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

State Demonstrations Group

June 25, 2025

Adela Flores-Brennan
Medicaid Director
Colorado Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

Dear Director Flores-Brennan:

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

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

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

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Expanding the Substance Use Disorder (SUD) Continuum of Care (Project Number 11-W-00336/8 and 21-W-00079/8) demonstration.

Reporting Cadence and Due Date

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

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

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

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

Structured Monitoring Report Template

As noted in STC 11.6, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

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

The base and policy-specific metrics include applicable established measures of quality of care and correlated outcomes, which will be standardized across all similar demonstrations. The state may continue reporting additional quality measures to address state goals and priorities. CMS

will no longer expect the state to report metrics that include elements from the draft CMS disparities-sensitive measure set, referenced in the demonstration STCs.

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

Demonstration Monitoring Calls

As STC 11.12 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

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

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Expanding the Substance Use Disorder (SUD) Continuum of Care section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

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

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Ronna Bach, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITIES

NUMBER: 11-W-00336/8 and 21-W-00079/8

TITLE: Expanding the Substance Use Disorder Continuum of Care Section 1115(a) Demonstration

AWARDEE: Colorado Department of Health Care Policy and Financing

Under the authority of the Section 1115(a)(1) of the Social Security Act ("the Act"), the following waivers are granted to enable Colorado (referred to herein as the state or the State) to operate the Expanding the Substance Use Disorder Continuum of Care Section 1115 Demonstration. These waivers are effective beginning January 13, 2025 and are limited to the extent necessary to achieve the objectives below. These waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs) set forth in the accompanying document.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the Expanding the Substance Use Disorder Continuum of Care demonstration, including the granting of the waivers described below, is likely to assist in promoting the objectives of title XIX and XXI of the Act.

Except as provided below with respect to expenditure authority, all requirements of the Medicaid program expressed in law, regulation and policy statement, not expressly waived in this list, shall apply to the demonstration project for the period beginning January 13, 2025 through December 31, 2025.

1. **Coverage of Certain Screening, Diagnostic, and Targeted Case Management Services for Eligible Juveniles in the 30 Days Prior to Release Section 1902(a)(84)(D)**

To enable the state not to provide coverage of the screening, diagnostic, and targeted case management services identified in section 1902(a)(84)(D) of the Act for eligible juveniles described in section 1902(nn)(2) of the Act as a state plan benefit in the 30 days prior to the release of such eligible juveniles from a public institution, to the extent and for the period that the state instead provides such coverage to such eligible juveniles under the approved expenditure authorities under this demonstration. The state will provide coverage to eligible juveniles described in section 1902(nn)(2) in alignment with section 1902(a)(84)(D) of the Act at a level equal to or greater than would be required under the state plan.

Title XXI Waiver Authority

All requirements of the CHIP program expressed in law, regulation and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities and/or these special terms and conditions , shall apply to the demonstration project through December 31, 2025. In addition, these waivers may only be implemented consistent with the approved STCs.

Under the authority of section 1115(a)(1) of the Act, the following waiver of state plan requirements contained in section 2102 of the Act are granted for the Expanding the Substance Use Disorder Continuum of Care section 1115 demonstration, subject to these STCs.

2. **Coverage of Certain Screening, Diagnostic, Referral, and Case Management Services for Targeted Low-Income Children in the 30 Days Prior to Release Section 2102(d)(2)**

To enable the state not to provide coverage of the screening, diagnostic, referral, and case management services identified in section 2102(d)(2) of the Act for a targeted low-income child as a state plan benefit in the 30 days prior to the release of such targeted low-income child from a public institution, to the extent and for the period that the state instead provides such coverage to such targeted low-income children under the approved expenditure authorities under this demonstration. The state will provide coverage to targeted low-income children in alignment with section 2102(d)(2) of the Act at a level equal to or greater than would be required under the state plan.

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITIES

NUMBER: 11-W-00336/8 and 21-W-00079/8

TITLE: Expanding the Substance Use Disorder Continuum of Care Section 1115 Demonstration

AWARDEE: Colorado Department of Health Care Policy and Financing

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Colorado for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 13, 2025 through December 31, 2025, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD), Serious Mental Illness (SMI), or Serious Emotional Disturbance (SED).** 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), or an SMI), or SED who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

2. **Health-Related Social Needs (HRSN) Services.** Expenditures for allowable HRSN services not otherwise covered that are furnished to individuals who meet the qualifying criteria as described in Section 10. This expenditure authority is contingent upon compliance with Section 11, as well as all other applicable STCs.

3. **Health-Related Social Needs Services Infrastructure**. Expenditures for allowable HRSN administrative and infrastructure costs not otherwise covered under section 1903 of the Act, as described in Section 10 of the STCs.

4. **Expenditures for Pre-Release Services.** Expenditures for pre-release services, as described in these STCs, provided to qualifying Medicaid individuals for up to 90 days immediately prior to the expected date of release from a correctional facility that is participating in the reentry demonstration initiative.

5. **Expenditures for Pre-Release Administrative Costs.** Capped expenditures for payments for allowable administrative costs, supports, transitional non-service expenditures, infrastructure and interventions, as is detailed in STC 9.12, which may not be recognized as medical assistance under section 1905(a) and may not otherwise qualify for federal

matching funds under section 1903, to the extent such activities are authorized as part of the reentry demonstration initiative.

6. **Continuous Eligibility.** Expenditures for continued state plan benefits for individuals who have been determined eligible as specified in Table 1 of STC 4.3, who are not otherwise excluded under STC 4.4 for the applicable continuous eligibility period, and who would otherwise lose coverage during an eligibility redetermination, except as noted in STC 4.4**.**

Medicaid Requirements Not Applicable to the Medicaid Expenditure Authority for Pre-Release Services:

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

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

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

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

Title XIX Requirements Not Applicable to the HRSN Expenditure Authority

9. **Comparability; Amount, Duration and Scope Section 1902(a)(10)(b), Section 1902(a)(17)**

To the extent necessary to allow the state to offer HRSN services and to vary the amount, duration, and scope of HRSN services covered for a subset of beneficiaries, depending on beneficiary needs as determined by the application of qualifying criteria, as specified in Section 10 of the STCs.

Title XXI Expenditure Authority

Under the authority of section 1115(a)(2) of the Act as incorporated into title XXI by section 2107(e)(2)(A), state expenditures described below, shall, for the period of this demonstration, and to the extent of the state's available allotment under section 2104 of the Act, be regarded as matchable expenditures under the state's title XXI plan. The following expenditure authority must only be implemented consistent with the approved STCs and shall enable Colorado to implement the section 1115 demonstration amendment. All other requirements of the CHIP program, including current and future guidance for continuous eligibility, as expressed in law, regulation, and policy statements must apply to these expenditures, unless identified as not applicable below.

10. **Continuous Eligibility.** Expenditures for continued state plan benefits for individuals who have been determined eligible under groups specified in Table 1 of STC 4.3, who are not otherwise excluded under STC 4.4 for the applicable continuous eligibility period who

would otherwise lose coverage during an eligibility redetermination, except as noted in STC 4.4.

