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

**State Demonstrations Group**

June 25, 2025

Todd Richardson
Director
P.O. Box 6500
Jefferson City, MO 65102-6500

Dear Director Richardson:

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

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

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

## Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Missouri Substance Use Disorder & Serious Mental Illness Demonstration (Project Number 11-W-00411/7) demonstration.

*Reporting Cadence and Due Date*

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

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

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

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

*Structured Monitoring Report Template*

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

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

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

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

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

*Demonstration Monitoring Calls*

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

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

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

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

Sincerely,

[redacted]

Karen LLanos
Director

Enclosure
cc: Rhonda Gray, State Monitoring Lead, Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES**
**SPECIAL TERMS AND CONDITIONS**

**NUMBER:** **11-W-00411/7**

**TITLE:** **Missouri Substance Use Disorder & Serious Mental Illness**

**AWARDEE:** **Missouri HealthNet Division**

## 1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Missouri Substance Use Disorder & Serious Mental Illness" (hereinafter "Missouri SMI & SUD") section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Missouri Healthnet Division (MHD) (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. There 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 December 6, 2023, through December 31, 2028
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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.

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|---|---|
| Attachment A: | Developing the Evaluation Design |
| Attachment B: | Preparing the Interim and Summative Evaluation Reports |
| Attachment C: | SUD Implementation Plan (Approved) |
| Attachment D: | SUD Monitoring Protocol (Reserved) |
| Attachment E: | SMI Implementation Plan (Approved) |
| Attachment F: | SMI Monitoring Protocol (Reserved) |
| Attachment G: | Evaluation Design (Reserved) |

## 2. PROGRAM DESCRIPTION AND OBJECTIVES

*Serious Mental Illness (SMI) Program*

This section 1115(a) demonstration program was originally approved on December 6, 2023. This program enables the state to provide Medicaid state plan services to eligible individuals in institutions for mental diseases (IMDs) ages 21-64 with a serious mental illness (SMI).

The goal of this program is to reduce utilization and lengths of stays (LOS) in emergency departments (EDs) for Medicaid beneficiaries with a SMI. This demonstration seeks to improve availability of crisis stabilization services and improve access to community-based services for beneficiaries with SMI as well as improve care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. Overall, this demonstration aims to reduce preventable readmissions to acute care hospitals and residential setting.

*Substance Use Disorder (SUD) Program*

This section 1115(a) demonstration program was originally approved on December 6, 2023. This program enables the state to provide medically necessary residential substance use disorder (SUD) services in facilities that qualify as an institution for mental disease (IMD).

The goal of the SUD program is to increase rates of identification, initiation, and engagement for individuals in treatment, increase adherence to and retention for individuals in treatment, reduce overdose deaths, reduce utilization of EDs, 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 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, Regulations 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.**

3.4.1. 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.

3.4.2. 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:

3.7.1. 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;

3.7.2. 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;

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

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

3.7.5. 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.

3.9.1. 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 ow the state considered the comments received when developing the revised transition and phase-out plan.

3.9.2. 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.

3.9.3. 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.

3.9.4. 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 §435.916(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 § 435.12.00(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.

3.9.5. 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).

3.9.6. 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.

3.9.7. 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 associates 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 system; 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.

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 services 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.

4.1.1. **Missouri SUD Program**: The SUD demonstration program will provide services to Medicaid enrollees ages 12-64 who are eligible for full Medicaid benefits.

4.1.1.1. Medicaid eligibility groups outlined in the table below received limited Medicaid benefits only and will be ineligible for the SUD demonstration program.

4.1.1.1.1. Medicaid Groups ineligible for the SUD Demonstration Program Chart.

| Eligibility Group Name |
|---|
| Limited Services Available to Certain Aliens |
| Qualified Medicare Beneficiaries (QMB) |
| Specified Low Income Medicare Beneficiaries (SLMB) |
| Qualified Individual (QI) Program |
| Qualified Disabled Working Individual (QDWI) Program |
| Presumptively Eligible Pregnant Women |

**Missouri SMI Demonstration Program:** The SMI demonstration program will provide services to Medicaid enrollees eligible for full Medicaid coverage between the ages of 21-64.

4.1.1.2. Medicaid eligibility groups outlined in the table below received limited Medicaid benefits only and will be ineligible for the SMI demonstration program.

4.1.1.2.1. Medicaid Groups ineligible for the SMI Demonstration Program Chart.

| Eligibility Group Name |
|---|
| Limited Services Available to Certain Aliens |
| Qualified Medicare Beneficiaries (QMB) |
| Specified Low Income Medicare Beneficiaries (SLMB) |
| Qualified Individual (QI) Program |
| Qualified Disabled Working Individual (QDWI) Program |
| Presumptively Eligible Pregnant Women |

## 5. DEMONSTRATION PROGRAM AND BENEFITS

5.1. **Substance Use Disorder Program Benefits**: Effective Upon CMS' approval of the SUD implementation plan the demonstration benefit package for Missouri Medicaid recipients will include SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Missouri Medicaid recipients residing in IMDs under terms of this demonstration for coverage of medical assistance, including 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 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 December 6, 2023 – December 31, 2028, remains in effect for the approval period from December 6, 2023 through December 31, 2028, and is affixed to the STCs as Attachment C. 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 can result 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.

5.2.1. 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 SUD program demonstration approval;

5.2.2. 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 SUD program demonstration approval.

5.2.3. 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;

5.2.4. Use of Nationally Recognized SUD-Specific Program Standards to set Provider Qualifications for Residential Treatment Facilities: Currently, the Missouri Department of Mental Health (DMH) maintains certification requirements for residential providers through the program reform, there providers will be required to enroll as Medicaid providers in order to receive reimbursement for the newly added Medicaid residential services. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, fee-for-service (FFS) contracts or credentialing, 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 SUD/OUD program demonstration approval;

5.2.5. 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;

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

5.2.7. Sufficient Provider Capacity at Each Level of Care Including MAT 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;

5.2.8. 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 (and other opioid antagonists);

5.2.9. SUD Health IT Plan: Implementation of the milestones and metrics as detailed in STC 5.3; and

5.2.10. 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 and SMI Health Information Technology Plan ("Health IT Plan")**. The SUD and SMI Health IT Plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003 and #18-011, respectively, states must submit to CMS the applicable Health IT Plans, to be included as sections of the associated Implementation Plans (See STC 5.2 & STC 5.6), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type (SUD and SMI).

The Health IT Plan should describe how technology can support outcomes through care coordination; linkages to public health and prescription drug monitoring programs; establish data and reporting structure to monitor outcomes and support data driven interventions. Such technology should, per 42 CFR § 433.112(b), use open interfaces and exposed application programming interfaces and ensure alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 42 CFR part 170, subpart B.

5.3.1. The state must include in its Monitoring Protocols (see STCs 5.2 and 5.3 an approach to monitoring its SUD and SMI Health IT Plan which will include performance metrics to be approved in advance by CMS.

5.3.2. The state must monitor progress, each Demonstration Year (DY), on the implementation of its SUD and SMI Health IT Plan in relationship to its milestones and timelines – and report on its progress to CMS in an addendum to its Annual Report (see STC 8.6).

5.3.3. As applicable, the state should advance the standards identified in the "Interoperability Standards Advisory – Best Available Standards and Implementation Specifications" (ISA) [1] in developing and implementing the state's SUD and SMI Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

5.3.4. Where there are opportunities at the state- and provider-level (up to and including usage in managed care organization (MCO) or accountable care organization (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 no other compelling state interest.

5.3.5. 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.

5.3.6. Components of the Health IT Plan include:

[1] Available at: https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf

5.3.6.1. The Health IT Plan must describe the state's alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP).[2]

5.3.6.2. The Health IT Plan must address how the state's Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[3] States should favor procurement strategies that incorporate qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in RX Check for Interstate data sharing.

5.3.6.3. The Health IT Plan will describe how technology will support SUD prevention and treatment outcomes described by the demonstration.

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

5.3.6.4.1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).

5.3.6.4.2. 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.

5.3.6.4.3. 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 interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

[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*.

5.3.6.4.4. States should review the Office of the National Coordinator's Interoperability Standards Advisory (https://www.healthit.giv/isa/) for information on appropriate standards which may not be required per 45 CFR part 170, subpart B for enhanced funding, but still should be considered industry standards per 42 CFR §433.112(b)(12)

5.4. **Unallowable Expenditures Under the SUD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

5.4.1. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

5.5. **Serious Mental Illness (SMI) Program Benefits**. Under this demonstration, beneficiaries will have access to, the full range of otherwise covered Medicaid services, including SMI treatment services. These SMI services will range in intensity from short-term acute care in inpatient settings for SMI to ongoing chronic care for such conditions in cost-effective community-based settings. The state will work to improve care coordination and care for co-occurring physical and behavioral health conditions. The state must achieve a statewide average length of stay of no more than 30 days for beneficiaries receiving treatment in an IMD treatment setting through this demonstration's SMI Program, to be monitored pursuant to the SMI Monitoring Protocol as outlined in STC 8.5 below.

5.6. **SMI Implementation Plan**.

5.6.1. The state must submit the SMI Implementation Plan within 90 calendar days after approval of the (March 3, 2024) demonstration for CMS review and comment. If applicable, the state must submit a revised SMI Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The state may not claim FFP for services provided to beneficiaries residing in IMDs primarily to receive treatment for SMI under expenditure authority until CMS has approved the SMI Implementation Plan and the SMI financing plan described in STC 5.6.3.5. After approval of the required Implementation Plan and Financing Plan, FFP will be available prospectively, but not retrospectively.

5.6.2. Once approved, the SMI Implementation Plan will be incorporated into the STCs as Attachment E, and once incorporated, may be altered only with CMS approval. Failure to submit an SMI Implementation Plan, within 90 calendar days after approval of the demonstration, will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI program under

this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 8.3.

5.6.3. At a minimum, the SMI Implementation Plan must describe the strategic approach, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program.

5.6.3.1. Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings.

5.6.3.1.1. Hospitals that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI program are residing must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals prior to the state claiming FFP for services provide to beneficiaries residing in a hospital that meet the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and either: a) be certified by the state agency as being in compliance with those conditions through a state agency survey, or b) have deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS;

5.6.3.1.2. Residential treatment providers that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI program are residing must be licensed, or otherwise authorized, by the state to primarily provide treatment for mental illnesses. They must also be accredited by a nationally recognized accreditation entity prior to the state claiming FFP for services provided to beneficiaries residing in a residential facility that meets the definition of an IMD;

5.6.3.1.3. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating hospitals and residential treatment settings in which beneficiaries receiving coverage pursuant to the demonstration are residing meet applicable state licensure or certification requirements as well as a national accrediting entity’s accreditation requirements;

5.6.3.1.4. Use of a utilization review entity (for example, a MCO or administrative service organization (ASO)) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals and residential treatment settings are receiving treatment in those facilities;

5.6.3.1.5. Establishment of a process for ensuring that participating psychiatric hospitals and residential treatment settings meet applicable federal program integrity requirements, and establishment of a state process to conduct risk-based screening of all newly enrolling providers, as well as revalidation of existing providers (specifically, under existing regulations, the state must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues);

5.6.3.1.6. Implementation of a state requirement that participating psychiatric hospitals and residential treatment settings screen beneficiaries for co-morbid physical health conditions and SUDs and demonstrate the capacity to address co-morbid physical health conditions during short-term stays in residential or inpatient treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).

5.6.3.2. Improving Care Coordination and Transitions to Community-Based Care.

5.6.3.2.1. Implementation of a process to ensure that psychiatric hospitals and residential treatment facilities provider intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that facilitate participation of community-based providers in transition efforts (e.g., by allowing beneficiaries to receive initial services from a community-based provider while the beneficiary is still residing in these settings and/or by engaging peer support specialists to help beneficiaries make connections with available community-based providers and where applicable, make plans for employment);

5.6.3.2.2. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and residential treatment settings and to connect beneficiaries who have been experiencing or are likely to experience homelessness or who would be returning to unsuitable or unstable housing with community providers that coordinate housing services, where available;

5.6.3.2.3. Implementation of a requirement that psychiatric hospitals and residential treatment settings that are discharging beneficiaries who have received coverage pursuant to this demonstration have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary and the community-based provider to which the beneficiary

was referred within 72 hours of discharge to help ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and, as appropriate, by contacting the community-based provider the person was referred to;

5.6.3.2.4. Implementation of strategies to prevent or decrease the length of stay in emergency departments (EDs) among beneficiaries with SMI (e.g., through the use of peer support specialists and psychiatric consultants in EDs to help with discharge and referral to treatment providers);

5.6.3.2.5. Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers, with the goal of enhancing coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI.

5.6.3.3. Increasing Access to Continuum of Care Including Crisis Stabilization Services.

5.6.3.3.1. Establishment of a process to annually assess the availability of mental health services throughout the state, particularly crisis stabilization services, and updates on steps taken to increase availability (the state must provide updates on how it has increased the availability of mental health services in every Annual Monitoring Report);

5.6.3.3.2. Commitment to implementation of the SMI financing plan described in STC 5.6.3.5). The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report Described in STC 5.7;

5.6.3.3.3. Implementation of strategies to improve the state's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible;

5.6.3.3.4. Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association (e.g., Level of Care Utilization System (LOCUS) or Child and Adolescent Service Intensity Instrument (CASII)) to determine appropriate level of care length of stay.

5.6.3.4. Earlier Identification and Engagement in Treatment and Increased Integration

5.6.3.4.1. Implementation of strategies for identifying and engaging individuals with SMI in treatment sooner, including through supported employment and supported education programs;

5.6.3.4.2. Increasing integration of behavioral health care in non-specialty care settings to improve identification of SMI conditions sooner and improve awareness of and linkages to specialty treatment providers; establishment of specialized settings and services, including crisis stabilization services.

5.6.3.5. **SMI Financing Plan**. As part of the SMI implementation plan referred to in STC 5.6.3.5, the state must submit, within 90 calendar days after approval of the demonstration, a financing plan for approval by CMS. Once approved, the Financing Plan will be incorporated into the STCs as part of the implementation plan in Attachment E and once incorporated, may only be altered with CMS approval. Failure to submit an SMI Financing Plan within 90 days of approval of the demonstration will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI program under this demonstration. Components of the financing plan must include:

5.6.3.5.1. A plan to increase the availability of non-hospital, non-residential crisis stabilization services, including but not limited to the following: services made available through crisis call centers, mobile crisis units, coordinated community response services that includes law enforcement and other first responders, and observation/assessment centers; and

5.6.3.5.2. A plan to increase availability of ongoing community-based services such as intensive outpatient services, assertive community treatment, and services delivered in integrated care settings.

5.7. **Maintenance of Effort**. The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 8.6.

5.8. **Availability of FFP for the SMI Services Under Expenditure Authority.** Federal Financial Participation is only available for services provided to beneficiaries who are residing is an IMD when the beneficiary is a short-term resident in the IMD to receive acute care for a primary diagnosis of SMI. The state may claim FFP for services

furnished to beneficiaries during IMD stays of up to 60 days, as long as the state shows at its Mid-Point Assessment that it is meeting the requirement of a 30-day average length of stay (ALOS) for beneficiaries residing in an IMD who are receiving covered services under the demonstration. Demonstration services furnished to beneficiaries whose stays in IMDs exceed 60 days are not eligible for FFP under this demonstration. If the state cannot show that it is meeting the 30-day or less ALOS requirement within one standard deviation at the Mid-Point Assessment, the state may only claim FFP for services furnished to beneficiaries during IMD stays of up to 45 days until such time that the state can demonstrate that it is meeting the 30-day or less ALOS requirement. The state will ensure that medically necessary services are provided to beneficiaries that have stays in excess of 60-days or 45-days, as relevant.

5.9. **Unallowable Expenditures Under the SMI Expenditure Authority**. In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

5.9.1. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act;

5.9.2. Costs for services furnished to beneficiaries who are residents in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD;

5.9.3. Costs for services furnished to beneficiaries who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law;

5.9.4. Costs for services provided to beneficiaries under age 21 residing in an IMD unless that IMD meets the requirements for the "inpatient psychiatric services for individuals under age 21" benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.

## 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**. No modifications to the current Missouri Medicaid delivery system are proposed through this demonstration. Missouri Medicaid beneficiaries will continue to receive services through the current delivery system.

## 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 2 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:

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

8.1.2. For each deliverable, the state may submit to CMS 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 will be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request;

8.1.3. If CMS agrees to an interim corrective plan in accordance with subsection 8.1.2, and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of 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.

