DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

February 26, 2024

Michael Randol
State Medicaid Director
Department of Public Health and Human Services
111 North Sanders, Room 301
Helena, MT 59620

Dear Director Randol:

The Centers for Medicare & Medicaid Services (CMS) is approving Montana's (the "state") request to amend the section 1115(a) demonstration titled, "Healing and Ending Addiction through Recovery and Treatment Demonstration" ("HEART", or the "demonstration") (Project Number 11-W-00395/8) to provide expenditure authority for contingency management services to individuals who have been diagnosed with a stimulant use disorder, pre-tenancy and tenancy support services to qualifying individuals, and pre-release services for qualifying incarcerated beneficiaries.

This amendment to the demonstration is likely to promote Medicaid objectives by expanding on the coverage of health care services that would otherwise not be available and increase access to an array of services that are expected to allow beneficiaries to more effectively access healthcare. In addition, the provision of this additional coverage may lower program costs through improved beneficiary health, making it possible for the state to expand other coverage with the dollars saved, further promoting the coverage objective of the Medicaid statute.

Extent and Scope of Demonstration Amendment

Montana's application for the HEART demonstration, submitted October 1, 2021, included a request to cover contingency management for individuals who have been diagnosed with a stimulant disorder, pre-release services for qualifying incarcerated individuals, and pre-tenancy and tenancy support services to qualifying individuals, which were not approved at the time of the demonstration's approval on June 30, 2022.

Contingency Management

Today, CMS is approving expenditure authority for contingency management services for beneficiaries who have been diagnosed with a stimulant use disorder. Contingency Management is an evidence-based tool used for the treatment of stimulant use disorder, consisting of a series of incentives for meeting treatment goals. The state will implement the contingency management benefit through eligible behavioral health providers. To be eligible for contingency management, an individual must be assessed and determined to have a stimulant use disorder as

a primary diagnosis and have a completed American Society of Addiction Medicine (ASAM) criteria assessment, the results of which indicate that outpatient treatment is medically appropriate for the individual's condition and that they are able to be treated safely in an outpatient setting. Continency management will be offered along with other therapeutic interventions, as appropriate, and the coverage of contingency management is not conditioned on an eligible beneficiary's engagement in other psychosocial services. This service will be provided as part of a twelve-week program in which a participating beneficiary can receive incentive payments, per an established schedule, for testing negative for identified stimulants.

Pre-Tenancy and Tenancy Support Services

CMS is also approving expenditure authority for pre-tenancy and tenancy support services which are coverable under 1915(c) and 1915(i) waiver authorities. To be eligible for these services, a beneficiary must be diagnosed with a serious mental illness (SMI) or substance use disorder (SUD), meet the state's needs-based criteria, and have at least one of the following risk factors: at-risk of homelessness; history of homelessness; or, within the last twelve months, have had frequent or lengthy stays in an institutional or residential setting, frequent emergency department (ED) visits or hospitalizations, a history of incarceration, or a loss of housing as a result of behavioral health symptoms.

Pre-Release Services under Reentry Demonstration Initiative

Expenditure authority is also being provided to Montana to provide limited coverage for a targeted set of services furnished to certain incarcerated individuals for up to 30 days immediately prior to the beneficiary's expected date of release. The state's proposed approach closely aligns with CMS's "Reentry Demonstration Opportunity" as described in the State Medicaid Director Letter (SMDL) released April 17, 2023.[1] In addition to expecting to achieve the goals outlined in our guidance, Montana also aims to provide intervention for certain behavioral health conditions and use stabilizing medications, such as long-acting injectable antipsychotics and medications for addiction treatment for SUDs, with the goal of reducing overdose, and overdose-related death in the near-term post-release under this initiative, similar to California and Washington.

Eligible Individuals
Montana will cover a set of pre-release Medicaid benefits for Medicaid beneficiaries, ages 19 and older, who are inmates in state prisons, and who have a confirmed mental health diagnosis or a confirmed or suspected SUD diagnosis. Individuals residing in a state prison must be eligible for Medicaid as determined pursuant to an application filed before or during incarceration, and have an expected release date not later than 30 days after initiation of demonstration-covered services to qualify for pre-release services.

Medicaid Eligibility and Enrollment
CMS is requiring, as a condition of approval of this demonstration amendment, that Montana make pre-release outreach, along with eligibility and enrollment support, available to all individuals incarcerated in the facilities where the pre-release demonstration coverage will be

[1] https://www.medicaid.gov/federal-policy-guidance/downloads/smd23003.pdf

available. Upon an individual who already is enrolled in Medicaid entering a state prison, Montana will suspend Medicaid eligibility. If an individual is not enrolled in Medicaid when entering a state prison, Montana will ensure that, during the period of incarceration, the individual receives assistance with completing and submitting a Medicaid application sufficiently prior to their anticipated release date, such that the individual can receive the full duration of pre-release services, unless the individual voluntarily refuses such assistance.

Scope of Pre-Release Benefit Package
The pre-release benefit package is designed to support the proactive identification of both physical and behavioral health needs and includes development of a plan to address health and health related social needs (HRSN) for beneficiaries participating in the reentry demonstration initiative, while seeking to promote coverage and quality of care to improve transitions for such beneficiaries. It also addresses the overarching demonstration goals, to ensure that participating state prisons can feasibly provide all pre-release benefits to qualifying incarcerated beneficiaries.

CMS is authorizing Montana to provide coverage for the following services:

- Limited clinical consultation;
- Case management to assess and address physical and behavioral health needs and HRSN;
- Medication-assisted treatment (MAT) services for all types of SUD as clinically appropriate, with accompanying counseling; and,
- A 30-day supply of all prescription medications that have been prescribed for the beneficiary at the time of release, provided to the beneficiary immediately upon release from the state prison.

CMS recognizes that many individuals exiting prisons may not have received sufficient health care to address all of their physical and/or behavioral health care needs while incarcerated. However, as described above, the purpose of this demonstration opportunity is to provide short-term Medicaid enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions as well as improve the identification and treatment of certain conditions to reduce acute care utilization in the period soon after release, and test whether these pre-release services improve uptake and continuity of MAT and other SUD and behavioral health treatment, as appropriate for the individual, to reduce suicide-related death, overdose, and overdose-related death. Therefore, CMS is approving a demonstration benefit package in Montana that is designed to improve identification of health needs and HRSN and facilitate connections to providers with the capacity to meet those needs in the community during the period immediately before an individual's expected release from a state prison. Once a beneficiary is released, the coverage for which the beneficiary is otherwise eligible must be provided consistent with all requirements applicable to such coverage.

Implementation and Reinvestment Plans
As described in the STCs of the demonstration, Montana is required to submit for CMS approval a Reentry Initiative Implementation Plan (Implementation Plan) and Reinvestment Plan documenting how the state will operationalize coverage and provision of pre-release services and how existing state funding for carceral health services will continue to support access to necessary care and achievement of positive health outcomes for the justice-involved population.

The Implementation Plan must describe the new key policies being tested under this demonstration amendment and provide operational details not captured in the STCs regarding implementation of those demonstration policies. At a minimum, the Implementation Plan is expected to include definitions and parameters related to the implementation of the reentry pre-release services. The Implementation Plan should also describe the state's strategic approach to implementing the policies, including goals and milestones, as well as associated timelines for meeting them, for both program policy implementation and investments in transitional non-service elements that accommodate the provision of pre-release services, as applicable. The Implementation Plan must also outline how the state will anticipate potential operational challenges and resolve the challenges the state is likely to encounter in implementing the reentry demonstration initiative.

Montana agrees to reinvest the total amount of new federal matching funds for the reentry demonstration initiative received under this demonstration amendment into activities and/or initiatives that increase access to or improve the quality of health care services for individuals who are incarcerated (including individuals who are soon-to-be released) or were recently released from incarceration, or for HRSN that may help prevent or reduce the likelihood of criminal justice system involvement. Consistent with this requirement, Montana is required to develop and submit a Reinvestment Plan to CMS outlining how the federal matching funds under the demonstration will be reinvested. The Reinvestment Plan should align with the goals of the state's reentry demonstration initiative. It should detail the state's plans to increase access to or improve the quality of health care services, as well as address HRSN of individuals who are incarcerated (including those who are soon-to-be released), those who have recently been released, and those who may be at higher risk of future criminal justice system involvement, particularly due to untreated behavioral health conditions. The Reinvestment Plan should describe the activities and/or initiatives selected by Montana for investment and a timeline for implementation. Any investment in carceral health care must add to and/or improve the quality of health care services and resources for individuals who are incarcerated and those who are soon to be released from carceral settings, and not supplant existing state or local spending on such services and resources.

Budget Neutrality

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstration is likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs in that state likely would have been without the demonstration. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" (WOW)

costs). As contingency management is not treated as a hypothetical expenditure for the purposes of budget neutrality, the state will finance the contingency management benefit with savings from Montana's other section 1115 demonstration, the Waiver for Additional Services and Populations (WASP) demonstration.

CMS and states have generally been applying an approach to calculating budget neutrality that CMS described in a 2018 SMDL.[2] Under this approval, projected demonstration expenditures associated with each new Medicaid Eligibility Group in the WOW baseline have been trended forward using the President's Budget trend rate to determine the maximum expenditure authority for the approval period. In contrast, under the approach described in the 2018 SMDL, CMS would use the lower of the state's historical trend or the President's Budget trend rate. Using the President's Budget trend rate instead aligns the demonstration trend rate with federal budgeting principles and assumptions.

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

Monitoring and Evaluation

The state is required to conduct systematic monitoring and robust evaluation of the demonstration amendment in accordance with the STCs. The state must update its demonstration Monitoring Protocol to incorporate how it will monitor the amendment components, including relevant metrics data as well as narrative details describing progress with implementing the amendment. In addition, the state is also required to conduct an independent Mid-Point Assessment of the Reentry Demonstration Initiative, as per the reentry SMDL, to support identifying risks and vulnerabilities and subsequent mitigation strategies.

The state is required to incorporate the amendment into its evaluation activities to support a comprehensive assessment of whether the initiatives approved under the demonstration are

[2] August 22, 2018. SMD#18-009 Re: Budget Neutrality Policies for Section 1115(a) Demonstration Projects. https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd18009.pdf

effective in producing the desired outcomes for the beneficiaries and the state's overall Medicaid program. Evaluation of the Reentry Demonstration Initiative must align with the requirements outlined in the SMDL, which are detailed in the STCs, including examining impacts on Medicaid coverage, continuity of care, access to and quality and efficiency of care, utilization of services, health outcomes, and carceral and community coordination in service provision, among others. The state must also evaluate the overall impact of the contingency management program, including assessing hypotheses that address the program's cost-effectiveness and its effects on beneficiary health and recovery outcomes. Additionally, hypotheses related to pre-tenancy and tenancy support services must focus on their impacts on health outcomes and experiences of beneficiaries with SUD or SMI. The state's monitoring and evaluation efforts must facilitate understanding the extent to which the amendment might support reducing existing disparities in access to and quality of care and health outcomes.

Consideration of Public Comments

The federal comment period was open from October 19, 2021, to November 18, 2021, for the demonstration application submitted October 1, 2021, during which CMS received five comments. One comment was from an individual and four were from organizations. The organizations' comments largely pertained to the state's request to receive expenditure authority for services provided to individuals diagnosed with a SUD, SMI, or severe emotional disturbance that are residing in an institution for mental disease (IMD), which we addressed in the approval of the HEART demonstration on July 1, 2022. Two organizations commented on the three policies being approved in this amendment, noting that coverage of these services will strengthen the state's behavioral health continuum of care and allow for better coordination of behavioral and physical healthcare. Regarding tenancy support services specifically, one organization noted that the addition of these services will help people find and maintain housing, which will provide the stability needed for beneficiaries to care for their health and engage in treatment services. The individual's comment focused exclusively on the benefits of pre-release services; they strongly supported the state's request to provide pre-release services to incarcerated individuals with an SMI or SUD.

After carefully reviewing the demonstration proposal and the public comments received during the federal comment period, CMS has concluded that the demonstration is likely to promote the objectives of the Medicaid program by increasing access to services for beneficiaries as well as expanding on the coverage of health care services that would otherwise not be available.

Other Information

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

Your project officer for this demonstration is Ms. Julia Buschmann. She is available to answer any questions concerning this amendment. Ms. Buschmann's contact information is as follows:

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7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: Julia.Buschmann@cms.hhs.gov

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

Sincerely,

Daniel Tsai
Deputy Administrator and Director

Enclosure

cc: Barbara Prehmus, Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: **11-W-00395/8**

TITLE: **Montana Healing and Ending Addiction through Recovery and Treatment Demonstration**

AWARDEE: **Montana Department of Public Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Montana for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from July 1, 2022 through June 30, 2027, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The Secretary of Health and Human Services (HHS) has determined that the Montana Healing and Ending Addiction through Recovery and Treatment (HEART) Demonstration, including the granting of the expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authorities may only be implemented consistent with the approved special terms and conditions (STC) and shall enable Montana to operate this section 1115(a) demonstration.

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

2. **Expenditures Related to Contingency Management.** Expenditures for contingency management services provided to qualifying beneficiaries from a provider that has been approved by the Department of Public Health and Human Services (DPHHS) to pilot the Contingency Management benefit**.**

3. **Expenditures Related to Pre-Tenancy and Tenancy Support Services.** Expenditures for pre-tenancy and tenancy support services provided to qualifying beneficiaries, from a provider that has been approved by DPHHS, and subject to annual enrollment limits.

4. **Expenditures Related to Pre-Release Services.** Expenditures for pre-release services, as described in these STCs, provided to qualifying Medicaid beneficiaries for up to 30 days immediately prior to the expected date of release from a participating state prison.

5. **Expenditures for Pre-Release Administrative Costs.** Capped expenditures for payments for allowable administrative costs, services, supports, transitional non-service expenditures, infrastructure and interventions, as is detailed in STC 43, which may not be recognized as medical assistance under Section 1905(a) or may not otherwise be reimbursable under Section 1903, to the extent such activities are authorized as part of the Pre-Release initiative.

Medicaid Requirements Not Applicable to the Above Medicaid Expenditure Authorities

1. Statewideness. **Section 1902(a)(1)**

To enable the state to provide contingency management services on a less than statewide basis to qualifying beneficiaries.

To enable the state to cover pre-tenancy and tenancy support services on a geographically limited basis.

To enable the state to provide pre-release services, as authorized under this demonstration, to qualifying beneficiaries on a geographically limited basis, in accordance with the Reentry Demonstration Initiative Implementation Plan.

2. Reasonable Promptness. **Section 1902(a)(8)**

To the extent necessary to enable the state to limit enrollment through waiting lists for pre-tenancy and tenancy support services.

3. Amount, Duration, Scope of Services, and Comparability. **Section 1902(a)(10)(B)**

To enable the state to provide contingency management services through approved providers to eligible individuals with stimulant use disorders, that are not otherwise available to other beneficiaries in the same eligibility group.

To the extent necessary to allow the state to offer a varying set of benefits to beneficiaries eligible for pre-tenancy and tenancy support services.

To enable the state to provide only a limited set of pre-release services, as specified in these STCs, to qualifying beneficiaries that is different than the services available to all other beneficiaries outside of carceral settings in the same eligibility groups authorized under the state plan or the demonstration.

4. Freedom of Choice. **Section 1902(a)(23)(A)**

To the extent necessary to enable the state to restrict freedom of choice of provider for beneficiaries who receive contingency management services.

To the extent necessary to enable the state to restrict freedom of choice of provider for beneficiaries who receive pre-tenancy and tenancy support services under the demonstration.

To enable the state to require qualifying beneficiaries to receive pre-release services, as authorized under this demonstration, through only certain providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00395/8**

TITLE: **Montana Healing and Ending Addiction through Recovery and Treatment 1115(a) Demonstration**

AWARDEE: **Montana Department of Public Health and Human Services**

I. PREFACE

The following are the Special Terms and Conditions (STC) for the "Montana Healing and Ending Addiction through Recovery and Treatment (HEART)" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Montana Department of Public Health and Human Services (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 match-able. 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 related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from July 1, 2022 through June 30, 2027, unless otherwise specified.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. SUD Program and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. Contingency Management Benefit
IX. Pre-Tenancy and Tenancy Support Services
X. Reentry Demonstration Initiative
XI. Monitoring and Reporting Requirements
XII. Evaluation of the Demonstration
XIII. General Financial Requirements Under Title XIX
XIV. Monitoring Budget Neutrality for the Demonstration
XV. Schedule of Deliverables for the Demonstration Period

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: SUD Implementation Plan and Health Information Technology (Health IT) Plan
- Attachment D: SUD Monitoring Protocol
- Attachment E: Evaluation Design (Reserved)
- Attachment F: Contingency Management Protocol (Reserved)
- Attachment G: Reentry Demonstration Initiative Qualifying Conditions and Services
- Attachment H: Reentry Demonstration Initiative Implementation Plan (Reserved)
- Attachment I: Reentry Demonstration Initiative Reinvestment Plan (Reserved)
- Attachment J: Reentry Monitoring Protocol (Reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for the state to enhance access to mental health services, opioid use disorder (OUD), and other SUD services and to provide a comprehensive continuum of behavioral health services and SUD treatment to Medicaid beneficiaries with SUD. This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with SUD while they are short-term residents in residential and inpatient treatment settings that qualify as an IMD. It will also support state efforts to link individuals with the appropriate level of care, improve the availability of Medication Assisted Treatment (MAT), and improve access to a continuum of SUD evidence-based services at varied levels of intensity, including withdrawal management services. This demonstration will also support access to contingency management services for qualifying individuals with a stimulant use disorder and will cover pre-tenancy and tenancy support services for qualifying individuals who are experiencing housing insecurity. Finally, the demonstration will allow the state to provide a targeted set of pre-release services to individuals who are Medicaid eligible and who are incarcerated in state prisons. This set of services will be covered for up to 30 days immediately prior to the expected date of release to improve transitions (in particular, transitions of health coverage and care) back to the community.

During the demonstration period, the state seeks to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries with SUD.
7. Improved access to community-based treatments and recovery supports, such as tenancy

supports and contingency management, to address the behavioral health needs of individuals with serious mental illness (SMI) or SUD.

8. For the Reentry Demonstration Initiative, the goals are described in STC 34.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

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

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

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

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, 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, whichever is sooner.

5. **State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments (SPAs) 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 and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, 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 either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 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 elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

    a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

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

    c. 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;

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

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

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

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

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

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

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

d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 35.916(f)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR part 431 subpart E,

including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.

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

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

g. Federal Financial Participation. 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.

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's determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

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

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State

Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. **Federal Financial Participation.** 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.

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.

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility and the standards and methodologies for eligibility remain set forth under the state plan. All enrollees ages 18 to 64 that are eligible to receive full Medicaid benefits under the Montana State Plan, Alternative Benefit Plan, or other section 1115 demonstrations will be eligible to receive services under this demonstration. Medicaid beneficiaries will qualify for services in this demonstration based on their diagnosis of a SUD.