11. **Expenditures for Pre-Release Services.** Expenditures for pre-release services, as described in these STCs, provided to qualifying Children's Health Insurance Program (CHIP) individuals who are or would be eligible for CHIP if not for their incarceration status, for up to 90 days immediately prior to the expected date of release from a correctional facility that is participating in the reentry demonstration initiative.

12. **Residential and Inpatient Treatment for Individuals with a SUD, SMI, or SED.** Expenditures for otherwise covered CHIP services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for a SUD, SMI, or SED who are short-term residents in facilities that meet the definition of an IMD.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00336/8 and 21-W-00079/8

TITLE: Expanding the Substance Use Disorder Continuum of Care

AWARDEE: Colorado Department of Health Care Policy and Financing

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Colorado Expanding the Substance Use Disorder Continuum of Care" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Colorado Department of Health Care Policy and Financing (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted authority waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and 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 demonstration will be statewide and is approved for a five-year period, from January 1, 2021 through December 31, 2025.

The STCs have been arranged into the following subject areas:

1. Preface
2. Program Description and Objectives
3. General Program Requirements
4. Eligibility and Enrollment
5. Demonstration Programs and Benefits
6. Cost Sharing
7. Delivery System
8. Serious Mental Illness/Serious Emotional Disturbance
9. Reentry Demonstration Initiative
10. Health-Related Social Needs Services
11. Monitoring and Reporting Requirements
12. Evaluation of the Demonstration
13. General Financial Requirements Under Title XIX
14. Monitoring Budget Neutrality for the Demonstration
15. Monitoring Allotment Neutrality
16. 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 IT Plan
Attachment D:	SUD Monitoring Protocol
Attachment E:	SUD Evaluation Design
Attachment F:	SMI/SED Implementation Plan [Reserved]
Attachment G:	Reentry Demonstration Initiative Services [Reserved]
Attachment H:	Reentry Demonstration Initiative Implementation Plan [Reserved]
Attachment I:	Reentry Demonstration Initiative Reinvestment Plan [Reserved]
Attachment J:	SMI/SED, HRSN, and Reentry Monitoring Protocol [Reserved]
Attachment K:	SMI/SED, HRSN, and Reentry Evaluation Design [Reserved]
Attachment L:	Protocol for Assessment of Beneficiary Eligibility Needs and Provider Qualifications for HRSN
Attachment M:	HRSN Services Matrix
Attachment N:	HRSN Infrastructure Protocol
Attachment O:	HRSN Implementation Plan [Reserved]

2. PROGRAM DESCRIPTION AND OBJECTIVES

As of January 1, 2021, through the approval of the demonstration, the demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with a substance use disorder (SUD) while they are short- term residents in residential and inpatient treatment settings that qualify as Institutions for Mental Diseases (IMD). It will also support state efforts to enhance provider capacity, 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. The state seeks to achieve the following goals:

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

As of November 14, 2024, an amendment to the demonstration provided continuous eligibility expenditure authority for children, including separate CHIP recipients, up to age three through the end of the month of their third birthday, and 12 months of continuous eligibility for beneficiaries ages 19 up to age 65 who are released from a state Department of Corrections institution. This amendment is intended to support consistent coverage and continuity of care by

keeping eligible beneficiaries enrolled, regardless of changes in circumstances that would otherwise cause a loss of eligibility or other changes that would affect eligibility, such as a change in income, thereby improving health outcomes, and reducing churn.

As of January 13, 2025, an amendment to the demonstration authorizes the state to receive federal financial participation (FFP) for delivering high-quality, clinically appropriate treatment to beneficiaries diagnosed with serious mental illness (SMI) and/or serious emotional disturbance (SED) and receiving treatment while they are short-term residents in settings that qualify as IMDs, subject to the requirements outlined in the STCs. This amendment also includes programs to improve health outcomes for beneficiaries reentering society from correctional facilities, beneficiaries facing food insecurity and diet-sensitive conditions, and beneficiaries without stable housing. These programs are intended to enable the state to achieve the following goals:

- Reduced utilization and lengths of stay in EDs among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings;
- Reduced preventable readmissions to acute care hospitals and residential settings;
- Improved availability of crisis stabilization services including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric hospitals, and residential treatment settings throughout the state;
- Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care;
- Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.
- Expanded support services to populations who face barriers to health care due to their social circumstances;
- Improved coordination and integration of physical, behavioral, and social services for beneficiaries who have complex health and social needs;
- Enhanced quality and efficiency of care delivery by addressing the root causes of poor health outcomes; and
- Reduced health disparities by targeting services and supports to beneficiaries who experience higher rates of morbidity and mortality due to their social risk factors.

3. GENERAL PROGRAM REQUIREMENTS

3.1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (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).

3.2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and 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.

3.3. **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 any 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 3.7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the 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 3.7 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.

3.5. **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.

3.6. **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 3.7 below, except as provided in STC 3.3.

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 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

b. A 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;

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

3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (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 3.9.

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

a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 3.12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. **Transition and Phase-out Plan Requirements.** The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews 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 comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. 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. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

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

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

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

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

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

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

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

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

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

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

4. ELIGIBILITY AND ENROLLMENT

4.1. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility and the standards and methodologies for eligibility remain set forth under the state plan.

4.2. **Continuous Eligibility:** Eligible populations, identified in STC 18, will receive continuous eligibility through the demonstration. The state is authorized to provide continuous eligibility for the populations for the durations specified in Table 1 below, regardless of the delivery system through which these populations receive Medicaid and separate CHIP (S-CHIP) benefits.

a. For individuals who qualify for continuous eligibility, the continuous eligibility period begins on the effective date of the individual's eligibility under 42 CFR 435.915 or 457.340(g), the effective date of the most recent redetermination, or the date of their release from a state Department of Corrections (DOC) facility.

b. Because individuals are continuously eligible regardless of changes in circumstances, the state does not need to conduct renewals or redeterminations of eligibility consistent with 42 CFR 435.916 and 435.919 or 457.343 and 457.344 for individuals who qualify for continuous eligibility until the end of the individual's continuous eligibility period, except in the limited circumstances of a beneficiary meeting one of the exceptions outlined in STC 4.4.

c. At the end of the continuous eligibility periods, Colorado must conduct a renewal of Medicaid or S-CHIP eligibility and consider eligibility on all bases consistent with 42 CFR 435.916(d)(1) or 42 CFR 457.343 prior to terminating coverage. Individuals determined eligible on another basis at the end of the continuous eligibility period will be moved to the appropriate group at that time. Individuals determined eligible on another basis resulting in a reduction of Medicaid eligibility or services or increase in cost sharing or premiums will be provided advance notice of termination in accordance with 42 CR 435.917 and 42 CFR 431, Subpart E. Individuals determined ineligible for Medicaid or S-CHIP on all bases will be provided advance notice of termination in accordance with 42 CR 435.917 and 42 CFR 431, Subpart E and 42 CFR 457.110 and 457.340 and assessed for potential eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(d)(2).