8.1.4. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified 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 Milestone**. 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:

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

8.4.2. Ensure all section 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and

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

8.5. **SUD and SMI Monitoring Protocol**. The state must submit a Monitoring Protocol for the SUD and SMI/SED programs authorized by this demonstration within 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 60 calendar days after receipt of CMS's comments, if any. Once approved, the SUD and SMI Monitoring Protocol will be incorporated into 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 must include:

8.5.1. 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 5.6 and reporting relevant information to the state's Health IT plan described in STC 5.3;

8.5.2. 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 8 (General Monitoring and Reporting Requirements) of the demonstration; and

8.5.3. 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 target will be benchmarked against performance in best practice settings.

8.6. **Monitoring Reports**. The state must submit three Quarterly Monitoring Reports and one 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 90 calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR § 431.428 and must 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.

8.6.1. 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. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these 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. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

8.6.2. 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 and SMI/SED 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 on beneficiaries' 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.

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

8.6.4. 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.

8.6.5. SUD and SMI/SED SUD Health IT. The state will include a summary of progress made in regards to SUD and SMI Health IT requirements outlined in STC 5.3

8.7. **SUD and SMI/SED Mid-Point Assessment**. The state must contract with an independent entity to conduct a Mid-Point Assessment by December 6, 2026. This timeline will allow for the Mid-Point Assessment to capture approximately the first two-and-a- half years of demonstration program data, accounting for data run-out and data completeness. 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: representatives of MCO, health care providers (including SUD and SMI treatment providers), beneficiaries, community groups, and other key partners.

The state must require that the assessor provide a Mid-Point Assessment 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 60 days after December 6, 2026. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment with 60 calendar days after receipt of CMS's comments, if any.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS proposed modifications to the SUD Implementation Plan, SMI Implementation Plan, the SMI Financing Plan, and the SUD and SMI Monitoring Protocol, for ameliorating these risks. Modifications to any of these plans or protocols are subject to CMS approval.

Elements of the Mid-Point Assessment must include:

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

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

8.7.3. A determination of 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;

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

8.7.5. 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 5.3. CMS will withdraw an authority, as described in STC 5.3 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.

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

8.9.2. 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 STCs 11.7 and 11.8, respectively.

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

8.9.4. The state must take into consideration CMS's comments for incorporation in the Final Close-Out Report.

8.9.5. The Final Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.

8.9.6. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.3

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

8.10.1. 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, enrollment and access, budget neutrality, and progress on evaluation activities.

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

8.10.3. 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 must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum. 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 Annual Monitoring Report.

## 9. GENERAL FINANCIAL REQUIREMENTS

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 states 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.

9.3.1. 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.

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

9.3.3. 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:

9.4.1. 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.

9.4.2. 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 435.51(c).

9.4.3. The state may use intergovernmental transfer (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.

9.4.4. 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 government, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner in consistent 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, 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.

9.4.5. 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:

9.5.1. 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:

9.6.1. 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).

9.6.2. 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).

9.6.3. 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.

9.6.4. 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).

9.6.5. 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:

9.7.1. 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;

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

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

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

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

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

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

9.7.8. 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 2:

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

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

9.8.3. 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 the 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 providers 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 Medicaid FFS | Hypo 1 | X | | X | All expenditures for services provided to an individual in FFS while they are a patient in an IMD for SUD treatment |
| SUD Medicaid Managed Care | Hypo 1 | X | | X | All expenditures for services provided to an individual in managed care while they are a patient in an IMD for SUD treatment unless they are in the adult expansion group |
| SUD Managed Care Adult Expansion Group | Hypo 1 | X | | X | All expenditures for services provided to an individual in managed care while they are a patient in an IMD for SUD treatment only if they are in the adult expansion group |
| SMI Adults Ages 21-64 FFS | Hypo 2 | X | | X | All expenditures for services provided to an individual ages 21-64 in FFS while they are a patient in an IMD for SMI treatment |
| SMI Adults Ages 21-64 Managed Care (Excluding Adult Expansion Group) | Hypo 2 | X | | X | All expenditures for services provided to an individual ages 21-64 in managed care while they are a patient in an IMD for SMI treatment unless they are in the adult expansion group |
| SMI Adults ages 21-64 Managed Care Adult Expansion Group | Hypo 2 | X | | X | All expenditures for services provided to an individual ages 21-64 in managed care while they are a patient in an IMD for SMI treatment only if they are in the adult expansion group |

BN – Budget Neutrality; MEG – Medicaid Expenditure Group; WOW – Without Waiver; WW – With Waiver.

9.11. **Report 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-00411/7). 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 expenditures. 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.

9.11.1. **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 10n (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.

9.11.2. **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 neutrality limits.

9.11.3. **Pharmacy Rebates**. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to the budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any 64.9 OR 64.9P WAIVER.

9.11.4. **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 10, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

9.11.5. **Member Months**. As part of the Quarterly and Annual Monitoring Reports described in Section 10, 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.

9.11.6. **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 | MEG End Date |
| SUD Medicaid FFS | All expenditures for services provided to an individual in FFS while they are a patient in an IMD for SUD treatment | N/A | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |
| SUD Medicaid Managed Care | All expenditures for services provided to an individual in managed care while they are a patient in an IMD for SUD treatment unless they are in the adult expansion group | N/A | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |
| SUD Medicaid Managed Care Adult Expansion Group | All expenditures for services provided to an individual in managed care while they are a patient in an IMD for SUD treatment only if they are in the adult expansion group | N/A | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |
| SMI Adults Ages 21-64 FFS | All expenditures for services provided to an individual ages 21-64 in FFS while they are a patient in an IMD for SMI treatment | | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SMI Adults Ages 21-64, Managed Care (Excluding Adult Expansion Group) | All expenditures for services provided to an individual ages 21-64 in managed care while they are a patient in an IMD for SMI treatment unless they are in the adult expansion group | | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |
| SMI Adults, Ages 21-64 Managed Care Adult Expansion Group | All expenditures for services provided to an individual ages 21-64 in managed care while they are a patient in an IMD for SMI treatment only if they are in the adult expansion group | | Follow standard CMS-64.9 Category of Service Definitions | Date of Service | MAP | Y | 12/6/23 | 12/31/28 |

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 1 | December 6, 2023, to December 31, 2024 | 13 Months |
| Demonstration Year 2 | January 1, 2025, to December 31, 2025 | 12 Months |
| Demonstration Year 3 | January 1, 2026, to December 31, 2026 | 12 Months |
| Demonstration Year 4 | January 1, 2027, to December 31, 2027 | 12 Months |
| Demonstration Year 5 | January 1, 2028, to December 31, 2028 | 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.

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:

9.15.1. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payment, 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 provision 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.

9.15.2. 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 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 if 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 det the budget neutrality expenditure limit are subject 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 it 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.

9.16.1. **Contents of Request and Process.** In its request, the state must provide a description of the expenditures 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 9.16.3. If approved, and 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 approval requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to the 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.

9.16.2. **Types of Allowable Changes.** Adjustment 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:

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

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

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

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

9.16.2.5. When not already accounted for under Emergency Medicaid 1115 demonstration, cost impacts from public health emergencies.

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

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

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

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

9.16.3.2. 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's 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 Per Member Per Month (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 Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests 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 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 no 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 refund the FFP to CMS.

10.6. **Hypothetical Budget Neutrality Test 1 (SUD)**: **SUD Medicaid FFS**, **SUD Medicaid Managed Care**, & **SUD Managed Care Adult Expansion Group**. The table below identifies the MEGs that are 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. Any expenditures in excess of the limit form Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

| MEG | PC or Agg | WOW Only, WW Only, or Both | Trend Rate | DY 1 | DY 2 | DY 3 | DY 4 | DY 5 |
|---|---|---|---|---|---|---|---|---|
| SUD Medicaid FFS | PC | Both | 5.7% | $9,383.51 | $9,936.71 | $10,503.10 | $11,101.78 | $11,734.58 |
| SUD Medicaid Managed Care | PC | Both | 5.7% | $6,166.14 | $6,529.66 | $6,901.85 | $7,295.26 | $7,711.09 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SUD Managed Care Adult Expansion Group | PC | Both | 5.5% | $7,990.62 | $8,445.16 | $8,909.64 | $9,399.67 | $9,916.65 |

10.7. **Hypothetical Budget Neutrality Test 2 (SMI)**: **SMI Adults, Ages 21-64, FFS; SMI Adults, Ages 21-64, Managed Care (Excluding Adult Expansion Group; SMI Adults, Ages 21-64, Managed Care Adult Expansion Group;**. The table below identifies the MEGs that are 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. Any expenditures in excess of the limit form Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

| MEG | PC or Agg | WOW Only, WW Only, or Both | Trend Rate | DY 1 | DY 2 | DY 3 | DY 4 | DY 5 |
|---|---|---|---|---|---|---|---|---|
| SMI Adults, Ages 21-64, FFS | PC | Both | 5.7% | $22,615.09 | $23,948.36 | $25,313.42 | $26,756.28 | $28,281.39 |
| SMI Adults, Ages 21-64, Managed Care (Excluding Adult Expansion Group) | PC | Both | 5.7% | $1,226.01 | $1,298.29 | $1,372.29 | $1,450.51 | $1,533.19 |
| SMI Adults, Ages, 21-64 Managed Care Adult Expansion Group | PC | Both | 5.5% | $6,161.79 | $6,512.30 | $6,870.48 | $7,248.35 | $7,647.02 |

10.8. **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.

10.9. **Exceeding Budget Neutrality**. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 12/6/2023 to 12/31/2028. If at the end of the demonstration approval period the Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

10.10. **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 6: Budget Neutrality Test Corrective Action Plan Calculation | | |
|---|---|---|
| **Demonstration Year** | **Cumulative Target Definition** | **Percentage** |
| DY 1 | Cumulative Budget Neutrality Limit Plus | 2.0 Percent |
| DY 1 through DY 2 | Cumulative Budget Neutrality Limit Plus | 1.5 Percent |
| DY 1 through DY 3 | Cumulative Budget Neutrality Limit Plus | 1.0 Percent |
| DY 1 through DY 4 | Cumulative Budget Neutrality Limit Plus | 0.5 Percent |
| DY 1 through DY 5 | 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 it 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**: 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 approved 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, change 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 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's evaluation design guidance for SUD and SME/SED demonstrations, including guidance for approaches to analyzing associated costs, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must be also 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 11.7 and 11.8.

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's 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 amended Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

11.4. **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.

11.5. **Evaluation Design Approval and Updates**. The state must submit a revised draft Evaluation Design within 60 days after receipt of CMS's 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 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. 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.

11.6. **Evaluation Questions and Hypotheses**. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) 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 its effectiveness in achieving the goals.

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.

Hypotheses for the SMI/SED component of the demonstration must relate to, for example, utilization and length of stay in emergency departments, reductions in preventable readmissions to acute care hospitals and residential settings, availability of crisis stabilization services, and care coordination.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid

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

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.

11.7. **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.

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

11.7.2. 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.

11.7.3. If the state is seeking a 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.

11.7.4. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report, if any.

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

11.7.6. 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.

11.8.1. The state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.

11.8.2. 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 Report, and/or the Summative Evaluation Report.

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 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports on 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 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 and SMI/SED Monitoring Protocol | STC 8.5 |
| No later than 60 calendar days after receipt of CMS comments | 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 11.5 |
| No later than 30 calendar days after CMS approval | Approved Evaluation Design published to state's website | STC 11.5 |
| No later than 60 calendar days after December 6, 2026 | Mid-Point Assessment Report | STC 8.7 |
| No later than December 31, 2028, or with extension application | Draft Interim Evaluation Report | STC 11.7.3 |
| No later than 60 calendar days after receipt of CMS comments | Final Interim Evaluation Report | STC 11.7.5 |
| No later than 18 months after the end of the demonstration | 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 |
| No later than 120 calendar days after the end of the demonstration | Draft Close-Out Report | STC 8.9 |
| No later than 30 calendar days after receipt of CMS comments | Revised Close-Out Report | STC 8.9 |
| **Monthly** | | |

| | | |
|---|---|---|
| Monthly Deliverables | Monitoring Calls | STC 8.10 |
| **Quarterly** | | |
| Quarterly Deliverables Due no later than 90 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**

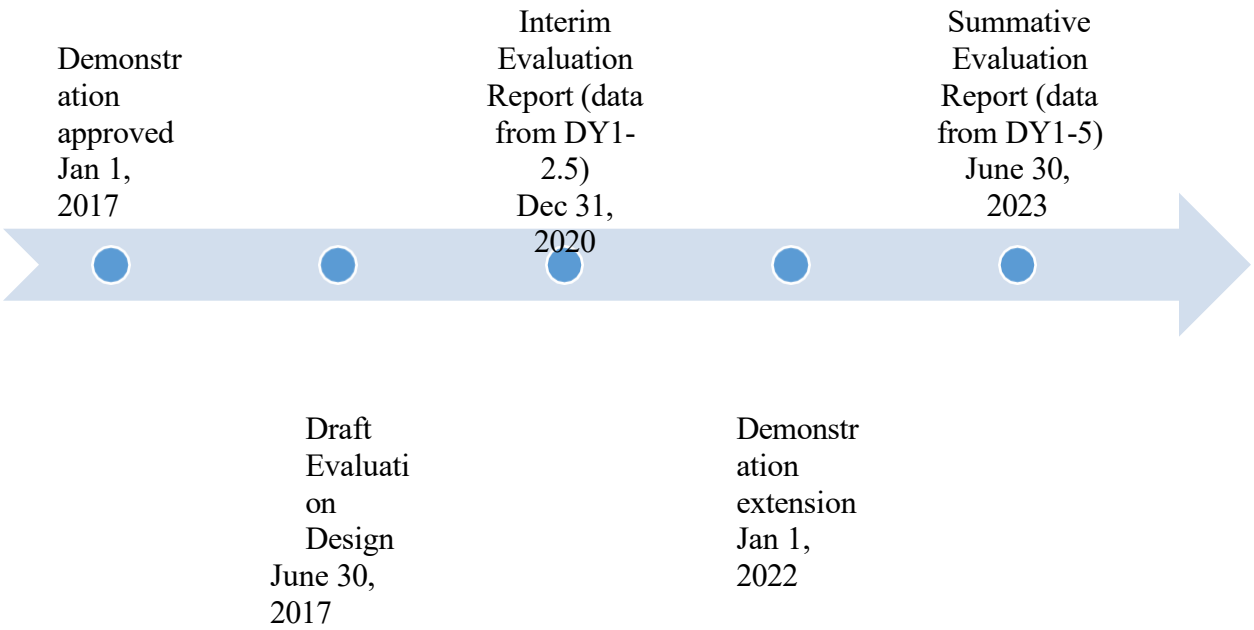
## Introduction

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

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

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

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

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

## E. Attachments

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

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

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

**Attachment B:**
**Preparing the Interim and Summative Evaluation Reports**

**Attachment C:**
**SUD Implementation Plan**

**Attachment D:**
**SUD Monitoring Protocol**

**(Reserved)**

**Attachment E:**
**SMI Implementation Plan**

**Attachment F:**
**SMI Monitoring Protocol**

**(Reserved)**

**Attachment G:**
**Evaluation Design**

Mercer

Government Human Services Consulting

# Missouri Substance Use Disorder and Serious Mental Illness 1115 Demonstration

## Evaluation Design

**State of Missouri**

*November 22, 2024*

# Contents

## Section A.

# General Background Information

On December 6, 2023, the State of Missouri (State) received approval from the Centers for Medicare and Medicaid Services (CMS) for a Section 1115 waiver demonstration. The *Missouri Substance Use Disorder & Serious Mental Illness Demonstration* (Demonstration) aims to expand benefits to cover a comprehensive array of services for substance use disorder (SUD) and serious mental illness (SMI)/serious emotional disturbance (SED) services, improve the capacity to provide these services and improve the quality of care that beneficiaries receive. The approval period for Missouri's SUD and SMI/SED Demonstration is December 6, 2023–December 31, 2028.

To meet CMS's special terms and conditions (STCs), the MO HealthNet Division (MHD) must contract with an independent third party to evaluate the Demonstration. MHD, in collaboration with the Department of Mental Health (DMH), contracted with Mercer Government Human Services Consulting (Mercer), as part of Mercer Health & Benefits LLC, to create an evaluation design for the Demonstration. MHD and DMH will also contract with Mercer to conduct the evaluation. The Mercer team includes Mercer and its subcontractor, TriWest Group.

