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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

State Demonstrations Group

August 28, 2023

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

Dear Michael Randol,

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) Monitoring Protocol, which is required by the Special Terms and Conditions (STC), specifically, STC #19, of Montana's section 1115 demonstration, Healing and Ending Addiction through Recovery and Treatment Demonstration" (HEART, or the "demonstration") (Project No: Project Number 11-W-00395/8), effective through June 30, 2027. CMS determined that the Monitoring Protocol, which was submitted on December 5, 2022 and revised on July 6, 2023, meets the requirements set forth in the STCs, and thereby approves the state's SUD Monitoring Protocol.

The Monitoring Protocol is approved for the demonstration period through June 30, 2027 and is hereby incorporated into the demonstration STCs as Attachment D (see attached). In accordance with STC #44, the approved SUD Monitoring Protocol may now be posted to your state's Medicaid website.

We look forward to our continued partnership on the Montana Healing and Ending Addiction through Recovery and Treatment Demonstration section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Paula M. Kazi -S

Digitally signed by Paula M. Kazi -S
Date: 2023.08.28 20:20:02 -04'00'

Paula Kazi
Acting Director
Division of Demonstration Monitoring and Evaluation

cc: Barbara Prehmus, State Monitoring Lead, CMS 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).

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. General Reporting Requirements
IX. Evaluation of the Demonstration
X. General Financial Requirements Under Title XIX
XI. Monitoring Budget Neutrality for the Demonstration
XII. 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: Reserved for SUD Monitoring Protocol
- Attachment E: Reserved for SUD Evaluation Design

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.

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.

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 annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request 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 beneficiary 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 section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 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(b)(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 members 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 19, 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 24.

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 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) [or 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 19) 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 28).

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

[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*.

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.[3]

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-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. SUD Monitoring Protocol. The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within one hundred fifty (150) calendar days after approval of the demonstration. The Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. 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:

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

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 reporting requirements described in Section VIII (General 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.

20. Evaluation. The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

21. 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

22. Cost Sharing. Monthly premiums will continue to be imposed upon beneficiaries enrolled in the demonstration consistent with the provisions in Montana's Health and Economic Livelihood Partnership (HELP) Demonstration. These premiums will be phased out by December 31, 2022. This demonstration does not impose new premiums or other cost sharing requirements.

VII. DELIVERY SYSTEM

23. 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. GENERAL REPORTING REQUIREMENTS

24. 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) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days (30) 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 and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.

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

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

e. 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.

25. **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 Plan 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.

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

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

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

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

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

28. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The state must submit a revised Monitoring Report within sixty (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 Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the monitoring reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed. 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 the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in

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

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

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

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

29. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by June 30, 2025. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), if applicable, SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after June 30, 2025. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

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 Plan 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:

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

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

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

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

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

30. Corrective Action. 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.

31. 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 draft close-out report must comply with the most current guidance from CMS.

b. The state will present to and participate in a discussion with CMS on the close-out report.

c. The state must take into consideration CMS's comments for incorporation into the final close-out report.

d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.

e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 24.

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

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

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

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

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

IX. EVALUATION OF THE DEMONSTRATION

34. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 24.

35. Independent Evaluator. Upon approval of the demonstration, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will 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.

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

    The draft Evaluation Design must be developed in accordance with:

    a. Attachment A (Developing the Evaluation Design) of these STCs;

    b. CMS's evaluation design guidance for SUD, including guidance for approaches to analyzing associated costs; and

    c. All applicable CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

    The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 37 and 40.

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

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

39. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. For example, hypotheses for the SUD program should include an assessment of the core goals of the program, to include (but are not limited to): initiation and engagement with treatment, reduction in unnecessary and inappropriate utilization of emergency department and inpatient hospitalization through expanded

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

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

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

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

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

d. The state must submit a revised Interim Evaluation Report sixty (60) calendar days after receiving CMS's comments on the draft Interim Evaluation Report.

e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's website.

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

41. Summative Evaluation Report. The state must submit a draft summative evaluation report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The summative evaluation report must include the information in the approved evaluation design.

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

b. Once approved by CMS, the final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

c. The summative evaluation report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.

42. 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.

43. State Presentations for CMS. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

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

45. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment 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.

X. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

46. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered 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.[4]

47. **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 for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate match-able 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 thirty (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.

48. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that the non-federal share is obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that such funds must not be used to match 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 regulations. In addition, CMS reserves the right to prohibit the use of any sources of non-federal share funding that it determines 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 fund the demonstration.
    b. If CMS determines that any funding sources are not consistent with applicable federal 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.