4.3. **Populations and Duration:** The state is authorized to provide continuous eligibility for the following populations for the associated durations:

a. **Children up to age three**. Except as provided in STC 4.4**,** individuals age zero through the end of the month of their third birthday, who enroll in Medicaid or S-CHIP, shall qualify for continuous eligibility until the end of the month in which their third birthday falls.

b. **Formerly Incarcerated**. Except as provided in STC 4.4, the state is authorized to provide 12 months of continuous eligibility for individuals aged 19 – 65 who are released from a state DOC facility. The period of continuous eligibility shall begin at the date of their release and will extend through the end of the 12th month following release.

Table 1: Eligible Populations and Associated Duration for Continuous Eligibility (CE)	
Population	**Duration of CE**
Children (including S-CHIP) up to age 3	Until the end of the month of their 3rd birthday
Beneficiaries leaving incarceration (aged 19 – 65)	Up to 12 months following their release from a state DOC facility

4.4. **Eligibility Exclusions:** The following adults and children are excluded from receiving continuous eligibility:

a. Have only established Medicaid eligibility as medically needy (as set forth in section 1902(a)(10)(C) of the Act),

b. Have been determined presumptively eligible for Medicaid or S-CHIP but have not yet received an eligibility determination based on a regular application, or

c. Upon the adult and child's renewal are determined to only be eligible for Medicaid based on transitional medical assistance (as set forth in section 1925 of the Act).

4.5. **Exceptions to Continuous Eligibility:** Notwithstanding STC 4.4, if any of the following circumstances occur during an individual's designated continuous eligibility period, the individual's Medicaid or S-CHIP eligibility shall be redetermined or terminated:

a. The beneficiary attains the age limit of the continuous eligibility period or eligibility group (if applicable);

b. The beneficiary is no longer a Colorado resident;

c. The beneficiary or their representative requests termination of eligibility;

d. The beneficiary dies;

e. The agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the individual; or

f. For S-CHIP, the child becomes eligible for Medicaid.

4.6. **Beneficiary-Reported Information and Periodic Data Checks**:

a. The state must have procedures designed to ensure that beneficiaries can make timely and accurate reports of any change in circumstances that may affect their continuous eligibility as outlined STC 4.5 (such as a change in state residency) and are able to report other information relevant to the state's implementation or monitoring and evaluation of this demonstration, such as changes in income. The beneficiary must be able to report this information through any of the modes of submission available at application (online, in person, by telephone, or by mail).

b. For individuals who qualify for a continuous eligibility period that exceeds 12 months, the state must continue to attempt to verify residency at least once every 12 months. The state should follow its typical processes that it would otherwise use to verify continued residency at renewal if continuous eligibility was not available for these individuals.

c. Additionally, at least once every 12 months, the state must follow its typical processes to attempt to confirm the individual is not deceased, consistent with the data sources outlined in the state's verification plan(s) and/or confirmed by the household per 42 CFR 435.952(d) or 457.380. The state must redetermine eligibility if the state receives information that indicates a change in state residency or that the individual is deceased, verifying the change consistent with 42 CFR 435.919 or 457.344 and in accordance with 42 CFR 435.940 through 435.960 and the state's verification plan developed under 42 CFR 435.945(j) or 457.380.

d. Because individuals are receiving continuous eligibility beyond their eligibility period, the state does not need to complete the individual's annual renewal or act on changes in circumstances that would otherwise affect eligibility, except as detailed in

STC 4.5, until the end of the individual's continuous eligibility period. Additionally, if the state obtains information about changes that may affect eligibility (e.g., change in income), they are not permitted to use the information related to the change to end the continuous eligibility period early and terminate coverage, unless the change relates to one or more of the exceptions detailed in STC 4.5.

4.7. **Annual Updates to Beneficiary Contact Information:** For all continuous eligibility periods longer than 12 months, the state must have procedures and processes in place to accept and update beneficiary contact information and must attempt to update beneficiary contact information on an annual basis, which may include examining data sources annually and partnering with managed care organizations to encourage beneficiaries to update their contact information. The state is reminded that updated contact information obtained from third-party sources with an in-state address is not an indication of a change affecting continuous eligibility. Contact information with an out-of-state or no forwarding address indicates a potential change in circumstance with respect to state residency, but without additional follow up by the state per 42 CFR 435.952(d) or 457.380(f), the receipt of this third-party data is not sufficient to make a definitive determination that beneficiaries no longer meet state residency requirements.

4.8. **Annual Reminders of Continued Eligibility:** The state must have procedures and processes in place to provide individuals who qualify for a continuous eligibility period that exceeds 12 months an annual reminder of continued eligibility. The annual reminder of continued eligibility must:

a. Be written in plain language;

b. Be accessible to persons who are limited English proficient and individuals with disabilities, consistent with 42 CFR 435.905(b); and

c. If provided in electronic format, comply with requirements for electronic notices in 42 CFR 435.918.

d. The annual reminder of continued eligibility must, at a minimum, include:

i. An explanation of the individual's continued eligibility, including the end date of the continuous eligibility period;

ii. The circumstances under which the individual must report, and procedures for reporting, any changes that may affect the individual's continuous eligibility;

iii. Basic information on the level of benefits and services available as described at 42 CFR 435.917(b)(1)(iv); and

iv. If the beneficiary's eligibility is based on having household income at or below the applicable MAGI standard, the content regarding non-MAGI eligibility described at 42 CFR 435.917(c).

4.9. **Cost Sharing within Continuous Eligibility:** Individuals receiving continuous eligibility enrolled in this demonstration may be subject to cost sharing responsibilities, such as monthly premiums and co-payments, to the extent allowable under titles XIX and XXI requirements or as approved under current section 1115 demonstration authority**.** However, beneficiaries may not be disenrolled from this demonstration for failure to pay a premium during the individual's continuous eligibility period approved in the demonstration.

5. DEMONSTRATION PROGRAMS AND BENEFITS

5.1. **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 Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance and SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 5.3, 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.

5.2. **SUD Implementation Plan and Health IT Plan**.

a. The state must submit the SUD Implementation Plan within 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 12.1.

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 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.** 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.

d. **SUD Health IT Plan.** Implementation of the milestones and metrics as detailed in STC 5.2 and Attachment C.

i. **SUD Health Information Technology Plan ("Health IT Plan").** The SUD 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, respectively, 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 5.2(a) and 5.2(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

ii. 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.

1. The state must include in its Monitoring Protocol (see STC 12.5) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
2. 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 12.6).

3. 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.
4. 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.
5. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.
6. Components of the Health IT Plan include:

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

    b. 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.

    c. The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data

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

[2] *Ibid*.

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

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

d. 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]

e. 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.

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

- 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/).
- 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.
- 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.

5.3. **SUD Monitoring Protocol.** The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within 150 calendar days after approval of the demonstration. The Monitoring Protocol 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 Monitoring Protocol include:

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 5.2 and reporting relevant information to the state's Health IT plan described in STC 5.2(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 12 of the demonstration; and

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

5.4. **Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections 12 (Monitoring and Reporting Requirements) and 13 (Evaluation of the Demonstration) of these STCs.