This document provides an overview of the planned evaluation design for assessing the effects of the Demonstration and follows CMS's recommended structure for evaluation designs (see outline below).

A. **General Background Information**. This section provides background on the issues faced by the State that prompted the Demonstration. It also describes the overall structure of the Demonstration, the Demonstration's goals and time period, and the evaluation time period.

B. **Evaluation Questions and Hypotheses**. This section presents driver diagrams that link the goals of the Demonstration to primary and secondary activities that will drive expected outcomes. Hypotheses behind each Demonstration goal are included, as well as a list of research questions that will be used to test the hypotheses.

C. **Methodology**. This section describes the proposed research methodology and explains the target and comparison populations, the evaluation period, measures, data sources, and quantitative and qualitative analytic methods.

D. **Methodological Limitations.** This section discusses limitations and confounding factors that could affect the evaluation results. In addition, it comments on proposed mitigation strategies.

E. **Attachments.** The Evaluation Design Report includes attachments that address the selection of the independent evaluator, the evaluation budget, and the timeline and major milestones related to the evaluation.

It is important to note that this Demonstration's monitoring protocol has not yet been submitted to CMS based on CMS's request for the State to wait until the new CMS template

is released. As a result, specific data sources and features of this design could change if CMS makes substantive changes to the monitoring protocol template or requirements.

### Historical Overview

Over the past several years, Missouri has been working diligently to ensure Medicaid eligibles have access to a comprehensive continuum of behavioral health services and has also been launching initiatives to address the opioid public health crisis. Additionally, the State began offering Medicaid coverage to the low-income adult Medicaid expansion group in late 2021, which resulted in an influx of new Medicaid enrollees. To complement the State's existing behavioral health initiatives and obtain federal financial participation for providing otherwise covered services to short-term residents in an Institution for Mental Disease (IMD), the State submitted two separate behavioral health demonstration applications during the latter part of 2022 (an SUD demonstration application and an SMI/SED demonstration application). At the end of 2023, CMS approved these applications as a single demonstration.

The Demonstration aims to expand access to critical services and help address the opioid public health crisis. The State intends to leverage the 1115 SUD and SMI/SED Demonstration to make critical improvements to both the child and adult mental health and substance use continuums of care. The following paragraphs provide data and outline why these critical improvements are necessary.

In terms of the suicide rate across all ages, a Missouri Institute of Mental Health publication[1] from August 2018 indicated that Missouri has the thirteenth highest rate of suicide in the nation. Suicide is the tenth leading cause of death in the State. Missouri has seen a 30% increase in the suicide rate since 1999 and Missouri's suicide rate in 2016 was above the national age-adjusted suicide rate per 100,000 (Missouri's average of 18.27 versus the national average of 13.42).

A March 2019 Missouri Hospital Association Policy Brief titled "Rates of Suicidality Following Psychiatric Hospitalizations for Children in Missouri"[2] found that suicidal ideation had grown by nearly 900% among children and adolescents during the prior decade. Suicide was identified as the second-leading cause of death in Missouri for children between the ages of five and nineteen, and Missouri had the eleventh highest rate of child and adolescent suicide in the country in 2017. The same policy brief found that between 2003 and 2017, the rate of suicide for children and adolescents increased by 129%, outpacing the national increase trend of 71% for the same time period. The policy brief goes on to outline potential drivers behind this trend including a shortage or lack of mental health providers specializing in working with children, adolescents, and their families. The brief indicates that 96.5% of the counties in Missouri were deemed geographic Mental Health Professional Shortage Areas, with 22% fewer psychiatrists and 14% fewer psychologists practicing in Missouri than the average across the country.

[1] Missouri Institute of Mental Health publication; https://dmh.mo.gov/sites/dmh/files/media/pdf/2019/02/where-we- stand.pdf

[2] Rates of Suicidality Following Psychiatric Hospitalizations for Children in Missouri; https://www.mhanet.com/mhaimages/policy_briefs/PolicyBrief_SuicidalityChildren_0319.pdf

The Center for Health Care Strategies (CHCS) conducted an environment scan on Missouri's Children's Behavioral Health Continuum of Care and identified gaps and challenges within the behavioral health service array.[3] The scan found that of the twenty-two behavioral health crisis centers (BHCCs) in the State, only five BHCCs indicated they serve children, youth, and their families. The scan compared children's behavioral health service utilization in calendar year 2022 to national data for 2011 and found the following four services in Missouri were utilized above national levels: emergency room, psychological testing, inpatient psychiatric hospital, and peer services. In comparison, four Missouri services with utilization that fell materially below national levels included: outpatient counseling; family therapy/family education and training; screening, assessment, and evaluation; and initial service planning.
Other services that fell below national utilization trends included: substance use outpatient, partial hospital/day treatment, residential treatment and therapeutic group homes, and substance use screening and assessment.

The CHCS scan also found that for Medicaid youth ages 0 years–17 years old, emergency room services are the second most utilized service for both fee-for-service (FFS) and managed care individuals. High emergency room utilization can be an indicator of insufficient capacity at low to moderate intensity behavioral health services. Based on interviews conducted by CHCS, there was indication that due to lack of options, families often escalated to seeking residential services, self-referring to child welfare agencies, or seeking to have their child committed to the juvenile justice system to access behavioral health services. There was also indication that few accessible services were available to youth and families who weren't yet in crisis.

Regarding drug overdose deaths, a Kaiser publication[4] indicated that Missouri's rate is slightly higher than the national rate of drug overdose deaths per 100,000 (Missouri's average of 36.5 versus national average of 32.4). Kaiser also indicated that Missouri was below the national average in its ability to meet mental health care needs (12.2% of need met versus 27.7% nationally). And while other types of health care services have rebounded since the lag in utilization due to Coronavirus Disease of 2019 (COVID-19), data shows that in Missouri utilization rates for mental health services have lagged among adult Medicaid beneficiaries with mental health diagnoses.

To conclude, the United States Department of Justice (DoJ) recently completed an investigation into Missouri's use of nursing facilities and guardianship for adults with mental health disabilities. The DoJ found that the State has unnecessarily institutionalized adults with mental health disabilities. This is a result of failing to provide services in the most integrated settings appropriate to their needs. The investigation found that of 333 adults with mental health diagnoses who had received community-based mental health services from 2019–2021 and were admitted to nursing facilities in 2022:

- Eight had received Assertive Community Treatment (ACT).
- Twenty-three had received Peer Support Services.

[3] CHCS's Missouri Children's Behavioral Health Environmental Scan: Executive Summary https://dss.mo.gov/re/pdf/mcbh-environmental-scan.pdf

[4] Mental Health and Substance Use State Fact Sheets: Missouri | KFF; https://www.kff.org/statedata/mental- health-and-substance-use-state-fact-sheets/missouri/

- Fifteen had received Intensive Community Psychiatric Rehabilitation (ICPR) Residential services (housing services).
- Zero had received supported employment.

Many Medicaid beneficiaries interviewed by DoJ indicated they had not received any community-based services prior to entering the nursing facility. The report indicated that while the State recognizes ACT is effective, there is limited availability across the State and the service is largely underused. There is a lack of ICPR Residential service options even though this was identified as a *major need* by the Missouri Institute of Mental Health a decade ago.

### SUD

Prior to the Demonstration, prevention and treatment services were offered through providers that contracted with the State. For individuals not enrolled in Medicaid or otherwise insured, the cost of services was based on the individual's ability to pay. For those enrolled in Medicaid, SUD services were carved out of managed care and reimbursed through the Comprehensive Substance Treatment and Rehabilitation (CSTAR) FFS program.

The CSTAR program was designed to provide an array of comprehensive, but individualized treatment services, with the aim of reducing the negative impacts of SUDs on individuals, family members, and society. CSTAR programs offered all levels of outpatient SUD services and could offer certified residential support services. CSTAR opioid treatment programs offered SUD services on an exclusively outpatient basis and offered referrals to residential support services as clinically indicated.

The CSTAR programs targeted specialized populations, including women and children, persons who inject drugs, pregnant women, and adolescents. The CSTAR programs were the only substance use treatment programs reimbursable by Medicaid in the State.

To address the opioid crisis, the State has launched various outpatient SUD and opioid use disorder (OUD) initiatives that included assessment, treatment planning, individual and group counseling, group rehabilitative support, community support, peer support, residential or housing support, and other services. These initiatives were intended to:

1. Curb the impact of SUD and OUD crises.
2. Serve the influx of new Medicaid enrollees to ensure beneficiaries have access to a comprehensive continuum of behavioral health services.

In addition, the State committed to investing $5 million in grants to support providers in transitioning business models and programs from residential-based care to community care settings.

Through the SUD Demonstration, the State will add Medicaid reimbursement for residential SUD services for individuals enrolled in Medicaid who meet medical necessity criteria, including the need for residential SUD services in facilities that qualify as an IMD. This will include transition to American Society of Addiction Medicine (ASAM) level of care criteria

and reimbursement for ASAM-level residential services. With the addition of residential services, the State will expand access to a full continuum of services across ASAM levels of care for OUD and other SUDs.

### SMI/SED

The State is responsible for ensuring that prevention, evaluation, treatment, and rehabilitation services are available for individuals and families who need public mental health services. The State's Community Psychiatric Rehabilitation (CPR) program offers services to Medicaid beneficiaries and provides an array of services in a community-based and consumer-centered manner. Many of the adult and youth services offered through the CPR program are reimbursed through Medicaid.

CPR services include evaluation, crisis intervention, community support, medication management, and psychosocial rehabilitation (PSR). Outpatient community-based services provide the least-restrictive environment for treatment. Day treatment offers the least-restrictive care to individuals diagnosed as having a psychiatric disorder who required a level of care greater than that provided in outpatient services, but not at a level requiring full-time inpatient services. Intensive CPR services include, but are not limited to, enhanced PSR, ACT, ACT for transition age youth, and integrated treatment for co-occurring disorders. Individuals whose psychiatric needs cannot be met in the community and who require 24-hour observation and treatment are placed in inpatient treatment. While Missouri Medicaid enrollees receiving services via managed care could receive treatment in IMDs through the *in lieu of* authority, individuals in FFS did not have the same access to IMDs.

Not long ago, the State added BHCCs and increased the number of certified community behavioral health clinics (CCBHCs). In addition, the State recently strengthened requirements around inpatient and residential facilities screening for co-morbid physical health conditions, SUDs, and suicidal ideation. Further, the State added requirements for providers regarding follow-up after a hospital or residential stay and requirements to assess housing needs and coordinate with housing service providers.

The SMI Demonstration will support access to a full continuum of mental health treatment services by allowing Medicaid coverage and reimbursement for inpatient psychiatric services provided to eligible adults with SMI in an IMD. Through the Demonstration, the State seeks to achieve comparable access to IMDs for Medicaid enrollees regardless of delivery system (FFS or managed care). The State also hopes to regain some of the benefits attained through participation in the State's previous participation in the Medicaid Emergency Psychiatric Services Demonstration.

## SUD and SMI/SED Demonstration

### Demonstration and Evaluation Periods

The approval period for Missouri's SUD and SMI/SED Demonstration is December 6, 2023-December 31, 2028, and the evaluation period is January 1, 2024-December 31, 2028. CMS requires the State to submit an Interim Evaluation Report that comments on Demonstration activities from January 1, 2024 through June 30, 2026. In addition, CMS requires a final evaluation deliverable, the Summative Evaluation Report, that encompasses Demonstration activities from January 1, 2024-December 31, 2028. Per the STCs, the Summative Evaluation Report is due within 18 months of December 31, 2028 (i.e., by June 30, 2030).

## Goals of the Demonstration

The Demonstration's goals can be organized by three key aims:

- Expand Medicaid benefits to increase access to a full continuum of care for SUD and SMI/SED services,
- Increase the capacity of providers in the State to provide these services, and
- Improve the quality of SUD, SMI, and SED services by moving toward a more person-centered system of physical and behavioral health care for Medicaid beneficiaries that facilitates coordinated treatment.

Within the State's Demonstration, there are separate SUD and SMI/SED elements. In addition, there are elements that impact both populations and impact those with co-occurring mental health and SUDs. The main objectives of the SUD components are to maintain and enhance access to OUD and other SUD services and to continue delivery system improvements to provide more coordinated and comprehensive treatment for Medicaid beneficiaries with SUD. The main goals of the SMI/SED components are to maintain and enhance access to mental health services and continue delivery system improvements to provide more coordinated and comprehensive treatment for Medicaid beneficiaries with SMI and SED.

The following 11 goals[5] inform the research questions and the measures that will be used to evaluate the Demonstration:

- Goal 1: Increased rates of identification, initiation, and engagement in treatment for SUD. (SUD-1 in STCs)
- Goal 2: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care. (SMI/SED-4 in STCs)
- Goal 3: Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs and psychiatric hospitals and residential treatment settings throughout the State. (SMI/SED-3 in STCs)
- Goal 4: Increased adherence to and retention in treatment. (SUD-2 in STCs)
- Goal 5: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. (SMI/SED-5 in STCs)
- Goal 6: Improved access to care for physical health conditions among beneficiaries with SUD. (SUD-6 in STCs)

[5] These 11 goals are outlined in the State Medicaid Director Letter (SMDL) #17-003, entitled "Strategies to Address the Opioid Epidemic", published on November 1, 2017. They also align with the demonstration goals outlined in the SMDL #18-911, entitled "Opportunities to Design Innovative Service Delivery Systems for Adults with Serious Mental Illness or

Children with a Serious Emotional Disturbance", published on November 13, 2018.

- Goal 7: Reduced utilization and lengths of stay in hospital emergency departments (ED) among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings. (SMI/SED-1 in STCs)
- Goal 8: Reduced utilization of hospital EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate, through improved access to other continuum of care services. (SUD-4 in STCs)
- Goal 9: Reduced preventable readmissions to acute care and specialty hospitals and residential settings. (SMI/SED-2 in STCs)
- Goal 10: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate. (SUD-5 in STCs)
- Goal 11: Reductions in overdose death, particularly those due to opioids. (SUD-3 in STCs)

### Demonstration Activities

Missouri's Demonstration will help support State efforts to enhance the SUD and SMI/SED service arrays. SUD initiatives aim to improve access to medication-assisted treatment (MAT) and support services at all levels in the continuum of care recommended by ASAM. SMI/SED initiatives aim to improve critical care access, as well as screening, standards of care, and care coordination. Demonstration initiatives are outlined in Missouri's SUD and SMI/SED implementation plans and include the initiatives listed below:

- Provide reimbursement for all ambulatory and residential SUD treatment services, including MAT, at varying levels of intensity across a continuum of care.
- Provide reimbursement for residential SUD treatment and inpatient SMI and SUD treatment in IMDs including guidance and coverage for all residential services.
- Improve availability of BHCCs including centers serving youth.
- Submit an updated Provider Network Adequacy review annually and conduct outreach/improvement activities where gaps in services are noted across the SUD/SMI/SED continuum of care.
- Continue telehealth initiatives and continue to improve access in rural communities.
- Implement planning and quality improvement projects in collaboration with Health Information Networks (HINs), members of the Missouri Medicaid Enterprise, and other stakeholders (to facilitate care coordination and continuity of care).
- Continue the Primary Care Health Home (PCHH) program, Hospital Care Transition program (HCT), and requirements of CCBHC and Community Mental Health Center Healthcare Homes (CMHC HCHs).
- Add requirements to assess housing and coordinate with housing services providers.
- Offer technical assistance and training on evidence-based practice (EBP) in clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis.

- Utilization review process to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight on lengths of stay for the full continuum of SMI/SED and SUD.
- Implement the prescription drug monitoring program fully and continue development of Missouri Care Coordination Insights Project technology.

### Impacted Population Groups

The Demonstration is open to Missouri individuals who are eligible for full Medicaid benefits and targets those with SUD and/or SMI/SED who are in need of critical levels of care and short-term residential or inpatient stabilization. This includes both Medicaid expansion and non-expansion individuals, as well as Medicaid enrollees in both the FFS and managed care delivery systems. The subset of these individuals who require a residential level of care for SUD treatment services or need an acute inpatient stay for SMI will be eligible for short-term stays in an IMD.

