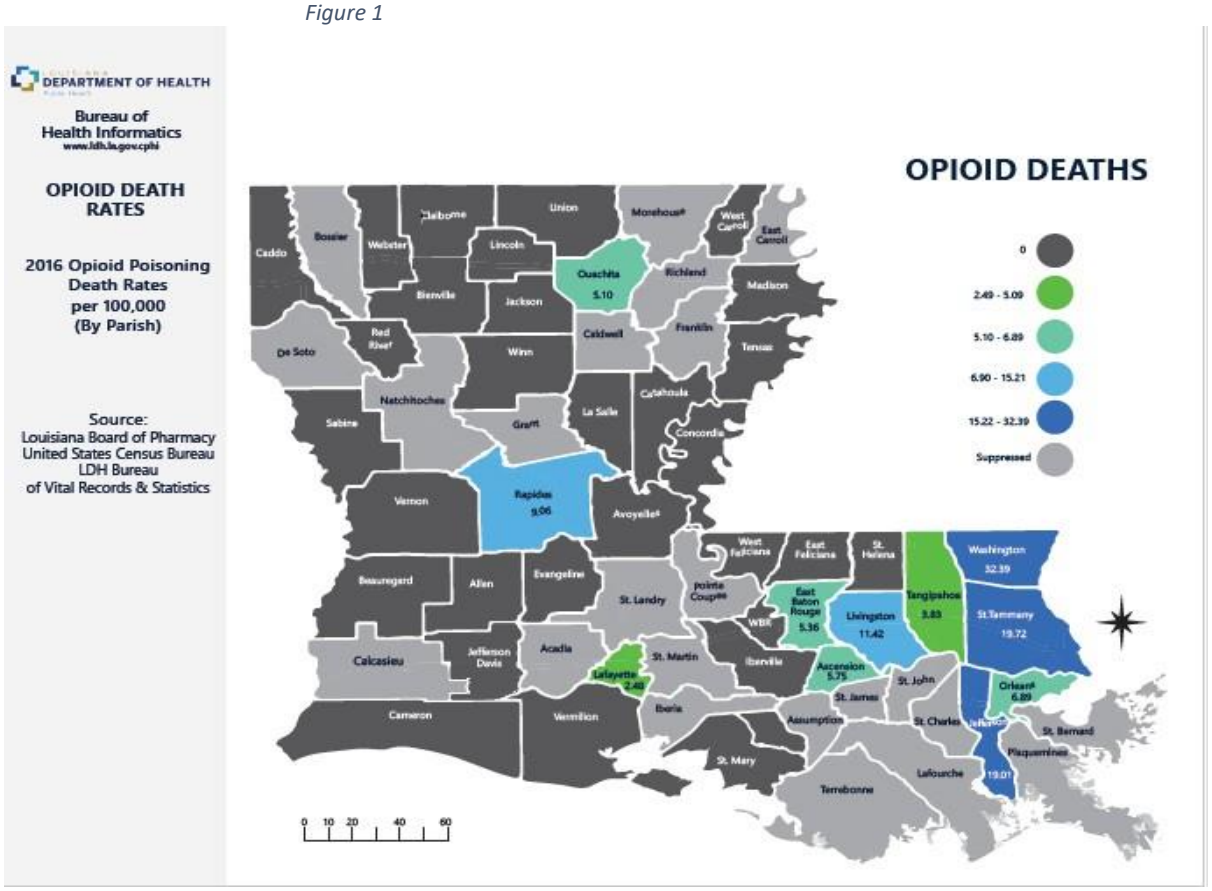
Nationwide, deaths due to opioids continue to increase, are under-reported, and have great variability in the specificity of how they are recorded across the country.[1][2] Contributing factors to the difficulty of verifying these opioid-related deaths are that a specific drug or cause of death may not be identified or reported, multiple drugs may be listed instead of one, or the primary cause of death may be listed with another diagnosis such as anoxic brain injury or congestive heart failure. From 1999 to 2015, the number of overdose deaths involving opioids in the United States has quadrupled.