5.5. **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.

6. COST SHARING

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

7. DELIVERY SYSTEM

7.1. **Delivery System.** The state's Medicaid SUD delivery system will continue to be operated under a capitated managed care structure and administered by Regional Accountable Entities (RAE). The inpatient and residential SUD treatment services, withdrawal management, and MAT services will be covered under the same delivery system, with capitation payments made from the state to the RAEs which, in turn, manage the delivery

of services. The new services, including care coordination, will be considered as the state develops the new capitation rate methodology.

8. SERIOUS MENTAL ILLNESS (SMI)/SERIOUS EMOTIONAL DISTURBANCE (SED) PROGRAM AND BENEFITS

8.1. **SMI/SED Program Benefits.** Under this demonstration, beneficiaries will have access to, the full range of otherwise covered Medicaid services, including SMI/SED treatment services. These SMI/SED services will range in intensity from short-term acute care in inpatient settings for SMI/SED, to ongoing chronic care for such conditions in cost-effective community-based settings. The state will work to improve care coordination and care for co-occurring physical and behavioral health conditions. The state must achieve a statewide average length of stay of no more than 30 days for beneficiaries receiving treatment in an IMD treatment setting through this demonstration's SMI/SED Program, to be monitored pursuant to the SMI/SED Monitoring Plan as outlined in STC 12.6.

8.2. **SMI/SED Implementation Plan.**

a. The state must submit the SMI/SED Implementation Plan within 90 calendar days after approval of the January 13, 2025 demonstration amendment for CMS review and comment. If applicable, the state must submit a revised SMI Implementation Plan within 60 calendar days after receipt of CMS's comments. The state may not claim FFP for services provided to beneficiaries residing in IMDs primarily to receive treatment for SMI/SED under expenditure authority until CMS has approved the SMI Implementation Plan and the SMI/SED financing plan described in STC 8.2(e). After approval of the required Implementation Plan and Financing Plan, FFP will be available prospectively, but not retrospectively.

b. Once approved, the SMI/SED Implementation Plan will be incorporated into the STCs as Attachment F, and once incorporated, may be altered only with CMS approval. Failure to submit an SMI/SED Implementation Plan, within 90 calendar days after approval of the demonstration, will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED 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 12.1.

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

i. **Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings.**

1. Hospitals that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI/SED program are residing must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals prior to the state claiming FFP for services provided to beneficiaries residing in a hospital that meets the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and either: a) be certified by the state agency as being in compliance with those conditions through a state agency survey, or b) have deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS.
2. Residential treatment providers that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI/SED program are residing must be licensed, or otherwise authorized, by the state to primarily provide treatment for mental illnesses. They must also be accredited by a nationally recognized accreditation entity prior to the state claiming FFP for services provided to beneficiaries residing in a residential facility that meets the definition of an IMD.
3. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating hospitals and residential treatment settings in which beneficiaries receiving coverage pursuant to the demonstration are residing meet applicable state licensure or certification requirements as well as a national accrediting entity's accreditation requirements;
4. Use of a utilization review entity (for example, a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals and residential treatment settings are receiving treatment in those facilities;
5. Establishment of a process for ensuring that participating psychiatric hospitals and residential treatment settings meet applicable federal program integrity requirements, and establishment of a state process to conduct risk-based screening of all newly enrolling providers, as well as revalidation of existing providers (specifically, under existing regulations, the state must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and establish

rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues);

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

ii. **Improving Care Coordination and Transitions to Community-Based Care.**

1. Implementation of a process to ensure that psychiatric hospitals and residential treatment facilities provide intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that facilitate participation of community-based providers in transition efforts (e.g., by allowing beneficiaries to receive initial services from a community-based provider while the beneficiary is still residing in these settings and/or by engaging peer support specialists to help beneficiaries make connections with available community-based providers and, where applicable, make plans for employment);
2. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and residential treatment settings and to connect beneficiaries who have been experiencing or are likely to experience homelessness or who would be returning to unsuitable or unstable housing with community providers that coordinate housing services, where available;
3. Implementation of a requirement that psychiatric hospitals and residential treatment settings that are discharging beneficiaries who have received coverage pursuant to this demonstration have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary and the community-based provider to which the beneficiary was referred within 72 hours of discharge to help ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and, as appropriate, by contacting the community-based provider the person was were referred to;
4. Implementation of strategies to prevent or decrease the length of stay in emergency departments among beneficiaries with SMI or SED (e.g., through the use of peer support specialists and psychiatric consultants in EDs to help with discharge and referral to treatment providers);

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

iii. **Increasing Access to Continuum of Care Including Crisis Stabilization Services.**

1. Establishment of a process to annually assess the availability of mental health services throughout the state, particularly crisis stabilization services, and updates on steps taken to increase availability (the state must provide updates on how it has increased the availability of mental health services in every Annual Monitoring Report);
2. Commitment to implementation of the SMI/SED financing plan described in STC 8.2(e). The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI/SED program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI/SED program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 12.6;
3. Implementation of strategies to improve the state's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible;
4. Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association [e.g., Level of Care Utilization System (LOCUS) or the Child and Adolescent Service Intensity Instrument (CASII)] to determine appropriate level of care and length of stay.

iv. **Earlier Identification and Engagement in Treatment and Increased Integration.**

1. Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with SMI/SED in treatment sooner, including through supported employment and supported education programs;
2. Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of SMI/SED conditions sooner and improve awareness of and linkages to specialty treatment providers;

3. Establishment of specialized settings and services, including crisis stabilization services, focused on the needs of young people experiencing SMI or SED.

d. **SMI/SED Health Information Technology (Health IT) Plan.** The Health IT plan is intended to apply only to those State Health IT functionalities impacting beneficiaries within this demonstration and providers directly funded by this demonstration. The state will provide CMS with an assurance that it has a sufficient health IT infrastructure "ecosystem" at every appropriate level (i.e., state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration. If the state is unable to provide such an assurance, it will submit to CMS a Health IT Plan, to be included as a section of the applicable Implementation Plan (see STC 8.2(c)), to develop the infrastructure/capabilities of the state's health IT infrastructure.

i. The Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SMI/SED 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 F) 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.

ii. The state will include in its Monitoring Plans (see STC 12.6) an approach to monitoring its SMI/SED Health IT Plan which will include performance metrics to be approved in advance by CMS.

iii. The state will monitor progress, each DY, on the implementation of its SMI/SED Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS within its Annual Monitoring Report (see STC 12.6).

iv. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications'[3] (ISA) in developing and implementing the state's SMI/SED Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

v. Where there are opportunities at the state- and provider-level (up to and including usage in managed care organization (MCO) or Accountable Care Organization (ACO) participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B "Standards and Implementation Specifications for HIT". If there is no relevant standard in 45 CFR 170 Subpart B, the state should review the Office of the National

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

Coordinator for Health Information Technology's Interoperability Standards Advisory (https://www.healthit.gov/isa/) to locate other industry standards in the interest of efficient implementation of the state plan.

vi. Components of the Health IT Plan include:

1. 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 SED/SMI care delivery. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
2. 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.
3. 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 electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

e. **SMI/SED Financing Plan.** As part of the SMI/SED implementation plan referred to in STC 8.2, the state must submit, within 90 calendar days after approval of the demonstration, a financing plan for approval by CMS. Once approved, the Financing Plan will be incorporated into the STCs as part of the implementation plan in Attachment F and, once incorporated, may only be altered with CMS approval.