V. SUBSTANCE USE DISORDER PROGRAM AND BENEFITS

17. **SUD Program Benefits.** Effective upon CMS's approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise match-able expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services, that would otherwise be match-able if the beneficiary were not residing in an IMD once CMS approves the state's Implementation

Plan. The state must achieve 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 50, to ensure short-term residential stays.

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

18. SUD Implementation Plan and Health Information Technology Plan.

a. The state must submit the SUD Implementation Plan within ninety (90) calendar days after approval of this demonstration. The state must submit the revised SUD Implementation Plan within sixty (60) days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.

b. Failure to submit a SUD Implementation Plan 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 SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 45.

c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

    i. **Access to Critical Levels of Care for OUD and other SUDs**. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval.

    ii. **Use of Evidence-based SUD-specific Patient Placement Criteria.** Establishment of a requirement that providers assess SUD treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;

iii. **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 demonstration approval;

iv. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities**. Currently, residential treatment service providers must be meet the minimum standards described in Montana Admin. Code 37.106.14. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other 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 demonstration approval;

v. **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 demonstration approval;

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

vii. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD**. An assessment of the availability of providers in the critical 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 demonstration approval;

viii. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD.** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. **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 demonstration approval.

x. **SUD Health Information Technology Plan.** Implementation of the milestones and metrics as detailed in STC 18(d) and Attachment C.

d. **SUD Health Information Technology Plan.** The SUD Health Information Technology (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, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) (see STC 18(a) and 18(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

The Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving them (see Attachment C), and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.

i. The state must include in its Monitoring Protocol (see STC 50) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

ii. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 52).

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

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

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

vi. Components of the Health IT Plan include:

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

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

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

4. The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.

5. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.

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

    a. 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/).

    b. 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-

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

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.

c. 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.

19. 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:

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

b. SUD services provided in the Montana State Hospital.

VI. COST SHARING

20. Cost Sharing. This demonstration does not impose premiums or other cost sharing requirements.

VII. DELIVERY SYSTEM

21. Delivery System. All demonstration beneficiaries will continue to receive services through the same fee-for-service delivery system arrangements as currently authorized in the state.

VIII. CONTINGENCY MANAGEMENT BENEFIT

22. Contingency Management Overview.

a. Beginning no earlier than October 1, 2024, DPHHS will implement a new contingency management benefit for eligible Medicaid beneficiaries with a stimulant use disorder in eligible provider settings.

b. Under this demonstration, the contingency management benefit will be available to qualified beneficiaries who meet the eligibility requirements described below, who may receive services from a participating provider approved by DPHHS to provide this benefit.

c. Motivational incentives earned through Montana's contingency management program fall under the "general welfare exclusion" federal tax exemption and are therefore excluded from participating beneficiaries' modified adjusted gross income (MAGI)-based

eligibility determinations, non-MAGI-based eligibility determinations, and share of cost determinations when determining those beneficiaries' eligibility for Montana Medicaid.

23. Eligibility. To qualify for the contingency management benefit, a beneficiary must meet the following conditions:

a. Be 18 years of age or older;

b. Have a completed an ASAM criteria assessment and are able to be treated safely in an outpatient setting;

c. Be assessed and determined to have a stimulant use disorder as the primary diagnosis for which the contingency management benefit is medically necessary and appropriate based on the fidelity of treatment to the evidence-based intervention. The presence of additional substance use disorders and/or diagnoses does not disqualify an individual from receiving contingency management services;

d. Not be enrolled in another contingency management program for stimulant use disorder;

e. Receive services from an eligible provider that offers the contingency management benefit in accordance with DPHHS requirements; and

f. Not receive contingency management as an alternative for medication treatment for other substance use disorders for which medication treatment is a medically appropriate option (e.g., for opioid use disorder or alcohol use disorder).

24. Service Description.

a. The contingency management benefit provides a series of motivational incentives for meeting treatment goals. The motivational incentives may consist of cash equivalents, e.g., gift cards of low retail value, with restrictions placed on the incentives so they are not used to purchase cannabis, tobacco, alcohol, firearms/ammunition, lottery tickets, and additional items as identified by the state. The motivational incentives are consistent with evidence-based clinical research for treating a stimulant use disorder and as described below. These motivational incentives are central to contingency management, based on the best available scientific evidence for treating a stimulant use disorder and not as an inducement to use other medical services.

b. The contingency management benefit uses an evidence-based approach that recognizes and reinforces individual positive behavior change consistent with substance non-use or treatment adherence. The contingency management benefit provides motivational incentives for treatment adherence or non-use of stimulants as evidenced by negative point of care, rapid, Clinical Laboratory Improvement Amendments (CLIA)-waived drug tests.

c. Contingency management is offered along with other therapeutic interventions, such as cognitive behavioral therapy, that meet the definition of rehabilitative services as defined by 1905(a) of the Social Security Act and 42 CFR 440.130(d). The provision of the

contingency management benefit is not conditioned on a beneficiary's engagement in other psychosocial services.

d. For purposes of this demonstration, these motivational incentives are a covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically appropriate contingency management protocol consistent with evidence-based research. Consequently, neither the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b), "AKS") nor the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (42 U.S.C. 1320a-7a(a)(5), "Beneficiary Inducements CMP") would be implicated.

e. The contingency management benefit consists of a set of modest motivational incentives available for beneficiaries who meet treatment goals. Under the benefit, a beneficiary will be limited in motivational incentives during the course of a contingency management treatment episode as detailed in the Procedures and Protocols in Attachment F.

    i. To qualify for a motivational incentive under the contingency management benefit, a beneficiary must participate in a twelve-week program and demonstrate non-use of stimulants. By participating in this twelve-week program, a beneficiary can receive incentive payments for each visit where they test negative for the substance being treated.

    ii. The size, nature, and distribution of all contingency management motivational incentives shall be determined in strict accordance with DPHHS procedures and protocols, listed in Attachment F. These procedures and protocols will be based on established clinical research for contingency management. The following guardrails shall ensure the integrity of the contingency management benefit and mitigate the risk of fraud, waste, or abuse associated with the motivational incentive:

        1. Providers have no discretion to determine the size or distribution of motivational incentives, which will be determined by DPHHS's schedule of incentive payments.

        2. Motivational incentives will be managed through an incentive management tool that includes safeguards against fraud and abuse. These safeguards will be detailed in DPHHS's guidance and listed in the Contingency Management Protocol Attachment F.

        3. To calculate and generate the motivational incentives in accordance with the schedule in Attachment F, providers shall enter the outcome of the test of the beneficiary receiving the contingency management benefit into an incentive management tool.

    iii. The aggregate annual amount of incentive payments that an individual can receive by participating in the twelve-week contingency management program shall be determined by DPHHS and memorialized in clinical policy.

iv. There is not a limit on the number of times a beneficiary can participate in the twelve-week program.

25. Eligible Contingency Management Providers.

a. The contingency management benefit will be delivered by eligible providers that meet specified programmatic standards and agree to deliver the contingency management benefit in strict accordance with standardized procedures and protocols that will be detailed in DPHHS guidance, the Contingency Management Protocol Attachment F, and other applicable laws, regulations, and requirements.

b. To be eligible to offer the contingency management benefit, a provider shall offer the benefit in strict accordance with DPHHS standards that will be detailed in DPHHS guidance included in Attachment F and shall meet the following requirements:

i. Must be a Medicaid enrolled provider;

ii. Must operate a SUD outpatient program within a state-approved SUD treatment provider, hospital, rural health center (RHC), federally qualified health center (FQHCs), or tribal 638 Indian Health Service (IHS) provider, or another provider type, that provides outpatient treatment services and may also have ability to offer or refer participants to other SUD treatment services (e.g., MAT, outpatient therapy, peer support services);

iii. Require the staff providing or overseeing the contingency management benefit to participate in contingency management-specific training and participate in ongoing training, and technical assistance offered by DPHHS;

iv. Undergo a readiness review by DPHHS to ensure that they are capable of offering the contingency management benefit in accordance with DPHHS standards that will be detailed in DPHHS guidance;

v. Shall comply with any billing and data reporting requirements established by DPHHS to support research, evaluation, and performance monitoring efforts, including but not limited to satisfactory claims submission, data and quality reporting, and survey participation; and

vi. Must employ or contract with a sufficient number of licensed mental health professionals that have SUD specific scope and training as further specified in STC 25(c), for provision of services and ensure:

1. They maintain their licensure in accordance with applicable laws and regulations governing their licensure; and

2. They provide services to beneficiaries receiving the contingency management benefit within the scope of their licensure.

c. The following practitioners delivering care at eligible providers can deliver the contingency management benefit through activities, such as administering point-of-care drug tests, informing beneficiaries of the results of the point-of-care drug test, entering the results into a software program, providing educational information, and distributing motivational incentives, as part of the contingency management benefit:

   i. Licensed mental health professional with SUD specific scope and training (e.g., licensed clinical social worker (LCSW), licensed professional counselors (LPCs) and licensed addiction counselors (LACs); or

   ii. Trained staff with appropriate supervision by licensed mental health professionals.

26. Program Oversight.

a. DPHHS shall monitor the ongoing performance, including fidelity of treatment to the evidence-based practice, of contingency management providers and identify and support providers requiring further training or technical assistance in accordance with DPHHS standards, to be outlined in DPHHS guidance.

b. DPHHS will provide training and technical assistance to providers throughout the implementation process and delivery of contingency management services. The training and technical assistance will include staff training, provider readiness reviews, and ongoing technical assistance.

27. Changes in Medicaid Policy on Contingency Management. In accordance with STC 3, nothing in this demonstration absolves the state of Montana from being subject to future requirements on contingency management set forth in Medicaid law, regulation, or policy and the state would otherwise need to come into compliance with such requirements.

IX. PRE-TENANCY AND TENANCY SUPPORT SERVICES

28. HCBS Requirements for Pre-Tenancy and Tenancy Support Services. Under the demonstration, the state will implement a pilot for provision of pre-tenancy and tenancy support services, as described in STC 31, that are similar to services that could be provided under a section 1915(i) state plan amendment for provision of home- and community-based services (HCBS). The state has elected to cover these services under expenditure authority in this demonstration to apply limitations on these services that would not be allowable under a section 1915(i) state plan amendment. This demonstration authorizes the state to implement this pilot less than statewide, limit access to the services by diagnosis, institute an annual enrollment limit, and employ a waiting list.

The state must comply with the following requirements, which are specified here by way of amplification and not limitation, as these requirements otherwise are applicable to HCBS provided under section 1915(i) state plan amendment for this pilot.

a. **Person-Centered Planning.** The state agrees to use person-centered planning processes to identify eligible clients' HCBS needs and the resources available to meet those needs, and to identify clients' additional service and support needs.

b. **Conflict of Interest.** The state agrees that the entity that authorizes the services is external to the agency or agencies that provide pilot services. The state also agrees that separation of assessment, treatment planning, and service provision functions are incorporated into the state's conflict of interest policies.

c. **HCBS Requirements.** The state will assure compliance with all HCBS requirements, including for those services that could be authorized under section 1915(i).

29. Eligibility for Pre-Tenancy and Tenancy Support Services. Pre-tenancy and tenancy support services are targeted to Medicaid beneficiaries ages 18 and older with a qualifying SUD and/or SMI who are eligible to receive full Medicaid benefits under the Montana State Plan, ABP, or Medicaid section 1115 demonstration project, and who meet at least one needs-based criterion and have at least one risk factor as identified in this STC.

a. Needs-Based Criteria:

i. The beneficiary has a need for improvement, stabilization, or prevention of deterioration of functioning resulting from the presence of the SMI.

ii. The beneficiary meets at least ASAM Criteria level 1.0, indicating the need for improvement, stabilization, or prevention of deterioration of functioning resulting from the presence of a SUD.

b. Risk Factors:

i. History of homelessness, defined as one of the following:

1. An individual who lacks a fixed, regular, and adequate nighttime residence;

2. An individual with a primary nighttime residence that is a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings, including a car, park, abandoned building, bus or train station, airport, or camping ground;

3. An individual in a supervised publicly or privately-operated shelter designated to provide temporary living arrangements (including hotels and motels paid for by Federal, State, or local government programs for low-income individuals or by charitable organizations), congregate shelters, and transitional housing;

4. An individual who was residing in a shelter or place not meant for human habitation and who is exiting an institution where he or she temporarily resided; or

5. An individual defined as homeless, per the definition of homeless used by the U.S. Department of Housing and Urban Development (HUD), who:

a. Has previously been unable to live independently in permanent housing;

b. Has experienced persistent instability as measured by more than one move over such period; and

c. Can be expected to continue in such status for an extended period of time because of chronic disabilities, chronic physical health or mental health conditions, substance addiction, histories of domestic violence or childhood abuse, the presence of a child or youth with a disability, or multiple barriers to employment.

ii. At risk of homelessness, defined as one of the following:

1. An individual who:

a. Has moved because of economic reasons;

b. Is living in the home of another because of economic hardship;

c. Has been notified that their right to occupy their current housing or living situation will be terminated;

d. Lives in a hotel or motel (including, but not limited to, hotels and motels paid for by Federal, State, or local government programs for low-income individuals or by charitable organizations), congregate shelters, or transitional housing;

e. Lives in severely overcrowded housing;

f. Is exiting an institution; or

g. Otherwise lives in housing that has characteristics associated with instability and an increased risk of homelessness, such as high housing costs relative to income or poor or unsafe housing quality.

2. An individual who:

a. Will imminently lose their housing, including housing they own, rent, live in without paying rent, are sharing with others, and rooms in hotels or motels not paid for by Federal, State, or local government programs for low-income individuals or by charitable organizations, as evidenced by one of the following:

i. A court order resulting in an eviction action that notifies the individual or family that they must leave within 14 days;

ii. The individual or family having a primary nighttime residence that is a room in a hotel or motel and where they lack the resources necessary to reside there for more than 14 days; or

iii. Credible evidence indicating that the owner or primary renter of the housing where the individual or family is residing will not allow the individual or family to stay there for more than 14 days, and any oral statement from an individual or family seeking assistance for homelessness that is found to be credible shall be considered credible evidence for purposes of this clause;

b. Has no subsequent residence identified that is a fixed, regular, and adequate nighttime residence; and

c. Lacks the resources or support networks needed to obtain other permanent housing.

iii. The member has experienced at least one of the following risk factors within the last 12 months:

1. More than two stays, or a single stay of more than two weeks, in an institutional setting, group home, assisted living facility, licensed residential healthcare setting, or detention center (including jail or prison) setting;

2. Three or more emergency department (ED) visits or hospitalizations;

3. Incarceration; or

4. Loss of housing as a result of behavioral health symptoms.

30. Annual Enrollment Limits. The state may implement annual enrollment limits and a waiting list in the provision of pre-tenancy and tenancy support services, as needed, to align with available resources.

31. Description of Pre-Tenancy and Tenancy Support Services.

a. Pre-Tenancy services includes screening, assessment, and development of a housing plan to support an individual's ability to identify, prepare for, and maintain stable housing. This also includes assistance with finding housing and support with moving in. Specifically, these services include:

i. Completing an eligibility screening;

ii. Completing a person-centered, comprehensive assessment for housing needs, barriers, preferences, and other supportive services (e.g., type, location, living alone or with someone else, identifying a roommate, accommodations needed, or other preferences); and

iii. Developing an individualized housing support plan based on the assessment that identifies short and long-term measurable goals, how goals will be achieved and how barriers to achieving goals will be addressed.

iv. Housing search and resource identification activities, to include:

1. Identifying resources to cover housing expenses (e.g., application fees, security deposit, rent, credit repair fees, utilities, internet);

2. Assisting in collecting required documentation; and,

3. Assisting with housing search, completing housing applications, and applying for housing vouchers.

v. Move in support activities, to include:

1. Assisting individuals in identifying resources to cover expenses related to move-in (e.g., truck rental; storage fees);

2. One-time transition and moving costs (i.e., security deposits and application fees); and

3. Ensuring housing unit is safe and ready for move-in.

b. Tenancy Support Services includes services providing assistance in working with landlords, property owners, or property managers; implementing housing plan goals, including connecting to additional supportive services, if needed; providing additional education to the tenant; and monitoring and follow up. Specifically, these services include:

i. Landlord/tenant relationship activities, to include:

1. Providing supports to assist the individual in communicating with the landlord and/or property manager to secure housing placement or prevent eviction;

2. Educating about tenant and landlord rights and responsibilities;

3. Training on responsible tenancy and household management (e.g., how to be a good neighbor, how to maintain your housing unit);

4. Providing supports to assist the individual in building relationships with landlords/property managers; and

5. Early identification and intervention for behaviors that may jeopardize housing.

ii. Connecting individuals to additional supportive services, to include linking and coordinating the recipient to services and service providers that support the person's housing stability, as identified through the assessment and housing plan development process. Examples include accessing healthcare (including behavioral health and substance use treatment), applying for other entitlement benefits, applying for rental assistance programs, accessing services for aging and disability, and obtaining legal services.

iii. Tenant education activities to include:

1. Providing fair housing information;

2. Educating and assisting with reasonable accommodations and home/safety modifications (ramps, rails, grab bars) when necessary to ensure occupant's health, and when modification is not covered by another entity as required by law; and

3. Helping tenants understand, negotiate, comply with a lease.

iv. Monitoring and follow up including the following activities:

1. Monitoring the housing plan to ensure successful outcomes;

2. Following up to ensure that service linkages are established and are addressing community integration needs to stabilize housing;

3. Coordinating with the tenant to review, update, and modify their housing plan as needed to reflect current needs and address existing or recurring housing retention barriers;

4. Assisting with the housing recertification process; and

5. Participating in person-centered plan meetings at redetermination or revision plan meetings, as needed.

c. The state will not cover the following services, and will not claim FFP, under this pilot for:

i. Payment of rent or other room and board costs not explicitly covered in this STC 31;

ii. Capital costs related to the development or modification of housing;

iii. Expenses for utilities or other regular occurring bills;

iv. Goods or services intended for leisure or recreation;

v. Duplicative services from other state or federal programs; and

vi. Services to individuals in a correctional institution or an IMD.

32. Provider Qualifications.

a. Pre-tenancy and tenancy service providers must:

i. Be agency-based;

ii. Have an integrated service model with connections to other supportive or wraparound services;

iii. Maintain housing navigator staff, who meet the qualifications set forth in STC 32(b)., sufficient to provide these services to eligible beneficiaries; and

iv. Complete tenancy services delivery and fiscal requirements.

b. To qualify be a housing navigator, an individual must have either:

i. An Associates degree or higher in Human Services, Social Services, Public Health; or

ii. A high school diploma or General Educational Development-equivalent and one-year experience in social or healthcare services, either paid or on a volunteer basis.

c. To qualify as a provider agency, an agency must develop policies and procedures, subject to DPHHS's approval, that address the following components of the roles and responsibilities of the housing navigator, and include: screening, assessment, housing plan development, delivery of tenancy services, monitoring and follow up, evaluation of outcomes, ensuring confidentiality, data collection (case records/case notes, document collection), providing resources on housing and fair housing rights, mediation and advocacy support, outreach to landlords and property owners, identifying behaviors that may jeopardize housing, coordination with other services providers as needed, managing caseloads, and participating in training requirements.