## Section B.

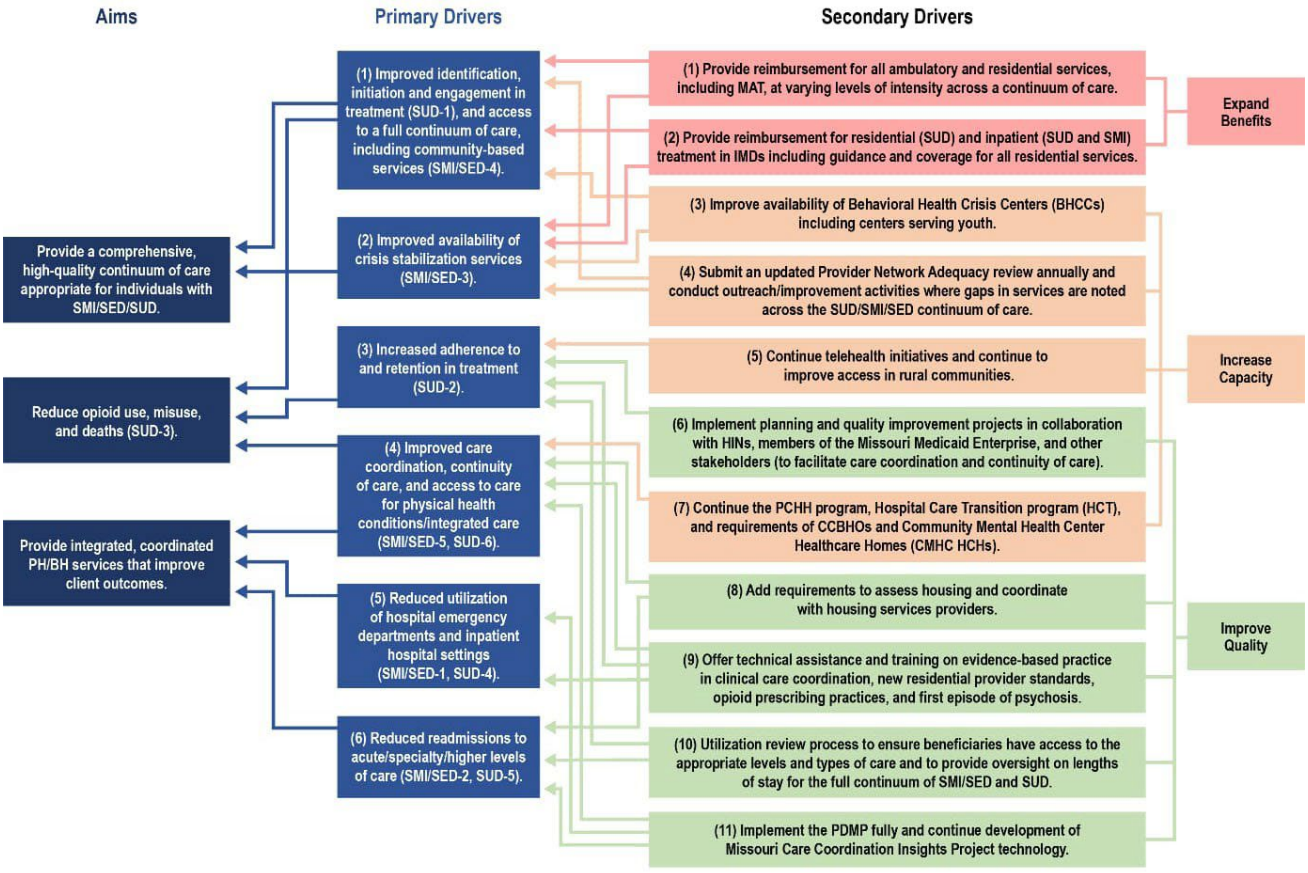
# Evaluation Research Questions and Hypotheses

### Driver Diagram

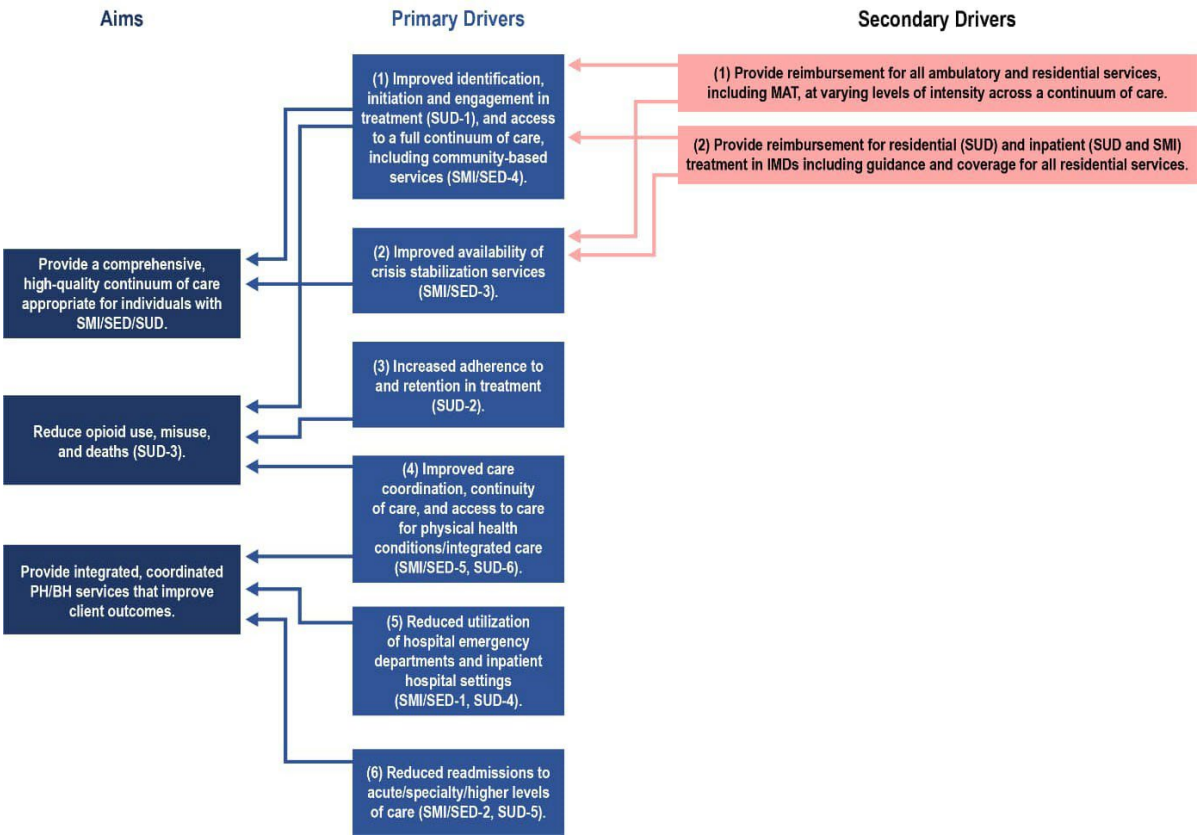
Section A summarized the State's vision for the Demonstration. The driver diagrams in this section show how the goals and activities from the State's SUD and SMI/SED Implementation Plans will advance the three key aims of the Demonstration. Missouri's intervention activities under the Demonstration are presented as secondary drivers. These secondary drivers are grouped into three domains: Expand Benefits, Increase Capacity, and Improve Quality; these domains align with the overarching aims of the Demonstration.

Figure 1 presents the overall driver diagram, whereas Figure 2 through Figure 4 break apart the overall driver diagram to show how the interventions in each domain map to the goals of the Demonstration.

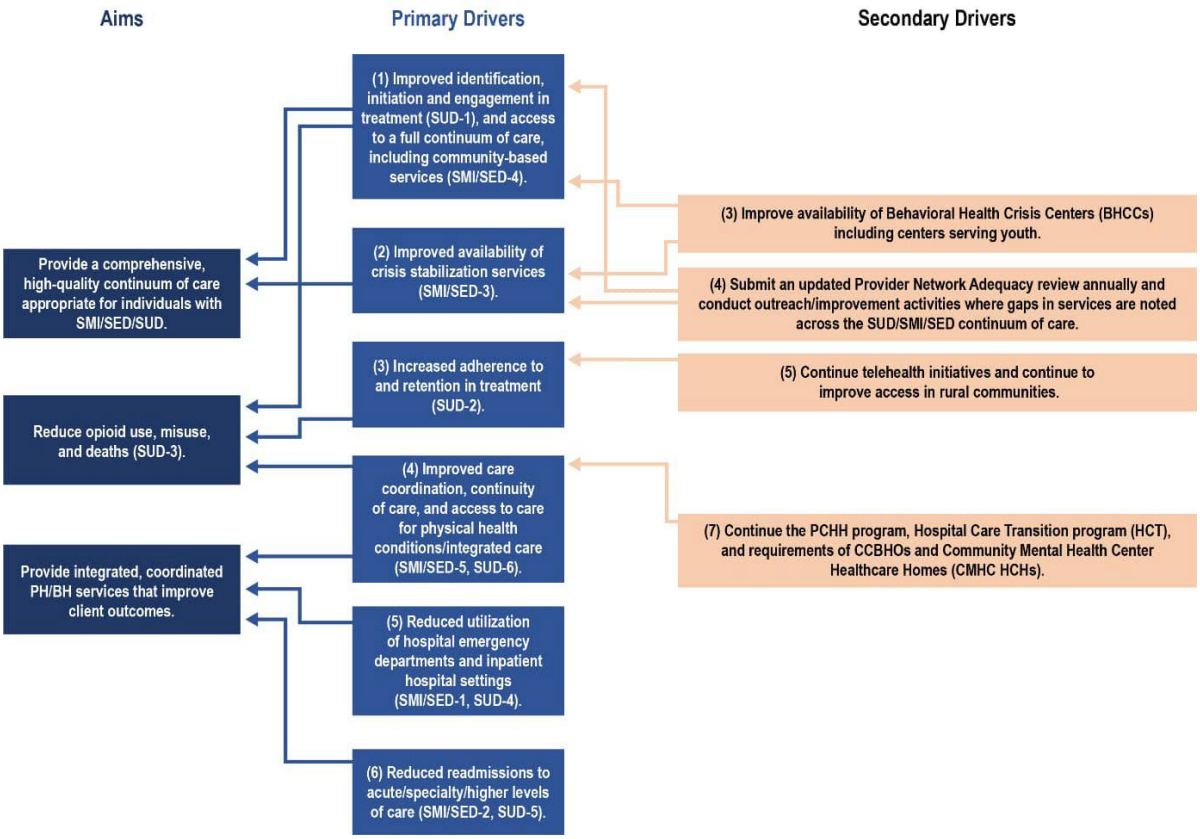
## Figure 1: Overall Driver Diagram



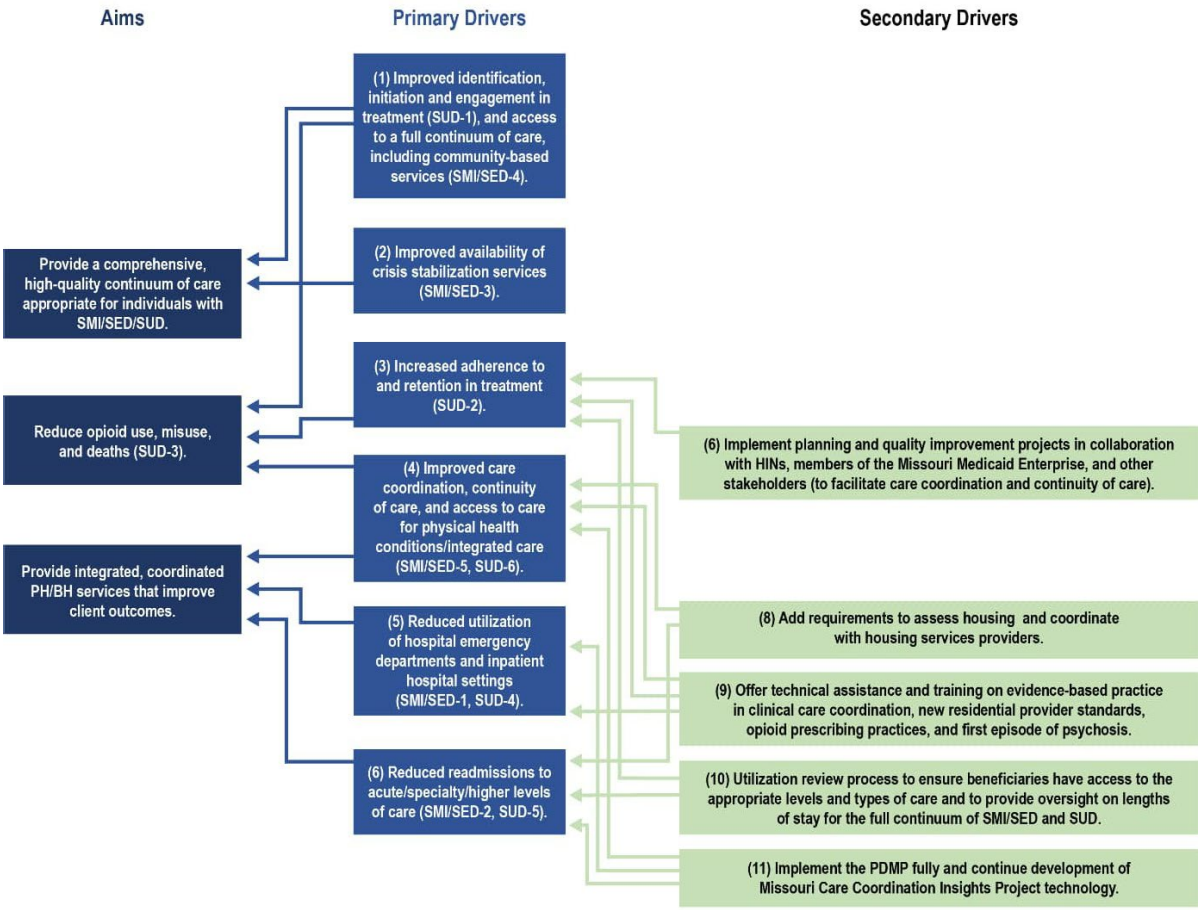
## Figure 2: Expand Benefits Driver Diagram



## Figure 3: Increase Capacity Driver Diagram



## Figure 4: Improve Quality Driver Diagram



## Hypotheses and Research Questions

The hypotheses below align with the aims and goals of the Demonstration. Research questions will be used to test each hypothesis, and quantitative and/or qualitative measures will be used to answer each research question. Refer to the Evaluation Design Tables in Section C for more detail.

### Demonstration Goal-Based Hypotheses and Research Questions

#### Goal 1: Increased rates of identification, initiation, and engagement in treatment for SUD. (SUD-1 in STCs)

Hypothesis 1.1 The Demonstration will increase the rates of identification, initiation, and engagement in treatment for SUD. The Demonstration will have similar impacts across all subpopulations reported.

- Research Question 1.1: Was there an increase in the identification and initiation of treatment for beneficiaries with SUD?
- Research Question 1.2: Did the number of providers who were enrolled in Medicaid and qualified to deliver SUD services increase during the Demonstration period?
- Research Question 1.3: How does the implementation of reimbursement for services provided in IMD settings influence access to specific SUD treatment services?
- Research Question 1.4: Was there an increase in community knowledge of available SUD treatment and services?
- Research question 1.5: Was there an increase in the utilization of SUD-specific treatment services?

#### Goal 2: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care. (SMI/SED-4 in STCs)

Hypothesis 2.1 The Demonstration will improve access to community-based services. The Demonstration will improve access equally across subpopulations.

- Research Question 2.1: Was there an increase in access to community-based SMI/SED treatment services?
- Research Question 2.2: Was there an increase in community knowledge of available community-based SMI/SED treatment and services?
- Research Question 2.3: Was there an increase in utilization of SMI/SED-specific treatment services?
- Research Question 2.4: How does the implementation of reimbursement for all ambulatory and residential services across the continuum of care influence access to services?
- Research Question 2.5: How does the implementation of reimbursement for residential and inpatient treatment in IMDs for SUD and SMI including guidance and coverage for all residential services influence access to services?

### Goal 3: Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs and psychiatric hospitals and residential treatment settings throughout the State. (SMI/SED-3)

Hypothesis 3.1 The Demonstration will improve the availability of crisis stabilization services. The Demonstration will improve the availability of crisis stabilization similarly across all subpopulations reported.

- Research question 3.1: Was there an increase in the availability of crisis stabilization services?

### Goal 4: Increased adherence to and retention in treatment. (SUD-2)

Hypothesis 4.1 The Demonstration will increase beneficiaries' adherence to treatment.