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

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

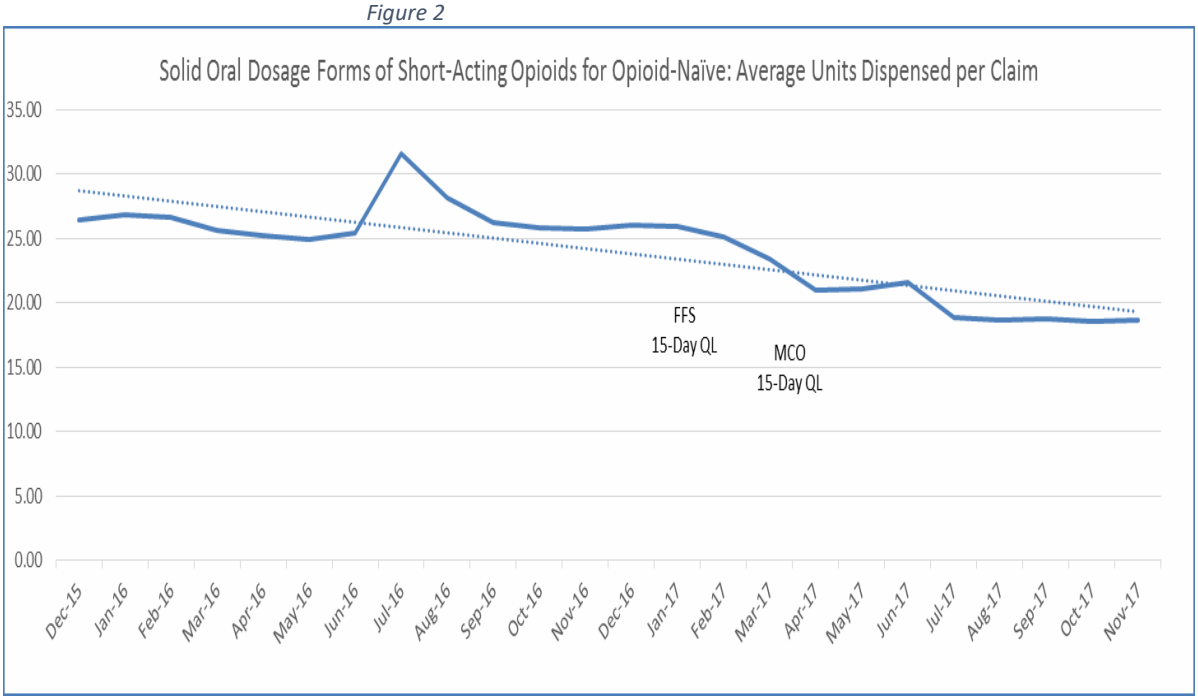
[2] Ruhm, CJ. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. American Journal of Preventive Medicine, Volume 53, Issue 6, 745 - 753

Figure 1



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

Figure 2



Program Overview

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

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

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

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

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

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

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

In February of 2015, LDH implemented its second-generation managed care program for physical and basic behavioral health services, including full-risk managed care organizations only. Later that year, the Office of Behavioral Health and Medicaid worked collaboratively to integrate specialized behavioral health services, previously provided separately by the LBHP, into the benefits coordinated by the Healthy Louisiana Managed

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

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

Specifications:

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

Current State

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

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

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

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

- Buprenorphine
- Buprenorphine-Naloxone [Suboxone]
- Buprenorphine-Naloxone [Bunavail]
- Buprenorphine-Naloxone [Zubsolv]
- Buprenorphine Implant [Probuphine]
- Suboxone Film

- Naloxone Injectable
- Naloxone Nasal Spray [Narcan]
- Naltrexone Tab
- Naltrexone ER Injectable [Vivitrol]

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

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

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

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

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

Future State

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

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

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

Summary of Actions Needed:

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

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

Specifications:

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

Current State

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

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

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

The State Plan establishes coverage using the ASAM levels of care and as such, service authorization criteria must meet this same standard in each MCO's policies and procedures. These policies are reviewed and

approved by LDH, but may warrant additional scrutiny as the program evolves. Additionally, the MCOs are required to take steps to ensure adoption of the clinical practice guidelines by specialized behavioral healthcare providers, and to measure compliance with the guidelines. The MCOs are contractually encouraged to employ substantive provider motivational incentive strategies, such as financial and non-financial incentives, to improve compliance. Additionally, the MCOs are required to perform record reviews. LDH is currently developing an audit tool for record review, including screening and assessments of SUD services, to collect additional data on providers in order to ensure that interventions are appropriate.

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

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

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

Future State

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

Summary of Actions Needed

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

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

Specifications:

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

Current State

Louisiana has established provider qualifications requirements, based on ASAM criteria, for SUD residential treatment providers through licensure standards, managed care contract requirements, and managed care provider manuals. Providers contracting to provide Medicaid services as part of the MCO networks are held to certain standards in their individual provider contracts and are required to be credentialed and accredited prior to participating in the network.