33. Quality Improvement Strategy.

a. In accordance with 1915(i)-like HCBS, the state must have an approved Quality Improvement Strategy for the Tenancy Supports program and, as part of this Quality Improvement Strategy, is required to develop performance measures within 90 days following approval of the demonstration to address the following requirements:

i. Person-Centered Service plans, as required by 42 CFR 441.745(b): a) address assessed needs of the participants; b) are updated annually; and c) document choice of services and providers.

ii. Eligibility Requirements: a) an evaluation for Tenancy Supports HCBS eligibility is provided to all applicants for whom there is reasonable indication that these services may be needed in the future; b) the processes and instruments described in the approved program for determining eligibility are applied appropriately; and c) the HCBS benefit eligibility of enrolled individuals is reevaluated at least annually or if more frequent, as specified in the approved program.

iii. Providers meet required qualifications.

iv. Settings meet the home and community-based setting requirements as specified in these STCs and in accordance with 42 CFR 441.710(a)(1) and (2).

v. The State Medicaid Agency retains authority and responsibility for program operations and oversight.

vi. The State Medicaid Agency maintains financial accountability through payment of claims for services that are authorized and furnished to qualified beneficiaries by qualified providers.

vii. The state identifies, addresses, and seeks to prevent incidents of abuse, neglect, and exploitation, including the use of restraints.

viii. The state must also describe the process for ongoing systems improvement and remediation when issues are identified, including an ongoing monitoring process to enable the identification and resolution of issues.

ix. The state must report annually the actual number of unduplicated individuals served and the estimated number of individuals to be served for the following year.

b. The state will submit a report to CMS following receipt of an Evidence Request letter and report template from the Division of HCBS Operations and Oversight (DHCBSO) no later than 21 months prior to the end of the approved waiver demonstration period which includes evidence on the status of the HCBS quality assurances and measures that adheres to the requirements outlined in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Waivers. Following receipt of the state's evidence report, the DHCBSO will issue a DRAFT report to the state and the state will have 90 days to respond. The DHCBSO will evaluate each evidentiary report to determine whether the assurances have been met and will issue a FINAL report to the state 60 days following receipt of the state's responses to the DRAFT report.

X. REENTRY DEMONSTRATION INITIATIVE

34. Overview of Pre-Release Services and Program Objectives. This component of the demonstration will provide for pre-release services up to 30 days immediately prior to the expected date of release to qualifying Medicaid beneficiaries who are residing in state prisons, as specified by the implementation timeline in STC 40 and the implementation plan in STC 41. The objective of this component of the demonstration is to facilitate beneficiaries' access to certain healthcare services and case management, provided by Medicaid participating providers, while beneficiaries are incarcerated and allow them to establish relationships with community-based providers from whom they can receive services upon reentry to communities. This bridge to coverage begins prior to release and is expected to promote continuity of care and improve health outcomes for justice-involved individuals. The purpose of this reentry demonstration initiative is to provide short-term Medicaid enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions, as well as improve the identification and treatment of certain chronic and other serious conditions to reduce acute care utilization in the period soon after release, and test whether it improves uptake and continuity of MAT and other SUD and behavioral health treatment, as appropriate for the individual, to reduce overdose, and overdose-related death.

During the demonstration, the state seeks to achieve the following goals:

a. Increase coverage, continuity of care, and appropriate service uptake through assessment of eligibility and availability of coverage for benefits in carceral settings prior to release;

b. Improve access to services prior to release and improve transitions and continuity of care into the community upon release;

c. Improve coordination and communication between correctional systems, the Montana state Medicaid agency, and community-based providers;

d. Increase additional investments in health care and related services, aimed at improving the quality of care for beneficiaries in carceral settings, and in the community to maximize successful reentry post-release;

e. Improve connections between carceral settings and community services upon release to address physical health, behavioral health, and health-related social needs (HRSN);

f. Reduce all-cause deaths in the near-term post-release;

g. Reduce the number of emergency department visits and inpatient hospitalizations among recently incarcerated Medicaid beneficiaries through increased receipt of preventive and routine physical and behavioral health care; and

h. Provide intervention for certain behavioral health conditions and use stabilizing medications like long-acting injectable antipsychotics and medications for addiction treatment for SUDs, with the goal of reducing overdose, and overdose-related death in the near-term post-release.

35. Qualifying Criteria for Pre-Release Services. In order to qualify to receive services under this component of the demonstration, a beneficiary must be 19 years of age or older and meet the following qualifying criteria:

a. Meet the definition of an inmate of a public institution, as specified in 42 CFR 435.1010, and be incarcerated in a state prison as defined in STC 37;

b. Be enrolled in Medicaid; and

c. Must meet at least one of the health-related criteria described below and further defined in Attachment G. Meeting such health-related criteria may be indicated by a beneficiary, found at an initial screening conducted by the correctional facility upon intake, determined during a beneficiary's incarceration, or found during assessment in the process of pre-release planning.

i. Mental illness, defined as a confirmed mental health diagnosis based on specified criteria as defined in Attachment G; or

ii. Substance use disorder, defined as a confirmed or suspected diagnosis based on specified criteria as defined in Attachment G.

36. Scope of Pre-Release Services. The pre-release services authorized under the reentry demonstration initiative include the following services, which are further described in Attachment G. Contingent upon CMS's approval of the state's Reentry Demonstration Initiative Implementation Plan (see STC 41), the state may begin claiming FFP for expenditures for services covered through the Reentry Demonstration Initiative beginning no earlier than the date that the expenditure authority for this initiative was approved as an amendment to the demonstration; the state anticipates starting to make expenditures for such services no later than September 1, 2025.

a. The pre-release services are:

i. Limited clinical consultation as clinically appropriate, provided through telehealth or in-person, as needed;

ii. Case management to assess and address physical health needs, behavioral health needs, and HRSN; and

iii. MAT for all types of SUD as clinically appropriate, including coverage for all Food and Drug Administration (FDA)-approved medications, with accompanying counseling.

b. A 30-day supply of all prescription medications and over-the-counter drugs (as clinically appropriate), provided to the beneficiary immediately upon release from the correctional facility, consistent with approved Medicaid state plan coverage authority and policy.

c. The expenditure authority for pre-release services through this initiative comprises a limited exception to the federal claiming prohibition for medical assistance furnished to

inmates of a public institution at clause (A) following section 1905(a) of the Act ("inmate exclusion rule"). Benefits and services for inmates of a public institution that are not approved in the reentry demonstration initiative as described in these STCs and accompanying protocols, and not otherwise covered under the inpatient exception to the inmate exclusion rule, remain subject to the inmate exclusion rule. Accordingly, other benefits and services covered under the Montana Medicaid State Plan that are not included in the above-described pre-release services (e.g., EPSDT benefits for qualifying beneficiaries under age 21) are not available to qualifying beneficiaries through the reentry demonstration initiative.

37. Participating Facilities. The pre-release services will be provided at state prisons or outside of the prison with appropriate transportation and security oversight provided by the carceral facility, subject to DPHHS's approval of a facility's readiness, according to the phase-in schedule described in STC 41.

38. Participating Providers.

a. Licensed, registered, certified, or otherwise appropriately credentialed or recognized practitioners under Montana's state scope of practice statutes shall provide services within their individual scope of practice and, as applicable, receive supervision required under their scope of practice laws, and enrolled as a Medicaid provider.

b. Participating providers eligible to deliver services under the reentry demonstration initiative may be either community-based or correctional-facility based providers.

c. All participating providers and provider staff, including correctional providers, shall have necessary experience and receive appropriate training, as applicable to a given carceral facility, prior to furnishing demonstration-covered pre-release services under the reentry demonstration initiative.

d. Participating providers of reentry case management services may be community-based or correctional providers who have expertise working with justice-involved individuals.

39. Suspension of Coverage. Upon entry of a Medicaid beneficiary into a participating state prison, DPHHS must not terminate and generally shall suspend their Medicaid coverage, as described in the Reentry Demonstration Initiative Implementation Plan.

a. If an individual is not enrolled in Medicaid when entering a correctional facility, the state must ensure that such an individual receives assistance with completing an application for Medicaid and with submitting an application to the state Medicaid department, unless the individual declines such assistance or wants to decline enrollment.

40. Reentry Demonstration Initiative Implementation Timeline. Delivery of pre-release services under this demonstration will be implemented as described below. All participating state prisons must demonstrate readiness, as specified below, prior to participating in this initiative. FFP will not be available in expenditures for services furnished to qualifying beneficiaries who are inmates in a facility before the facility meets the applicable readiness criteria for participation in this initiative. DPHHS will determine if and when each

applicable facility is ready to participate in the reentry demonstration initiative under this demonstration based on a facility-submitted assessment (and appropriate supporting documentation) of the facility's readiness to implement:

a. Pre-release Medicaid application and enrollment processes for individuals who are not enrolled in Medicaid prior to incarceration and who do not otherwise become enrolled during incarceration;

b. The screening process to determine a beneficiary's qualification for pre-release services;

c. The provision or facilitation of pre-release services for a period of up to 30 days immediately prior to the expected date of release, including the facility's ability to support the delivery of services furnished by providers in the community that are delivered via telehealth. If a facility is not equipped to provide or facilitate the full set of the pre-release services, as listed in STC 36, the facility must provide a timeline of when it will be equipped to do so, including concrete steps and their anticipated completion dates that will be necessary to ensure that qualifying beneficiaries are able to receive timely any needed pre-release services;

d. Coordination amongst partners with a role in furnishing health care and HRSN services to beneficiaries, including, but not limited to, social service departments and community-based providers;

e. Appropriate reentry planning, pre-release care management, and assistance with care transitions to the community, including connecting beneficiaries to physical and behavioral health providers, and making referrals to care management and community supports providers that take place throughout the 30-day pre-release period, and providing beneficiaries with covered outpatient prescribed medications and over-the-counter drugs (a minimum 30-day supply as clinically appropriate) upon release, consistent with approved Medicaid state plan coverage authority and policy;

f. Operational approaches related to implementing certain Medicaid requirements, including but not limited to applications, suspensions, notices, fair hearings, reasonable promptness for coverage of services, and any other requirements specific to receipt of pre-release services by qualifying individuals under the reentry demonstration initiative;

g. A data exchange process to support the care coordination and transition activities described in (d) and (e) of this subsection, subject to compliance with applicable Federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;

h. Reporting of data requested from DPHHS to support program monitoring, evaluation, and oversight; and

i. A staffing and project management approach for supporting all aspects of the facility's participation in the reentry demonstration initiative, including information on qualifications of the providers that the correctional facilities will partner with for the provision of pre-release services.

41. Reentry Demonstration Initiative Implementation Plan. The state is required to submit a Reentry Demonstration Initiative Implementation Plan to describe, at a minimum, the state's approach to implementing the reentry demonstration initiative, including timelines for meeting critical implementation stages or milestones, as applicable, to support successful implementation. The state must submit the draft Implementation Plan to CMS no later than nine months after approval of the reentry demonstration initiative. The state must submit any required clarifications or revisions to their draft Implementation Plan no later than 60 calendar days after receipt of CMS feedback. Once approved, the finalized Implementation Plan will be incorporated into the STCs as Attachment H and may be further altered only with CMS approval.

In the Implementation Plan, the state is expected only to provide additional details regarding the implementation of the reentry demonstration initiative that are not already captured in the STCs (including any other attachments). CMS will provide the state with a template to support developing and obtaining approval of the Implementation Plan. Contingent upon CMS's approval of the state's Implementation Plan, and the state's determination that participating facilities have demonstrated readiness, the state may begin claiming FFP for services provided through the reentry demonstration initiative, expected to begin no later than September 1, 2025.

The Reentry Demonstration Initiative Implementation Plan must describe the implementation settings, the time period that pre-release services are available, and the state's phase-in approach to implementation, as applicable. Other than providing such contextual information, the core requirement of the Implementation Plan is for the state to describe the specific processes, including timelines and programmatic content where applicable, for meeting the below milestones, such as to remain on track to achieve the key goals and objectives of the program. For each milestone—and specifically for any associated actions that are integral aspects for attaining the milestone—the Implementation Plan must document the current state of affairs, the intended end state to meet the milestone, the date by which the milestone is expected to be achieved, and the activities that must be executed by that date for the milestone to be achieved. Furthermore, for each milestone, the Implementation Plan must identify the main anticipated implementation challenges and the state's specific plans to address these challenges. The Implementation Plan is also required to document the state's strategies to drive positive changes in health care quality for all beneficiaries, thereby reducing disparities and improving health equity. The state will be required to provide the following information related to, but not limited to, the following milestones and actions.

a. **Milestone 1: Increasing coverage and ensuring continuity of coverage for individuals who are incarcerated.** The state must describe its plans to fully effectuate, no later than two years from approval of the expenditure authority, a state policy to identify Medicaid eligible individuals and suspend a beneficiary's eligibility or benefits during incarceration. It must describe its processes to undertake robust outreach to ensure beneficiary and applicant awareness of the policy and assist individuals with Medicaid application, enrollment, and renewal processes. Additionally, the state must describe how it will notify individuals of any Medicaid eligibility determinations or actions. Other aspects to be included in the Implementation Plan related to this milestone include the state's plan to make available a Medicaid identification number or card to an

individual, as applicable, upon release; and establish processes to allow and assist all individuals who are incarcerated at a participating facility to access and complete a Medicaid application, including providing information about where to complete the Medicaid application for another state (e.g., relevant state Medicaid agency website) if the individual will be moving to a different state upon release.

b. **Milestone 2: Covering and ensuring access to the expected minimum set of pre-release services for individuals who are incarcerated, to improve care transitions upon return to the community.** The state must describe its plan to implement a screening process to identify individuals who qualify for pre-release services, consistent with the qualifying criteria outlined in these STCs. The state must detail how the Medicaid agency and the carceral facilities will ensure that beneficiaries can access the pre-release benefit package, as clinically appropriate. The state must describe its approach and plans for implementing processes to assure that all pre-release service providers, as appropriate for the provider type, have the necessary experience and training, and case managers have knowledge of (or means to obtain information about) community-based providers in the communities where individuals will be returning upon release.

c. **Milestone 3: Promoting continuity of care.** The state must describe its process to ensure that beneficiaries receive a person-centered service plan for coordination post-release to address health needs, including HRSN and long-term services and supports (LTSS), as applicable. The state must detail its plans and timeline for implementing state policies to provide or facilitate timely access to post-release medical supplies, equipment, medication, additional exams, or other post-release services to address the physical and behavioral health care needs identified during the case management assessment and the development of the person-centered care plan. The state must describe its processes for promoting and ensuring collaboration between case managers, providers of pre-release services, and providers of post-release services, to ensure that appropriate care coordination is taking place. As applicable, the state must also describe the planning or projected activities to ensure there are requirements and processes for transfer of relevant health information among the carceral facility, community-based providers, and/or state Medicaid agency to support continuity and coordination of care post-release.

d. **Milestone 4: Connecting to services available post-release to meet the needs of the reentering population.** The state must describe how it will develop and implement a system to monitor the delivery of post-release services and ensure that such services are delivered within the appropriate timeframe. The Implementation Plan must also capture how the state will monitor and adjust, as needed, ongoing post-release case management and describe its process to help ensure the scheduling and receipt of needed services. The state must describe how it will connect demonstration beneficiaries to other services needed to address HRSN, LTSS, and other social supports as identified in the development of the person-centered care plan. Additionally, the state must describe how it will ensure that case managers are able to effectively serve demonstration beneficiaries transitioning into the community and recently released beneficiaries who are no longer demonstration beneficiaries.

e. **Milestone 5: Ensuring cross-system collaboration.** The state must provide an assessment that outlines how the Medicaid agency and participating correctional systems will confirm they are ready to ensure the provision of pre-release services to eligible beneficiaries, including but not limited to how correctional facilities will facilitate access to incarcerated beneficiaries for community health care providers, including case managers, either in person or via telehealth. The state must also document its plans for establishing communication, coordination, and engagement between corrections systems, community supervision entities, health care provider and provider organizations, the state Medicaid agency, and supported employment and supported housing organizations. The state must also develop a system (for example, a data exchange, with requisite data-sharing agreements) and establish processes to monitor individuals' health care needs, HRSN, and their access to and receipt of health care services pre- and post-release, and identify anticipated challenges and potential solutions. Further, the state must develop and share its strategies to improve awareness and education about Medicaid coverage and health care access among stakeholders, including those who are incarcerated, community supervision agencies, corrections institutions, health care providers, and relevant community organizations (including community organizations serving the reentering population).

42. Reentry Initiative Reinvestment Plan. To the extent that the reentry demonstration initiative covers services that are the responsibility of and were previously provided or paid by the carceral facility or carceral authority with custody of qualifying beneficiaries, the state must reinvest all new federal dollars, equivalent to the amount of FFP projected to be expended for such services, as further defined in the Reentry Demonstration Initiative Reinvestment Plan ("Reinvestment Plan"). The Reinvestment Plan will define the amount of reinvestment required over the term of the demonstration, based on an assessment of the amount of projected expenditures for which reinvestment is required pursuant to this STC. FFP projected to be expended for new services covered under the reentry demonstration initiative, defined as services not previously provided or paid by the carceral facility or carceral authority with custody of qualifying beneficiaries prior to the individual facility's implementation of the reentry demonstration initiative (including services that are expanded, augmented, or enhanced to meet the requirements of the reentry demonstration initiative, with respect to the relevant increase in expenditures, as described in the Reentry Demonstration Initiative Reinvestment Plan), is not required to be reinvested pursuant to this STC.

a. Reinvestments in the form of non-federal expenditures totaling the amount of new federal dollars, as described above, must be made over the course of the demonstration period. Allowable reinvestments include, but are not limited to:

i. The state share of funding associated with new services covered under the reentry demonstration initiative, as specified in this STC;

ii. Improved access to behavioral and physical community-based health care services and capacity focused on meeting the health care needs and addressing the HRSN of individuals who are incarcerated (including those who are soon-to-be released), those

who have recently been released, and those who may be at higher risk of criminal justice involvement, particularly due to untreated behavioral health conditions;

iii. Improved access to and/or quality of carceral health care services, including by covering new, enhanced, or expanded pre-release services authorized via the reentry demonstration initiative opportunity;

iv. Improved health information technology (IT) and data sharing, subject to compliance with applicable Federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;

v. Increased community-based provider capacity that is particularly attuned to the specific needs of, and able to serve, justice-involved individuals or individuals at risk of justice involvement;

vi. Expanded or enhanced community-based services and supports, including services and supports to meet the HRSN of the justice-involved population; and,

vii. Any other investments that aim to support reentry, smooth transitions into the community, divert individuals from incarceration or re-incarceration, or better the health of the justice-involved population, including investments that are aimed at interventions occurring both prior to and following release from incarceration into the community.

b. Within nine months of approval, the state will submit a Reentry Demonstration Initiative Reinvestment Plan as part of the implementation plan referred to in STC 41 for CMS approval that memorializes the state's reinvestment approach. The Reinvestment Plan will also identify the types of expected reinvestments that will be made over the demonstration period. Actual reinvestments will be reported to CMS in Attachment H.