- Research Question 4.1: Did the demonstration increase adherence to SUD treatment?

Hypothesis 4.2 The Demonstration will increase beneficiaries' engagement in treatment.

- Research Question 4.2: Has the continued support of telehealth facilitated treatment engagement?
- Research Question 4.3: How have quality improvement efforts impacted engagement in SUD treatment?
- Research Questions 4.4: Has technical assistance and training led to increased use of and fidelity to EBPs? Has this led to increased engagement in SUD treatment?

### Goal 5: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. (SMI/SED-5)

Hypothesis 5.1 The Demonstration will increase utilization of follow-up services after episodes of acute care.

- Research Question 5.1: Was there an increase in utilization of follow-up services for beneficiaries with SMI/SED after episodes of acute care in hospitals?

Hypothesis 5.2 The Demonstration will improve care coordination.

- Research Question 5.2: Did the PCHH, HCT, CCBHC, and CMHC HCH programs improve care coordination?
- Research Question 5.3: Did housing assessments and coordination with housing providers improve care coordination?
- Research Question 5.4: Did care coordination improve for beneficiaries with SMI/SED?

Hypothesis 5.3 The Demonstration will improve integrated care for beneficiaries with SMI or SED.

- Research Question 5.5: Did the Demonstration increase integration of primary and

behavioral health care for beneficiaries with SMI or SED?

### Goal 6: Improved access to care for physical health conditions among beneficiaries with SUD. (SUD-6/integrated care)

Hypothesis 6.1 The Demonstration will increase access to care for physical health conditions among beneficiaries with SUD.

- Research Question 6.1: Was there an increase in access to care for physical health conditions among beneficiaries with SUD?

Hypothesis 6.2: The Demonstration will improve care coordination for beneficiaries with SUD.

- Research Question 6.2: Did care coordination improve for beneficiaries with SUD?

### Goal 7: Reduced utilization and length of stay in hospital ED among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings. (SMI/SED-1)

Hypothesis 7.1 The Demonstration will result in a decrease in utilization of ED services by beneficiaries with SMI or SED. The Demonstration will decrease utilization of ED services by beneficiaries with SMI or SED similarly across all subpopulations reported.

- Research Question 7.1: Was there a decrease in ED services by beneficiaries with SMI/SED?
- Research Question 7.2: Did technical assistance and training on EBPs reduce the use of ED services?
- Research Question 7.3: Did the utilization review process reduce the use of ED services?

### Goal 8: Reduced utilization of hospital EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate, through improved access to other continuum of care services. (SUD-4)

Hypothesis 8.1 The Demonstration will result in a decrease in utilization of ED and inpatient services by beneficiaries. The Demonstration will decrease utilization of ED and inpatient services by beneficiaries similarly across all subpopulations reported.

- Research Question 8.1: Was there a reduction in ED or inpatient utilization for beneficiaries with SUD?
- Research Question 8.2: How does the Demonstration influence preventable utilization of ED or inpatient care through improved access to other continuum of care services?

### Goal 9: Reduced preventable readmissions to acute care and specialty hospitals and residential settings. (SMI/SED-2)

Hypothesis 9.1 The Demonstration will decrease preventable readmissions to acute care, specialty hospitals, and residential settings for beneficiaries with SMI/SED.

- Research Question 9.1: Was there a decrease in preventable readmissions to acute care, specialty hospitals, and residential settings for beneficiaries with SMI/SED?

### Goal 10: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate. (SUD-5)

Hypothesis 10.1 The Demonstration will decrease preventable or medically inappropriate readmissions to the same or higher level of care for beneficiaries with SUD.

- Research Question 10.1: Was there a decrease in preventable or medically inappropriate readmissions to the same or higher level of care for beneficiaries with SUD?

### Goal 11: Reductions in overdose deaths, particularly those due to opioids. (SUD-3)

Hypothesis 11.1 The Demonstration will decrease the rate of overdose deaths. Reductions in overdose deaths will be similar across each age group (e.g., children, adults, seniors).

- Research Question 11.1: Was there a decrease in the rate of overdose deaths?

## Research Questions for Cost Analysis

The evaluation will also include a cost analysis that covers the following questions.

### Goal 12: Improvements in outcomes for members using SUD or SMI/SED services result in similar or lower costs.

Hypothesis 12.1 The Demonstration will result in improvements in outcomes for members using SUD or SMI/SED services and maintain or reduce Medicaid costs, where possible.

- Research Question 12.1: Have increasing trends in total cost of care been slowed for individuals with SUD diagnoses?
- Research Question 12.2: Have increasing trends in total cost of care been slowed for individuals with SMI/SED diagnoses?

## Section C.

# Methodology

This section explains the methodology for the evaluation. Mercer will work closely with the State to refine the methodology, as needed, based on CMS's feedback. Note that refinements may be subject to data availability and feasibility of analysis.

Per CMS guidance, this section includes the following components:

- Evaluation design.
- Target and comparison populations.
- Evaluation period.
- Evaluation measures.
- Data sources.
- Analytic methods.

### Evaluation Design

The evaluation of the Demonstration will utilize a mixed-methods evaluation design with three main goals:

1. Describe the progress made on specific waiver-supported activities (process/implementation evaluation).
2. Demonstrate change/accomplishments in each of the waiver milestones (short-term outcomes).
3. Demonstrate progress in meeting the overall project goals/aims.

A combination of qualitative and quantitative approaches will be used throughout the evaluation.

- **Qualitative methods** will include informant interviews with key State implementation staff, provider staff, and other stakeholders identified in the qualitative data collection process. Topics covered will include Demonstration activities, as well as document reviews of contracts, policy guides, and manuals. These methods will also include consumer voice to describe changes in access to and perceptions of care over the Demonstration period. In addition, the State is exploring opportunities to deploy modifications to the Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey or other routine survey methods to obtain consumer views. To the extent possible, existing consumer advisory/advocacy groups will also be leveraged to conduct focus group data collection efforts. Thematic and content analysis will be used to draw conclusions from data collected for qualitative review. Thematic analysis (TA) is a method

for identifying, analyzing, and interpreting patterns of meaning within qualitative data.[6] Since key informant interview and focus group data includes individual opinions and subjective perspectives, thematic analysis allows for comparisons across different stakeholders and stakeholder groups and uses systematic procedures for generating text coding and themes.

- **Quantitative methods** will include descriptive statistics showing changes over time in both counts and rates for specific metrics and interrupted time series (ITS) analysis to assess the degree to which the timing of Demonstration interventions affected changes across specific outcome measures. The data sources for the quantitative analyses include Medicaid claims and other administrative data.

### Target and Comparison Populations

The Demonstration is open to Missouri individuals who are eligible for full Medicaid benefits and targets those with SUD and/or SMI/SED who are in need of critical levels of care and short-term residential or inpatient stabilization. This includes both Medicaid expansion and non-expansion individuals, as well as Medicaid enrollees in both the FFS and managed care delivery systems. The subset of these individuals who require a residential level of care for SUD treatment services or need an acute inpatient stay for SMI will be eligible for short-term stays in an IMD.

The comparison population group in this design will be comprised of the target population, which will serve as its own comparison group longitudinally, in which the research question will compare service utilization differences across the Demonstration period.

### Evaluation Period

The evaluation period encompasses a look back period (pre-demonstration period), January 1, 2022 to December 31, 2023, the first half of the demonstration period for the interim evaluation report (January 1, 2024, to June 30, 2026), and the full demonstration period (January 1, 2024, to December 31, 2028).

Table 1 shows evaluation periods for monthly versus annual measures.

**Table 1: Demonstration Evaluation Periods**

| Measurement Frequency | Pre-Demonstration Period | Interim Evaluation Period | Summative Evaluation Period |
|---|---|---|---|
| **Monthly** | 1/1/2022–12/31/2023 | 1/1/2024–6/30/2026 | 1/1/2024–12/31/2028 |
| **Yearly** | 2022–2023 | 2024–2025 | 2024–2028 |

### Evaluation Measures

A mix of quantitative and qualitative measures will be used to evaluate the effects of the Demonstration. The Evaluation Measures table below describes each measure and outlines the data sources and analytic methods that will be used. The table links the goals and hypotheses with the research questions and proposed measures/research domains. The

[6]Clarke, V., & Braun, V. (2017). Thematic analysis. The Journal of Positive Psychology, 12(3), 297–298.

measure names, descriptions, numerators, and denominators/populations of interest are drawn directly from CMS's specifications for monitoring metrics, where available.

Mercer plans to leverage the SUD and SMI/SED monitoring metrics that the State will regularly report to CMS. Other quantitative measures will be drawn from the Healthcare Effectiveness Data and Information Set, Medicaid Core Set, or other standardized measure sets. Mercer will also use descriptive quantitative and qualitative measures to evaluate the implementation of the Demonstration, including barriers, challenges, and innovations. When quantitative measures are unavailable or impractical, Demonstration effects will be described in a qualitative manner.

In certain cases, Mercer will create measures for beneficiary subpopulations (when applicable and dependent on whether the subpopulation sizes are sufficiently large to allow for the measures to be defined). Some of the potential beneficiary subpopulations include:

- Dually eligible for Medicare.
- Age group.
- Pregnant.
- Legal-involved.
- OUD.
- SMI/SED.

Table 2, on the following page, outlines each evaluation measure and summarizes the data sources and analytic methods that will be used for each.