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

[4] For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

a. Units of state or local government, including health care providers that are units of state or local government, certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 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 would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot be used as the non-federal share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local revenues and are transferred by units of government within the state. Any transfers from units of government must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, 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.

50. 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 MCO, 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.

b. For non-risk-based PIHPs and PAHPs, arrangements comply with the upper payment limits specified in 42 CFR 447.362, and if payments exceed the cost of services, the state will recoup the excess and return the federal share of the excess to CMS.

51. Requirements for health care related taxes and provider donations. As a condition of demonstration approval, the state attests to the following, as applicable:

a. 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. 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 Social Security 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.

52. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XI (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.

53. 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.

54. 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.

[Instructions: Choose the appropriate MEGs above—in most cases only the "IMD Services SP" MEG will be needed—however, each of the MEGs may also be broken-out into multiple MEGs based on, for example, diagnosis-type. Once chosen, POs send request to FMG representative and Regional Office financial lead to add MEG(s) into MBES.]

Table 1: 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	Individuals eligible for expanded Medicaid, receiving services in an IMD
IMD Standard Medicaid	Hypo	X		X	Individuals eligible for Medicaid, receiving services in an IMD

55. **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 DY 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 DY will be offset against

expenditures incurred in the DY 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 Master MEG Chart table, 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, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

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

Table 2: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 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

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

Table 3: 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

57. **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 demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.[5]

[5] 42 CFR 431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS'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 in states agree to use the tool as a condition of demonstration approval.

58. 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.

59. 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 letters, 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.

XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

60. 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 may consist 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.

61. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. 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 i**n** 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.

62. 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.

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

64. 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), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. 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 otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, 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 supplemental 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 or for standalone SUD demos use this by refunding] the FFP to CMS.

65. **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 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 5: Hypothetical Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR *2020*	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
IMD Services MEG #1	**PC**	Both	$7,022.08	5.6%	$7,830.57	$8,269	$8,732	$9,221	$9,738
IMD Services MEG #2	**PC**	Both	$7,021.30	5.5%	$7,814.88	$8,244.70	$8,698	$9,177	$9,681

66. **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 Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

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

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

Table 6: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
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

XII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 7: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after demonstration approval	SUD Implementation Plan (including Health IT Plan)	STC 18(a)
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 18(a)
150 calendar days after demonstration approval	Monitoring Protocol	STCs 19
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STCs 19
180 calendar days after demonstration approval	Draft Evaluation Design	STC 36
60 days after receipt of CMS comments	Revised Evaluation Design	STC 38
No later than 60 calendar days after July 1, 2023	SUD Mid-Point Assessment	STC 29
June 30, 2024, or with renewal application	Draft Interim Evaluation Report	STC 40(c)
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 40(d)
Within 18 months after June 30, 2025	Draft Summative Evaluation Report	STC 41
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 41(a)
Monthly Deliverables	Monitoring Calls	STC 32
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 28
	Quarterly Expenditure Reports	STC 28(c)
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 28

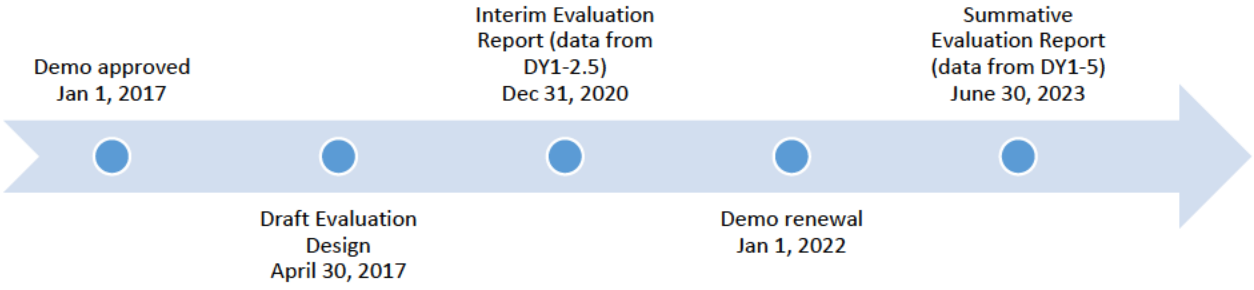
ATTACHMENT A
DEVELOPING THE EVALUATION DESIGN