43. The Reentry Demonstration Initiative Planning and Implementation.

a. The Reentry Demonstration Initiative will provide expenditure authority to fund supports needed for Medicaid pre-release application and suspension/unsuspension planning and purchase of certified electronic health record (EHR) technology to support Medicaid pre-release applications. Reentry demonstration initiative planning and implementation funds will provide funding over the course of the demonstration to support planning and IT investments that will enable implementation of the reentry demonstration initiative services covered in a period for up to 30 days immediately prior to the expected date of release, and for care coordination to support reentry. These investments will support collaboration and planning among DPHHS and the Department of Corrections, community-based providers, probation offices, and others. The specific use of this funding will be proposed by the Qualified Applicant (as defined in STC 44) submitting the application, as the extent of approved funding will be determined according to the needs of the entity. Allowable expenditures are limited to only those that support Medicaid-related expenditures and/or demonstration-related expenditures (and not other activities or staff in the carceral facility) and must be properly cost-allocated to Medicaid,

as necessary, and once finalized will be included in the Reentry Demonstration Initiative Implementation Plan at Attachment H within the STCs. These allowable expenditures may include the following:

i. **Technology and IT Services.** Expenditures for the purchase of technology for Qualified Applicants which are to be used for assisting the reentry demonstration initiative population with Medicaid application and enrollment for demonstration coverage and coordinating pre-release and post-release services for enrollees. This includes the development of electronic interfaces for state prisons to communicate with Medicaid IT systems to support Medicaid enrollment and suspension/unsuspension and modifications. This also includes support to modify and enhance existing IT systems to create and improve data exchange and linkages with correctional facilities, DPHHS, and others, such as community-based providers, in order to support the provision of pre-release services delivered in the period up to 30 days immediately prior to the expected date of release and reentry planning.

ii. **Hiring of Staff and Training.** Expenditures for Qualified Applicants to recruit, hire, onboard, and train additional and newly assigned staff to assist with the coordination of Medicaid enrollment and suspension/unsuspension, as well as the provision of pre-release services in a period for up to 30 days immediately prior to the expected date of release and for care coordination to support reentry for justice-involved individuals. Qualified Applicants may also require training for staff focused on working effectively and appropriately with justice-involved individuals.

iii. **Adoption of Certified Electronic Health Record Technology.** Expenditures for providers' purchase or necessary upgrades of certified EHR technology and training for the staff that will use the EHR.

iv. **Purchase of Billing Systems.** Expenditures for the purchase of billing systems for Qualified Applicants.

v. **Development of Protocols and Procedures.** Expenditures to support the specification of steps to be taken in preparation for and execution of the Medicaid enrollment process and suspension/unsuspension process for eligible individuals and coordination of a period for up to 30 days immediately prior to the expected date of release and reentry planning services for individuals qualifying for reentry demonstration initiative services.

vi. **Additional Activities to Promote Collaboration.** Expenditures for additional activities that will advance collaboration among Montana's state prisons, community-based providers, and others involved in supporting and planning for the reentry demonstration initiative. This may include conferences and meetings convened with the agencies, organizations, and stakeholders involved in the initiative.

vii. **Planning.** Expenditures for planning to focus on developing processes and information sharing protocols to: (1) identifying uninsured who are potentially

eligible for Medicaid; (2) assisting with the completion of an application; (3) submitting an application to the state Medicaid agency for the state where the individual plans to reside upon release or coordinating suspension/unsuspension; (4) screening for eligibility for pre-release services and reentry planning in a period for up to 30 days immediately prior to the expected date of release; (5) delivering necessary services to eligible individuals in a period for up to 30 days immediately prior to the expected date of release and care coordination to support reentry; and (6) establishing on-going oversight and monitoring process upon implementation.

viii. **Other activities to support a milieu appropriate for provision of pre-release services.** Expenditures to provide a milieu appropriate for pre-release services in a period for up to 30 days immediately prior to the expected date of release, including accommodations for private space such as movable screen walls, desks, and chairs, to conduct assessments and interviews within correctional institutions, and support for installation of audio-visual equipment or other technology to support provision of pre-release services delivered via telehealth in a period for up to 30 days immediately prior to the expected date of release and care coordination to support reentry. Expenditures may not include building, construction, or refurbishment of correctional facilities.

b. The state may claim FFP in Reentry Demonstration Initiative Planning and Implementation Program expenditures for no more than the annual amounts outlined in Table 2. In the event that the state does not claim the full amount of FFP for a given demonstration year, as defined in STC 84, the unspent amounts will roll over to one or more demonstration years not to exceed this demonstration period and the state may claim the remaining amount in a subsequent demonstration year.

Table 2. Annual Limits of Total Computable Expenditures for Reentry Demonstration Initiative Planning and Implementation Program

	DY 2	DY 3	Total
Total Computable Expenditures	$1,533,333	$766,667	$2,300,000

c. Reentry Demonstration Initiative Planning and Implementation funding will receive the applicable administrative match for the expenditure.

44. Qualified Applicants. Qualified Applicants for the Reentry Demonstration Initiative Planning and Implementation Program will include the Montana Department of Corrections, other state agencies supporting carceral health, Probation Offices, and other entities as relevant to the needs of justice-involved individuals as approved by the state Medicaid agency.

XI. MONITORING AND REPORTING REQUIREMENTS

45. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per

deliverable (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 are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. 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) 30 days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) 30 days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

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

b. For each deliverable, the state may submit 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, the steps the state has taken to address such issue, and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan as an interim step before applying the deferral, if a corrective action plan is proposed in the state's written extension request.

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

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

46. Deferral of Federal Financial Participation from IMD Claiming for Insufficient Progress Toward Milestones. Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Protocol and the required

performance measures in the Monitoring Plan 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.

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

48. **Electronic Submission of Reports.** The state must submit all monitoring and evaluation report deliverables required in these STCs (e.g., quarterly reports, annual reports, evaluation reports) electronically, through CMS' designated electronic system.

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

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

    b. Ensure all section 1115 demonstration, 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

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

50. **SUD Monitoring Protocol.** The state must submit a Monitoring Protocol for the SUD 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 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 SUD Monitoring Protocol must include:

    a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18(a) and 18 (c) and reporting relevant information to the state's Health IT plan described in STC 18(d);

    b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general monitoring and reporting requirements described in Section XI (Monitoring and Reporting Requirements) of the demonstration; and

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

51. Monitoring Protocol(s). The state must submit to CMS a Monitoring Protocol(s) addressing components of the demonstration not covered by the SUD Monitoring Protocol no later than 150 calendar days after the approval of the demonstration amendment (to include but may not be limited to: Reentry). The state must submit a revised Monitoring Protocol within 60 calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated in the STCs as Attachment J. In addition, the state must submit an updated or a separate Monitoring Protocol for any amendments to the demonstration no later than 150 calendar days after the approval of the amendment. Such amendment Monitoring Protocols are subject to the same requirement of revisions and CMS approval, as described above.

At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, if applicable and relevant for different policies. Any proposed deviations from CMS's guidance should be documented in the Monitoring Protocol. The Monitoring Protocol must describe the quantitative and qualitative elements on which the state will report through Quarterly and Annual Monitoring Reports. For the overall demonstration as well as for specific policies where CMS provides states with a suite of quantitative monitoring metrics (e.g., the performance metrics section in STC 52), the state is required to calculate and report such metrics leveraging the technical specifications provided by CMS. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, sexual orientation and gender identity, and geography) and demonstration component.

The Monitoring Protocol requires specifying a selection of quality of care and health outcomes metrics and population stratifications based on CMS's upcoming guidance on the Disparities Sensitive Measure Set, and outlining the corresponding data sources and reporting timelines, as applicable to the demonstration initiatives and populations. If needed, the state may submit an amendment to the Monitoring Protocol within 150 days after the receipt of the final Disparities Sensitive Measure Set from CMS. This slate of measures represents a critical set of metrics known to be important for closing key gaps in Medicaid/CHIP (e.g., the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizes key outcome measures and their clinical and non-clinical (i.e. social) drivers. The Monitoring Protocol must also outline the state's planned approaches and parameters to track implementation progress and performance relative to the goals and milestones including relevant transitional, non-service expenditures investments, as captured in these STCs, or other applicable implementation and operations protocols.

In addition, the state must describe in the Monitoring Protocol methods and timeline to collect and analyze non-Medicaid administrative data to help calculate applicable monitoring metrics. These sources may include, but are not limited to, data related to carceral status Medicaid eligibility and the health care needs of individuals who are incarcerated and returning to the community. Across data sources, the state must make efforts and consult

with relevant non-Medicaid agencies to collect data in ways that support analyses of data on beneficiary subgroups.

For the qualitative elements (e.g., operational updates as described in STC 52, CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's Quarterly and Annual Monitoring Reports.

52. Monitoring Reports. The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each demonstration year (DY). The fourth-quarter information that would ordinarily be provided in a separate Quarterly Monitoring Report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 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 should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Quarterly and Annual Monitoring Reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

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

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting goals and milestones including relative to their projected timelines – of the demonstration's program and policy implementation and infrastructure investments, and transitional non-service expenditures, as applicable and must cover all key policies under this demonstration. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as on beneficiaries' outcomes as well as outcomes of care, quality and cost of care, and access to care. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

The demonstration's metrics reporting must cover categories including, but not limited to: beneficiary participation in demonstration components, provider participation, utilization of services, and quality of care and health outcomes. The state must undertake robust reporting of quality of care and health outcomes metrics aligned with the demonstration's policies and objectives to be reported for all demonstration populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

i. The state's selection and reporting of quality of care and health outcome metrics outlined above must also accommodate the newly approved reentry demonstration initiative. In addition, the state is required to report on metrics aligned with tracking progress with implementation and toward meeting the milestones and goals of the reentry demonstration initiative. CMS expects such metrics to include, but not be limited to: administration of screenings to identify individuals who qualify for pre-release services, utilization of applicable pre-release and post-release services (e.g., case management, MAT, clinical/behavioral health assessment pre-release and primary and behavioral health services post-release), provision of health or social service referral pre-release, participants who received case management pre-release and were enrolled in case management post-release, and take-up of data system enhancements among participating carceral settings. In addition, the state is expected to monitor the number of beneficiaries served and types of services rendered under the demonstration. Also, in alignment with the state's Reentry Initiative Implementation Plan, the state must also provide in its Monitoring Reports narrative details outlining its progress with implementing the initiative, including any challenges encountered and plans for addressing them. This information must also capture the transitional, non-service expenditures, including enhancements in the data infrastructure and information technology. In addition to tracking enrollment and renewal metrics, systematic monitoring of the continuous eligibility policies must support—at a minimum—understanding the trends in preventive care services, including vaccination among populations of focus, and utilization of costlier and potentially avoidable services, such as inpatient hospitalizations and non-emergent use of emergency departments.

ii. For the SUD component, the state's monitoring must align with the CMS approved SUD Monitoring Protocol (see STC 50), and will cover metrics in alignment with assessment of need and qualification for SUD treatment services and the demonstration's six milestones as outlined in the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17-003).

iii. For the Contingency Management program, the state's reporting must cover metrics for domains including but not limited to enrollment, overall incentives provided, and average incentives provided per beneficiary during the treatment phase as well as

types and counts of aftercare and treatment services rendered during the aftercare phase.

iv. For pre-tenancy and tenancy support services, the state should plan to track, at a minimum, the numbers of screenings, assessments, and housing plans developed and executed. The state should also track activities related to housing search, move-in, landlord/tenant relationship, and any other key services rendered.

In addition, if the state, health plans, or health care providers will contract or partner with organizations to implement the demonstration, the state must use monitoring metrics that track the number and characteristics of contracted or participating organizations and corresponding payment-related metrics.

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

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

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

e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 18(d).

53. SUD Mid-Point Assessment. The state must contract with an independent entity to conduct an independent Mid-Point Assessment by June 30, 2025. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of the demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and conduct of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, health care providers (including SUD treatment providers), beneficiaries, community groups, and other key partners.

a. The state must require that the assessor provide a Mid-Point Assessment Report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 calendar days after June 30, 2025. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.

b. For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan and SUD Monitoring Protocol for ameliorating these risks. Modifications to the applicable Implementation, Financing, and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

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

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

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

   iv. For milestones or targets identified by the independent assessor as at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan, or to pertinent factors that the state can influence that will support improvement; and an assessment of whether the state is on track to meet the budget neutrality requirements in these STCs.

54. Reentry Demonstration Initiative Mid-Point Assessment. The state must contract with an independent entity to conduct a mid-point assessment of the reentry demonstration initiative and complete a Reentry Demonstration Initiative Mid-Point Assessment Report.

The Mid-Point Assessment Report must integrate all applicable implementation and performance data from the first two-and-a-half years of implementation of the reentry demonstration initiative. The report must be submitted to CMS by the end of the third year of demonstration implementation. In the event that the reentry demonstration initiative is implemented at a timeline within the demonstration approval period, the state and CMS will agree to an alternative timeline for submission of the mid-point assessment. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.

The state must require the independent assessor to provide a draft of the Mid-Point Assessment Report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies used, the findings on demonstration progress and

performance, including identifying any risks of not meeting milestones and other operational vulnerabilities, and recommendations for overcoming those challenges and vulnerabilities. In the design, planning, and execution of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: pre- and post-release providers participating in the state's reentry demonstration initiative, eligible and participating beneficiaries, and other key partners in carceral and community settings.

For milestones and measure targets at medium to high risk of not being achieved, the state and CMS will collaborate to determine whether modifications to the Reentry Demonstration Initiative Implementation Plan and the Monitoring Protocol are necessary for ameliorating these risks subject to CMS approval.

Elements of the Mid-Point Assessment Report must include, but not be limited to:

a. An examination of progress toward meeting each milestone and timeframe approved in the Reentry Demonstration Initiative Implementation Plan and toward meeting the targets for performance metrics as approved in the Monitoring Protocol;

b. A determination of factors that affected achievement on the milestones and progress toward performance metrics targets to date;

c. 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;

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

CMS will provide additional guidance for developing the state's Reentry Initiative Mid-Point Assessment Report.

55. Compliance with Managed Care, Network Adequacy, Quality Strategy and EQR Reporting Requirements. The state must comply with all managed care reporting regulations at 42 CFR Part 438 except as expressly identified as not applicable in the expenditure authorities incorporated into these STCs.

56. State Data Collection. The state must collect data and information necessary to oversee service utilization and rate setting by provider/plan, comply with the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, obtain NCQA and other accreditations that the state may seek, and comply with other existing federal measure sets. The state will use this information in ongoing monitoring of individual well-being, provider/plan performance, and continuous quality improvement efforts, in addition to complying with CMS reporting requirements. The state must maintain data dictionary and file layouts of the data collected. The raw and edited data will be made available to CMS within 30 days of a written request.

57. Corrective Action Plan Related to 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 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

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

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

b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STC 67 and 68, respectively.

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

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

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

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 45.

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

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

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

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

60. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six 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 Medicaid website. The state must also post the most recent Annual Monitoring Report on its Medicaid website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public in the Annual Monitoring Report associated with the year in which the forum was held.

XII. EVALUATION FOF THE DEMONSTRATION

61. Cooperation with Federal Evaluators and Learning Collaborative. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state's participation – including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable – in a federal learning collaborative aimed at cross-state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and 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 45.

62. 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 accordance with the CMS-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, changes in the methodology in appropriate circumstances.

63. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs, CMS's evaluation design guidance for SUD, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with

CMS guidance on applying robust evaluation approaches such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined culturally appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic) – as these implementation strategies help create strong comparison groups and facilitate robust evaluation. The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design must also include a timeline for key evaluation activities, including the deliverables outlined in STCs 67 and 68.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design or submit a new Evaluation Design to accommodate the amendment components. 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 amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

64. **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.

65. **Evaluation Design Approval and Updates.** The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. 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 Medicaid website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Quarterly and Annual 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.

66. **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. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by National Quality Forum (NQF).

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with the various demonstration policy components, including but not limited to the reentry demonstration initiative, and beneficiary experiences with access to and quality of care as well as changes in incidence of beneficiary medical debt. In addition, the state is strongly encouraged to evaluate the implementation of the demonstration components in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. Implementation research questions can also focus on beneficiary and provider experience with the demonstration. The implementation evaluation can 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.

Evaluation of the reentry demonstration initiative must be designed to examine whether the initiative expands Medicaid coverage through increased enrollment of eligible individuals, and efficient high-quality pre-release services that promote continuity of care into the community post-release. In addition, in alignment with the goals of the reentry demonstration initiative in the state, the evaluation hypotheses must focus on, but not be limited to: cross-system communication and coordination; connections between carceral and community services; access to and quality of care in carceral and community settings; preventive and routine physical and behavioral health care utilization; non-emergent emergency department visits and inpatient hospitalizations; and all- cause deaths.

The demonstration's evaluation efforts will be expected to include an examination of correctional provider qualifications and standards, as well as the experiences of carceral and

community providers, including challenges encountered, as they develop relationships and coordinate to facilitate transition of individuals into the community. The state must conduct a comprehensive cost analysis to support developing estimates of implementing the reentry demonstration initiative, including covering associated services.

Hypotheses for the SUD program must include an assessment of the objectives of the SUD component of this section 1115 demonstration. Examples include but are not limited to): initiation and engagement with treatment, utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes, such as deaths due to overdose. Additionally, the state must include an evaluation of the effectiveness of pre-tenancy and tenancy support services, as described in Section IX, on overall health outcomes.

Hypotheses for the contingency management program must align with the goals of the SUD program. They should aim to increase rates of identification, initiation, and engagement in treatment; increase adherence to and retention in treatment; reduce overdose deaths; reduce utilization of emergency departments and inpatient hospital settings for treatment where preventable or medically inappropriate; reduce readmissions where preventable or medically inappropriate; and improve access to care for physical health outcomes among beneficiaries.

As part of its evaluation efforts, the state must also conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation, Medicaid health services expenditures, and provider uncompensated care costs. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program. Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes, and help inform how the demonstration's various policies might support reducing such disparities.

67. Interim Evaluation Report. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent 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 Medicaid website with the application for public comment.

a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.

b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/ phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.

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

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

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

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

68. 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 Reports) of these STCs, and in alignment with the approved Evaluation Design.

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

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

69. 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. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

70. **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.

71. **Public Access.** The state shall post the final documents (e.g., Implementation Plan, Monitoring Protocol, Monitoring Reports, Mid-Point Assessment, Close-Out Report, the approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's website within 30 calendar days of approval by CMS.