Failure to submit an SMI/SED Financing Plan within 90 days of approval of the demonstration will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED program under this demonstration. Components of the financing plan must include:

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

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

8.3. **Maintenance of Effort (MOE).** The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI/SED program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI/SED program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 12.6.

8.4. **Availability of FFP for the SMI/SED Services Under Expenditure Authority #1.** Federal Financial Participation is only available for services provided to beneficiaries who are residing in an IMD when the beneficiary is a short-term resident in the IMD primarily to receive treatment for mental illness. The state may claim FFP for services furnished to beneficiaries during IMD stays of up to 60 days, as long as the state shows at its Mid-Point Assessment that it is meeting the requirement of a 30-day average length of stay (ALOS) for beneficiaries residing in an IMD who are receiving covered services under the demonstration. Demonstration services furnished to beneficiaries whose stays in IMDs exceed 60 days are not eligible for FFP under this demonstration. If the state cannot show that it is meeting the 30 day or less ALOS requirement within one standard deviation at the Mid-Point Assessment, the state may only claim FFP for services furnished to beneficiaries during IMD stays of up to 45 days until such time that the state can demonstrate that it is meeting the 30 day or less ALOS requirement. The state will ensure that medically necessary services are provided to beneficiaries that have stays in excess of 60 days or 45 days, as relevant.

8.5. **Unallowable Expenditures Under the SMI/SED 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. Costs for services furnished to beneficiaries who are residents in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.

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

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

9. REENTRY DEMONSTRATION INITIATIVE

9.1. Overview of Pre-Release Services and Program Objectives.

This component of the demonstration will provide coverage for pre-release services up to 90 days immediately prior to the expected date of release to certain individuals who are inmates residing in jails, prisons, and youth correctional facilities (hereinafter "correctional facilities"). To qualify for services covered under this demonstration, individuals residing in correctional facilities must be eligible for Medicaid or CHIP as determined pursuant to an application filed before or during incarceration and must have an expected release date no later than 90 days as further specified in the STCs below.

9.2. The objective of this component of the demonstration is to facilitate individuals' access to certain healthcare services and case management, provided by Medicaid and CHIP participating providers, while individuals are incarcerated and allow them to establish relationships with community-based providers from whom they can receive services upon reentry to their communities. This bridge to coverage begins within a short time prior to release and is expected to promote continuity of coverage and care and improve health outcomes for justice-involved individuals. The reentry demonstration initiative provides short-term Medicaid and CHIP enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions, as well as improve the identification and treatment of certain chronic and other serious conditions to reduce acute care utilization in the period soon after release, and test whether it improves uptake and continuity of medication-assisted treatment (MAT) and other Substance Use Disorder (SUD) and behavioral health treatments, as appropriate for the individual.

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

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

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

c. Improve coordination and communication between correctional systems, Medicaid and CHIP systems, managed care plans (as applicable), and community-based providers;

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

e. Improve connections between correctional facility settings and community services upon release to address physical and behavioral health needs, and health-related social needs;

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

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

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

9.3. **Qualifying Criteria for Pre-Release Services**. To qualify to receive services under this component of the demonstration, an individual must meet the following qualifying criteria:

a. Meet the definition of an inmate of a public institution, as specified in 42 CFR 435.1010, and be incarcerated in a correctional facility specified in STC 9.1;

b. Have been determined eligible for Medicaid or CHIP if not for their incarceration status; and

c. Have an expected release date within 90 days.

9.4. **Scope of Pre-Release Services**. The pre-release services authorized under the reentry demonstration initiative include the following services, which are described in Attachment G, Reentry Demonstration Initiative Services.

a. The covered pre-release services are:

i. Case management to assess and address physical and behavioral health needs, and health-related social needs; and

ii. MAT for all types of SUDs as clinically appropriate, including coverage for medications in combination with counseling/behavioral therapies.

b. The state must also provide a 30-day supply of all prescription medications and over-the-counter drugs (as clinically appropriate), provided to the individual immediately upon release from the correctional facility, consistent with approved Medicaid or CHIP state plan coverage authority and policy.

c. The expenditure authority for pre-release services through this initiative constitutes a limited exception to the federal claiming prohibition for medical assistance furnished to inmates of a public institution at clause (A) following section 1905(a) of the Act ("inmate exclusion rule"). Similarly, for CHIP, the expenditure authority for pre-release services constitutes a limited exception to the general exclusion of children who are inmates of a public institution from the definition of a targeted low-income child under section 2110(b)(2)(A) of the Act ("child exclusion rule"). Benefits and services for inmates of a public institution that are not approved in the reentry demonstration initiative as described in these STCs and accompanying protocols, and not otherwise covered under the inpatient exception to the inmate exclusion rule or an exception in section 2110(b)(7) of the Act to the child exclusion rule remain subject to the inmate exclusion rule or the child exclusion rule, as applicable. Accordingly, other benefits and services covered under the Colorado Medicaid or CHIP State Plans, as relevant, that are not included in the above-described pre-release services (e.g., EPSDT treatment services for qualifying Medicaid beneficiaries under age 21) are not available to qualifying individuals through the reentry demonstration initiative.

9.5. **Participating Correctional Facilities**. The pre-release services will be provided at state prisons and local jails, tribal jails, and youth correctional facilities, or outside of the correctional facilities, with appropriate transportation and security oversight provided by the correctional facility, subject to Colorado Department of Health Care Policy and Financing approval of a facility's readiness, according to the implementation timeline described in STC 9.9. States must be mindful of and ensure the policies, procedures, and processes developed to support implementation of these provisions do not effectuate a delay of an individual's release or lead to increased involvement in the juvenile and adult justice systems. Correctional facilities that are also institutions for mental diseases (IMDs) are not allowed to participate in the reentry demonstration initiative.

9.6. **Participating Providers.**

a. Licensed, registered, certified, or otherwise appropriately credentialed or recognized practitioners under Colorado scope of practice statutes shall provide services within their individual scope of practice and, as applicable, receive supervision required under their scope of practice laws and must be enrolled as Medicaid or CHIP providers.

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

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

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

9.7. **Suspension of Coverage**. Upon entry of a Medicaid-enrolled or CHIP individual into a correctional facility, Colorado Department of Health Care Policy and Financing must not terminate and generally shall suspend their Medicaid coverage or CHIP eligibility.