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

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

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

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

Additionally, the Food and Drug Administration (FDA) approved a risk evaluation and mitigation strategy (REMS) on July 9, 2012, for extended release long acting opioid medications. The Collaborative on REMS Education has developed tools, resources, and outcomes to meet the FDA requirements. The Louisiana State

Medical Society (LSMS) received a REM grant to facilitate opioid educational offerings throughout the state. LSMS partnered with the in collaboration with the East Baton Rouge Parish Coroner (current head of the Louisiana State Coroner's Association) to perform an opioid educational seminar to physicians, nurses, behavioral health providers and pharmacists. An educational event was held September 21, 2016, and was well received within the healthcare community. The grant facilitated a second educational offering in Shreveport, LA on November 11, 2016. The opioid educational offering solidified a relationship with LSMS which facilitated educating the provider community statewide utilizing national best practices and the CMS guidelines. Additional trainings will be hosted in collaboration with LSMS and providers participating in the Louisiana Opioid STR Initiative will be invited to attend.

Future State

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

The current use of abstinence-based care models will require an increased level of education and guidance necessary to facilitate MAT services in collaboration with those facilities in the future. In addition to guidance and education by a board-certified psychiatrist and addictionologist, Substance Abuse and Mental Health Services Administration (SAMHSA) materials will be utilized to provide education to these facilities. Examples of these materials include *Methadone Treatment for Pregnant Women; SAMHSA Opioid Overdose Prevention Toolkit;* and *An Introduction to Extended Release Injectable Naltrexone for the Treatment of People with Opioid Dependence*. Board certified psychiatrists and addictionologists will be used to assist with assessment protocols necessary for pregnant women within residential programs.

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

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

for Opioid Addiction in Opioid Treatment Programs.

Summary of Actions Needed

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

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

Specifications:

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

Current State

LDH currently monitors provider sufficiency through MCO reporting. MCOs submit network adequacy reports to LDH on a quarterly basis inclusive of counts of available network providers by levels of care and by provider type. Current ASAM levels of care as reported by the Healthy Louisiana Managed Care Organizations (MCOs) via quarterly network provider reports indicate an average of the following numbers of providers by Louisiana Department of Health (LDH) administrative region.

Table 1

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

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

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

Table 2

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

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

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

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

The managed care organizations are tasked with monitoring provider capacity of their networks. Each MCO develops and maintains a provider Network Development and Management Plan which ensures that the provision of core benefits and services will occur. It includes the MCO's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services. The plan

demonstrates access to behavioral health services, identifies gaps in network and describes the process to assure services are delivered. The plans provide GEO mapping of providers to geographically demonstrate network capacity. The MCOs have policies detailing how the MCO will provide or arrange for medically necessary covered services should the network become temporarily insufficient and will monitor the adequacy, accessibility and availability of its provider network to meet the needs of its members. MCO Network Development and Management Plans are updated at least annually or more often as needed to reflect material changes in network status.