72. **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 or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration, over which the state has control. 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 calendar days to review and comment on publications before they are released. CMS may choose to decline to comment on 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.

XIII. GENERAL FINANCIAL REQUIREMENTS

73. **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.

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

75. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further

certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

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

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

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

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

d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care

providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

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

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

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

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

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

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

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

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

79. 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 46. This report must include:

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

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

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

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

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

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

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

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

80. 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 section XIV (Monitoring Budget Neutrality for the Demonstration):

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

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

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

81. 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.

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

Table 3: Master MEG Chart					
MEG	**To Which BN Test Does This Apply?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
IMD Expansion Group	Hypo	X		X	Expenditures for individuals eligible for expanded Medicaid, receiving services in an IMD
IMD Standard Medicaid	Hypo	X		X	Expenditures for individuals eligible for Medicaid, receiving services in an IMD
Contingency Management Benefit	Main			X	Expenditures for evidence-based motivational incentives for meeting treatment goals.
Pre-Tenancy and Tenancy Support Services	Hypo	X		X	Expenditures for pre-tenancy and tenancy support services provided to eligible individuals.
Reentry Initiative Services	Hypo	X		X	Expenditures for targeted services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 30 days immediately prior to the expected date of release from participating state prisons.
Reentry Transitional Non-Service Expenditures	Hypo		X	X	Expenditures for planning and supporting the reentry demonstration initiative.

83. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00395/8). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (DY) (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

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

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

c. 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 budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

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

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section VIII (General Reporting Requirements), the state must report the actual number

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

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

Table 4: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
IMD Services MEG #1	Individuals eligible for expanded Medicaid, receiving services in an IMD	See STC #21	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	7/1/22	6/30/27
IMD Services MEG #2	Individuals eligible for Medicaid, receiving services in an IMD	See STC #21	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	7/1/22	6/30/27
Contingency Management	Expenditures for evidence-based motivational incentives for meeting treatment goals.		Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	N	2/26/24	6/30/27
Pre-Tenancy and Tenancy Support Services	Expenditures for approved pre-tenancy and tenancy services provided to eligible beneficiaries.		Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	2/26/24	6/30/27

Reentry Initiative Services	Expenditures for targeted services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 30 days immediately prior to the expected date of release from participating state prisons.		Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	2/26/24	6/30/27
Reentry Transitional Non-Service Expenditures	Expenditures for planning and supporting the reentry demonstration initiative.		Follow CMS 64.10 Base Category of Service Definitions	Date of service	ADM	N	2/26/24	6/30/27

84. Demonstration Years. Demonstration Years for this demonstration are defined in the Demonstration Years table below.

Table 5: Demonstration Years		
Demonstration Year 1	July 1, 2022 to June 30, 2023	12 months
Demonstration Year 2	July 1, 2023 to June 30, 2024	12 months
Demonstration Year 3	July 1, 2024 to June 30, 2025	12 months
Demonstration Year 4	July 1, 2025 to June 30, 2026	12 months
Demonstration Year 5	July 1, 2026 to June 30, 2027	12 months

85. 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 XI. CMS will provide technical assistance, upon request.[3]

[3] Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms

86. 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.

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

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

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

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

88. Budget Neutrality Mid-Course Correction Adjustment Request. No more than once per demonstration year, the state may request that CMS make an adjustment to its budget

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and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 88(c). If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

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

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

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

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

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

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

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

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

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

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

XIV. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

89. 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 a Main Budget Neutrality Test, and 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.

90. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 3, Master MEG Chart and Table 4, 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.

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

92. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that approval of the demonstration has not resulted in Medicaid costs to the federal government that are greater than what the federal government's Medicaid costs would likely have been absent the demonstration, and that federal Medicaid "savings" have been achieved

sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as "WOW Only" or "Both" are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of the limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as "Both." Accrued savings from the Montana Waiver for Additional Services and Populations (WASP) demonstration shall be included when calculating the Main Budget Neutrality limit. For the current demonstration period, $600,000 will be transferred from the WASP demonstration to the HEART demonstration. These savings will expire at the end of the current WASP demonstration period, which is December 31, 2027.

Table 6. Main Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only or Both	Trend Rate	DY2	DY3	DY4	DY5
Contingency Management	Agg	WW Only	N/A	The state must have savings to offset these expenditures.			

* PC: Per Capita; Agg: Aggregate

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

94. Hypothetical Budget Neutrality Test 1: SUD Services (See Expenditure Authority #1). 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 from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7. Hypothetical Budget Neutrality Test 1

MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5
IMD Services MEG #1	**PC**	Both	5.6%	$7,830.57	$8,269	$8,732	$9,221	$9,738
IMD Services MEG #2	**PC**	Both	5.5%	$7,814.88	$8,244.70	$8,698	$9,177	$9,681

95. Hypothetical Budget Neutrality Test 2: Pre-Tenancy and Tenancy Support Services. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. 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 from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 8. Hypothetical Budget Neutrality Test 2

MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend Rate	DY 2	DY 3	DY 4	DY 5
Pre-Tenancy and Tenancy Support Services	**PC**	Both	4.8%	—	$585.40	$613.50	$642.95

96. Hypothetical Budget Neutrality Test 3: Reentry Services. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. 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 from Hypothetical Budget Neutrality Test 3 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 9. Hypothetical Budget Neutrality Test 3

MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend Rate	DY 2	DY 3	DY 4	DY 5
Reentry Services	**PC**	Both	4.8%	—	—	$1,395.96	$1,462.97
Reentry Non-Services	**Agg**	Both	N/A	$1,533,333	$766,667		

97. 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.

98. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration period, which extends from July 1, 2022 to June 30, 2027. If at the end of the demonstration approval period the Main Budget Neutrality Limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

99. 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 10: 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

XV. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 11: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
No later than 30 calendar days of demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
No later than 90 calendar days of demonstration approval	SUD Implementation Plan (including Health IT Plan)	STC 18
No later than 60 calendar days of receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 18
No later than nine months after approval	Reentry Demonstration Initiative Implementation Plan	STC 41
No later than 60 calendar days of receipt of CMS comments	Revised Reentry Demonstration Initiative Implementation Plan	STC 41
No later than 150 calendar days of demonstration approval	SUD Monitoring Protocol	STCs 50
No later than 60 calendar days of receipt of CMS comments	Revised SUD Monitoring Protocol	STCs 50
No later than 150 calendar days of demonstration approval	Monitoring Protocol	STCs 51
No later than 60 calendar days of receipt of CMS comments	Revised Monitoring Protocol	STCs 51
No later than 180 calendar days of demonstration approval	Draft Evaluation Design	STC 46
No later than 60 days of receipt of CMS comments	Revised Evaluation Design	STC 46
No later than 60 calendar days after July 1, 2023	SUD Mid-Point Assessment	STC 53
No later than 60 days of receipt of CMS comments	Revised SUD Mid-Point Assessment	STC 53
No later than three years after implementation	Reentry Demonstration Initiative Mid-Point Assessment	STC 54
No later than 60 days of receipt of CMS comments	Revised Reentry Demonstration Initiative Mid-Point Assessment	STC 54
June 30, 2026, or with renewal application	Draft Interim Evaluation Report	STC 67
No later than 60 calendar days of receipt of CMS comments	Revised Interim Evaluation Report	STC 67
Within 18 months after June 30, 2025	Draft Summative Evaluation Report	STC 68

No later than 60 calendar days of receipt of CMS comments	Revised Summative Evaluation Report	STC 68
Monthly Deliverables	Monitoring Calls	STC 59
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 52
	Quarterly Expenditure Reports	STC 52
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 52

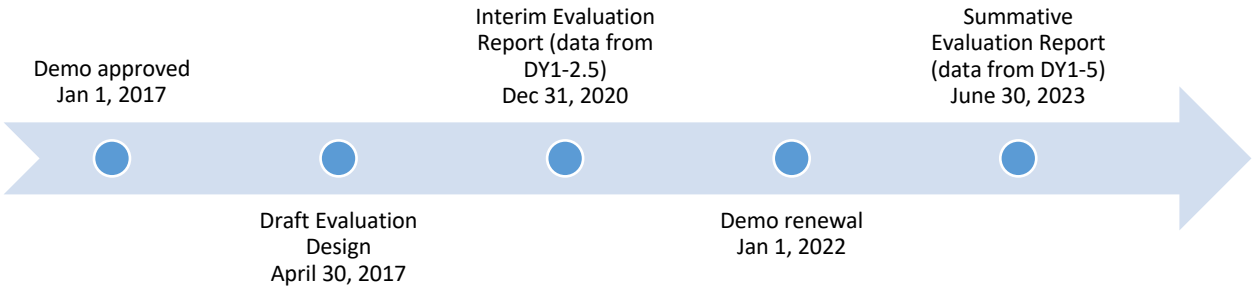
ATTACHMENT A
DEVELOPING THE EVALUATION DESIGN

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 target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration).

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 thirty (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.

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 issues that the state is trying to address with the approved section 1115 demonstration waivers and expenditure authorities, the potential magnitude of the issues, and why the state selected this course of action to address the issues (e.g., a narrative on why the state submitted a section 1115 demonstration application).
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, renewal, or expansion of, the demonstration.
5. For renewals, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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 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 aim, the primary drivers that contribute directly to achieving

the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

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.

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. *Target and Comparison Populations* – Describe the characteristics of the target 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. The state also should 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'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. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

5. *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
6. *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative analysis measures that will adequately assess the effectiveness of the demonstration. This section should:
    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
    b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
    c. Include a discussion of how propensity score matching and difference-in-differences designs may be used to adjust for differences in comparison populations over time, if applicable.
    d. Consider the application of sensitivity analyses, as appropriate.
7. *Other Additions* – The state may provide any other information pertinent to the Evaluation Design for the demonstration.

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

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

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

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

1. When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).
2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes;

b. No or minimal appeals and grievances;
c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans for the demonstration.

E. Attachments

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

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

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

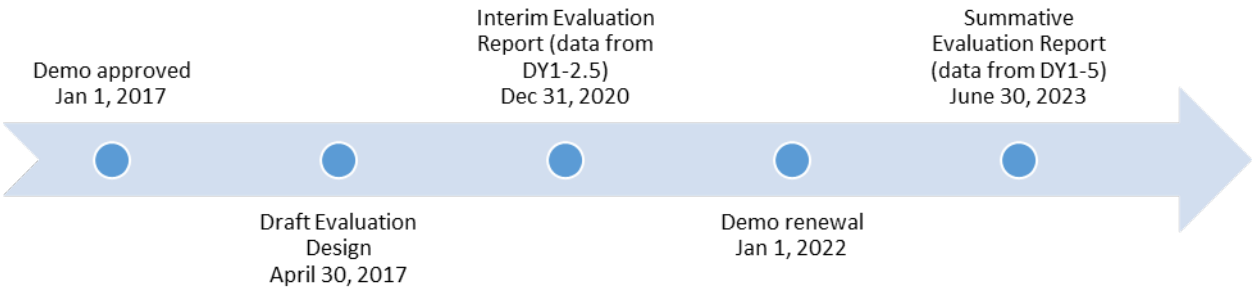
Attachment B:
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

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



Expectations for Evaluation Reports

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

the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

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

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

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

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

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

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

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

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

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

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of titles XIX and XXI.
3. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
4. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

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

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

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

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

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

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

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

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

2. If the state did not fully achieve its intended goals, why not?
3. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

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

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

ATTACHMENT C
Reserved for SUD Implementation Plan and HIT Plan

State of Montana
Department of Public Health and Human Services

Montana Substance Use Disorder Plan Protocol

May 2022

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Introduction

Similar to all other states in the country, Montana has been working to address a persistent and shifting substance use disorder (SUD) crisis that impacts individuals and families throughout the state. The state's opioid-related overdose deaths have remained relatively steady over the past few years compared to those of other states due to the state's coordinated efforts to address the SUD crisis. Since 2016, the state has created strong partnerships between local, tribal, and state health and justice partners. The state has also expanded access to evidence-based treatment and recovery services while promoting harm reduction and appropriate justice system diversion.

Montana's Department of Public Health and Human Services (DPHHS) is seeking federal authority to build upon the strides made by the state over the past decade to establish a comprehensive continuum of behavioral health—mental health and SUD—services for its Medicaid-enrolled residents that will complement the state's comprehensive strategy to expand access to behavioral health treatment for Medicaid members. DPHHS is pursuing a joint Section 1115 SUD and serious mental illness (SMI)/serious emotional disturbance (SED) demonstration to strengthen its behavioral health delivery system, specifically, by:

- Expanding its SUD benefits to offer additional residential treatment and withdrawal management services, contingency management as part of a comprehensive treatment model for individuals with stimulant disorder, and tenancy support services;
- Providing targeted Medicaid services to eligible inmates of state prisons with SUD, SMI, or SED in the 30 days prior to their release into the community;
- Obtaining a waiver of the Medicaid institution for mental diseases (IMD) exclusion for SUD services;
- Building SUD provider capacity; and
- Strengthening care coordination and care management for individuals with SUD.

The following implementation plan details Montana's approach for meeting the six milestones identified by the Centers for Medicare & Medicaid Services (CMS) as a condition of obtaining a waiver of the IMD exclusion for SUD services.

Milestone 1: Access to Critical Levels of Care for SUD

Montana's Medicaid State Plan covers a wide range of SUD services for Medicaid beneficiaries across outpatient, residential and inpatient care settings. Montana's Medicaid program currently covers many services along the American Society of Addiction Medicine (ASAM) continuum of care, and the state seeks to expand its coverage of the ASAM continuum by adding 3.3 (clinically managed population-specific high-intensity residential programs), 3.2-WM (clinically managed residential withdrawal management), and a bundled rate for 3.1 (clinically managed low-intensity residential) to its State Plan and expanding 0.5 (early intervention). The table below provides an overview of Montana Medicaid coverage for each ASAM level of care, proposed changes, and a summary of actions needed to implement the changes.

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
0.5	Early Intervention	Montana Medicaid covered services include Screening, Brief Intervention, and Referral to Treatment (SBIRT). SBIRT involves the use of a structured screening to determine risk factors related to substance use, a brief intervention and possible referral for treatment. Services can be provided by an LAC or LAC licensure candidate, a physician, or a midlevel provider. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and*	Currently covered in State Plan for all.	Will include targeted services for youth who are at risk of developing substance-related problems, or a service for those for whom there is not yet sufficient information to document a diagnosable substance use disorder. Providers will also include physicians and other practitioners, including LAC candidates, LCPCs, LCSWs, LMFTs, and	• Promulgate Administrative Rule to revise provider manual to add targeted services for youth and expanded providers. Date: Effective October 1, 2022 • Promulgate State Licensure rules. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA. Date: Effective October 1, 2022 • Enroll providers to offer new services. Date: Ongoing

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		Adult Mental Health, Policy Number 125: Screening, Brief Intervention, and Referral to Treatment (SBIRT), located here.		paraprofessionals supervised by licensed professionals.	
1	Outpatient Services	Medicaid-funded outpatient SUD therapy services include recovery or motivational enhancement therapies/strategies. Services include individual, family, and group therapy in which diagnosis, assessment, psychotherapy, and related services are provided. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 520: SUD Outpatient (OP) Therapy (ASAM 1.0) Adult and Adolescent, located here.*	Currently covered in State Plan for all beneficiaries meeting medical necessity criteria.	No change expected.	N/A
2.1	SUD Intensive Outpatient Services	Montana Medicaid intensive outpatient services are covered as a bundled service	Currently covered in State Plan for	Creation of a bundled rate to be consistent with	• Promulgate Administrative Rule to revise provider

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		package which includes individual, group, and family therapy; educational groups; psychosocial rehabilitation; co-occurring mental health; face-to-face crisis services; and face-to-face care coordination. Intensive outpatient programs are provided to Medicaid beneficiaries for nine or more hours of structured programming per week (adults) or six or more hours per week (adolescents) to treat multi-dimensional instability. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 525: SUD Intensive Outpatient (IOP) Therapy (ASAM 2.1) Adult and Adolescent, located here.*	all beneficiaries meeting medical necessity criteria.	other ASAM level of care (LOC).	manual to add bundled rate. Date: Effective October 1, 2022 • Promulgate State Licensure rules. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to add bundled rate. Date: Effective October 1, 2022

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
2.5	Partial Hospitalization Services	Montana Medicaid partial hospitalization services are covered as a bundled service package that includes individual, group, and family therapy, and psychosocial rehabilitation. Partial hospitalization services include therapeutic and behavioral interventions to address SUD in the structured setting and improve the member's successful functioning in the home, school, and/or community setting. Partial hospitalization includes a minimum of 20 hours of skilled treatment services per week and is provided in a setting that complies with licensure rule and has direct access to psychiatric, medical, and laboratory services on-site. *Additional coverage and billing details can be found in the Medicaid Services*	Currently covered in State Plan for all beneficiaries meeting medical necessity criteria.	Creation of a bundled rate to be consistent with other ASAM level of care (LOC)	• Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to add bundled rate. Date: Effective October 1, 2022 • Promulgate Administrative Rule to revise provider manual to add bundled rate. Date: Effective October 1, 2022 • Promulgate State Licensure rules. Date: Effective October 1, 2022

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 530: SUD Partial Hospitalization (ASAM 2.5) Adult and Adolescent, located here.			
3.1	SUD Clinically Managed Low-Intensity Residential	SUD clinically managed low-intensity residential services are provided in a residential home that functions as a supportive, structured living environment. Members are provided stability and skills building to help prevent or minimize continued substance use. SUD treatment services are provided on-site or off-site. This service includes a minimum of five hours per week of professionally directed treatment services. Montana Medicaid covered services include individual, group, and family therapy; targeted case management; and certified peer support services. Peer supports will	The therapy provided in this level of care is covered fee for service though this service is not covered as a bundle.	Creation of a bundled rate to be consistent with other ASAM LOC.	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022 • Promulgate State ASAM Licensure rules. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to provide discrete coverage for ASAM LOC 3.1. Date: Effective

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		be billable outside of the bundled rate. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 535: SUD Clinically Managed Low-Intensity Residential (ASAM 3.1) Adult and Adolescent, located here.*			October 1, 2022
3.3	Clinically Managed Population-Specific High-Intensity Residential Programs	Clinically managed high-intensity SUD residential services are geared toward adults with cognitive impairments, including developmental delays, and are provided in a structured residential treatment environment with daily clinical services provided at a pace to accommodate cognitive impairments.	No coverage.	Will be covered for all adult enrollees meeting medical necessity criteria which will be targeted toward individuals with significant cognitive impairments (temporary or permanent) resulting from substance use or	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Promulgate ASAM Licensure rules. Date: Effective October 1, 2022