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

9.8. **Interaction with Mandatory State Plan Benefits for Eligible Juveniles and Targeted Low-Income Children**. To the extent Colorado's reentry demonstration initiative includes coverage otherwise required to be provided under section 1902(a)(84)(D) and section 2102(d)(2) of the Act, and because this coverage is included in the base expenditures used to determine the budget neutrality or allotment neutrality expenditure limit, the state will claim for these expenditures and related transitional non-service expenditures under this demonstration as well as include this coverage in the monitoring and evaluation of this demonstration.

9.9. **Reentry Demonstration Initiative Implementation Timeline**. Delivery of pre-release services under this demonstration will be implemented as described below. All participating correctional facilities must demonstrate readiness, as specified below, prior to participating in this initiative (FFP will not be available in expenditures for services furnished to qualifying individuals who are inmates in a facility before the facility meets the below readiness criteria for participation in this initiative). The Department of Health Care Policy and Financing will determine that each applicable facility is ready to participate in the reentry demonstration initiative under this demonstration based on a facility-submitted assessment (and appropriate supporting documentation) of the facility's readiness to implement:

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

b. The screening process to determine an individual's qualification for pre-release services, per the eligibility requirements described in STC 9.3;

c. The provision or facilitation of pre-release services for a period of up to 90 days immediately prior to the expected date of release, including the facility's ability to

support the delivery of services furnished by providers in the community that are delivered via telehealth, as applicable;

d. Coordination amongst partners with a role in furnishing health care services to individuals who qualify for pre-release services, including, but not limited to, physical and behavioral health community-based providers, and social service departments;

e. Appropriate reentry planning, pre-release case management, and assistance with care transitions to the community, including connecting individuals to physical and behavioral health providers and their managed care plan (as applicable), and making referrals to case management and community supports providers that take place throughout the 90-day pre-release period, and providing individuals with covered outpatient prescribed medications and over-the-counter drugs (a minimum 30-day supply as clinically appropriate) upon release, consistent with approved Medicaid or CHIP state plan coverage authority and policy;

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

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

h. Reporting of data requested by the Colorado Department of Health Care Policy and Financing to support program monitoring, evaluation, and oversight; and

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

9.10. **Reentry Demonstration Initiative Implementation Plan**. The state is required to submit a Reentry Demonstration Initiative Implementation. As such, the implementation plan will identify for each milestone, as well as each associated action, what the state anticipates to be the key implementation challenges and the state's specific plans to address these challenges. This will include any plans to phase in demonstration components over the lifecycle of the demonstration.

The state must submit the draft Implementation Plan to CMS no later than 120 calendar days after approval of the reentry demonstration initiative. The state must submit any required clarifications or revisions to its draft Implementation Plan no later than 60 calendar days after receipt of CMS feedback. The finalized Implementation Plan will be

incorporated into the STCs as Attachment H titled "Reentry Demonstration Initiative Implementation Plan."

CMS will provide the state with a template to support developing the Implementation Plan.

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

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

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

    ii. Improved access to behavioral and physical community-based health care services and capacity focused on meeting the health care needs and addressing the needs of individuals who are incarcerated (including those who are soon-to-be released), those who have recently been released, and those who may be at higher risk of criminal justice involvement, particularly due to untreated behavioral health conditions;

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

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

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

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

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

b. The reinvestment plan will describe whether privately-owned or -operated carceral facilities would receive any of the reinvested funds and, if so, the safeguards the state proposes to ensure that such funds are used for the intended purpose and do not have the effect of increasing profit or operating margins for privately-owned or -operated carceral facilities.

c. Within six months of approval, the state will submit a Reentry Demonstration Initiative Reinvestment Plan (Attachment I) for CMS approval that memorializes the state's reinvestment approach. The Reinvestment Plan will also identify the types of expected reinvestments that will be made over the demonstration period. Actual reinvestments will be reported to CMS in Attachment I titled "Reentry Demonstration Initiative Reinvestment Plan."

9.12. **Reentry Demonstration Initiative Planning and Implementation.**

The Reentry Demonstration Initiative Planning and Implementation Program will provide expenditure authority to fund supports needed for Medicaid and CHIP pre-release application and suspension/unsuspension planning and purchase of certified electronic health record (EHR) technology to support Medicaid and CHIP pre-release applications. In addition, reentry demonstration initiative planning and implementation funds will provide funding over the course of the demonstration to support planning and IT investments that will enable implementation of the reentry demonstration initiative services covered in a period for up to 90 days immediately prior to the expected date of release, and for care coordination to support reentry. These investments will support collaboration and planning among the Department of Health Care Policy and Financing and Qualified Applicants listed in STC 9.12(d) below. The specific use of this funding will be proposed by the qualified applicant submitting the application, as the extent of approved funding will be determined according to the needs of the entity. Allowable expenditures are limited to only those that support Medicaid-related expenditures and/or demonstration-related expenditures (and not other activities or staff in the correctional facility) and must be properly cost-allocated to Medicaid and CHIP. These allowable expenditures may include the following:

a. **Technology and IT Services**. Expenditures for the purchase of technology for Qualified Applicants which are to be used for assisting the reentry demonstration initiative population with Medicaid and CHIP application and enrollment for demonstration coverage (e.g., for inmates who would be eligible for CHIP but for their incarceration status and coordinating pre-release and post-release services for enrollees). This includes the development of electronic interfaces for Qualified Applicants listed in STC 9.12(d) to communicate with Medicaid and CHIP IT systems to support Medicaid and CHIP enrollment and suspension/unsuspension and modifications. This also includes support to modify and enhance existing IT systems to create and improve data exchange and linkages with Qualified Applicants listed in STC 9.12(d), in order to support the provision of pre-release services delivered in the period up to 90 days immediately prior to the expected date of release and reentry planning.

b. **Hiring of Staff and Training**. Expenditures for Qualified Applicants listed in STC 9.12(d) to recruit, hire, onboard, and train additional and newly assigned staff to assist with the coordination of Medicaid and CHIP enrollment and suspension/unsuspension, as well as the provision of pre-release services in a period for up to 90 days immediately prior to the expected date of release and for care coordination to support reentry for justice-involved individuals. Qualified Applicants may also require training for staff focused on working effectively and appropriately with justice-involved individuals.

c. **Adoption of Certified Electronic Health Record Technology**. Expenditures for providers' purchase or necessary upgrades of certified electronic health record (EHR) technology and training for the staff that will use the EHR.