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

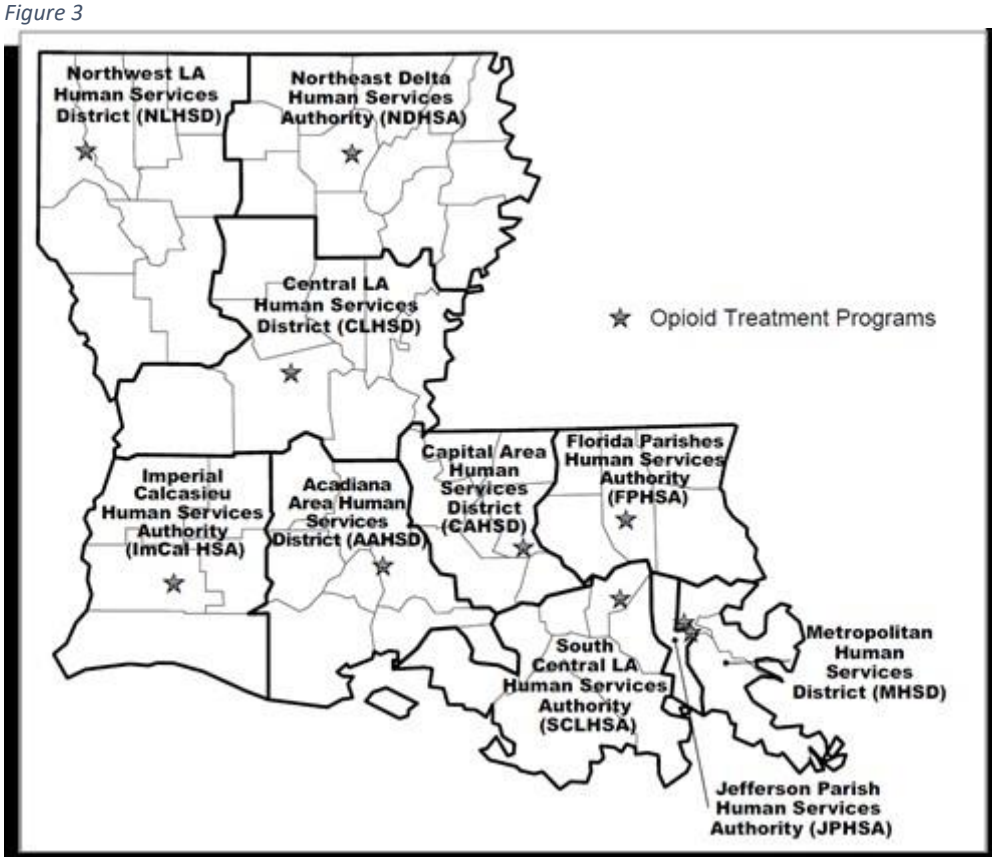
- Travel distance to behavioral health specialists [i.e., psychologists, medical psychologists, advanced practice registered nurses (APRN) practicing as a Clinical Nurse Specialist (CNS) in mental health, or Licensed Clinical Social Workers (LCSWs)] and to psychiatrists for members living in rural parishes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

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

There is one Opioid Treatment Program (OTP) located in each Louisiana Department of Health region, called Local Governing Entity (LGE) regions (see Figure 3). All ten OTPs are privately owned and have historically received no state or federal funding to support MAT, with the exception of Behavioral Health Group (BHG) located in New Orleans, which is currently receiving funds through the recent award of the Medication-Assisted Treatment Prescription Drug and Opioid Addiction (MAT-PDOA) grant. Through the Louisiana Opioid State Targeted Response (STR) grant, funding was recently allocated to the remaining nine OTPs who are not receiving funding to support MAT for under- and uninsured individuals diagnosed with OUD. Current capacity of the 10 OTP sites is approximately 5,000. However, OTP sites have flexibility and capacity, and census is a

moving target. Capacity is based upon the current census and LA regulations which indicate 75:1 patient/counselor ratio. Most of the clinics utilize 50:1 ratio and if they receive additional admits they would hire additional counselors to provide services. LDH has observed that at any single point in time over the last two years, no OTP site was at full capacity and total census averaged approximately 3800 to 4000 patients. However, it is anticipated that use of OTPs will expand if methadone becomes a Medicaid covered service.

Figure 3



Future State

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

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

special registration requirements defined in the Controlled Substances Act.

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

Physicians are also required to complete buprenorphine training to receive their training certificate after completing the Waiver Notification Form. These waiver applications are forwarded to the DEA, which assigns the physician a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the physician's regular DEA registration number. SAMHSA reviews waiver applications within 45 days of receipt. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number. A list of buprenorphine providers can be assessed through SAMHSA website treatment locator.