**Table 2: Evaluation Design Summary**

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Goal 1: Increased rates of identification, initiation, and engagement in treatment for substance use disorder (SUD). (SUD-1 in Special Terms and Conditions [STCs])** | | | | | | | |
| **Primary Driver 1:** Improved identification, initiation, and engagement in treatment (SUD-1), and access to a full continuum of care, including community-based services (SMI/SED) (SMI/SED-4) | **Research Question 1.1:** Was there an increase in the identification and initiation of treatment for beneficiaries with SUD? | | | | | | |
| | Number and rate of Medicaid Beneficiaries with SUD Diagnosis (monthly) | Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period and/or in the 11 months before the measurement period | CMS SUD Monitoring Metric #3 | Number of beneficiaries with a SUD and a Medicaid enrollees SUD-related service during the measurement period and/or in the 11 months before the measurement period | (For rate calculation) Total number of diagnosis during the measurement period | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) | Percentage of beneficiaries with a new episode of alcohol or other drug (AOD) abuse or dependence who received Initiation AOD Treatment | National Committee for Quality Assurance (NCQA), National Quality Forum (NQF) #0004 SUD Monitoring Metric #15(a) | Initiation of AOD treatment within 14 days<br><br>the index episode | Number of unique members with a new episode of AOD abuse or of dependence | Claims; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion to post-demonstration period proportion |
| | Consumer perceptions of access to care | Consumer perceptions regarding current state of access to care | Consumer survey - CAHPS | NA | Consumers | CAHPS or other consumer survey; Yearly | Frequency distributions and thematic summary |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Secondary Driver 1:** Provide reimbursement for all ambulatory and residential services, including MAT, at varying levels of intensity across a continuum of care | **Research Question 1.2:** Did the number of providers who were enrolled in Medicaid and qualified to deliver SUD services increase during the Demonstration period? | | | | | | |
| | SUD Provider Availability across the continuum of care (Annual) | Number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period | CMS SUD Monitoring Metric #13 | Number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period | NA | Provider enrollment database; Yearly | Descriptive time series<br><br>Percent change (no significance testing) |
| **Secondary Driver 4:** Submit an updated Provider Network Adequacy review annually and conduct outreach/improvement activities where gaps in services are noted across the SUD/SMI/SED continuum of care | Provider capacity (Qualitative) | Capacity of newly enrolled Medicaid providers qualified to deliver SUD services | NA | NA | Provider Network Adequacy review document<br><br>Key informant interviews or focus groups with State staff, providers, and managed care organizations (MCOs) | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | TA |
| | New providers and provider quality (Qualitative) | Increase in newly enrolled Medicaid providers qualified to deliver SUD services | NA | NA | Provider guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers, and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and | TA |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | | | | | summative reports) | |
| **Secondary Driver 2:** Provide reimbursement for residential and inpatient treatment in IMDs for SUD and SMI including guidance and coverage for all residential services | **Research Question 1.3:** How does the implementation of reimbursement for services provided in IMD settings influence access to specific SUD treatment services? | | | | | | |
| | Reimbursement including withdrawal management (Qualitative) | Availability of in reimbursement for services in IMD settings | NA | NA | State policies<br><br>Key informant interviews or focus groups with State staff, providers, and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | TA |
| | Reimbursement (Qualitative) | Content of policy reimbursement policy for services in IMD settings (which services are covered and at what rate) | NA | NA | State policies<br><br>Key informant interviews or focus groups with State staff, providers, and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | TA |
| | Provider reimbursement awareness (Qualitative) | Awareness of reimbursement for services in IMD settings | NA | NA | State policies, provider guidance documents<br><br>Key information interviews or focus groups with State | Document Reviews, Interviews<br><br>Key program intervals (preceding | TA |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | | | | staff, providers, and MCOs | midpoint, interim, and summative reports) | |
| **Primary Driver 1:** Improved identification, initiation, and engagement in treatment (SUD-1), and access to a full continuum of care, including community-based services (SMI/SED-4) | **Research Question 1.4:** Was there an increase in community knowledge of available SUD treatment and services? | | | | | | |
| | Community awareness of services | Changes in community awareness of available SUD services due to the Demonstration | NA | NA | NA | Consumer surveys, if possible or focus groups with consumers and advocacy groups<br><br>Yearly or key program intervals (preceding midpoint, interim, and summative reports) | Narrative, thematic analysis |
| | **Research question 1.5:** Was there an increase in the utilization of SUD-specific treatment services? | | | | | | |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Any SUD Treatment | Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period | CMS SUD Monitoring Metric #6 | Number of unique beneficiaries (de-duplicated) enrolled in the measurement period receiving at least one SUD treatment service or pharmacy claim during the measurement period | All Medicaid beneficiaries enrolled for any amount of time during the measurement period (population parameter) | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| **Primary Driver 1 (continued)** | Early Intervention | Number/percen t of beneficiaries who receive prevention or early intervention services | CMS SUD Monitoring Metric #7 | Number of unique members in the denominator with a claim for early intervention services | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Outpatient Services | Number/percen t of beneficiaries who receive outpatient services | CMS SUD Monitoring Metric #8 | Number of unique members in the denominator with a claim for outpatient services for SUD | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | Intensive Outpatient and Partial Hospitalization Services | Number/percen t of beneficiaries who receive intensive outpatient and partial hospitalization services | CMS SUD Monitoring Metric #9 | Number of unique members in the denominator with a claim for intensive outpatient or partial hospitalization services for SUD | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Primary Driver 1 (continued)** | Residential and Inpatient Services | Number/percen t of beneficiaries who receive residential and inpatient services | CMS SUD Monitoring Metric #10 | Number of unique members in the denominator with a claim for residential or inpatient services for SUD | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | Withdrawal Management | Number/percen t of beneficiaries who receive withdrawal management services | CMS SUD Monitoring Metric #11 | Number of unique members in the denominator with a claim for withdrawal management services for SUD | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | MAT | Number/percen t of beneficiaries who receive MAT services | CMS SUD Monitoring Metric #12 | Number of unique members in the denominator with a claim for MAT services for SUD | Members with a SUD diagnosis (CMS #3 SUD) for percentage | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Goal 2: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care. (SMI/SED-4 in STCs)** | | | | | | | |
| **Secondary Driver 4:** Submit an updated Provider Network Adequacy review annually and conduct outreach/improvement activities where gaps in services are noted across the SUD/SMI/SED continuum of care | **Research Question 2.1:** Was there an increase in access to community-based SMI/SED treatment services? | | | | | | |
| | Mental health providers | Number of mental health providers who enrolled in Medicaid and qualified to deliver services to beneficiaries with SMI/SED under the demonstration, in total and stratified by type (e.g., Mental Health Rehabilitation Services providers, physicians, other licensed practitioners) | NA | Total number of eligible mental health practitioners qualified to deliver services to SMI/SED beneficiaries (includes stratifications for provider type) | NA | Provider enrollment database; Yearly | Descriptive time series |
| **Primary Driver 1:** Improved identification, initiation, and engagement in treatment (SUD- 1), and access to a full continuum of care, including | **Research Question 2.2:** Was there an increase in community knowledge of available community-based SMI/SED treatment and services? | | | | | | |
| | Community awareness of services | Changes in community awareness of available SMI/SED treatment services due to | NA | NA | Consumers | Consumer surveys or focus groups<br><br>Key program intervals (preceding | Narrative, thematic analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| community-based services (SMI/SED-4) | | the Demonstration | | | | midpoint, interim, and summative reports) | |
| | **Research Question 2.3:** Was there an increase in utilization of SMI/SED-specific treatment services? | | | | | | |
| | Mental Health Services Utilization — Any Services | Number/percen t of beneficiaries in the demonstration with SMI/SED who used any services related to mental health during the measurement period | CMS SMI Monitoring Metric #18 | Number of unique beneficiaries (de-duplicated total) with a service claim for any services to mental health during the measurement period | Medicaid beneficiaries in the demonstration or with SMI/SED enrolled for any amount of time during the related measurement period *(Population of interest)* | Claims data; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| **Primary Driver 1 (continued)** | Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics | Percentage of children and adolescents ages 1 year–17 years old who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment | NCQA NQF #2801 SMI Monitoring Metric #2 | Number of Medicaid beneficiaries in denominator who received psychosocial care | Number of Medicaid beneficiaries ages the 1 year-17 years old who had a new prescription for an antipsychotic medication | Claims; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion to post-demonstration period proportion |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Secondary Driver 1:** Provide reimbursement for all ambulatory and residential services, including MAT, at varying levels of intensity across a continuum of care. | **Research Question 2.4:** How does the implementation of reimbursement for all ambulatory and residential services across the continuum of care influence access to services? | | | | | | |
| | Availability of reimbursement across continuum of care (Qualitative) | Availability of reimbursement for all ambulatory and residential services (SUD) across a continuum of care | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers, and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| | Awareness of reimbursement across continuum of care (Qualitative) | Awareness of reimbursement for all ambulatory and residential (SUD) services across a continuum of care | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers, and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| | Perceptions of reimbursement efficacy across continuum of care (Qualitative) | Perceptions of the extent to which reimbursement for all ambulatory and residential (SUD) services incentivized or | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | facilitated expanded access to treatment services | | | staff, providers and MCOs. | summative reports) | |
| **Secondary Driver 2:** Provide reimbursement for residential (SUD) and inpatient treatment (SMI) in IMDs including guidance and coverage for all residential services | **Research Question 2.5:** How does the implementation of reimbursement for residential (SUD) and inpatient treatment (SMI) in IMDs including guidance and coverage for all residential services influence access to services? | | | | | | |
| | Availability of reimbursement in IMDs (Qualitative) | Availability of reimbursement for residential (SUD) and inpatient treatment (SMI) in IMDs including guidance and coverage for all residential (SUD) services | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs. | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| | Awareness of reimbursement in IMDs (Qualitative) | Awareness of reimbursement for residential (SUD) and inpatient treatment (SMI) in IMDs including guidance and coverage for all residential (SUD) services | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Perceptions of reimbursement efficacy (in IMDs) | Perceptions of whether reimbursement for residential (SUD) and inpatient treatment (SMI) in IMDs including guidance and coverage for all residential services (SUD) incentivized or facilitated expanded access to services | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Goal 3: Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs and psychiatric hospitals and residential treatment settings throughout the State. (SMI/SED-3)** | | | | | | | |
| **Secondary Driver 3:** Improve availability of BHCCs including centers serving youth | **Research question 3.1:** Was there an increase in the availability of crisis stabilization services? | | | | | | |
| | Mental Health Services Utilization — Inpatient | Number/percen t of beneficiaries in the demonstration with SMI/SED who used Inpatient services related to mental health during | CMS Monitoring Metric #13 | Number of unique beneficiaries with SMI/SED (de-duplicated total) with an inpatient service claim for any services related to mental health | Number of unique beneficiaries with SMI/SED (CMS #21 SMI/SED) | Claims; SMI Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | the measurement period | | during the measurement period | | | |
| | Mental Health Services Utilization — Intensive Outpatient and Partial Hospitalization | Number/percen t of beneficiaries in the demonstration with SMI/SED who used Intensive Outpatient and Partial Hospitalization services related to mental health during the measurement period | CMS SMI Monitoring #14 | Number of unique Metric beneficiaries with SMI/SED (de-duplicated total) with an intensive outpatient or partial hospitalization service claim for any services related to mental health during the measurement period | Number of unique beneficiaries with SMI/SED (CMS #21 SMI/SED) | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| **Secondary Driver 3 (continued)** | Mental Health Services Utilization — Outpatient | Number of beneficiaries in the demonstration with SMI/SED who used Outpatient services related to mental health during the measurement period | CMS SMI Monitoring #15 | Number of unique Metric beneficiaries with SMI/SED (de-duplicated total) with an outpatient service claim for any services related to mental health during the measurement period | Number of unique beneficiaries with SMI/SED (CMS #21 SMI/SED) | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Mental Health Services Utilization — Telehealth | Number of beneficiaries in the demonstration with SMI/SED who used Telehealth services related to mental health during the measurement period | CMS SMI Monitoring Metric #17 | Number of unique beneficiaries with SMI/SED (de-duplicated total) with a telehealth service claim for any services related to mental health during the measurement period | Number of unique beneficiaries with SMI/SED (CMS #21 SMI/SED) | Claims; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | Awareness of available crisis stabilization services (Qualitative) | Awareness of available crisis stabilization services | NA | NA | Consumers | Consumer surveys or focus groups<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Goal 4: Increased adherence to and retention in treatment. (SUD-2)** | | | | | | | |
| **Primary Driver 3:** Increased adherence to and retention in treatment (SUD-2) | **Research Question 4.1:** Did the demonstration increase adherence to SUD treatment? | | | | | | |
| | IET-AD | Percentage of beneficiaries with a new episode of AOD abuse or dependence | NCQA, NQF #0004 SUD Monitoring Metric #15(b) | Engagement of AOD treatment within 14 days of the index episode | Medicaid beneficiaries aged 18 years and older during the measurement | Claims data; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion to |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | who received Engagement of AOD Treatment | | | period *(Denominator)* | | post-demonstration period proportion |
| | Continuity of Pharmacothera py for Opioid Use Disorder | Number and percentage of beneficiaries who have at least 180 days of continuous pharmacothera py with a medication prescribed for OUD without a gap of more than seven days | USC, NQF#3175 SUD Monitoring Metric #22 | Number of beneficiaries who have at least 180 days of continuous pharmacothera py with a medication prescribed for OUD without a gap of more than seven days | Individuals who had a diagnosis of OUD and at least one claim for an OUD medication *(Denominator)* | Claims data; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period |
| | Consumer adherence to treatment plans | Beneficiary self-report of how well they have adhered to their providers' treatment advice | NA | NA | Consumers | Consumer surveys or focus groups<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Frequency Distribution; Thematic analysis |
| | Consumer perceptions of treatment plans | Perceptions of facilitators and barriers to adherence to SUD treatment | NA | NA | Consumers | Consumer surveys or focus groups | Frequency Distribution; Thematic analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | | | | | Key program intervals (preceding midpoint, interim, and summative reports) | |
| **Secondary Driver 5:** Continue telehealth initiatives and continue to improve access in rural counties | **Research Question 4.2**: Has the continued support of telehealth facilitated treatment engagement? | | | | | | |
| | Telehealth utilization | Stakeholder reports of telehealth utilization | NA | NA | Consumers | Consumer surveys or focus groups<br><br>Key program intervals (preceding midpoint, interim and summative reports). | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Telehealth efficacy (Qualitative) | Perception of the role of telehealth in promoting retention and engagement | NA | NA | State policies, guidance documents, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Secondary Driver 6:** Implement planning and quality improvement projects in collaboration with HINs, members of the Missouri Medicaid Enterprise, and other stakeholders (to facilitate care coordination and continuity of care | **Research Question 4.3:** How have quality improvement (QI) efforts impacted engagement in SUD treatment? | | | | | | |
| | QI Efforts in Care Coordination (Qualitative) | Perceptions of how QI efforts have affected quality of care coordination and continuity of care | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs. | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Secondary Driver 9:** Offer technical | **Research Questions 4.4:** Has technical assistance and training led to increased use of and fidelity to EBPs? Has this led to increased engagement in SUD treatment? | | | | | | |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| assistance (TA) and training on EBP in clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis | TA and training for EBPs (Qualitative) | Perceptions of the effects of TA and training in the use of EBPs | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br><br>Key informant interviews or Focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Goal 5: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. (SMI/SED-5)** | | | | | | | |
| **Primary Driver 4:** Improved care | **Research Question 5.1**: Was there an increase in utilization of follow-up services for beneficiaries with SMI/SED after episodes of acute care in hospitals? | | | | | | |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| coordination, continuity of care, and access to care for physical health conditions/integrated care (SMI/SED- 5, SUD-6) | Follow-up After Hospitalization for Mental Illness: Age 18 Years and Older (FUH-AD) | Percentage of discharges for beneficiaries aged 18 years and older who were hospitalized for treatment of selected mental illness diagnoses or intentional self- harm and who had a follow-up visit with a mental health practitioner within seven days or within 30 days | NCQA, NQF #0576 SMI Monitoring Metric #8 | A follow-up visit with a mental health practitioner within seven days or 30 days after discharge | Number of discharges for beneficiaries age 18 years and older who were hospitalized for treatment of selected mental illness diagnoses or intentional self-harm *(Denominator)* | Claims data; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period |
| | Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD) | Percentage of ED visits for beneficiaries age 18 years and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness within | NCQA, NQF #2605 SMI Monitoring and Metric #10 | A follow-up visit with any practitioner, with a principal diagnosis of a mental health disorder or with a principal diagnosis of intentional self-harm and any diagnosis of mental health disorder | Number of ED visits for beneficiaries age 18 years and older with a principal diagnosis of mental illness or intentional self-harm *(Denominator)* | Claims data; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | seven days of the ED visit or within 30 days of the ED visit | | within seven days or 30 days after the ED visit | | | |
| **Secondary Driver 7:** Continue the PCHH program, HCT, and requirements of CCBHCs and CMHC HCHs. | **Research Question 5.2** Did the PCHH, HCT, CCBHO and HCH programs improve care coordination? | | | | | | |
| | Care coordination improvement efforts (Qualitative) | Perceptions of effects of PCHH, HCT, CCBHOs, and HCHs on improved care coordination | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Secondary Driver 8:** Add requirements to assess housing and coordinate with housing service providers | **Research Question 5.3** Did housing assessments and coordination with housing providers improve care coordination? | | | | | | |
| | Housing coordination efforts (Qualitative) | Perceptions of effects of housing assessments and collaboration with service providers on care coordination | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| **Secondary Driver 9:** Offer TA and training on EBP in | **Research Question 5.4:** Did care coordination improve for beneficiaries with SMI/SED? | | | | | | |
| | Diabetes Care for People with | Percentage of beneficiaries | NCQA NQF #2607 | Number of beneficiaries in | Number of Medicaid | Claims; Yearly | Descriptive time series; pre-post |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis | SMI: Hemoglobin A1c (HbA1c) Poor Control (> 9.0%) (HPCMI-AD) | ages 18 to 75 with a serious mental illness and diabetes (type 1 or type 2) who had HbA1c in poor control (> 9.0%) | SMI Monitoring Metric #23 | the denominator who had HbA1c > 9.0% | beneficiaries with a SMI and diabetes (type 1 or type 2) | | Chi-square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period |
| | Care coordination for beneficiaries with SMI/SED | Beneficiary perceptions of how their health care providers work together | NA | Number of beneficiaries who rate their providers' collaboration highly | Total number of survey participants *(Denominator)* | CAHPS, or other member survey<br><br>Yearly | Frequency distributions |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
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| **Primary Driver 4:** Improved care coordination, continuity of care, and access to care for physical health conditions/integrated care (SMI/SED- 5, SUD-6) | **Research Question 5.5:** Did the Demonstration increase integration of primary and behavioral health care for beneficiaries with SMI or SED? | | | | | | |
| | Effects of integrated care improvements (Qualitative) | Perceptions of whether the Demonstration increased integration of primary and behavioral health care for beneficiaries with SMI or SED | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |
| | Integrated care improvements (Qualitative) | Descriptions of ways primary and behavioral health care are integrated for beneficiaries with SMI or SED | NA | NA | Stakeholder engagement and workgroup meeting materials, monitoring reports<br><br>Key informant interviews or focus groups with State staff, providers and MCOs | Document Reviews, Interviews<br><br>Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Documents | Data Source & Measure Source Frequency | Analytic Approach |
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| **Goal 6: Improved access to care for physical health conditions among beneficiaries with SUD. (SUD-6/integrated care)** | | | | | | | |
| **Primary Driver 4:** Improved care coordination, continuity of care, and access to care for physical health conditions/integrated care (SMI/SED- 5, SUD-6) | **Research Question 6.1:** Was there an increase in access to care for physical health conditions among beneficiaries with SUD? | | | | | | |
| | Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD | Percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period | NCQA, Adjusted HEDIS Measure — SUD Monitoring Metric #32 | Number of Medicaid beneficiaries who had an ambulatory or preventive care visit during the measurement period | Number of Medicaid beneficiaries with a diagnosis of SUD during the measurement period *(Denominator)* | Claims data; Yearly | Descriptive time series; pre-post chi-square test of significance comparing baseline proportion to post-demonstration period proportion |
| **Secondary Driver 9:** Offer TA and training on EBP in clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis | **Research Question 6.2:** Did care coordination improve for beneficiaries with SUD? | | | | | | |
| | Care coordination for beneficiaries with SUD | SUD Beneficiary perceptions of how their health care providers work together | NA | Number of SUD beneficiaries who rate their providers' collaboration highly | Total number of survey participants *(Denominator)* | Survey or focus group<br><br>Key reporting periods | Descriptive Statistics<br><br>Frequency Distribution with chi-square test of significance comparing reporting periods |
| **Goal 7: Reduced utilization and length of stay in hospital ED among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings. (SMI/SED-1)** | | | | | | | |
| **Primary Driver 5:** Reduced utilization of hospital EDs and inpatient hospital | **Research Question 7.1:** Was there a decrease in ED services by beneficiaries with SMI/SED? | | | | | | |
| | Mental Health Services | Number and percentage of beneficiaries in | CMS — SMI Monitoring Metric #16 | The total number of unique | Number of unique beneficiaries with | Claims data; Monthly | ITS, with analysis for each subgroup, |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
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| settings (SMI/SED-1, SUD-4) | Utilization — ED | the demonstration or with SMI/SED who use ED services for mental health during the measurement period | | beneficiaries (de-duplicated total) who have a claim for emergency services for mental health during the measurement period | SMI/SED (CMS #21 SMI/SED) | | as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| **Secondary Driver 9:** Offer TA and training on EBP in clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis | **Research Question 7.2:** Did TA and training on EBPs reduce the use of ED services? | | | | | | |
| | Effect of EBPs on ED use (Qualitative) | Perceptions of the how TA and training in the use of EBPs affected ED use | NA | NA | Key informant interviews or focus with State providers and MCOs | Key program intervals groups (preceding staff, midpoint, interim, and summative reports) | Thematic Analysis |
| **Secondary Driver 10:** Utilization review process to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight on lengths of stay for the full continuum | **Research Question 7.3:** Did the utilization review process reduce the use of ED services? | | | | | | |
| | Efficacy of the utilization review process (Qualitative) | Perceptions of the how the utilization process affected rates of ED use | NA | NA | Key informant interviews or focus with State providers and MCOs | Key program intervals groups (preceding staff, midpoint, interim, and summative reports) | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
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| of SMI/SED and SUD | | | | | | | |
| **Goal 8: Reduced utilization of hospital EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate, through improved access to other continuum of care services. (SUD-4)** | | | | | | | |
| **Primary Driver 5:** Reduced utilization of hospital EDs and inpatient hospital settings (SMI/SED-1, SUD- 4) | **Research Question 8.1:** Was there a reduction in ED or inpatient utilization for beneficiaries with SUD? | | | | | | |
| | Inpatient stays for SUD per 1,000 Medicaid Beneficiaries | Total number of SUD-related inpatient stays per 1,000 beneficiaries in the measurement period | CMS-constructed<br><br>SUD Monitoring Metric #24 | The number of inpatient discharges related to a SUD stay during the measurement period | Beneficiaries with diagnosed SUD enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period *(Denominator)* | Claims data; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |
| | ED Utilization for SUD per 1,000 Medicaid Beneficiaries | Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period | CMS SUD Monitoring Metric #23 | The number of ED visits for SUD during the measurement period | Beneficiaries with diagnosed SUD enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period *(Denominator)* | Claims data; Monthly | ITS, with analysis for each subgroup, as listed on page 21<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Documents | Data Source & Measure Source Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Secondary Driver 9:** Offer TA and training on EBP in clinical care coordination, new residential provider standards, opioid prescribing practices, and first episode of psychosis | **Research Question 8.2:** How does the Demonstration influence preventable utilization of ED or inpatient care through improved access to other continuum of care services? | | | | | | |
| | Beneficiary knowledge of crisis response services | Perceptions of whether Demonstration activities can reduce preventable utilization of ED or inpatient care | NA | Number of beneficiaries who report that they know they can get help when in crisis outside of the ED | Total number of survey participants *(Denominator)* | Survey or Focus Group<br><br>Key reporting intervals (preceding midpoint, interim; and summative reports) | Descriptive Statistics Frequency Distribution with chi-square test of significance comparing reporting periods<br><br>Thematic Analysis |
| **Secondary Driver 11:** Implement the Prescription Drug Monitoring Program (PDMP) fully and continue development of Missouri Care Coordination Insights Project technology | Effect of the PDMP on preventable ED use (Qualitative) | Perceptions of how the Demonstration has reduced preventable utilization of ED or inpatient care | NA | NA | Key informant interviews or focus groups with State staff, providers and MCOs | Key program intervals (preceding midpoint, interim, and summative reports) | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Goal 9: Reduced preventable readmissions to acute care and specialty hospitals and residential settings. (SMI/SED-2)** | | | | | | | |
| **Primary Driver 6: Reduced readmissions to acute/specialty/higher levels of care (SMI/SED-2, SUD-5)** | **Research Question 9.1:** Was there a decrease in preventable readmissions to acute care, specialty hospitals, and residential settings for beneficiaries with SMI/SED? | | | | | | |
| | 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF) | The rate of unplanned, 30-day, readmission rate for demonstration beneficiaries with a primary discharge diagnosis of a psychiatric disorder or dementia/Alzheimer 's disease | Inpatient Psychiatric Facility Quality Reporting (IPFQR), NQF #2860 SMI Monitoring Metric #4 | The count of 30-day readmissions. A readmission is defined as any admission, for any reason, to an IPF or a short-stay acute care hospital (including critical access hospitals) that occurs within 30 days after the discharge date from an eligible index admission to an IPF, except those considered planned. The measure uses the CMS 30-day Hospital-Wide Readmission Measure | The count of index hospital admissions to IPFs *(Denominator)* | Claims data; Yearly | Descriptive statistics<br><br>Percent change (no tests for significance) |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | | | Planned Readmission Algorithm, Version 4.0 | | | |
| **Primary Driver 6 (continued)** | Effect of demonstration on readmissions acute care, specialty hospitals, and residential settings (Qualitative) | Perceptions of whether there was a decrease in preventable readmissions to acute care and specialty hospitals and residential settings | NA | NA | Key informant interviews or Focus groups with staff, providers, and MCOs | Key program intervals (preceding State midpoint, interim, and summative reports) | Thematic Analysis |
| **Goal 10: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate. (SUD- 5)** | | | | | | | |
| **Primary Driver 6:** Reduced readmissions to acute/specialty/higher levels of care (SMI/SED-2, SUD-5) | **Research Question 10.1:** Was there a decrease in preventable or medically inappropriate readmissions to the same or higher level of care for beneficiaries with SUD? | | | | | | |
| | Readmissions among beneficiaries with SUD | The rate of all-cause readmissions during the measurement period among beneficiaries with SUD | CMS SUD Monitoring Metric #25 | The count of day readmissions: at least one acute readmission for any diagnosis within 30 days of the Index Discharge Date | The count of Index Hospital Stays for beneficiaries with SUD *(Denominator)* | Claims data; 30- Yearly | Descriptive statistics<br><br>Percent change |
| | Demonstration implementation and effects | Perceptions of whether there was a decrease | NA | NA | Key informant interviews or focus groups with State | Key program intervals (preceding | Thematic Analysis |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator(s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | in preventable or medically inappropriate readmissions to the same or higher level of care for beneficiaries with SUD | | | staff, providers, and MCOs | midpoint, interim, and summative reports) | |
| **Goal 11: Reductions in overdose deaths, particularly those due to opioids. (SUD-3)** | | | | | | | |
| **Primary Driver:** All primary drivers | **Research Question 11.1:** Was there a decrease in the rate of overdose deaths? | | | | | | |
| | Overdose deaths | Number and percentage of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration | CMS SUD Monitoring Metric #26 | Number of SUD overdose deaths during the measurement period among Medicaid beneficiaries | Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period or the 30 days prior to the beginning of the measurement period *(Denominator)* | Vital records data; Yearly | Descriptive statistics (also looking at the subpopulation for Opioid related deaths, if possible)<br><br>Percent change (no tests for significance) |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| **Goal 12: Improvements in outcomes for members using SUD or SMI/SED services with similar or lower service costs.** | | | | | | | |
| **Research Question 1:** Have increasing trends in total cost of care been slowed for individuals with SUD diagnoses? | | | | | | | |
| | SUD Spending | Total SUD spending | CMS SUD Monitoring Metric #28 | The sum of all Medicaid spending on SUD treatment services | None | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | SUD Spending within IMDs | Total SUD spending within IMDs | CMS SUD Monitoring Metric #29 | The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs | None | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | Per Capita SUD Spending | Total SUD spending per Medicaid beneficiary | CMS SUD Monitoring Metric #30 | The sum of all Medicaid spending on SUD treatment services (CMS #28 SUD) | Members with a SUD diagnosis (CMS #4 SUD) | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | Per Capital SUD Spending within IMDs | Total SUD spending in IMDs per Medicaid beneficiary | CMS SUD Monitoring Metric #31 | The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs (CMS #29) | Number of members with a claim for inpatient/ residential treatment for SUD in an IMD | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Total Cost per member per month (PMPM) for members with an SUD diagnosis | Total Cost per member per month (PMPM) for members with an SUD diagnosis | CMS SUD and SMI/SED Evaluation Design Guidance, Appendix C https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smi-sed-sud-cost-appendix-c_196.pdf | The sum of all Medicaid spending (Inpatient, Outpatient, Pharmacy, Long-Term Care, Capitation payments, Administrative Costs, Federal Costs) for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SUD Cost Drivers — Total SUD Spending PMPM | Total SUD spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on SUD treatment services (CMS #28) | Member months per quarter for members with a SUD diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SUD Cost Drivers —IMD SUD Spending PMPM | Total SUD IMD spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on SUD treatment services within an IMD | Member months per quarter for members with a SUD diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SUD Cost Drivers —Non-IMD SUD Spending PMPM | Non-IMD spending per | CMS SUD Evaluation Design | The sum of all Medicaid spending on SUD | Member months per quarter for | Claims/encounters | ITS |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | member per month | Guidance, Appendix C | treatment services not within an IMD | members with a SUD diagnosis | Quarterly | F-statistic (regression model) for tests of statistical significance |
| | SUD Cost Drivers —Non-SUD Spending PMPM | Non-SUD Medicaid spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on non-SUD treatment for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SUD — Inpatient services PMPM | Inpatient treatment spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on inpatient treatment for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis (CMS #4) | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SUD — ED services PMPM | ED services spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on emergency department services for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis (CMS #4) | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with | Non-ED outpatient services spending per | CMS SUD Evaluation Design | The sum of all Medicaid spending on non-ED | Member months per quarter for members with | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | SUD — non-ED Outpatient services PMPM | member per month | Guidance, Appendix C | Outpatient services for members with a SUD diagnosis | a SUD diagnosis (CMS #4) | | model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SUD — Pharmacy PMPM | Pharmacy spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on Pharmacy for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis (CMS #4 SUD) | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SUD — Long-Term Care PMPM | Long-term care spending per member per month | CMS SUD Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on Long-Term Care for members with a SUD diagnosis | Member months per quarter for members with a SUD diagnosis (CMS #4 SUD) | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| **Research Question 2:** Have increasing trends in total cost of care been slowed for individuals with SMI/SED diagnoses? | | | | | | | |
| | SMI/SED Spending within IMDs | Total Medicaid spending for mental health treatment in and IMD | CMS SMI Monitoring Metric #39 | The sum of all Medicaid spending for mental health treatment services in an IMD | None | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | Per capita costs associated with treatment for mental health in and IMD among | Total per capita Medicaid spending for mental health | CMS SMI Monitoring Metric #40 | The sum of all Medicaid spending for mental health treatment | Number of members with a claim for mental health | Claims/encounters; Yearly | Descriptive time series |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | beneficiaries with SMI/SED | for beneficiaries with SMI/SED | | services in an IMD | treatment for SMI/SED | | Percent change (no tests for significance) |
| | SMI/SED Spending — not Inpatient or Residential | Total spending for SMI/SED Medicaid treatment services not inpatient or residential | CMS SMI Monitoring Metric #32 | The sum of all Medicaid spending on SMI/SED treatment services not inpatient or residential | None | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | Per Capita SUD Spending not within Inpatient/ Residential | Per capita Medicaid spending for treatment of SMI/SED within inpatient or residential | CMS SMI Monitoring Metric #34 | Medicaid spending not on inpatient/ residential treatment for SMI/SED | Number of members with a claim for mental health non-inpatient/ residential treatment for SMI/SED | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | SMI/SED Spending within Inpatient/ Residential | Total Medicaid SMI/SED Spending within Inpatient/ Residential | CMS SMI Monitoring Metric #33 | The sum of all Medicaid spending on inpatient/ residential treatment for SMI/SED | None | Claims/encounters; Yearly | Descriptive time series<br><br>Percent change (no tests for significance) |
| | Per Capita SUD Spending within Inpatient/ Residential | Per capita Medicaid SUD spending for inpatient/ | CMS SMI Monitoring Metric #35 | Medicaid spending on inpatient/ residential | Number of members with a claim for mental health inpatient/ residential | Claims/encounters | Descriptive time series |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | residential treatment | | treatment for SMI/SED | treatment for SMI/SED | | Percent change (no tests for significance) |
| | Total Cost PMPM | Total Medicaid spending per member per month | CMS SUD and SMI/SED Evaluation Design Guidance, Appendix C<br><br>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smi-sed-sud-cost-appendix-c_196.pdf | The sum of all Medicaid spending (Inpatient, Outpatient, Pharmacy, Long-Term Care, Capitation payments, Administrative Costs, Federal Costs) for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SMI/SED Cost Drivers — Total SMI/SED Spending PMPM | Total Medicaid spending PMPM on SMI/SED treatment services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on SMI/SED treatment services | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SMI/SED Cost Drivers —IMD SMI/SED Spending PMPM | Medicaid IMD spending on SMI/SED treatment services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on SMI/SED treatment | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | | | | services within an IMD | | | of statistical significance |
| | SMI/SED Cost Drivers — Non-IMD Mental Health Spending PMPM | Total Medicaid spending PMPM on non IMD mental health services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on mental health treatment services not within an IMD | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | SMI/SED Cost Drivers — Non-Mental Health Spending PMPM | Total Medicaid spending PMPM on non- mental health services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on non- mental health treatment for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SMI/SED — Inpatient services PMPM | Total Medicaid spending PMPM on mental health services for SMI/SED | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on inpatient treatment for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SMI/SED — ED services PMPM | Total Medicaid spending PMPM on ED mental health services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on ED services for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |