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

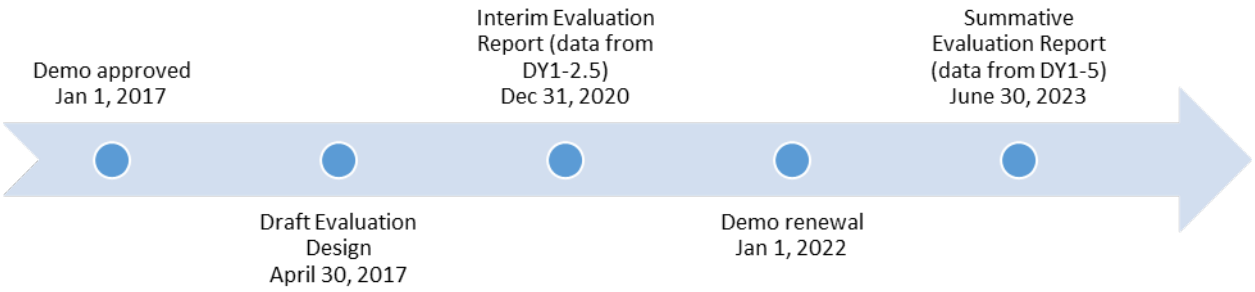
Attachment B:
Preparing the Interim and Summative Evaluation Reports

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 issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, 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,	• 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.		LCSWs, LMFTs, and 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 Substance Use Disorder and*	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
		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.[6]

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.

[6] https://leg mt.gov/bills/mca/title_0530/chapter_0240/part_0020/section_0080/0530-0240-0020-0080.html

- **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.[7]

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.

[7] "Summary of Methamphetamine Use in Montana." Public Health in the 406. August 2020. https://dphhs mt.gov/assets/publichealth/Epidemiology/MethamphetamineSummary2020.pdf

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.[8] 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

[8] https://leg mt.gov/bills/mca/title_0500/chapter_0320/part_0060/sections_index html

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

What follows are the Planned Metrics and Reporting Schedule tabs from the SUD monitoring protocol workbook (part A). The full workbook is also available in spreadsheet format on Medicaid.gov

Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) - Planned Metrics (Version 7.0)
State: Montana
Demonstration Name: Healing and Ending Addiction through Recovery and Treatment Demonstration