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

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

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

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

Summary of Actions Needed

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

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

Specifications

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

Current State

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

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

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

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

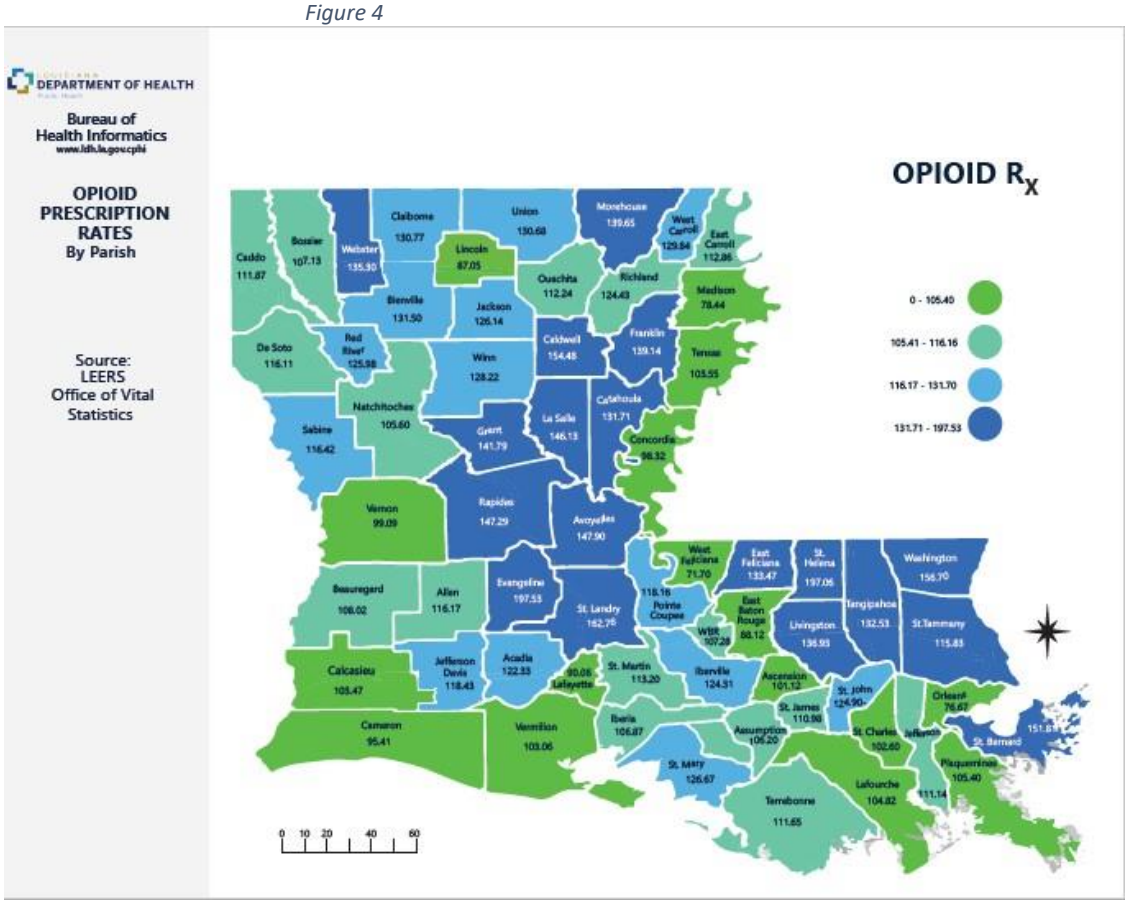
- Prevention: Each LGE is hiring an Educational Outreach Consultant to provide education and awareness activities, dependent upon local needs and targets. A statewide campaign is currently in development to ensure consistent messaging across the state.
- Intervention: OBH is providing distribution of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

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

- Pharmacies and other dispensers are required to report their eligible prescription transactions to the program database no later than the next business day following the date of dispensing, instead of the previous seven day allowance.
- Authorized prescribers and dispensers are allowed to appoint delegates for the purpose of retrieving data from the program's database.
- Prescribers of certain controlled substances for the treatment of certain conditions to access the patient's history in the program database prior to initiating such treatment. The same measure will require pharmacists dispensing certain controlled substances to certain patients to access the patient's history in the program database prior to dispensing such medications.
- The state's controlled substance law was amended to require the automatic issuance of PMP access privileges to all practitioners with prescriptive authority for controlled substances except veterinarians. Another measure amended the PMP law to enable additional categories of authorized users, e.g., medical examiners, substance abuse counselors, and probation and parole officers, as well as judicially supervised specialty courts.