| Goal/Driver | Measure Name | Measure Description | Measure Steward | Numerator | Denominator( s), Population, or Source Documents | Data Source & Measure Frequency | Analytic Approach |
|---|---|---|---|---|---|---|---|
| | Source of treatment cost drivers for members with SMI/SED — non-ED Outpatient services PMPM | Total Medicaid spending PMPM on non- ED outpatient services | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on non-ED Outpatient services for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SMI/SED — Pharmacy PMPM | Total Medicaid pharmacy spending PMPM | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on Pharmacy for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |
| | Source of treatment cost drivers for members with SMI/SED — Long-Term Care PMPM | Total Medicaid spending PMPM on long-term care | CMS Evaluation Design Guidance, Appendix C | The sum of all Medicaid spending on Long-Term Care for members with a SMI/SED diagnosis | Member months per quarter for members with a SMI/SED diagnosis | Claims/encounters; Quarterly | ITS<br><br>F-statistic (regression model) for tests of statistical significance |

## Data Sources

Mercer will use various data sources to answer the evaluation questions. Qualitative data collection will include document reviews, as well as key informant interviews and focus groups with State implementation staff, providers, and other key stakeholders. Work is also underway to identify an existing beneficiary survey that questions can be added to in order to elicit further data related to consumer experiences. For purposes of the quantitative analysis, Medicaid claims and other administrative data will be collected in coordination with the State. This design assumes that Mercer will work with the State to summarize claims and administrative data and report on certain metrics required in the monitoring protocol.

### Qualitative Data

Qualitative data collection will help to:

- Describe the systems changes made as part of the Demonstration, including the challenges, successes, and the strategies to overcome barriers.
- Assess the extent to which these changes help the State achieve the Demonstration goals.
- Understand provider and beneficiary awareness of and experiences with the changes.

Mercer will review relevant State documents to understand system changes that occur under the Demonstration and overlapping initiatives that may complicate or support Demonstration activities. Examples of key documents to review include:

- Demonstration Implementation and Health Information Technology Plans.
- Demonstration Monitoring Reports.
- State policies (e.g., rules, legislation, contract language).
- Provider guidance documents (e.g., bulletins).
- Assessment and placement tools.
- Stakeholder engagement and workgroup meeting materials.
- Materials about co-occurring initiatives (e.g., grant narratives, reports).

At key program intervals (e.g., prior to interim evaluation report, summative report, etc.), Mercer will conduct individual and focus group interviews with representatives from State implementation staff, providers, MCOs, as well as community stakeholders recruited from existing consumer advisory/advocacy groups. The primary goals of the key informant/focus group interviews are to clarify information available via the document reviews as needed, to identify the challenges and facilitators to implementing Demonstration drivers, and to identify further potential outcomes that cannot be measured with existing metrics. Using focus groups can help to efficiently increase the number of perspectives included in the qualitative data. This also allows the State and Mercer to take advantage of existing group forums and meetings which, in Mercer's experience, increases participation and allows observation of the level of consensus or discord on specific qualitative measures.

Additionally, Mercer is working with the State to identify existing consumer surveys to which 1115 evaluation-specific questions could be added to capture consumer perspectives. If this is not possible, Mercer will conduct focus groups with groups of consumers and existing consumer advocacy groups to add these perspectives.

### Quantitative Data

In terms of quantitative data, Mercer will work with the State to summarize claims data related to the Medicaid FFS and managed care programs. The data will come from the State's Medicaid Management Information System. Administrative data needed for the evaluation will be extracted from other State data sources. To determine if data to be used for the evaluation are complete and accurate, Mercer will review the quality and completeness of data sources (including, but not limited to claims data for pharmacy, professional, and facility services, as well as eligibility data). Examples of analyses that will be performed to determine reliability and accuracy of claims data include, but are not limited to: frequency and volume reports, valid value assessment, missing value review, date and numerical distribution review, checks for duplicates, and reasonability and benchmarking checks against other relevant data sources. As often as possible, measures in the evaluation have been selected from nationally recognized measure stewards for which there are strict data collection processes and audited results.

Information from additional data sources, such as Vital Records data on overdose deaths, will be assessed for completeness and accuracy based on State's knowledge and to the best of Mercer's ability. Regarding overdose death data, the State is currently exploring options for obtaining this data from the State Department of Health and Senior Services. Assuming the State can obtain the level of detail needed to link Medicaid data to overdose deaths, the evaluation will make this link using Medicaid identification numbers (or, if needed, via other potential data fields such as name and date of birth). If Medicaid member deaths cannot be linked to Vital Records data, then the State will utilize statewide overdose death data for reporting and will note this in the evaluation and monitoring protocol.

It is important to note that this Demonstration's monitoring protocol has not yet been submitted to CMS based on CMS's request for the State to wait until the new CMS template is released. As a result, specific data sources and features of this design could change if CMS makes substantive changes to the monitoring protocol template and requirements.

## Analytic Methods

Depending on the type of data for the measure and the use of the measure in the evaluation design (e.g., process measure versus outcome measures), multiple analytic techniques will be used.