Table: Substance Use Disorder Demonstration Planned Metrics

Standard information on CMS-provided metrics											Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting	
#	Metric name	Metric description	Milestone or renewal	Metric type	Reporting frequency	Data source	Measurement period	Reporting window	Reporting lag	State will report?	Baseline period	Annual goal	Overall demonstration target	Aligned with planned specification	Explanation of any deviation from the CMS specification	State plans to phase in	Explanation of any plans to phase in renewal over time
EXAMPLE: 1 (Do not delete or edit this row)	*EXAMPLE: Assessed for SUD Treatment Needs Using a Standardized Screening Tool*	*EXAMPLE: Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period*	*EXAMPLE: Assessment of need and qualification for SUD treatment services*	*EXAMPLE: CMS-constructed*	*EXAMPLE: Other monthly and quarterly metrics*	*EXAMPLE: Medical record review or claims*	*EXAMPLE: Month*	*EXAMPLE: Quarterly*	*EXAMPLE: Recommended*	*EXAMPLE: Y*	*EXAMPLE: 07/01/2018-06/30/2019*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: N*	*EXAMPLE: The Department will use state-defined procedure codes (list specific codes) to calculate this metric.*	*EXAMPLE: Y*	*EXAMPLE: This measure requires an update to the Adult Needs and Strengths Assessment tool that reflects an ASAM level of treatment. The work is in the testing phase with anticipated go live in mid to late 2021.*
1	Assessed for SUD Treatment Needs Using a Standardized Screening Tool	Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Medical record review or claims	Month	Quarterly	Recommended	N							
2	Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period but not in the three months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Recommended	N							
3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to modify criteria to adjust for state specific claims coding. Step 2 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a SUD treatment service. Step 3 - 1. Add Provider type 32 (Chemical Dependency Clinic). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Add revenue code 944 (substance use treatment). FQHCs use this revenue code for members receiving SUD services. 3. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 12 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase	N	MT proposes to modify criteria to adjust for state specific claims coding. Step 2 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a SUD treatment service. Step 3 - 1. Add Provider type 32 (Chemical Dependency Clinic). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Add revenue code 944 (substance use treatment). FQHCs use this revenue code for members receiving SUD services. 3. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for inpatient/residential treatment for SUD in an IMD during the measurement period.	Milestone 2	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1b - Add HCPCS Code H0010 with a place of service of 99. MT has three SUD IMDs each of which has been instructed to subrat claims using H0010 (ASAM 3.5) with a place of service 99 to indicate the residential step	N	
6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-6/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 2 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a SUD treatment service. Step 3 - 1. Add Provider type 32 (Chemical Dependency Clinic). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Add revenue code 944 (substance use treatment). FQHCs use this revenue code for members receiving SUD services. 3. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to skip step #1 since the diagnosis code lists are limited to abuse and dependence. MT intends to use the procedure codes identified in step #2. By nature of the service, members would not meet diagnostic criteria for an abuse or dependence diagnosis and review of claims indicates that members often have diagnosis codes not present on the lists in step #1.	N	
8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the third spot on claims might not reflect a current SUD treatment service. Step 2 - 1. Add Provider type 32 (Chemical Dependency Clinic) and exclude residential/inpatient codes (H0010, H0011, H0018, H0019, H2036). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Add revenue code 944 (substance use treatment). FQHCs use this revenue code for members receiving SUD services. 3. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
9	Intensive Outpatient and Partial Hospitalization Services	Number of beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a current SUD treatment service. Step 2 - Add HCPCS code H0012. This is the procedure code used by MT for SUD Partial Hospitalization.	N	
10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1 - Add HCPCS code H2034. MT uses this code for ASAM 3.1 (Clinically Managed Low Intensity Residential Services)	N	
11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1 - Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a current SUD treatment service. Step 2 - MT will exclude H0012, which is the procedure code the state uses for SUD Partial Hospitalization (not detox).	N	
12	Medication-Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-06/30/2023	Increase	Increase	Y		N	
13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Milestone 4	CMS-constructed	Other annual metrics	Provider enrollment database; Claims	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase	Y	MT defines SUD providers as those enrolle PT2hed providers who provided SUD treatment services to beneficiaries with a primary SUD diagnosis during the measurement period. Enrollment data does not indicate SUD providers so MT will use claims data for this metric.	N	
14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Milestone 4	CMS-constructed	Other annual metrics	Provider enrollment database; Claims; SAMHSA datasets	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase	Y	MT defines SUD providers as those providers who prescribed FDA approved medications (buprenorphine, methadone, or naltrexone) for beneficiaries with a primary Opioid Use Disorder during the measurement period. MT uses claims data to identify these providers. Providers are identified at the individual level on claims. Providers include physicians, mid-levels (nurse practitioners and physician assistants), and psychiatrists.	N	
15	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) [NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following: • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims or EHR	Year	Annually	Required	Y	1/1/2022-12/31/2022	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Appendix C Value Sets; Step 3 - 1. Add Provider type 32 (Chemical Dependency Clinic). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
16	SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission]	SUB-3: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment. SUB-3a: Patients who are identified with alcohol or drug disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Medical record review or claims	Year	Annually	Recommended	N							
17(1)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence: Age 18 and Older (FUA-AD) [NCQA; NQF #3488; Medicaid Adult Core Set; Adjusted HEDIS measure]"	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a principal diagnosis of alcohol or other drug (AOD) abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported: - Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). - Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days)	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2022-12/31/2022	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Appendix C Value Sets; Step 3 - 1. Add Provider type 32 (Chemical Dependency Clinic). All SUD related HCPCS codes are included on a PT32 charge file in MMIS. 2. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
17(2)	Follow-up after Emergency Department Visit for Mental Illness: Age 18 and Older (FUM-AD) [NCQA; NQF #3489; Medicaid Adult Core Set; Adjusted HEDIS measure]"	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported: - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days)	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2022-12/31/2022	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Appendix C Value Sets; Step 3 - 1. Add Provider type 50 (Mental Health Center) & 88 (HCBC SDMI waiver). MH specific HCPCS codes are available to these provider types in MMIS. 2. Exclude Provider type 28 (HCBS Big Sky waiver). PT28 claims focus on members with physical disabilities and the fee schedules uses some HCPCS codes different than indicated on the HEDIS lists.	N	
18	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) [PQA; NQF #2940; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative care are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2022-12/31/2022	Decrease	Decrease	Y		N	
19	Use of Opioids from Multiple Providers in Persons without Cancer (UOMP) [PQA; NQF #2950]	The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Recommended	N							
20	Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) [PQA, NQF #2951]	The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Recommended	N							