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
				other co-occurring disorders.	• Promulgate rule to implement bundled rate. Effective October 1, 2022 • Amend Other Rehabilitation SPA to provide coverage for ASAM LOC 3.3 Date: Effective October 1, 2022
3.5	SUD Clinically Managed High-Intensity Residential Services	Montana Medicaid clinically managed residential treatment programs provide 24-hour structured residential treatment. This service is covered as a bundled service package based on staffing that includes individual, group, and family therapy, and psychosocial rehabilitation. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for*	Currently covered in State Plan for all enrollees meeting medical necessity criteria.	Creation of a bundled rate to be consistent with other ASAM LOC	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Promulgate ASAM Licensure rules. Date: Effective October 1, 2022

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		Substance Use Disorder and Adult Mental Health, Policy Number 540: SUD Clinically Managed High-Intensity Residential (ASAM 3.5) Adult and SUD Clinically Managed Medium-Intensity Residential (ASAM 3.5) Adolescent, located here.			• Promulgate rule to implement bundled rate. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to align services with ASAM LOC. Date: Effective October 1, 2022
3.7	SUD Medically Monitored Intensive Inpatient Services	Beneficiaries receiving this level of care are provided a planned regimen of 24-hour professionally directed evaluation, observation, medical management/monitoring, and SUD treatment. This service is covered as a bundled service package based on staffing that includes individual, group, and family therapy; nurse intervention and monitoring; and psychosocial rehabilitation.	Currently covered in State Plan for adult enrollees meeting medical necessity criteria.	Creation of a bundled rate to be consistent with other ASAM LOC	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Promulgate ASAM Licensure rules. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 545: SUD Medically Monitored Intensive Inpatient (ASAM 3.7) Adult and AUD Medically Monitored High-Intensity Inpatient (ASAM 3.7) Adolescent, located here.			to align services with ASAM LOC. Date: Effective October 1, 2022
4.0	Medically Managed Intensive Inpatient Services	DPHHS currently covers medically managed intensive inpatient services with 24-hour nursing care and daily physician care. This level of care is clinically appropriate for individuals presenting with severe, unstable problems in ASAM dimension beyond medical monitoring that require the full resources of the hospital: (1) acute intoxication and/or withdrawal potential; (2) biomedical conditions and	Covered for all enrollees meeting medical necessity criteria.	No change	N/A

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		complications; or (3) emotional, behavioral, or cognitive conditions and complications.			
MAT	Medication-Assisted Treatment (MAT)	MAT is the use of medications approved by the US Food and Drug Administration (FDA), in combination with behavioral therapies and support services, to provide a whole-patient, patient-centered approach to the treatment of alcohol and opioid use disorders. MAT is currently provided to Montana Medicaid beneficiaries by opioid treatment programs (OTPs) and office-based opioid treatment (OBOT) providers. *Additional coverage and billing details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 550: Medication*	Currently covered for all enrollees meeting medical necessity criteria.	Consistent with the SUPPORT Act requirements, DPHHS has submitted a MAT SPA to CMS that includes the FDA-approved medications for opioid use disorder, counseling services, and behavioral therapy. To complement these efforts, DPHHS is in the process of creating a new MAT Medicaid provider type, which will include OBOTs and OTPs. DPHHS will also adjust the bundled rate to be	• Amend MAT SPA to adjust bundled rates to be consistent with ASAM Criteria. Date: Effective October 2023

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		Assisted Treatment, located here.		consistent with other ASAM LOC.	
3.2-WM	Clinically managed residential withdrawal (residential withdrawal management)	An organized, clinically managed residential withdrawal management service for individuals who are experiencing moderate withdrawal symptoms and who require 24-hour supervision, observation, and support; uses physician-approved protocols to identify individuals who require medical services beyond the capacity of the facility and to transfer these individuals to the appropriate levels of care.	No coverage.	Will be covered for all beneficiaries meeting medical necessity criteria.	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022 • Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Promulgate ASAM Licensure rules. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to add coverage for ASAM LOC. Date: Effective October 1, 2022
3.7-WM	Medically monitored inpatient withdrawal management	An organized, medically monitored inpatient withdrawal management service under the supervision of a physician that provides 24-hour observation,	Provided by licensed ASAM level 3.7 residential treatment providers.	Creation of a bundled rate to be consistent with other ASAM LOC	• Promulgate Administrative Rule to revise provider manual. Date: Effective October 1, 2022

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Summary of Action Items Needed
		monitoring, and treatment for individuals who are experiencing severe withdrawal symptoms and require 24-hour nursing care.			• Promulgate rule to add bundled rate to fee schedule. Date: Effective October 1, 2022 • Promulgate State ASAM Licensure rules. Date: Effective October 1, 2022 • Amend Other Rehabilitation SPA to align with ASAM LOC. Date: Effective October 1, 2022
4-WM	Medically managed intensive inpatient withdrawal (hospital-based behavioral health services)	An organized, medically managed inpatient service under the supervision of a physician that provides 24-hour, medically directed evaluation and withdrawal management for individuals who are experiencing severe, unstable withdrawal and require an acute care setting.	Covered for all Medicaid beneficiaries meeting medical necessity criteria by inpatient hospitals.	No change.	N/A

Summary of Actions Needed Across Milestone

Action	Timeline
Promulgate Administrative Rule to revise provider manual	Effective October 1, 2022
Amend Other Rehabilitation SPA	Effective October 1, 2022
Promulgate State ASAM Licensure rules	Effective October 1, 2022

Milestone 2: Use of Evidence-Based SUD-Specific Patient Placement Criteria

Montana has robust, evidence-based policies in place to ensure that enrollees have access to appropriate SUD services according to their diagnosis and ASAM level-of-care determination. Over the course of the 1115 demonstration, Montana will strengthen its assessment policy, which is a prerequisite for obtaining most SUD services, by working to standardize the multi-dimensional assessment tool providing additional training on the ASAM Criteria for its SUD providers.

Provider/Patient Assessments

Current State
Montana Medicaid requires each Medicaid member receiving SUD treatment to have a current comprehensive assessment, but does not currently have a standardized statewide assessment instrument/tool. The comprehensive assessment must be conducted by an appropriately licensed clinical mental health professional or licensed addictions counselor trained in clinical assessments and operating within the scope of practice of their respective license and be organized according to the six dimensions of the ASAM Criteria.

The assessment must include the following information in order to substantiate the member's diagnosis and provide sufficient detail to individualize the member's treatment plan goals and objectives:

- Presenting problem and history of problems;
- Family history *(including substance use, medical, psychiatric, religious/spiritual, and social history);*
- Developmental history *(including pregnancy, developmental milestones, and temperament)*;
- Substance use and addictive behavior history;
- Personal/social history *(including school, work, peers, leisure activities, sexual activity, abuse, disruption of relationships, military service, financial resources, living arrangements, and religious/spiritual beliefs)*;
- Legal history relevant to history of mental illness, substance use, and addictive behaviors *(including guardianships, civil commitments, criminal mental health commitments, current criminal justice involvement, and prior criminal background)*;
- Psychiatric history *(including psychological symptoms, cognitive issues, and behavioral complications)*;
- Medical history *(including current and past problems, treatment, and medications)*;
- Mental status examination *(including memory and risk factors such as suicidal or homicidal ideation)*;
- Physical examination *(specifically focused on physical manifestations of withdrawal symptoms or chronic illnesses)*;
- Diagnosis *(diagnostic interview and impressions)*;

- Survey of strengths, skills, and resources; and
- Treatment recommendations.

Future State
To further strengthen use of the ASAM multi-dimensional patient assessment, Montana is in the process of taking necessary steps to build or select and procure a standardized, statewide multi-dimensional assessment tool that follows the ASAM Criteria for patient placement for its SUD providers. Use of the tool will help standardize assessments and better support providers throughout the assessment process. Montana will also provide and require all providers administering SUD assessments to obtain training in the ASAM Criteria.

Summary of Actions Needed
- Revise assessment policy and administrative rules to require that licensed providers providing SUD services or assessments document their training with respect to the ASAM Criteria: October 2022
- Conduct ASAM trainings through vendor(s) and other partnering entities: Ongoing
- Montana will continue to work with the vendor and complete an analysis of the current environment; identify necessary stakeholders, determinate requirements, and specifications toward implementation; and take steps for implementation of a standardized assessment: July2023
- Promulgate new administrate rule as needed: July 2024
- Implement requirement for use of a standardized assessment: July 2024

Utilization Management

Current State
Montana Medicaid providers must use the Mountain-Pacific Quality Health Utilization Management Portal, Telligen, to request prior and continuing stay authorization for SUD services when authorization is required. Prior authorization may be issued for as many days as deemed medically necessary up to the maximum number of days allowed for the service. Additional prior authorization procedure requirement details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 205: Requesting Prior Authorization – Non-Acute Services, located here. Additional continued stay details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 210: Requesting a Continued Stay Review – Non-Acute Services, located here.

In addition, Montana Medicaid providers may implement an auto-authorization process for acute psychiatric hospitalizations (out of state), SUD medically monitored intensive inpatient (ASAM 3.7), and the crisis stabilization program for Medicaid beneficiaries who receive treatment. Additional auto-authorization details can be found in the Medicaid Services Provider Manual for Substance Use Disorder and Adult Mental Health, Policy Number 206: Requesting Auto-Authorization – Acute Services, located here.

Medicaid clinical coverage policies:
- **ASAM Level 1: SUD Outpatient Therapy.** Prior authorization and continued stay review are not required. The provider must document the medical necessity criteria the member meets in their file.

- **ASAM Level 2.1: SUD Intensive Outpatient Therapy (IOP).** Prior authorization is not required. Continued stay review is required for the IOP bundle after the first 60 billable days for up to 15 billable days. Continued stay review is not required if the provider is not billing the IOP bundled rate. Member must continue to meet the SUD criteria as described in this manual and meet the ASAM Criteria diagnostic and dimensional admission criteria for SUD IOP Services (ASAM 2.1) Adult and Adolescent level of care.
- **ASAM Level 2.5: Partial Hospitalization.** Prior authorization and continued stay review are not required. Member must continue to meet the SUD criteria as described in this manual and meet the ASAM Criteria diagnostic and dimensional admission criteria for SUD Partial Hospitalization (ASAM 2.5) Adult and Adolescent level of care.
- **ASAM Level 3.1: SUD Clinically Managed Low-Intensity Residential.** Prior authorization is required and may be issued for as many days as deemed medically necessary up to 90 days. Continued stay review is required for up to 30 days. Member must continue to meet the SUD criteria as described in this manual with a severity specifier of moderate or severe and meet the ASAM Criteria diagnostic and dimensional admission criteria for SUD Clinically Managed Low-Intensity Residential (ASAM 3.1) level of care.
- **ASAM Level 3.5: SUD Clinically Managed High-Intensity Residential.** Prior authorization is required and may be issued for as many days as deemed medically necessary up to 21 days. Continued stay review is required for up to five days. Member must continue to meet the SUD criteria as described in this manual with a severity specifier of moderate or severe and meet the ASAM Criteria diagnostic and dimensional admission criteria for SUD Clinically Managed High-Intensity Residential (ASAM 3.5) level of care.
- **ASAM Level 3.7: Medically Monitored Intensive Inpatient.** Prior authorization is required and may be submitted via auto-authorization. The initial three days are automatically authorized. The ASAM 3.7 prior authorization form must be submitted within three calendar days of admission. Continued stay review is required after the first three days of service. Member must continue to meet the SUD criteria as described in this manual with a severity specifier of moderate or severe and meet the ASAM Criteria diagnostic and dimensional admission criteria for ASAM 3.7 level of care.

Future State

For newly added SUD services—ASAM 3.3: Clinically managed population-specific high-intensity residential services, and ASAM 3.2-WM: Clinically managed residential withdrawal—the Department will establish prior authorization and utilization management requirements consistent with ASAM standards of care to ensure the appropriateness of patient placement. The clinical coverage policies for these new services will include these prior authorization and utilization management requirements.

Summary of Actions Needed

- Promulgate Administrative Rule to revise provider manual: Effective October 2022
- Promulgate Administrative Rules to add levels of care to Montana's Office of Inspector General (OIG) licensure rules: Effective October 1, 2022
- Amend Other Rehabilitation SPA: Effective October 1, 2022

Summary of Actions Needed Across Milestone

Action	Timeline
Promulgate Administrative Rules to add levels of care to OIG licensure rules and require licensed providers providing SUD services or assessments to document their training with respect to the ASAM Criteria	Effective October 1, 2022
Promulgate Administrative Rule to revise provider manual	Effective October 1, 2022
Amend Other Rehabilitation SPA	Effective October 1, 2022
Conduct ASAM trainings through vendor(s) and other partnering entities	Ongoing
Work with the vendor and complete an analysis of the current environment; identify necessary stakeholders, determinate requirements, and specifications toward implementation; and take steps for implementation of a standardized assessment	Effective July 1, 2023
Promulgate new administrate rule as needed	Effective: July 2024
Implement requirement for use of a standardized assessment	July 2024

Milestone 3: Use of Nationally Recognized SUD-Specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

DPHHS' OIG licenses SUD residential facilities. DPHHS monitors outpatient SUD providers using a state-approved list that is separate from licensure requirements. The current licensure rules for SUD residential providers include standards regarding the services that must be offered, program hours, and staff credentials. Today, the degree of alignment between licensure rules for SUD providers and the ASAM Criteria varies across provider types. DPHHS, through cross-division collaboration, is in the process of updating its licensure rules for SUD providers to align with the ASAM Criteria. DPHHS is also working to ensure that residential treatment providers either provide medication-assisted treatment (MAT) on-site or facilitate access to off-site MAT providers within a specified distance, and do not deny admission to individuals obtaining MAT. The Department will also conduct more robust monitoring of SUD treatment providers to ensure compliance with the ASAM Criteria.

Provider Licensure

Current State

Today, OIG's Licensing Bureau licenses and regulates non-acute residential facilities pursuant to Title 50. Chapter 5. Hospital and Related Facilities of the Montana Code. Requirements are

codified in Administrative Rules of Montana, Title 37, Chapter 106, subchapter 14. The licensure rules for SUD residential treatment providers were based in part on the ASAM Criteria, but have not been updated to align with the most current edition of the criteria.

The licensing standards for covered residential services are located here.

Future State

OIG in collaboration with Montana Medicaid is in the process of updating its licensure rules for SUD residential treatment providers to align its provider qualifications with the ASAM Criteria. OIG is also preparing to expand the SUD provider types it licenses to include outpatient clinic-based providers and align staffing requirements with ASAM 2.1 and 1.0 in the ASAM Criteria. DPHHS will continue to monitor SUD providers and ensure quality of care through the state approval process which is required to enroll in Montana Medicaid. State approval requires programs to identify local need (county level) and services they intend to offer in their application. DPHHS will also be updating these rules to streamline the process and distinguish between prevention providers, individual providers, and facilities licensed by OIG. When developing licensure rules for new services or new populations that will be able to access a service (e.g., adolescents), OIG will ensure that they reflect ASAM's specifications regarding service definitions, hours of clinical care provided, and program staff credentialing.

Specifically, OIG is proposing new licensure rules that align with the ASAM Criteria for the following levels of care:

- ASAM 2.5 – Partial Hospitalization Substance Use Disorder Facility; and
- ASAM 3.3 – Clinically Managed Population-Specific High-Intensity Residential (Adult Only) Substance Use Disorder Facility

In addition, OIG is revising its current licensure rules to align with the ASAM Criteria for the following levels of care:

- ASAM 3.1 – Clinically Managed Low-Intensity Residential (Adult or Adolescent) Substance Use Disorder Facility;
- ASAM 3.5 – Clinically Managed High-Intensity Residential (Adult)/Medium-Intensity Residential (Adolescent) Substance Use Disorder Facility Requirements;
- ASAM 3.7 – Medically Monitored Intensive Inpatient Services;
- ASAM 3.2 WM – Clinically Managed Residential Withdrawal Management Services; and
- ASAM 3.7 WM – Medically Monitored Withdrawal Management Services.

Summary of Actions Needed

- Promulgate new state ASAM Licensure rules: Effective October 1, 2022
- Promulgate updated/revised state ASAM Licensure rules: Effective October 1, 2022
- Promulgate updated/revised state approval rules: Effective October 1, 2022
- Amend Other Rehabilitation SPA: Effective October 1, 2022

Monitoring of SUD Treatment Providers

Current State

To ensure that high-quality SUD treatment services are delivered in accordance with state licensure rules, OIG regularly monitors SUD residential treatment providers. OIG's monitoring of residential providers includes surveys every one to three years, complaint investigations, and follow-up surveys to determine compliance with the program rules regarding services offered, hours of clinical care, and program staffing. Providers not in compliance with rules submit a plan of correction that is approved by the OIG.

Future State

OIG will incorporate questions assessing compliance with ASAM Criteria standards, as memorialized in the state's updated licensure rules, into its surveys of licensed SUD treatment providers. OIG, in collaboration with Montana Medicaid, will train its inspectors to ensure they are equipped to monitor providers for compliance with the ASAM standards. Montana Medicaid or its designee will conduct clinical reviews to ensure quality of care and appropriateness of services in accordance with the ASAM standards.

Summary of Actions Needed

- Revise OIG's survey process to provide the ability to assess compliance with ASAM standards: Effective October 1, 2022

Requirement That Residential Treatment Providers Offer MAT On-Site or Facilitate Access to Off-Site Providers

Current State

DPHHS does not currently require residential providers to provide MAT for all Food and Drug Administration-approved types of medication on-site or coordinate care with a licensed OTP or OBOT provider.

Future State

DPHHS will require residential treatment providers that do not provide MAT on-site to have the ability to facilitate off-site access by linking individuals to a licensed OBOT or OTP. As part of this requirement, DPHHS will issue updated rulemaking, policies, and/or care agreements as needed. To ensure provider compliance with this requirement, DPHHS will conduct provider training and provide technical assistance to residential treatment providers.

Summary of Actions Needed

- Promulgate ASAM Licensure rules: Effective October 1, 2022
- Promulgate Administrative Rule to revise provider manual: Effective October 1, 2022

Summary of Actions Needed Across Milestone

Action	Timeline
Promulgate State ASAM Licensure rules	Effective October 1, 2022
Promulgate State Approval rules	Effective October 1, 2022
Revise OIG survey process to provide the ability to assess compliance with ASAM standards	Effective October 1, 2022
Promulgate Administrative Rule to revise provider manual	Effective October 1, 2022
Promulgate Administrative Rule to revise state approval process	Effective October 1, 2022

Milestone 4: Sufficient Provider Capacity at Critical Levels of Care, Including for Medication-Assisted Treatment for Opioid Use Disorder (OUD)

As Montana is a fee-for-service state, DPHHS enrolls SUD providers into Montana Medicaid and manages networks of providers directly. Rural and frontier areas, in particular, face gaps in access to treatment services at critical levels of SUD care, driven by staffing shortages, particularly with respect to residential treatment services. DPHHS has employed a number of strategies to expand its network of providers, including using telemedicine and streamlining state provider requirements to expand the network of state-approved SUD providers at critical levels of care. To ensure that Medicaid members have access to SUD treatment providers at critical levels of care, DPHHS will conduct an assessment of all Medicaid-enrolled providers. As part of this assessment, DPHHS will identify providers that are accepting new patients. DPHHS will use the results of the assessment to target network development efforts.