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

e. **Development of Protocols and Procedures**. Expenditures to support the specification of steps to be taken in preparation for and execution of the Medicaid and CHIP enrollment process, suspension/unsuspension process for eligible individuals, and provision of care coordination and reentry planning for a period for up to 90 days immediately prior to the expected date of release for individuals qualifying for reentry demonstration initiative services.

f. **Additional Activities to Promote Collaboration**. Expenditures for additional activities that will advance collaboration among Colorado's Qualified Applicants in STC 9.12(d). This may include conferences and meetings convened with the agencies, organizations, and other stakeholders involved in the initiative.

g. **Planning**. Expenditures for planning to focus on developing processes and information sharing protocols to: (1) identifying individuals who are potentially eligible for Medicaid and CHIP; (2) assisting with the completion of a Medicaid or CHIP application; (3) submitting the Medicaid or CHIP application to the county

social services department or coordinating suspension/unsuspension; (4) screening for eligibility for pre-release services and reentry planning in a period for up to 90 days immediately prior to the expected date of release; (5) delivering necessary services to eligible individuals in a period for up to 90 days immediately prior to the expected date of release and care coordination to support reentry; and (6) establishing on-going oversight and monitoring process upon implementation.

h. **Other activities to support a milieu appropriate for provision of pre-release services**. Expenditures to provide a milieu appropriate for pre-release services in a period for up to 90 days immediately prior to the expected date of release, including accommodations for private space such as movable screen walls, desks, and chairs, to conduct assessments and interviews within correctional institutions, and support for installation of audio-visual equipment or other technology to support provision of pre-release services delivered via telehealth in a period for up to 90 days immediately prior to the expected date of release and care coordination to support reentry. Expenditures may not include building, construction, or refurbishment of correctional facilities.

i. The state may claim FFP in Reentry Demonstration Initiative Planning and Implementation Program expenditures for no more than the annual amounts outlined in Table 2. In the event that the state does not claim the full amount of FFP for a given demonstration year as defined in STC 14.12, the unspent amounts will roll over to one or more demonstration years not to exceed this demonstration period and the state may claim the remaining amount in a subsequent demonstration year.

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

	DY 1 CY 2021	DY 2 CY 2022	DY 3 CY 2023	DY 4 CY 2024	DY 5 CY 2025	Total
Total Computable Expenditures	n/a	n/a	n/a	n/a	$4,400,000	$4,400,000

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

iii. Qualified Applicants for the Reentry Demonstration Initiative Planning and Implementation Program will include the state Medicaid/CHIP Agency, correctional facilities, other state agencies supporting carceral health, Probation Offices, and other entities as relevant to the needs of justice-involved individuals, including health care providers, as approved by the state Medicaid/CHIP agency.

10. HEALTH-RELATED SOCIAL NEEDS SERVICES

10.1. **Health-Related Social Needs (HRSN) Services**. The state may claim FFP for expenditures for certain qualifying HRSN services identified in STC 10.2 and Attachment L, subject to the restrictions described below. Expenditures are limited to expenditures for items and services not otherwise covered under Title XIX, but consistent with Medicaid demonstration objectives that enable the state to continue to increase the efficiency and quality of care. All HRSN interventions must be evidence-based and medically appropriate for the population of focus based on clinical and social risk factors. The state is required to align clinical and health-related social risk criteria across services and with other relevant, non-Medicaid social support agencies, to the extent possible and appropriate. The HRSN services may not supplant any other available funding sources such as housing or nutrition supports available to the beneficiary through other local, state, or federal programs. The HRSN services will be the choice of the beneficiary; a beneficiary can opt out of HRSN services anytime; and the HRSN services do not absolve the state or its managed care plans, as applicable, of their responsibilities to make payment for other covered services. Under no circumstances will the state be permitted to condition Medicaid coverage, or coverage of any benefit or service, on a beneficiary's receipt of HRSN services. The state must submit additional details on covered services as outlined in STC 10.2 (Service Delivery) and Attachment L.

10.2. **Allowable HRSN services**. The state may cover the following HRSN services:

a. Case management services for access to housing supports (e.g., outreach and education; linkages to other state and federal benefit programs, benefit program application assistance, and benefit program application fees).

b. Housing Interventions, including:

i. Housing supports without room and board, including:

1. Pre-tenancy navigation services (e.g., finding and securing housing).
2. One-time transition and moving costs other than rent, to assist with identifying, coordinating, securing, or funding one-time necessary services and modifications to help a person establish a basic household (e.g., security deposit, application and inspection fees, utilities activation fees and payment in arrears as necessary to re-establish utility service (capped at a total of six months of total arrear and prospective payments), movers, relocation expenses, pest eradication, pantry stocking (up to 30 days of food), cooking supplies, and the purchase of household goods and furniture). Allowable utilities include water, garbage, sewage, recycling, gas, electric, internet, and phone services. This does not include clothing.
3. Tenancy and sustaining services (e.g., eviction prevention, tenant rights education).

ii. Utility assistance, capped at six months per demonstration period for total prospective/retrospective payments (utility assistance provided as a one-time transition service under STC 10.2(b)(i)(2) is included in this limit), including activation expenses and back payments to secure utilities, limited to individuals receiving housing supports with or without room and board as described in this STC. Allowable utilities include water, garbage, sewage, recycling, gas, electric, internet, and phone services.

iii. Episodic housing interventions with clinical services with room and board, limited to a clinically appropriate amount of time, including:

1. Short-term post-transition housing (e.g., post-hospitalization), where integrated, clinically oriented rehabilitative services and supports are provided, but ongoing monitoring of the individual's condition by clinicians is not required.

iv. Room and board-only supports (also referred to as "rent-only" supports or interventions), limited to a clinically appropriate amount of time, including:

1. First month's rent as a transitional service.
2. Short-term rental assistance with room alone or with room and board together, without clinical services included in the rental assistance payment.

c. Nutrition Interventions (standalone, outside of joint room and board interventions):

i. Nutrition interventions without provision of food, including nutrition counseling and instruction, tailored to health risk, nutrition-sensitive health conditions, and/or demonstrated outcome improvement (for example, guidance on selecting healthy food and healthy meal preparation).

ii. Nutrition interventions with provision of food, including:

1. Home delivered meals or pantry stocking (also referred to as grocery provisions), appropriate for the beneficiary's health condition or status as a child or pregnant person.
2. Medically tailored meals to individuals with nutrition-sensitive conditions (e.g., pregnant individuals, individuals with diabetes), as specified in STC 10.6.

10.3. **HRSN Intervention Duration and Frequency.**

a. Housing interventions with room and board.

i. Housing interventions that are classified as episodic interventions, as described in STC 10.2(b)(iii) may be covered for a qualifying beneficiary, as medically appropriate, up to a combined 6 months per rolling year. For purposes of this demonstration, rolling year is defined as a continuous 12-

month period with the start date beginning when the beneficiary begins receiving the service.

ii. Housing interventions that are classified as room and board-only support, as described in STC 10.2(b)(iv), may be covered for a qualifying beneficiary up to a combined 6 months per household per demonstration period.

iii. For each of these 6-month caps, coverage will be permitted in one or more spans or episodes, as long as the total duration remains under the cap for the rolling year or demonstration period. CMS will also apply a total combined cap of 6 months for all types of HRSN housing interventions with room and board (including episodic interventions and room and board-only supports), per beneficiary, in any 12-month period. However, if a beneficiary is considered to have received room and board-only support because that intervention was covered for another member of the beneficiary's household as specified in STC 10.3(b), the beneficiary still may receive up to 6 months of coverage for episodic interventions in the same 12-month period without violating this STC.

b. Nutrition interventions with provision of food.

i. HRSN nutrition interventions with provision of food (full board, i.e., 3 meals/day or any other complete nutritional regimen) are limited to a duration of 6 months, renewable while the beneficiary continues to meet qualifying criteria.

ii. HRSN nutrition interventions with provision of food are not available to the extent that that benefit, together with any other service payments that include payment for food made on behalf of the beneficiary, would exceed full board for the beneficiary, as the HRSN nutrition benefit or payment would be duplicative. For example, medically tailored meal delivery is not available for an individual who is receiving short-term rental assistance for a stay in a facility that provides 3 meals per day included in the payment to the facility, and pantry stocking or nutrition prescriptions are not available for an individual who is receiving a full board regimen of medically tailored meals.

c. The state will define other HRSN service duration limitations in Attachment L, subject to CMS approval as indicated in STC 10.7.