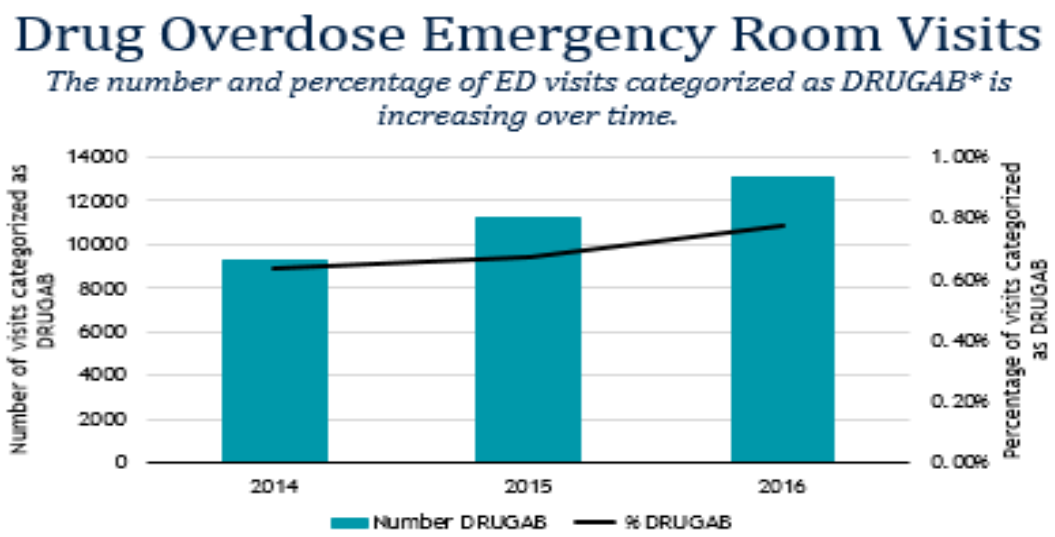
As a result of CDC grants around data surveillance on opioids, the Louisiana Office of Public Health (OPH) has been working in collaboration with the Board of Pharmacy and the PMP to provide data on opioid prescriptions. In 2016, it was found that there were 110 prescriptions per 100 citizens in Louisiana.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

Figure 4



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

Figure 5



*Source: Louisiana Early Event Detection System, 2014-2016***

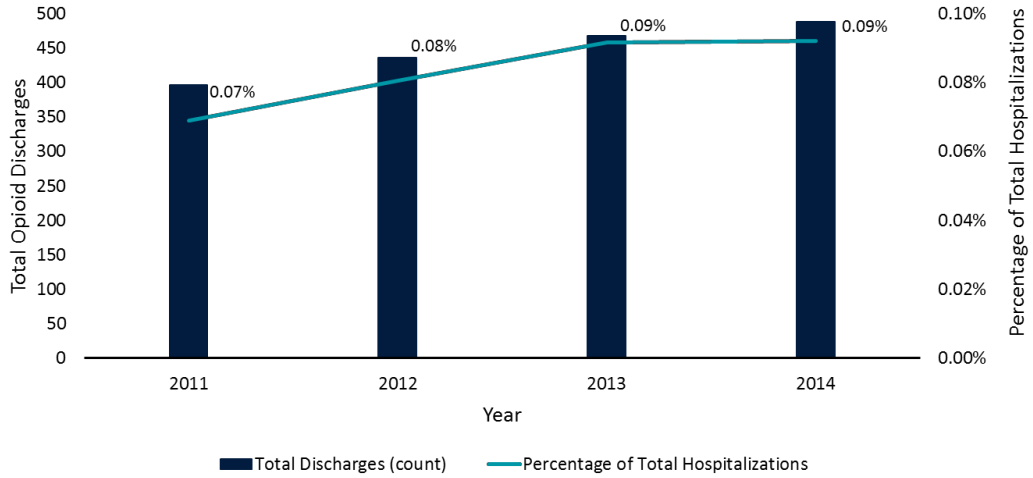
*The syndrome that captures drug overdose visits is called DRUGAB (for "Drug Abuse")

**Emergency Departments (EDs) reporting to LEEDS represent approximately 61% of all EDs in the state of Louisiana. This 61% of EDs cover all 9 Public Health Regions.

Figure 6

The number of opioid-related hospitalizations* increased, but the percentage of overall hospitalizations remained the same (<0.1%)

Produced by the Louisiana Opioid Surveillance Initiative, Bureau of Health Informatics



Source: Louisiana Hospital Inpatient Discharge Database, 2011-2014

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

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

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

response to combat opioid abuse.

- Act 241 (SB 96 by Sen. Ronnie Johns)
  - Provides for access to prescription monitoring information, including medical examiners, coroners, licensed substance abuse or addiction counselors, and probation and parole officers to those who may access prescription monitoring program information in certain circumstances.

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

Future State

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

Summary of Actions Needed

Implementation Action Item	Timeline
Coordinate with stakeholders on establishing required reporting for Naloxone administration.	24 months
Coordinate with Board of Pharmacy to create Medicaid access to monitor prescribing practices of opioids under the PMP.	24 months
Work with Board of Pharmacy to track Naloxone distribution under the	6 months

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

Specification:

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

Current State

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

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

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

Future State

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

Summary of Actions Needed

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

Attachment D:
Reserved for SUD Monitoring Protocol

Attachment E:
Reserved for Evaluation Design