Current State

DPHHS is actively committed to monitoring and expanding provider access and capacity at all critical levels of care. DPHHS is responsible for the enrollment, disenrollment, credentialing, and assessment of qualifications and competencies of state-approved SUD providers and health care facilities, in accordance with applicable state and federal regulations. To ensure that enrollees have sufficient access to services, DPHHS enrolls any willing qualified and licensed provider, reviews the adequacy of its network on a service-level basis, and collaborates with stakeholders to expand its network for services where shortages exist.

The state faces gaps in access in rural and frontier counties across multiple levels of care with the majority of providers concentrated in the six largest towns—Bozeman, Kalispell, Helena, Missoula, Billings, and Great Falls. DPHHS plans to assess the use of telehealth whenever possible as a key tool to increase access.

Montana has expanded telehealth access during COVID-19 by allowing services to be furnished via audio-only capabilities and by providing payment parity for all telehealth. Even prior to COVID-19, the state had progressive telehealth policies to maximize care access and services. For example:

- **Practice Standards and Licensure:** Montana providers, including state-approved SUD providers, do not need to establish a relationship with a patient prior to engaging with them via telemedicine with the exception of MAT; a telepresenter

or health care provider does not need to be present with a patient during a telemedicine encounter.

- **Medicaid Coverage and Reimbursement:** Montana state law requires Medicaid reimbursement for telehealth services at the same rate as for services delivered in person.
- **Medicaid-Eligible Patient Settings:** Montana Medicaid has historically allowed the following patient settings for telehealth encounters, including for SUD treatment: Outpatient Hospital; Federally Qualified Health Center; Rural Health Center; Indian Health Service; Mental Health Center; Chemical Dependency Clinic; Group/Clinic; Public Health Clinic; Family Planning Clinic; or Home.

In an effort to expand access to SUD treatment providers throughout the state, the state eliminated a historic geographic restriction of the number of state-approved SUD providers per county in 2017, which resulted in a significant expansion of SUD treatment providers across the state, particularly at outpatient levels of care. As a result of the changes, the state went from 32 providers with 92 locations to 69 providers with 163 locations. State law requires SUD treatment providers to obtain state approval in order to bill Medicaid for services.[4]

As described above, Montana faces particular gaps in residential treatment levels of care and medications for opioid use disorder (MOUD) providers, largely due to staffing shortages where providers have difficulty finding staff that can provide continuous coverage. Currently, ASAM residential levels 3.1, 3.5, and 3.7 all have waiting lists for beds. In addition, the state has had difficulty standing up adolescent ASAM residential levels of care and is working with existing mental health group homes for adolescents to offer ASAM level 3.5 for adolescents. DPHHS plans to undertake a comprehensive rate review of all Medicaid covered services, including SUD, to ensure that reimbursement is sufficient and can allow SUD providers to attract and retain staff.

Future State

Within 12 months of the demonstration approval, the Department will complete its statewide assessment of the availability of enrolled Medicaid providers, which will include identifying those that are accepting new patients at the critical levels of care. In order to expand access to SUD treatment across critical levels of care, DPHHS plans to continue leveraging telehealth and engaging current SUD treatment providers to expand service locations and offerings across levels of care.

Building Capacity for New and Expanded Services

The state intends to build network capacity for new or expanded services.

- **Expand service offerings to include ASAM level 3.2-WM and 3.5.** DPHHS plans to work with its residential treatment providers to expand their service offerings to include ASAM level 3.2-WM. To build capacity for adolescent ASAM 3.5, DPHHS will continue to work with its therapeutic group home providers to integrate appropriate ASAM program standards into their treatment programs.
- **Engage with stakeholders** and providers **for ASAM level 3.3.** To build sufficient networks for ASAM level 3.3 (clinically managed population-specific high-intensity residential programs), the state will work to identify providers that may be interested in offering this service.
- **Provide training for new Medicaid SUD providers.** DPHHS will educate and require training for new Medicaid SUD providers, to orient them to Medicaid, including topics such as utilization management, credentialing, and billing.

Expanding Access to MAT

Montana relies on OTP and OBOT providers to provide MAT to state residents, including Medicaid members. Currently, the state has one OTP provider with five locations operating within the state. The number of providers waivered to prescribe buprenorphine in Montana increased by over 700%, from 22 in 2017 to over 180 in 2021. Sixty-eight percent of those waivered providers are located in the six most-populated counties. DPHHS is working to identify the number of active buprenorphine providers that serve Medicaid members, and is creating a new MAT Medicaid provider type that will include OTPs and OBOTs and be reimbursed using a bundled rate that includes the dispensing, administering, or prescribing of the MOUD and care coordination.

Summary of Actions Needed

Action	Implementation Timeline
Conduct an assessment of all Medicaid-enrolled providers, to include the identification of providers that are accepting new patients at the critical levels of care	April 2022 – April 2023
Work to build Medicaid provider networks for new Medicaid levels of care	January 2022 – January 2024
Expand service offerings service to include ASAM level 3.2-WM and 3.3	Effective October 1, 2022
Engage with stakeholders and providers for ASAM level 3.3	April 2022 – April 2024
Provide training for new Medicaid SUD providers	Ongoing

Milestone 5: Implementation of Comprehensive Strategies to Address Prescription Drug Abuse and Opioid Use Disorders

Like all other states in the country, Montana has been working to comprehensively address a persistent and shifting SUD crisis that impacts individuals and families throughout the state. Beginning in 2016, the state has created strong partnerships between local, tribal, and state

health and justice partners to address emerging SUD issues. The state has also worked to improve its opioid prescribing guidelines, increase prevention efforts, and expand access to evidence-based treatment and recovery services while promoting harm reduction and appropriate justice system diversion. As a result of the state's coordinated efforts, the state's opioid-related overdose deaths have remained relatively steady over the past few years compared to those of other states throughout the country that have seen a rise. However, even with these efforts, opioids still account for the largest percentage of drug overdoses in the state.[5]

Montana Substance Use Disorder Task Force

In order to develop more robust, evidence-based systems to prevent, treat, and manage SUD, the state created the Montana Substance Use Disorder Task Force in 2017; in 2020, the task force issued its updated strategic plan for 2020 – 2023. This plan outlines how the state will reduce drug-related mortality, hospitalizations, and emergency department visits related to drug misuse across all populations in Montana. Please see the 2020 – 2023 Montana Substance Use Disorder Task Force Strategic Plan, available here, for more information.

Opioid Prescriptions

Montana is working with its health care providers and health systems to balance the appropriate prescribing of opioid medications, while ensuring that patients, particularly those with chronic pain, receive the care they need.

Prescribing Limits: The 2019 Montana Legislature passed House Bill 86 to limit prescriptions for opioid-naïve members to seven days with the exception of cancer and palliative care patients. Montana's Medicaid Drug Utilization Board limits prescriptions to 90 morphine milligram equivalents (MME) without prior authorization. The goals of this law are to:

- Prevent new cases of opioid dependence;
- Prevent opioid-related overdose; and
- Ensure that members are using the lowest possible dose for the shortest amount of time.

Prescribers can exercise their medical judgment to prescribe more than a seven-day prescription to treat chronic pain, pain associated with cancer, or pain experienced while the patient is in palliative care.

Montana Prescription Drug Registry (MPDR): The Montana Board of Pharmacy manages MPDR, which became functional in 2012. All pharmacies with an active Montana license are required to report to the MPDR. Pharmacies must submit detailed information on all controlled substances—Schedules II, III, IV, and V drugs—dispensed to Montana patients by the next

business day after the date the prescription was dispensed. Prescribers are also required to review the patient's record in the MPDR prior to prescribing an opioid or benzodiazepine in almost all cases; exceptions include prescriptions for patients receiving hospice care, for patients in chronic pain provided the prescriber reviews the patient's record every three months, or where the prescription is being administered to patient in a health care facility.

Naloxone

The 2017 Montana Legislature passed House Bill 333, the Help Save Lives from Overdose Act (Act), authorizing the broadest possible access to naloxone, the lifesaving opioid antagonist medication used to reverse an opioid-related drug overdose. The law made amendments to Title 50 of the Montana Code Annotated (MCA) to implement increased access to naloxone.[6] The law requires DPHHS to issue a statewide standing order that authorizes pharmacists who maintain a current active license practicing in a pharmacy located in Montana to initiate a prescription and dispense a naloxone opioid antagonist formulation to eligible recipients. Additionally, the law addresses professional immunity and Good Samaritan laws by allowing medical practitioners to dispense naloxone and protecting eligible recipients from arrest, charge, or prosecution who, acting in good faith, seek medical assistance for an individual experiencing an actual or reasonably perceived drug-related overdose. For more information on DPHHS' implementation of naloxone, see the Montana Implementation Guide for Access to Naloxone Opioid Antagonist available here and the Standing Order for Naloxone Opioid Antagonists available here.

Under the State Opioid Response (SOR) grant, contractor Best Practice Medicine offers master training sessions and master trainers then train authorized users on how to administer naloxone, free of charge. Most of the master trainers are law enforcement officers and EMS personnel, and 47 out of the 56 counties in Montana have master trainers. The state contracted with Ridgeway Pharmacy to distribute naloxone to all those trained to use the medication and to organizations under a Memorandum of Understanding (MOU) with DPHHS. The MOU gives organizations access to distribute naloxone directly to eligible recipients. With the addition of MOUs from some groups—the Department of Corrections, harm reduction organizations, and tribes—Montana has distributed more than twice the amount of naloxone as planned.

MAT

In 2017, Montana expanded the use of MAT, which involves the use of medications and can be supported using behavioral health services, peer support services, and team-coordinated care to effectively treat opioid use disorders and prevent opioid overdose. Since the start of the State Targeted Response Program in 2017, a total of 1,426 patients received MOUD, behavioral health counseling, and recovering support services; most of these patients were between the

ages of 25 and 44. Of these patients, 38% were American Indian and 28% were patients with criminal justice involvement.

To bolster the statewide effort to increase the number of practitioners who deliver MOUD, the Montana Primary Care Association (MTPCA) has provided training throughout the state to help practitioners obtain federal buprenorphine waivers. The number of providers waivered to prescribe buprenorphine in Montana increased by over 700%, from 22 in 2017 to over 180 in 2021. In addition to the buprenorphine waiver training, MTPCA has delivered more advanced education about MOUD service provision at all levels, and intensive technical assistance to providers to support the effective integration of care coordination, medications, and behavioral health services into clinic settings to ensure sustainability and quality of services. In FY 2020, 2,194 participants attended 192 educational events delivered by MTPCA, including community meetings, buprenorphine waiver trainings, substance use disorder trainings, American Society of Addiction Medicine (ASAM) trainings, advanced skill trainings, and Screening, Brief Intervention, and Referral to Treatment (SBIRT) trainings.

State Epidemiological Outcomes Workgroup (SEOW)

As part of the state's ongoing analysis of substance use disorder needs and outcomes, Montana established the SEOW for the purpose of identifying, interpreting, and distributing data relevant to substance use and mental health (SUMH). The SEOW aims to inform prevention practices and policies by providing meaningful data about the consequences, related behaviors, and contributing risk and protective factors of SUMH disorders in Montana.

Summary of Actions Needed

None needed.

Milestone 6: Improved Care Coordination and Transitions Between Levels of Care

Care Coordination and Transitions of Care

Current State
DPHHS is responsible for reimbursing care coordination for Medicaid enrollees. Montana has multiple pathways for the provision of case management and care coordination for Medicaid members, including members with SUD. First, nearly all Medicaid members participate in Passport to Health, the Medicaid program's primary care case management (PCCM) program where primary care providers serve as the member's medical home and help address the member's medical and social determinants of health needs, though referrals are not needed for MH and SUD services. The PCCM helps coordinate and refer members, including those with SUD, to specialty services and to more intensive and specialized care coordination services, as needed.

Adult and youth Medicaid members with SUD and SMI are also eligible to receive targeted case management (TCM), which helps link these members to medical, social, educational, and other services to mitigate SUD symptoms. TCM provides a comprehensive assessment and

reassessment; development of a care plan, referrals, and other coordination-related activities; and monitoring and follow-up activities such as scheduling appointments for the member, to help members obtain needed services to address identified needs and achieve goals specified in the care plan. Members with SUD/SMI may also receive care coordination through the high-risk pregnant women TCM program.

In addition to the care coordination programs listed above, care coordination is provided as part of select Medicaid SUD services, including intensive outpatient (IOP) services (ASAM 2.1) currently and MAT effective April 1, 2022.

SUD treatment providers are required to provide and document discharge planning in each patient's individualized treatment plan. Licensed SUD facility providers, including residential treatment providers, are required as a condition of licensure to develop and share a continuing care plan with the member or the member's legal guardian, parent, or representative at the time of discharge or transfer to another level of care, which must include a discharge summary in the clinical record within one month of the date of the member's formal discharge from services or within three months of the date of the member's last services when no formal discharge occurs. For cases left open when a member has not received services for over 30 days, documentation must be entered into the record indicating the reason for leaving the case open. The discharge summary must include:

- The reason for discharge;
- A summary of the services provided by the provider, including recommendations for aftercare services and referrals to other services, if applicable;
- An evaluation of the member's progress as measured by the treatment plan and the impact of the services provided; and
- The signature of the staff person who prepared the summary and the date of preparation.

Future State

DPHHS plans to update its Medicaid provider manuals to require residential treatment providers to coordinate and monitor services provided to enrollees during transitions of care for members moving from one clinical setting to another. These updates will require the following information in the discharge summary:

- A written summary of services provided, including the patient's participation and progress;
- Community substance use treatment provider's contact name, contact number, and time and date of an initial appointment;
- Health care follow-up including provider's contact name, contact number, and initial appointment (if necessary);
- Current medications, dosage taken, number of times per day, and name of prescribing licensed health care professional;
- Name and contact number of the recovery supports identified in the treatment plan;
- Housing and employment plan; and

- Medical, dental, and psychiatric care received during placement.

DPHHS will require discharge/transfer planning when entering any level of care; this requirement will not duplicate transitional care coordination requirements already in place. Discharge/transfer planning will involve input from the patient, family, staff members, and referral sources. SUD providers will be required to:

- Conduct outreach to the member's primary care provider;
- Facilitate clinical handoffs, including those to behavioral health providers;
- Ensure that a follow-up visit is scheduled within a clinically appropriate time window; and
- Develop relationships with local hospitals, nursing homes, external BH providers and facilities (inpatient, residential, outpatient), and inpatient psychiatric facilities to promote smooth care transitions.

Summary of Actions Needed

Action	Timeline
Promulgate Administrative Rule to revise provider manual to incorporate discharge planning requirements.	Effective October 1, 2022

SUD HIT Plan: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
1. Enhanced interstate data sharing in order to better track patient-specific prescription data.	▪ Montana Prescription Drug Registry (MPDR) is connected to 28 other states, including all border states, via PMPinterconnect to enable two-way data sharing. ▪ As of May 2021, MPDR is connected with military health systems (MHS).	▪ MPDR is currently in the process of connecting with RxCheck to allow states to share interstate data either through PMPinterconnect or RxCheck.	▪ Appriss, Montana's PMP vendor, is setting up the required hardware to connect to RxCheck: January 2022
2. Enhanced "ease of use" for prescribers and other state and federal stakeholders.	▪ MPDR recently changed software vendors to increase ease of use, including auto-license verification for easier registration for Montana licensed health care providers.	▪ MPDR is partnering with Department of Public Health and Human Services (DPHHS) to fund statewide integration for providers and pharmacists.	▪ DPHHS completion of contract with Appriss to fund the Statewide Integration Project: October 2021 ▪ Appriss and MPDR State Administrator to kick off Statewide Integration Project with

	Current State	Future State	Summary of Actions Needed
	▪ MPDR allows delegates to query for an authorized prescriber or pharmacist. ▪ Law enforcement must submit subpoenas and board investigators must submit requests to access information from the MPDR.	▪ This will allow access to MPDR data directly from the registered user's electronic health record (EHR), pharmacy management system (PMS), or health information exchange (HIE). ▪ Out-of-state direct integration will be evaluated on a case-by-case basis after statewide integration is completed, with a higher priority given to border states. The MPDR also plans to integrate directly with the VHA system.	statewide marketing targeting eligible health care facilities and pharmacies: October 2021 ▪ Completion of Statewide Integration Project: August 2022
3. Enhanced connectivity between the state's PDMP and any statewide, regional,	▪ The MPDR does not currently	▪ MPDR integration with the BSCC	▪ DPHHS completion of contract

	Current State	Future State	Summary of Actions Needed
or local health information exchange.	connect with Big Sky Care Connect (BSCC), Montana's HIE.	will occur during the Statewide Integration Project operated with Appriss. ▪ Appriss has the ability to integrate with Dr. First and Collective Medical, vendors for BSCC.	with Appriss to fund the Statewide Integration Project: October 2021 ▪ Appriss and MPDR State Administrator to kick off Statewide Integration Project with statewide marketing which will include BSCC: October 2021 ▪ Completion of Statewide Integration Project: August 2022
4. Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns (see also "Use of PDMP" #6, below).	▪ DPHHS receives annual de-identified data to evaluate Montana opioid prescribing habits. The Board of Pharmacy has created administrative rules for factors that are suggestive of	▪ MPDR will continue to partner with DPHHS to monitor Montana opioid prescribing trends. ▪ MPDR will include new analytic tools to identify trends or thresholds to update clinical alerts and	▪ MPDR State Administrator review of data in Tableau. (January 2022 – January 2023.) ▪ Solicit clinical feedback from the Montana Prescription Drug Registry Advisory Group on clinical alert

	Current State	Future State	Summary of Actions Needed
	potential misuse or diversion. ▪ Law enforcement must submit subpoenas and board investigators must submit requests to access information from the MPDR.	administrative rules to guide prescribing habits.	thresholds and increasing linked resources. (January 2022 – June 2022.)
Current and Future PDMP Query Capabilities			
5. Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e., the state's master patient index (MPI) strategy with regard to PDMP query).	▪ While DPHHS does not currently have an MPI strategy, Medicaid does have several proDUR edits in place to prevent inappropriate payment for opioids. These include, but are not limited to, morphine milligram equivalent (MME) limits, quantity limits, therapeutic	▪ DPHHS will work to properly match patients receiving opioid prescriptions with patients in the PDMP.	▪ DPHHS will complete an analysis of the current environment; identify necessary stakeholders, determinate requirements, and specifications toward implementation; and take steps for implementation of an MPI. (January 2022 – June 2022.)