Table: Substance Use Disorder Demonstration Planned Metrics

Standard information on CMS-provided metrics											Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting	
21	Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA, NQF #3389; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2022-12/31/2022	Decrease	Decrease	Y		N	
22	Continuity of Pharmacotherapy for Opioid Use Disorder [USC; NQF #3175]	Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment	Milestone 1	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2021-12/31/2022	Increase	Increase	Y		N	
23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Milestone 5	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-6/30/2023	Decrease	Decrease	Y		N	
24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2022-6/30/2023	Decrease	Decrease	Y		N	
25	Readmissions Among Beneficiaries with SUD	The rate of all-cause readmissions during the measurement period among beneficiaries with SUD	Milestone 6	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2022-6/30/2023	Decrease	Decrease	Y		N	
26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual metrics	State data on cause of death	Year	Annually	Required	Y	07/01/2022-6/30/2023	Decrease	Decrease	Y		N	
27	Overdose Deaths (rate)	Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Milestone 5	CMS-constructed	Other annual metrics	State data on cause of death	Year	Annually	Required	Y	07/01/2022-6/30/2023	Decrease	Decrease	Y		N	
28	SUD Spending	Total Medicaid SUD spending during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Recommended	N							
29	SUD Spending Within IMDs	Total Medicaid SUD spending on inpatient/residential treatment within IMDs during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Recommended	N							
30	Per Capita SUD Spending	Per capita SUD spending during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Recommended	N							
31	Per Capita SUD Spending Within IMDs	Per capita SUD spending within IMDs during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Recommended	N							
32	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD [Adjusted HEDIS measure]	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Other SUD-related metrics	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	1/1/2022-12/31/2022	Increase	Increase	N	MT proposes to add criteria to identify state specific claims coding. Step 1: Identify claims with a diagnosis code (principal & secondary only) listed. MMIS captures up to 24 diagnoses on a claim and many of those are historical. Diagnoses beyond the second spot on claims might not reflect a	N	
33	Grievances Related to SUD Treatment Services	Number of grievances filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	N							
34	Appeals Related to SUD Treatment Services	Number of appeals filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	N							
35	Critical Incidents Related to SUD Treatment Services	Number of critical incidents filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	N							
36	Average Length of Stay in IMDs	The average length of stay for beneficiaries discharged from IMD inpatient/residential treatment for SUD.	Milestone 2	CMS-constructed	Other annual metrics	Claims; State-specific IMD database	Year	Annually	Required	Y	07/01/2022-6/30/2023	Stabilize	no more than 30 days	N	MT proposes to add criteria to identify state specific claims coding. Step 1b - Add HCPCS Code H0018 with a place of service of 99. MT has three SUD IMDs each of which has been instructed to submit claims using H0018 (ASAM 3.5) with a place of service 99 to indicate the residential stay occurred in an IMD primarily for SUD.	N	
Q1	Physicians connected to the HIE.	Total number of physicians connectad to the statewide HIE (Big Sky Care Connect) in the measurement period.	Health IT	State-specific	Other annual metrics	Statewide HIE	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase		MT sends all claims data for every SUD individual to the Statewide Health Information Exchange (Big Sky Care Connect data to HIE) to be combined with clinical data to facilitate more timely and accurate diagnosis of SUD beneficiaries.	N	
Q2	Count of SUD continued stay requests	Total number of continued stay requests (CSR) created for SUD beneficiaries by level of care in the me	Health IT	State-specific	Other annual metrics	State-specific data from Utilization Management Contractor.	Year	Annually	Required	Y	07/01/2022-6/30/2023	Stabilize	Stabilize		Mountain Pacific Quality Health (MPQH) is the state's utilization management contractor to evaluate an individuals need for specific services. The staff at MPQH uses clinical documentation to make determinations of need. If approved, MQPH creates a prior authorization record in MMIS that allows providers to submit claims for a particular service that requires either a PA or CSR.	N	
Q3	SUD prior authorization requests	Total number of prior authorizations (PA) created for SUD beneficiaries by level of care in the measure	Health IT	State-specific	Other annual metrics	State-specific data from Utilization Management Contractor.	Year	Annually	Required	Y	07/01/2022-6/30/2023	Stabilize	Stabilize		Mountain Pacific Quality Health (MPQH) is the state's utilization management contractor to evaluate an individuals need for specific services. The staff at MPQH uses clinical documentation to make determinations of need. If approved, MQPH creates a prior authorization record in MMIS that allows providers to submit claims for a particular service that requires either a PA or CSR.	N	
State-specific metrics																	
S1	Hospitals connected to the HIE.	Total number of hospitals connected to the statewide HIE (Big Sky Care Connect) in the measurement period.	Health IT	State-specific	Other annual metrics	Statewide HIE	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase		MT sends all claims data for every SUD individual to the Statewide Health Information Exchange (Big Sky Care Connect data to HIE) to be combined with clinical data to facilitate more timely and accurate diagnosis of SUD beneficiaries.	N	
S2	Clinics connected to the HIE.	Total number of clinics connected to the statewide HIE (Big Sky Care Connect) in the measurement period.	Health IT	State-specific	Other annual metrics	Statewide HIE	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase		MT sends all claims data for every SUD individual to the Statewide Health Information Exchange (Big Sky Care Connect data to HIE) to be combined with clinical data to facilitate more timely and accurate diagnosis of SUD beneficiaries.	N	
S3	Other providers connected to the HIE.	Total number of other providers connected to the statewide HIE (Big Sky Care Connect) in the measurement period.	Health IT	State-specific	Other annual metrics	Statewide HIE	Year	Annually	Required	Y	07/01/2022-6/30/2023	Increase	Increase		MT sends all claims data for every SUD individual to the Statewide Health Information Exchange (Big Sky Care Connect data to HIE) to be combined with clinical data to facilitate more timely and accurate diagnosis of SUD beneficiaries.	N	