Narrative thematic analsyis will be used to present data related to qualitative evaluation measures gathered from document reviews and key informant interviews, as discussed previously. Qualitative analysis software (R Qualitative or ATLAS) will be used to organize documentation, including key informant interview transcripts. Analysis will identify common themes across interviews and documents. In some cases, checklists may be used to analyze documentation for compliance with standards. These data will be summarized to describe the

activities undertaken for each project goal, including highlighting specific successes and challenges.

Descriptive statistics, including frequency distributions and time series (presentation of rates over time), will be used for quantitative process measures to describe the output of specific Demonstration activities. These analysis techniques will also be used for some short-term outcome measures in cases in which the role of the measure is to describe changes in the population, but not to show specific effects of the Demonstration.

An ITS design will be used to describe the effects of waiver implementation. ITS models are commonly used in situations in which a contemporary comparison group is not available. An ITS design is the most rigorous design possible due to the lack of an available comparison group. Because the implementation effects all Medicaid members, the only possible in-State comparison group would be privately insured individuals, which would not be comparable to the Medicaid population. Additionally, the State has no mechanism for gathering claims data for those individuals in order to make those comparisons.

Out of state comparisons cannot be made with states who are not Demonstration states, as they are unlikely to be calculating/reporting the same metrics to provide them for comparison. The amount of data processing needed to calculate those metrics (assuming states would be willing to share raw claims data) would be cost prohibitive.

Specific outcome measure(s) will be collected for multiple time periods both before and after the start of the intervention. Segmented regression analysis will be used to statistically measure the changes in level and slope in the post-intervention period (after the Demonstration was initiated) compared to the pre-intervention period (before the Demonstration). The ITS design will be dependent on the availability of historical data for specific outcome measures (see Section D: Methodology Limitation section for more information). The ITS design uses historical data to forecast the *counterfactual* of the evaluation (i.e., what would happen if the Demonstration did not occur). Mercer proposes using basic time series linear modeling to forecast these *counterfactual* rates for three years following the Demonstration implementation. The more historical data available, the better these predictions will be.

In cases in which both ITS and descriptive time series analyses are used, the t-test statistic will be reviewed to understand the significance of changes across evaluation time periods: pre-Demonstration and the Demonstration period.

For this Demonstration, establishing the counterfactual is somewhat nuanced. The Driver Diagram and evaluation hypotheses assume that Demonstration activities will have overall positive impacts on outcome measures. The figure below illustrates an ITS design that uses basic regression forecasting to establish the counterfactual — this is represented by the grey line in the graphic. The counterfactual is based on historical data (the blue line). It uses time series averaging (trend smoothing) and linear regression to create a predicted trend line (shown below as the grey line). The orange line in the graph is the (sample) actual observed data. Segmented regression analysis will be used to statistically measure the changes in level and slope in the post-intervention period compared to the predicted trend (see *effect* in the graph below).

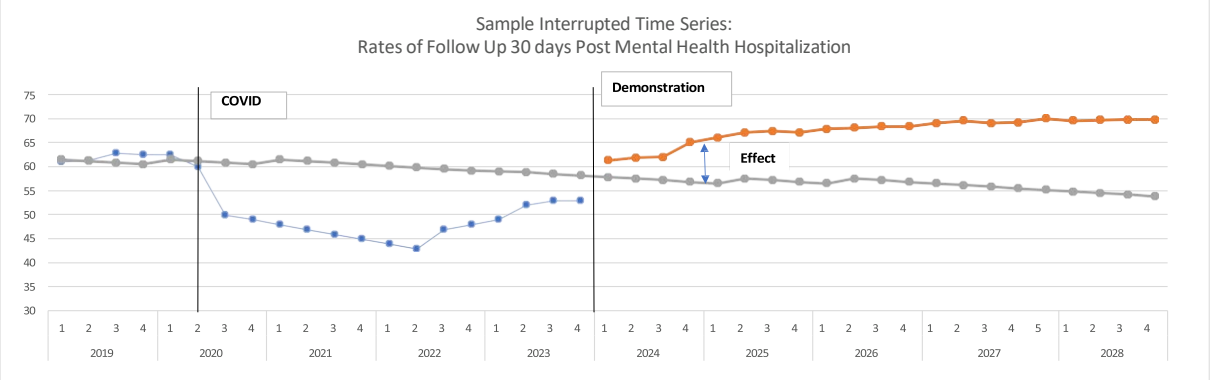
The ITS regression equation is:

$$Y_t = \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 T X_t$$

Where $\beta_0$ represents the baseline observation, $\beta_1$ is the change in the measure associated with a time unit (quarter or year) increase (representing the underlying pre-intervention trend), $\beta_2$ is the level change following the intervention, and $\beta_3$ is the slope change following the intervention (using the interaction between time and intervention: $TX_t$).[7]

This can be represented graphically as follows:

**Figure 5: (Sample Data Only) Rates of Follow-Up Post Mental Health Hospitalization**




The evaluation will include a sensitivity analysis that considers the effects of the COVID-19 public health emergency, particularly on the pre-Demonstration period data. A more general sensitivity analysis will also be conducted to test robustness of the model. Sensitivity tests will be included for the ITS to assess the model's robustness when time periods are varied. The length of the pre-Demonstration period will be varied to determine whether shorter or longer periods change the estimated impacts of the Demonstration. Additionally, the definition of the beginning of the first Demonstration period will be varied to account for the possibility that Demonstration effects may have lagged behind the implementation start date.

[7] Bernal JL, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial (2017 Feb.). International Journal of Epidemiology 46(1): 348-355.

## Section D.

# Methodological Limitations

There are two primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either are not sufficient to conduct the analysis proposed here (e.g., not enough historical data for needed prior time periods) and/or data containing errors. The second limitation is related to the design itself. Because this evaluation plan relies heavily on descriptive time series analysis and qualitative data, it can easily demonstrate what happened after the Demonstration was implemented, but it will be difficult to isolate why the changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. These limitations are discussed in greater detail within this section.

### Potential Data Issues

There could be issues with data completeness, consistency, and accuracy if the pre-Demonstration period for the ITS analysis is extended prior to 2022. One of the main reasons for this is that Missouri had a large-scale transition beginning in 2018 with the initiation of CCBHC services, as well as a large influx of Medicaid expansion members in late 2021. Therefore, Mercer will instead begin the look back period in 2022 and rely on the ITS sensitivity analysis to help mitigate any issues remaining in the data during 2022–2023; qualitative data will be used to inform interpretations.

The COVID-19 pandemic may impact the historical data being used in the ITS analyses. This could present a challenge in the evaluation's ability to create an accurate prediction of the counterfactual, or what would have happened if the Demonstration had not been implemented. The 2022–2023 historical data will likely reflect some impact of the pandemic as emergency orders were lifted. The mitigation strategies that will be used to address this challenge include following an ITS design, inclusion of covariates that capture COVID-19 severity in regression models, and a sensitivity analysis that varies the historical time parameters to determine how the regression model changes when different time periods are used.

According to the literature on ITS analysis, estimating the level and slope parameters requires a minimum of eight observations before and after implementation in order to have sufficient power to estimate the regression coefficients. Mercer will work closely with the State and its data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

Also, vital records data on opioid overdose deaths may not be available at a member level with enough detail to match with Medicaid data; the reporting lag for this data is usually also longer than other secondary data sources. These limitations may require reporting this measure at a statewide level and may impact the reporting timing of the measure.

Qualitative data, while useful in confirming quantitative data and providing rich detail, can be compromised by individual biases or perceptions. Key informant interviews, for example, represent a needed perspective around context for Demonstration activities and outcomes. However, individuals may be limited in their insight or understanding of specific programmatic components, meaning the data reflects perceptions rather than objective program realities. The

evaluation will work to address these limitations by collecting data from a variety of different perspectives to help validate individuals' reports. In addition, standardized data collection protocols will be used in interviews, and interviewers will be trained to avoid *leading* the interviewee or inappropriately biasing the interview. It will also utilize multiple *coders* to analyze data and will create a structured analysis framework based on research questions that analysts will use to organize the data and to check interpretations across analysts. Finally, results will be reviewed with stakeholders to confirm findings.

Another potential threat to validity in this design is the potential incompleteness of data both before and after Demonstration implementation for a specific measure. Evaluators will work closely with the State and its data teams to ensure that complete data is available for each measure and discuss any specific data concerns or considerations on a measure-by-measure basis.

**Potential Design Issues**

A threat to the validity of this evaluation is external (history such as the pandemic). Because a comparison group cannot not be identified (e.g., a group of Medicaid consumers eligible for the Demonstration interventions, but who will not receive them and/or for whom data will not be collected), it will be difficult to attribute causality. It will be unclear whether the changes observed in outcomes are due entirely to the waiver interventions, rather than some external, outside cause (including other program and policy changes described earlier). However, the ITS design controls for this threat, to some degree, by linking what would have likely happened (e.g., forecasting the trajectory of counts and rates over time) without any program changes and comparing this forecast to actual changes over time. To strengthen this design as much as possible, as many data points will be collected as possible across multiple years preceding waiver changes. This will allow for adjustment of seasonal or other, cyclical variations in the data. Additionally, the design will examine multiple change points, identifying key areas of major program and policy adjustments, so that with each major milestone accomplishment, corresponding changes to metrics can be observed.

The ITS analysis will also include a sensitivity analysis to determine the degree to which specific ITS assumptions impact the analysis. Specifically, the degree to which the assumption that trends in time are linear versus non-linear will be addressed. Additionally, this model assumes that changes will occur directly after the intervention. However, it is possible that for some outcomes, there will be a lag between the start of the waiver and observed outcomes.

Mercer will also attempt to limit this threat to validity by triangulating the data. Data trends across multiple time periods will be compared to trends happening at other points in time (other large policy or program shifts that might influence the slope of the trend in addition to the Demonstration). Also, key informant interviews will be used to inform the quantitative findings and explain the degree to which individuals are seeing Demonstration impacts. Where available, comparisons will be made to national and other state data to determine whether Missouri is performing in a similar fashion to other Demonstration states, non-Demonstration states, or national benchmarks overall.

It should also be noted that the ITS cannot be used to make inferences about any one individual's outcomes as a result of the waiver. Conclusions can be drawn about changes to population rates, in aggregate, but cannot speak to the likelihood of any individual Medicaid member having positive outcomes as a result of the Demonstration.

# Section E.
# Attachments

## Independent Evaluator

As part of the STCs set forth by CMS, the State is required to arrange with an independent party to conduct an evaluation of the Demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. Through a request for proposal process, the State initiated a contract with Mercer for Medicaid consulting services and technical assistance. Under this contract, the State requested Mercer's assistance in developing the evaluation design; the State has also requested that Mercer conduct the waiver evaluation. Mercer will develop the Evaluation Design, conduct the analyses specified within this Evaluation Design, evaluate the results for conclusions, and draft the Interim and Summative Evaluation Reports.

Mercer has over 25 years of experience assisting state governments with the design, implementation, and evaluation of publicly sponsored health care programs. Across those years, Mercer has worked with over 35 different states. In addition, Mercer is currently assisting multiple states in performing independent evaluations of their 1115 Demonstration waivers. Beyond our 1115 expertise, Mercer also has unique knowledge of the State of Missouri based on our 25+ years working with State staff on a variety of Medicaid initiatives. Several projects have included the collection and analysis of eligibility, enrollment, encounter and financial data and production of year-over-year comparisons. Given Mercer's previous work with the State, our extensive experience with publicly sponsored health care, and our specialized knowledge in independent evaluation work performed for other state 1115 waivers, the Mercer team is well-equipped to work effectively as the State's external evaluator for the SUD and SMI/SED Demonstration.

## Conflict of Interest Statement

The State has taken steps to ensure that Mercer is free of any conflict of interest and will remain free from any such conflicts during the contract term. The State considers it a conflict if Mercer currently 1) provides services to MCOs or health care providers doing business in Missouri under the MO HealthNet program; or 2) provides direct services to individuals in State-administered programs included within the scope of the technical assistance contract. If the State discovers a conflict during the contract term, the State may terminate the contract pursuant to the provisions in the contract.

One of the byproducts of being a nationally operated group dedicated to the public sector is the ability to identify and avoid potential conflicts of interest with our firm's multitude of clients. To accomplish this, market space lines have been established by Mercer (US), Inc. Mercer Government Human Services Consulting (GHSC) was established within Mercer's Health & Benefits LLC practice to consult with singular, full-time focus on government entities and specifically avoid any conflicts of interest across our various consulting practices. Mercer GHSC exercises great caution to protect our reputation as an independent, trusted advisor to our clients, avoiding any conflicts of interest by working almost exclusively on the state side in publicly financed health care programs. Mercer GHSC does not have any conflicts of interest,

such as providing services to any MCOs or health care providers doing business in Missouri under the MO HealthNet program or providing direct services to individual recipients enrolled in State-administered programs.

Before signing a contract to work in the Medicaid market, either at the state-level or otherwise, Mercer businesses are required to discuss the potential work with Mercer's GHSC group. If there is a potential conflict (i.e., work for a Medicaid health plan or provider), the engagement is not accepted. If there is potential for a perceived conflict of interest, Mercer's GHSC group will ask the state client if they approve of this engagement. If the client approves, Mercer will develop appropriate safeguards such as staffing projects with separate teams, restricting access to files, and establishing process firewalls to avoid the perception of any conflict of interest. If the client does not approve, the engagement will not be accepted.

Given that Mercer is acting as both a technical assistance provider and independent evaluator for this project, the State and Mercer have implemented measures to ensure there are no perceived conflicts of interest. The Mercer evaluation team (subcontractor TriWest Group) will be functionally and physically separate from the technical assistance team, and the contract will not include any performance incentives that would contribute to a perception of conflicted interests between technical assistance services and the independence of the evaluation process. As an additional firewall, the evaluation analyses will be conducted by a Mercer subcontractor using data that has been reviewed and accepted by CMS (through monitoring protocol submissions) — the subcontractor will be focused on the evaluation analyses and will not be part of the technical assistance team.

Mercer's subcontractor has assured Mercer they have no conflicts and that they will take steps required by Mercer or the State to mitigate any perceived conflict of interest. To the extent that a conflict mitigation plan needs to be implemented with our subcontractor, Mercer will do so consistent with policies and processes outlined here.

Mercer, through our contract with the State, has assured that it presently has no interest and will not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance of its services. Mercer has further assured that in the performance of this contract, it will not knowingly employ any person having such interest. Mercer additionally certifies that no member of Mercer's Board or any of its officers or directors has such an adverse interest.

**Table 3: Evaluation Budget Estimate**

| Key Tasks | DY 1 (2024) | DY2 (2025) | DY3 (2026) | DY4 (2027) | DY5 (2028) | Final Evaluation (2029–2030) | Total Evaluation Cost |
|---|---|---|---|---|---|---|---|
| Evaluation Design | $110,000 | | | | | | |
| Data Collection and Analysis | $90,000 | $200,000 | $150,000 | $150,000 | $150,000 | $150,000 | |
| Mid-Point Assessment | $40,000 | $60,000 | | | | | |
| Interim Evaluation Report | | | | $20,000 | $130,000 | | |
| Summative Evaluation Report | | | | | $30,000 | $120,000 | |
| Project Management | $40,000 | $50,000 | $30,000 | $30,000 | $50,000 | $50,000 | |
| **Total Estimated Budget** | **$280,000** | **$310,000** | **$170,000** | **$190,000** | **$360,000** | **$330,000** | **$1,650,000** |

### Timeline and Major Milestones

The table below highlights key evaluation milestones and activities for the waiver and the dates for completion.

**Table 4: Evaluation Timeline**

| Deliverable | STC Reference | Date |
|---|---|---|
| Submit draft evaluation design plan to CMS | 11.3 | June 3, 2024 |
| Update evaluation design to incorporate feedback from CMS and send final evaluation design plan to CMS | 11.5 | 60 days after State receives comments from CMS |
| Submit mid-point assessment report to CMS | 8.7 | December 31, 2026 |
| Update mid-point assessment report to incorporate feedback from CMS and send final mid-point assessment report to CMS | 8.7 | 60 days after State receives comments from CMS |
| Submit draft interim evaluation report to CMS | 11.7.3 | December 31, 2027<br>(or with renewal application) |
| Update interim evaluation report to incorporate feedback from CMS and send final interim evaluation report to CMS | 11.7.5 | 60 days after State receives comments from CMS |
| Submit draft summative evaluation report to CMS | 11.8 | June 30, 2030 |
| Update summative evaluation report to incorporate feedback from CMS and send final summative evaluation report to CMS | 11.8 | 60 days after State receives comments from CMS |

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