	Current State	Future State	Summary of Actions Needed
	duplication controls, and denial of opioid claims for members with a history of opioid use disorder treatment.		
Use of PDMP – Supporting Clinicians With Changing Office Workflows			
6. Develop enhanced provider workflow/business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance, to address the issues that follow.	▪ MPDR allows delegates to query for an authorized prescriber or pharmacist. ▪ Practitioners use the MPDR separately from their EHR to acquire patient controlled substance prescription history. ▪ Prescriber mandatory use of the MPDR legislation went into effect on July 1, 2021.	▪ DPHHS is working with Appriss Health to integrate MPDR into the user's EHR or PMS. The integrated solution will allow users to access the same information that is available in the MT PDMP within their clinical workflows, including patient prescription history, summary information, and clinical risk indicators.	▪ DPHHS completion of contract with Appriss to fund the Statewide Integration Project: October 2021 ▪ Appriss and MPDR State Administrator to kick off Statewide Integration Project with statewide marketing targeting eligible health care facilities and pharmacies: October 2021 ▪ Completion of Statewide Integration Project: August 2022 ▪ Increase knowledge of

	Current State	Future State	Summary of Actions Needed
			mandatory use regulations through Integration Project communications, board meetings, and other outreach opportunities. (Timeframe: ongoing.)
7. Develop enhanced supports for clinician review of the patient's history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription.	▪ NarxCare and clinical alert tools are available in the MPDR software. These give clinicians a quick summary of their patients' controlled substance history in the form of NarxScore and overdose risk score and alert the provider when its patients reach certain thresholds. ▪ Resources are available in the format of	▪ Review of current Board of Pharmacy Administrative Rules on what is considered suggestive of misuse or diversion. ▪ Solicit feedback from registered users on increasing linked resources.	▪ MPDR State Administrator review of data in Tableau. (January 2022 – January 2023.) ▪ Solicit clinical feedback from the Montana Prescription Drug Registry Advisory Group on clinical alert thresholds and increasing linked resources. (January 2022 – June 2022.)

	Current State	Future State	Summary of Actions Needed
	patient handouts from the CDC and links to the state's naloxone and opioid information provided by DPHHS.		
Master Patient Index/Identity Management			
8. Enhance patient and prescriber profiles by leveraging other state databases in support of SUD care delivery.	▪ While DPHHS does not currently have an MPI strategy, Medicaid does have several proDUR edits in place to prevent inappropriate payment for opioids. These include, but are not limited to, morphine milligram equivalent (MME) limits, quantity limits, therapeutic duplication controls, and denial of opioid claims	▪ DPHHS will work to properly match patients receiving opioid prescriptions with patients in the PDMP.	▪ DPHHS will complete an analysis of the current environment; identify necessary stakeholders, determinate requirements, and specifications toward implementation; and take steps for implementation of an MPI. (January 2022 – June 2022.)

	Current State	Future State	Summary of Actions Needed
	for members with a history of opioid use disorder treatment. ▪ DPHHS does not currently prevent members from paying cash for medications that are not covered by Medicaid.		
Overall Objective for Enhancing PDMP Functionality and Interoperability			
9. Leverage the above functionalities/capabilities/supports (in concert with any other state health IT, technical assistance, or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing and to ensure that Medicaid does not inappropriately pay for opioids.	▪ The Montana Board of Pharmacy located within the Montana Department of Industry and Labor maintains the Montana Prescription Drug Registry (MPDR), which is tightly governed by state law and regulation. The scope of data sharing from the MPDR to DPHHS is generally	▪ DPHHS will continue to use its proDUR edits to prevent inappropriate payments for opioids.	N/A

	Current State	Future State	Summary of Actions Needed
	limited by a memorandum of understanding (MOU) between the two parties to "line-level" MPDR data, including the identities of the patient, prescribing health care provider, dispensing pharmacy, and prescription information, for public health surveillance and epidemiologic analysis conducted by the DPHHS' Public Health and Safety Division. ▪ While DPHHS does not currently have an MPI strategy, Medicaid does have several proDUR edits in place to prevent		

	Current State	Future State	Summary of Actions Needed
	inappropriate payment for opioids. These include, but are not limited to, morphine milligram equivalent (MME) limits, quantity limits, therapeutic duplication controls, and denial of opioid claims for members with a history of opioid use disorder treatment. ▪ DPHHS does not currently prevent members from paying cash for medications that are not covered by Medicaid.		

Section II. Implementation Administration

Montana's point of contact for the SUD Health IT Plan is:
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ATTACHMENT D
Reserved for SUD Monitoring Protocol

ATTACHMENT E
Reserved for SUD Evaluation Design

ATTACHMENT F
Contingency Management Protocol

I. Background

In accordance with the State's "Healing and Ending Addiction through Recovery and Treatment Demonstration" Section 1115(a) Demonstration Waiver (Project Number 11-W-00395/8) and Special Terms and Conditions (STCs) (hereinafter "HEART" or the "demonstration"), this protocol provides additional detail regarding the distribution of motivational incentives to Montana Medicaid beneficiaries receiving contingency management as required by STC 24. Montana's Department of Public Health and Human Services (DPHHS) contingency management program is based on established clinical research demonstrating effective contingency management treatment and Montana's unique state needs. The initiative consists of a structured 12-week outpatient contingency management program, during which motivational incentives will be available. DPHHS' contingency management program may be provided to eligible Medicaid beneficiaries and is intended to complement other substance use disorder (SUD) treatment services.

II. Treatment Framework

A. **Beneficiary Enrollment and Participation.** Beneficiaries who meet the contingency management eligibility criteria detailed in STC 23 and who consent to treatment may participate in the contingency management program. A participating beneficiary will be considered to have dropped out of the contingency management program if they are absent from contingency management services for eight (or more) consecutive unexcused absences. An excused absence includes, but is not limited to, emergencies, illness, or clinic closures. If the beneficiary later returns to the contingency management provider, and they continue to meet eligibility criteria, they w ill be invited to re-start the contingency management program. Participation in contingency management will have no impact on beneficiary eligibility for other HEART Demonstration services.

B. **Incentives.** Beneficiaries will receive motivational incentives, as defined in STC 24, for meeting the target behavior of stimulant-non-use as demonstrated by point-of-care, urine drug tests (UDTs) that are rapid and CLIA-waived. During the initial phase of the pilot, DPHHS shall set a maximum dollar amount of total incentives in a calendar year that participating beneficiaries will be able to receive for successful completion of the treatment protocol. As described below, and consistent with the guardrails described in STC 24, providers have no discretion to determine the size or distribution of motivational incentives. The final delivery schedule and corresponding dollar amounts are subject to change by DPHHS.

   Motivational incentives earned through DPHHS' contingency management program shall be excluded from participating beneficiaries' modified adjusted gross income (MAGI)-based eligibility determinations, non-MAGI-based eligibility determinations, and share of cost determinations when determining a beneficiaries' eligibility for Medicaid.

C. **Treatment Schedule Overview.** During the initial phase of the pilot, DPHHS shall set a maximum dollar amount of total incentives in a calendar year (January 1 through December 31) that participating beneficiaries will be able to receive for successful completion of the treatment protocol. During the 12 weeks of the contingency management treatment, participating beneficiaries will be asked to visit the treatment setting in person for a minimum of two treatment visits per week. Visits will be separated by at least 72 hours (e.g., Monday and Thursday/Friday, or Tuesday and Friday) to help ensure that drug metabolites from the same drug use episode will not be detected in more than one UDT. Participating beneficiaries will be able to earn motivational incentives during each visit when the UDT indicates they have a negative sample for stimulants. The following is an example of how DPHHS will implement the incentive delivery schedule and corresponding dollar amounts.

Example: The initial motivational incentive value for the first sample negative for stimulants in a series is $12. After the initial week, for every two weeks that the participating beneficiary demonstrates non-use of stimulants (i.e., two consecutive UDTs negative for stimulants), the value of the motivational incentive is increased by $2 as illustrated by the hypothetical schedule in section D below. The maximum annual aggregate motivational incentive a participating beneficiary can receive is $596. DPHHS reserves the right to establish and update these amounts based on best available evidence of the minimum incentive amounts likely to produce the desired outcome of verified stimulant non-use.

A "reset" will occur when the participating beneficiary submits a positive sample or has an unexcused absence. The next time the beneficiary submits a stimulant-negative UDT, their motivational incentive amount will return to the initial value of $12.

A "recovery" of the pre-reset value will occur after two consecutive stimulant-negative UDTs. At that time, the participating beneficiary will recover their previously earned motivational incentive level without having to completely restart the process.

D. **Hypothetical Example: Incentive Delivery Schedule for Perfect Performance.** Table 1 illustrates an incentive delivery schedule for a participating beneficiary in a scenario where the beneficiary has a consistent attendance record and submits samples that are stimulant-negative during each visit over the 12-week period.

Table 1: Sample Incentive Delivery Schedule (full attendance and negative results)

Week	Visit #	*Voucher Earned During Visit*	*Total Available funds*
1	1	$12.00	$12.00
1	2	$14.00	$26.00
2	3	$14.00	$40.00
2	4	$16.00	$56.00
3	5	$16.00	$72.00
3	6	$18.00	$90.00

Table 1: Sample Incentive Delivery Schedule (full attendance and negative results)			
4	7	$18.00	$108.00
4	8	$20.00	$128.00
5	9	$20.00	$148.00
5	10	$22.00	$170.00
6	11	$22.00	$192.00
6	12	$24.00	$216.00
7	13	$24.00	$240.00
7	14	$26.00	$266.00
8	15	$26.00	$292.00
8	16	$28.00	$320.00
9	17	$28.00	$348.00
9	18	$30.00	$378.00
10	19	$30.00	$408.00
10	20	$32.00	$440.00
11	21	$32.00	$472.00
11	22	$34.00	$506.00
12	23	$34.00	$540.00
12	24	$36.00	$576.00

Note: The incentive delivery schedule and corresponding dollar amounts in the section above are an illustrative example of how DPHHS will implement the contingency management program. This incentive delivery schedule and corresponding dollar amounts are subject to change by DPHHS.

III. Contingency Management Provider and Staffing Criteria

A. Provider Eligibility and Qualifications

To participate in the contingency management pilot, a provider must meet the requirements specific in STC 25.

Based on the criteria specified in STC 25, the following is a framework for required and potential provider roles and responsibilities for delivering contingency management services:

- Contingency Management Delivery Staff (required): The practitioners conducting the contingency management visits, including the collection and evaluation of the objective measurement (i.e., UDTs), and administration of the motivational incentive. Delivery staff should be well-trained in procedures for tracking the delivery of incentive payments. Delivery staff are also responsible for encouraging clients to continue, or re-attempt (in the event of a reset), achieving the target behavior.
- Contingency Management Support Staff (required): Support staff may include those who identify and recruit clients into the contingency management program, payout of electronic vouchers or schedule and remind clients of the next visit.

- Contingency Management Mentor: An individual outside the program's agency with a thorough knowledge of contingency management to help answer the contingency management provider's questions as they arise.
- Program Lead(s): Staff from the program's agency, who has been trained in contingency management and the protocol design who can answer procedural questions specific to the program and provide guidance for client-specific issues.
- Incentive Coordinator and Supervisor: One person (and a trained back up), who manages the incentive program for all patients. The contingency management security and distribution system requires active supervision by a senior person in the organization who regularly audits the security and distribution of the incentives. Access to the IT system used to calculate the incentive values and record contingency management distribution should be password protected; password information should be limited to the incentive coordinator and supervisor. The supervisor should conduct quarterly audits of the gift card supply and the distribution sheet, to ensure incentives are distributed per the protocol.
- Contingency Management Supervisor. It is recommended that the designated supervisor perform fidelity checks for contingency management clinicians and staff. These fidelity checks involve scheduling regular check-ins to assure that the contingency management program is being delivered consistently and rigorously over time. Regular check-ins provide a routine that can help detect when procedural shifts or misunderstandings have occurred.

IV. Urine Drug Testing

During each visit, the contingency management delivery staff will collect a urine sample from the participating beneficiary. The sample will be tested for stimulants, including cocaine, amphetamine, and methamphetamine, consistent with STC 24. Samples will be collected in a rapid, CLIA-waived, point-of-care test cup with specimen validity measures.

V. Incentive Delivery

A. **Overview.** The contingency management delivery staff will immediately inform the participating beneficiary of the results of the UDT, and enter the results into a secure incentive management program that includes strict safeguards against fraud and abuse. The incentive management program will compute the appropriate motivational incentive earned according to the protocol detailed in Section III above. The incentive amount can be immediately delivered electronically to participating beneficiaries via electronic gift cards sent to participating beneficiaries' emails, sent to the provider to print the gift card, or delivered using other strategies developed by the incentive management program. The immediate delivery of the motivational incentive to the beneficiary following the determination of the motivational incentive amount earned by the incentive management program is a critical component of the contingency management benefit and consistent with the evidence-base.

B. **Incentive Calculations.** Providers will calculate the appropriate motivational incentive amount based on the UDT results with adjustments for the escalating value, reset and recovery features as described in Section III above. Providers will be required to submit calculation amounts to DPHHS on a quarterly basis; DPHHS will internally audit these calculations. A positive test for stimulants will result in the participating beneficiary receiving no motivational incentive. A negative test for stimulants will result in an incentive amount as indicated by the software, considering escalations, resets, and recoveries.

C. **Oversight.** As a safeguard against fraud, waste, and abuse, the incentive coordinator will be permitted to enter the results of the participating beneficiary's UDT into the incentive management program during the visit. On a recurring basis, the incentive supervisor must conduct and document that a regular audit of the incentive delivery functions has been completed, including the software calculations recommended and incentive distributed. This provider audit must be conducted by an individual who has responsibility for overseeing the use of organizational funds (e.g., program or fiscal manager). The providers will be required to submit the results of the audit to DPHHS on a quarterly basis to be monitored internally.

D. **Incentive Delivery Method and Parameters.** After the motivational incentive amount is determined, providers will disburse the motivational incentive and DPHHS will track all motivational incentives awarded to all participating beneficiaries, including the date the incentive was distributed and the amount of the motivational incentive.

E. **Incentive Types.** To redeem earned motivational incentives consistent with the described protocol, participating beneficiaries will be able to choose gift cards from a range of retail outlet options to use or redeem the incentive balance. Restrictions will be placed on the incentives so they are not used to purchase certain items, including cannabis, tobacco, alcohol, firearms/ammunition, lottery tickets, and additional items as identified by the state.

ATTACHMENT G
Reentry Demonstration Initiative Qualifying Conditions and Services

Table 1. Health Care Need Criteria Definitions for Reentry Demonstration Initiative.

Qualifying Condition	Definition
Mental Illness	A person with a mental illness is a person who is currently receiving mental health services or medications OR meets both of the following criteria: i. The beneficiary has one or both of the following: a. Significant impairment, where impairment is defined as distress, disability, or dysfunction in social, occupational, or other important activities; AND/OR b. A reasonable probability of significant deterioration in an important area of life functioning; AND ii. The beneficiary's condition as described in paragraph (i) is due to a diagnosed mental health disorder, according to the criteria of the current editions of the Diagnostic and Statistical Manual of Mental Disorders or the International Statistical Classification of Diseases and Related Health Problems.
Substance Use Disorder (SUD)	A person with a "Substance Use Disorder" shall either: i. Meet SUD criteria, according to the criteria of the current edition of the Diagnostic and Statistical Manual of Mental Disorders or the International Statistical Classification of Diseases and Related Health Problems; OR ii. Have a suspected SUD diagnosis that is currently being assessed through either Alcohol Use Disorders Identification Test (AUDIT) or Texas Christian University (TCU) Drug Screen 5 criteria.

Table 2. Reentry Service Definitions.

Covered Service	Definition
Case Management	Case management will be provided by community-based providers in in the period of up to 30 days immediately prior to the expected date of release, as authorized by the DPHHS and the DOC. In-reach case management will include, but will not be limited to: i. Conducting a health care needs assessment, as appropriate; ii. Developing a transition person-centered care plan for community-based health services in partnership with the incarcerated individual, with input from the clinician providing consultation services and the correctional facility's reentry planning team; a. While the person-centered care plan is created in the pre-release period and is part of the case management pre-release service to assess and address physical and behavioral health needs and HRSN identified, the scope of the plan extends beyond release; iii. Developing a medication management plan, with input from the clinician providing consultation services and the correctional facility's reentry planning team; iv. Providing a warm hand-off, as appropriate, to post-release case managers who will provide services under the Medicaid state plan or other waiver or demonstration authority; v. Making referrals to and scheduling appointments for physical and behavioral health providers post release; vi. Linking justice-involved populations to other critical supports that address health related social needs, such as educational, social, prevocational, vocational, housing, nutrition, transportation, childcare, child development, and mutual aid support groups, as appropriate; vii. Linking justice-involved populations to peer supports, as applicable; viii. Monitoring and follow-up activities, including activities and contacts that are necessary to ensure that the care plan is effectively implemented and adequately addresses the needs of the eligible individual and which may be with the individual, family members, service providers, or other entities or individuals and conducted as frequently as necessary;

	ix. Conducting follow-up with community-based providers to ensure engagement was made with individual and community-based providers as soon as possible and no later than 30 days from release; and x. Conducting follow up with the individual to ensure engagement with community-based providers, behavioral health services, and other aspects of discharge/reentry planning, as necessary, no later than 30 days from release.
Limited Clinical Consultation	To connect justice involved individuals with ongoing, community-based physical and behavioral health services that can improve physical and behavioral health outcomes and reduce avoidable health care utilization, the Demonstration will cover a limited set of in-reach limited clinical consultations in the 30 days leading up to release. Limited clinical consultations will be performed by embedded or community-based providers, and may be completed via telehealth or in-person, as authorized by DPHHS and DOC. The scope of limited clinical consultation services and supports may include, but will not be limited to: i. Supporting re-entry plans into the community, including but not limited review of discharge plans and medication management plans; ii. Supporting physical and behavioral health assessments, as needed; and iii. Providing warm-hand offs to community-based behavioral health professionals who will provide mental health and/or SUD services upon release.
Medications for Addiction Treatment (MAT)	Medications for Addiction Treatment coverage will include: i. Medications for Addiction Treatment (also known as medication assisted treatment) for Opioid Use Disorders (OUD). This includes all medications approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under Section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders as authorized by Social Security Act Section 1905(a)(29); ii. Medications for Addiction Treatment for Alcohol Use Disorders (AUD) and Non-Opioid Substance Use Disorders. This includes all FDA-approved drugs and services to treat AUD and other non-opioid SUDs; and iii. MAT-related benefits, such as assessment, individual/group counseling, patient education, and

	prescribing, administering, dispensing, ordering, monitoring and/or managing MAT.
Medications Upon Release	The Demonstration will cover a minimum 30-day supply (i.e., equal to or more than 30 days) of outpatient medications and over-the-counter drugs as clinically appropriate, consistent with the approved Medicaid State Plan.

ATTACHMENT H
Reentry Demonstration Initiative Implementation Plan (Reserved)

ATTACHMENT I
Reentry Demonstration Initiative Reinvestment Plan (Reserved)