[a] There are no CMS-provided metrics related to milestone 3.
[b] If the state is not reporting a required metric (i.e., column K = "N"), enter explanation in corresponding row in column P.
[c] The state should use column P to outline calculation methods for specific metrics as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions.
[d] Ratio 1 and 2 reported for Metric #17(1) correspond to ratio 2 and 3 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics
[e] Ratio 1 and 2 reported for Metric #17(2) correspond to ratio 1 and 2 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics
[f] While grievances and appeals metrics are recommended for reporting, the state is required, per 42 CFR 431.428(a)(5, to provide updates on the results of beneficiary satisfaction surveys, if conducted during the reporting year, including updates on grievances and appeals from beneficiaries, in in its annual (Q4) monitoring report.

Medicaid Section 1115 SUD Demonstrations: Monitoring Protocol (Part A) - Reporting Schedule (Version 7.0)
State: Montana
Demonstration Name: Healing and Ending Addiction through Recovery and Treatment Demonstration

Instructions:

(1) In the reporting periods input table (Table 1), use the prompt in column A to enter the requested information in the corresponding row of column B. All monitoring report names and reporting periods should use the format DYNQ# or CY# and all dates should use the format MM/DD/YYYY with no spaces in the cell. The information entered in these cells will auto-populate the SUD demonstration reporting schedule in Table 2. All cells in the input table must be completed in entirety and in the correct format for the standard reporting schedule to be accurately auto-populated.

(2) Review the state's reporting schedule in the SUD demonstration reporting schedule table (Table 2). For each of the reporting categories listed in column F, select Y or N in column H, "Deviation from standard reporting schedule (Y/N)" to indicate whether the state plans to report according to the standard reporting schedule. If a state's planned reporting does not match the standard reporting schedule for any quarter and/or reporting category (i.e., column H = "Y"), the state should describe these deviations in column I, "Explanation for deviations (if column H='Y')" and use column J, "Proposed deviation from standard reporting schedule," to indicate the SUD measurement periods with which it wishes to overwrite the standard schedule (columns G). All other columns are locked for editing and should not be altered by the state.

Table 1. Substance Use Disorder Demonstration Reporting Periods Input Table

	Demonstration somewhat mirrors state's fiscal year
Dates of first SUD demonstration year (SUD DY1):	
Start	07/01/2022
End	06/30/2023
Dates of first quarter of the baseline period for CMS-constructed metrics	
Reporting unit	DYNQ1
Start	07/01/2022
End	09/30/2022
Broader section 1115 demonstration reporting period corresponding with the first SUD reporting quarter, if applicable. If there is no broader demonstration, fill in the first SUD reporting period. (Format: DYNQ#; e.g., DYNQ1)	
First SUD monitoring report due date (per STC) (MM/DD/YYYY):	11/29/2022
First SUD monitoring report in which the state plans to report annual metrics that are established/quality measures: (DYNQ#)	
Reporting unit	CY2022
SUD DY#	DYNQ1
SUD DY# start date	07/01/2023
SUD DY# end date	09/30/2023
Dates of last SUD reporting quarter	
Start	04/01/2027
End	06/30/2027

Table 2. Substance Use Disorder Demonstration Reporting Schedule

SUD reporting quarter start date (MM/DD/YYYY)	SUD reporting quarter end date (MM/DD/YYYY)	Monitoring report due date (per STC) (MM/DD/YYYY)	Broader section 1115 reporting period, if applicable (Format: DYNQ# or... DY1Q#)	SUD reporting period (Format: DY#Q# or... DY1Q1)	Reportable category	For each reporting category, measurement period for which information is captured in monitoring report per standard reporting schedule (Format: DYNQ#; e.g., DYNQ3)? SUD	Deviation from standard reporting schedule (Y/N) (e.g.)	Explanation for deviations (if column H='Y')	Proposed deviation in measurement period from standard reporting schedule in column G (Format: DY#Q#; or... DY1Q1)
07/01/2022	09/30/2022	11/29/2022		DY1Q1	Narrative information	DY1Q1	N		
					Governance and consult	DY1Q1	N		
					Other monthly and quarterly metrics				
					Annual metrics that are established/quality measures				
					Other annual metrics				
10/01/2022	12/31/2022	03/01/2023		DY1Q2	Narrative information	DY1Q2	N		
					Governance and consult	DY1Q2	N		
					Other monthly and quarterly metrics	DY1Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
01/01/2023	03/31/2023	05/30/2023		DY1Q3	Narrative information	DY1Q3	N		
					Governance and consult	DY1Q3	N		
					Other monthly and quarterly metrics	DY1Q3	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
04/01/2023	06/30/2023	08/29/2023		DY1Q4	Narrative information	DY1Q4	N		
					Governance and consult	DY1Q4	N		
					Other monthly and quarterly metrics	DY1Q4	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
07/01/2023	09/30/2023	11/29/2023		DY2Q1	Narrative information	DY2Q1	N		
					Governance and consult	DY2Q1	N		
					Other monthly and quarterly metrics	DY2Q1	N		
					Annual metrics that are established/quality measures	CY2023	N		
					Other annual metrics	DY2	N		
10/01/2023	12/31/2023	02/29/2024		DY2Q2	Narrative information	DY2Q2	N		
					Governance and consult	DY2Q2	N		
					Other monthly and quarterly metrics	DY2Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
01/01/2024	03/31/2024	05/30/2024		DY2Q3	Narrative information	DY2Q3	N		
					Governance and consult	DY2Q3	N		
					Other monthly and quarterly metrics	DY2Q3	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
04/01/2024	06/30/2024	08/29/2024		DY2Q4	Narrative information	DY2Q4	N		
					Governance and consult	DY2Q4	N		
					Other monthly and quarterly metrics	DY2Q4	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
07/01/2024	09/30/2024	11/29/2024		DY3Q1	Narrative information	DY3Q1	N		
					Governance and consult	DY3Q1	N		
					Other monthly and quarterly metrics	DY2Q4	N		
					Annual metrics that are established/quality measures	CY2023	N		
					Other annual metrics	DY2	N		
10/01/2024	12/31/2024	02/28/2025		DY3Q2	Narrative information	DY3Q2	N		
					Governance and consult	DY3Q2	N		
					Other monthly and quarterly metrics	DY3Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
01/01/2025	03/31/2025	05/30/2025		DY3Q3	Narrative information	DY3Q3	N		
					Governance and consult	DY3Q3	N		
					Other monthly and quarterly metrics	DY3Q3	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
04/01/2025	06/30/2025	08/29/2025		DY3Q4	Narrative information	DY3Q4	N		
					Governance and consult	DY3Q4	N		
					Other monthly and quarterly metrics	DY3Q4	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
07/01/2025	09/30/2025	11/29/2025		DY4Q1	Narrative information	DY4Q1	N		
					Governance and consult	DY4Q1	N		
					Other monthly and quarterly metrics	DY3Q4	N		
					Annual metrics that are established/quality measures	CY2024	N		
					Other annual metrics	DY3	N		
10/01/2025	12/31/2025	02/28/2026		DY4Q2	Narrative information	DY4Q2	N		
					Governance and consult	DY4Q2	N		
					Other monthly and quarterly metrics	DY4Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
01/01/2026	03/31/2026	05/30/2026		DY4Q3	Narrative information	DY4Q3	N		
					Governance and consult	DY4Q3	N		
					Other monthly and quarterly metrics	DY4Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
04/01/2026	06/30/2026	08/29/2026		DY4Q4	Narrative information	DY4Q4	N		
					Governance and consult	DY4Q4	N		
					Other monthly and quarterly metrics	DY4Q3	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
07/01/2026	09/30/2026	11/29/2026		DY5Q1	Narrative information	DY5Q1	N		
					Governance and consult	DY5Q1	N		
					Other monthly and quarterly metrics	DY4Q4	N		
					Annual metrics that are established/quality measures	CY2025	N		
					Other annual metrics	DY4	N		
10/01/2026	12/31/2026	02/28/2027		DY5Q2	Narrative information	DY5Q2	N		
					Governance and consult	DY5Q2	N		
					Other monthly and quarterly metrics	DY5Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
01/01/2027	03/31/2027	05/30/2027		DY5Q3	Narrative information	DY5Q3	N		
					Governance and consult	DY5Q3	N		
					Other monthly and quarterly metrics	DY5Q2	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				
04/01/2027	06/30/2027	08/29/2027		DY5Q4	Narrative information	DY5Q4	N		
					Governance and consult	DY5Q4	N		
					Other monthly and quarterly metrics	DY5Q3	N		
					Annual metrics that are established/quality measures				
					Other annual metrics				

Add rows for all additional demonstration reporting quarters

[a] **SUD demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval note that the demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the demonstration. Note that that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2020, with an effective date of January 1, 2021 for the new demonstration period. In many cases, the effective date also differs from the date a state began implementing its demonstration. To generate an accurate reporting schedule, the start date as listed in Table 1 of the "SUD reporting schedule tab" should align with the first day of a month. If a state's SUD demonstration began on any day other than the first day of the month, the state should list its start date as the first day of the month in which the effective date occurs. For example, if a state's effective date is listed as January 15, 2020, the state should indicate "01/01/2020" as the start date in Table 1 of the "SUD reporting schedule" tab. Please see Appendix A for more information on determining demonstration quarter timing.

[b] The only-populated reporting schedule in Table 2 outlines the date the state is expected to report for each demonstration year and quarter. However, states are not expected to begin reporting any metrics data until after monitoring protocol approval. The state should see Section B of the Monitoring Report Instructions for more information on retrospective reporting of data following protocol approval.

Medicaid Section 1115 Substance Use Disorder Demonstrations
Monitoring Protocol Template

Note: PRA Disclosure Statement to be added here

1. Title page for the state's substance use disorder (SUD) demonstration or the SUD component of the broader demonstration

The state should complete this title page as part of its SUD monitoring protocol. Definitions for certain rows are provided below the table. The Performance Metrics Database and Analytics (PMDA) system will populate some rows of the table. The state should complete the rest of the table. The state can revise the demonstration goals and objectives if needed. PMDA will use this information to populate part of the title page of the state's monitoring reports.

State	*Montana*
Demonstration name	*Healing and Ending Addiction through recovery and Treatment Demonstration*
Approval period for section 1115 demonstration	*07/01/2022-06/30/2027*
SUD demonstration start date[a]	*07/01/2022*
Implementation date of SUD demonstration, if different from SUD demonstration start date[b]	*07/01/2022*
SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives	• *Increased rates of identification, initiation, and engagement for SUD;* • *Increased adherence to and retention in treatment;* • *Reductions in overdose deaths, particularly those due to opioids;* • *Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;* • *Fewer readmissions to the same or higher level of care where readmission is preventable or medically inappropriate; and* • *Improved access to care for physical health conditions among beneficiaries with SUD*

[a] **SUD demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval note that the SUD demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the SUD demonstration. Note that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2020, with an effective date of January 1, 2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

[b] **Implementation date of SUD demonstration:** The date the state began claiming or will begin claiming federal financial participation for services provided to individuals in institutions for mental disease.

2. Acknowledgement of narrative reporting requirements

☒ The state has reviewed the narrative questions in the Monitoring Report Template provided by CMS and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested narrative information (with no modifications).

3. Acknowledgement of budget neutrality reporting requirements

☒ The state has reviewed the Budget Neutrality Workbook (which can be accessed via PMDA – see Monitoring Protocol Instructions for more details) and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (with no modifications).

4. Retrospective reporting

The state is not expected to submit metrics data until after monitoring protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to monitoring protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

For a state that has monitoring protocols approved after one or more initial quarterly monitoring report submissions, it should report metrics data to CMS retrospectively for any prior quarters (Qs) of the section 1115 SUD demonstration that precede the monitoring protocol approval date. A state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data— in its second monitoring report submission that contains metrics. The retrospective monitoring report for a state with a first SUD demonstration year (DY) of less than 12 months, should include data for any baseline period Qs preceding the demonstration, as described in Part A of the state's monitoring protocols. (See Appendix B of the Monitoring Protocol Instructions for further instructions on determining baseline periods for first SUD DYs that are less than 12 months.) If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its section 1115 SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its monitoring report submission (Section 3: Narrative information on implementation, by milestone and reporting topic). This general assessment is not intended to be a comprehensive description of every trend observed in the metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metric changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for a state to provide context on its retrospective metrics

data and to support CMS's review and interpretation of these data. For example, consider a state that submits data showing an increase in the number of medication-assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. This state may decide to highlight this trend for CMS in Part B of its monitoring report (under Milestone 4) by briefly summarizing the trend and explaining that during this period, a grant supporting training for new MAT providers throughout its state was implemented.

For further information on how to compile and submit a retrospective monitoring report, the state should review Section B of the Monitoring Report Instructions document.

☒ The state will report retrospectively for any Qs prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after monitoring protocol approval.

☐ The state proposes an alternative plan to report retrospectively for any Qs prior to monitoring protocol approval: *Insert narrative description of proposed alternative plan for retrospective reporting. Regardless of the proposed plan, retrospective reporting should include retrospective metrics data and a general assessment of metric trends for the period. The state should provide justification for its proposed alternative plan.*

ATTACHMENT E
Reserved for SUD Evaluation Design