10.4. **Excluded Services.** Excluded items, services, and activities that are not covered as HRSN services include, but are not limited to:

a. Construction (bricks and mortar) except as needed for approved medically necessary home modifications specified in STC 10.2;

b. Capital investments;

c. Room and board outside of specifically enumerated care or housing transitions or beyond 6 months, except as specified in STC 10.2 and 10.3;

d. Research grants and expenditures not related to monitoring and evaluation;

e. Services furnished to beneficiaries for which payment is not available under the inmate payment exclusion in the matter following the last numbered paragraph of section 1905(a) of the Act except case management of HRSN services provided as part of an approved reentry demonstration initiative;

f. Services provided to individuals who are not lawfully present in the United States;

g. Expenditures that supplant services and/or activities funded by other local, state and/or federal governmental entities;

h. General workforce activities, not specifically linked to Medicaid or Medicaid beneficiaries; and

i. Any other projects or activities not specifically approved by CMS as qualifying for demonstration coverage as a HRSN item or service under this demonstration.

    i. For all HRSN housing interventions with room and board, the following setting exclusions apply: Congregate sleeping space, facilities that have been temporarily converted to shelters (e.g., gymnasiums or convention centers), facilities where sleeping spaces are not available to residents 24 hours a day, and facilities without private sleeping space.

10.5. **HRSN Infrastructure.**

a. The state may claim FFP for expenditures for infrastructure investments to support the development and implementation of HRSN services, subject to STC 10.3. This FFP will be available for the following activities:

    i. Technology – e.g., electronic referral systems, shared data platforms, electronic heath record (EHR) modifications or integrations, screening tool and/or case management systems, licensing, databases/data warehouses, data analytics and reporting, data protections and privacy, and accounting and billing systems.

    ii. Development of business or operational practices – e.g., developing policies, procedures and workflows, training and technical assistance, and administrative activities to support or expand HRSN operations.

    iii. Workforce development – e.g., recruiting and hiring, salary and fringe benefits for staff, necessary certifications, cultural competency training, trauma-informed training, developing and training staff on new policies and procedures, and training materials.

iv. Outreach, education, and interested parties convening – e.g., design and production of outreach and education materials, translation, obtaining community input, and interested parties convening and community engagement activities.

b. The state may claim FFP for HRSN infrastructure expenditures for no more than the annual amounts outlined in Table 3. In the event that the state does not claim the full amount of FFP for a given demonstration year, the unspent amounts will roll over to one or more demonstration years, not to exceed this demonstration period and the state may claim the remaining amount in a subsequent demonstration year.

Table 3. Annual Limits of Allowable Total Computable Expenditures for HRSN Infrastructure

	DY 1 CY 2021	DY 2 CY 2022	DY 3 CY 2023	DY 4 CY 2024	DY 5 CY 2025	Total
Total Computable Expenditures	n/a	n/a	n/a	n/a	$6,915,303	$6,915,303

c. Infrastructure expenditures will receive the FFP match for applicable administrative costs for the expenditure.

d. This infrastructure funding is separate and distinct from payments for delivery of HRSN services. The state must ensure that HRSN infrastructure expenditures described in STC 10.5 are not included in HRSN service payments (including capitation payments, as applicable) and that there is no duplication of payments to entities providing or administering HRSN service benefits.

e. The state may not claim any FFP in HRSN infrastructure expenditures until Attachment N: HRSN Infrastructure Protocol is approved, as described in STC 10.9. Once approved, the state can claim FFP in HRSN infrastructure expenditures retrospectively to the beginning of when the demonstration expenditure authority for HRSN infrastructure was approved.

f. To the extent the state requests any additional infrastructure funding, or changes to its scope as described within this STC, it must submit an amendment to the demonstration for CMS's consideration.

10.6. **Covered Populations.** Expenditures for HRSN services may be made for the populations of focus specified in Attachment L, consistent with this STC. To qualify to receive coverage for HRSN services, individuals must be Medicaid (or Medicaid demonstration)-eligible and have a documented medical/clinical need for the services and the services must be determined medically/clinically appropriate, as described STC 10.1, to address the documented need. Medical appropriateness must be based on clinical and health-related social risk factors. This determination must be documented in the beneficiary's care plan or medical record. Additional detail, including the clinical and other health

related-social needs criteria, is outlined in Attachment L. Attachment M, the HRSN Service Matrix, describes the full list of clinical and social risk factors the state anticipates incorporating into Attachment L over the course of the demonstration at the time of the demonstration approval of the expenditure authority for HRSN services. While Attachment M reflects the full list of clinical and social risk factors the state is authorized to implement, the state is not required to implement all of the clinical and social risk factors outlined in Attachment M. Additionally, the state can later include additional clinical and social risk factors in compliance with STC 10.7 and 10.8.

10.7. **Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications for HRSN Services.** The state must submit, for CMS approval, a Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications to CMS no later than 90 days after approval of the HRSN expenditure authority. The protocol must include, as appropriate, a list of the HRSN services and service descriptions, the criteria for defining a medically appropriate population of focus for each service, the process by which those criteria will be applied including care plan requirements and/or other documented processes, and provider qualification criteria for each service. Any changes to the initial scope of clinical and social risk factors reflected in Attachment M must be effectuated through the process indicated in STC 10.8. The state must resubmit a revised protocol if required by CMS feedback on the initial submission. The state may not claim FFP for HRSN services until CMS approves the initial protocol. Once the initial protocol is approved, the state can claim FFP in expenditures for HRSN services retrospectively to the date of approval of the expenditure authority for HRSN services. The approved protocol will be appended to the STCs as Attachment L.

If the state adds new HRSN services beyond those specified in STC 10.2 through a demonstration amendment, the state must also submit revisions to the Protocol to CMS no later than 90 days after the approval of the amendment to the demonstration. The Protocol revisions must include a list of the new services and service descriptions provided through all delivery systems applicable, the criteria for defining a medically appropriate population of focus for each new service, the process by which those criteria will be applied including service plan requirements and/or other documented processes, and provider qualification criteria for each new service. This revised protocol must comply with applicable STCs.

Specifically, the protocol must include the following information:

a. A list of the covered HRSN services (not to exceed those allowed under STC 10.2), with associated service descriptions and service-specific provider qualification requirements.

b. A description of the process for identifying beneficiaries with health-related social needs, including outlining beneficiary qualifications, implementation settings, screening tool selection, and rescreening approach and frequency, as applicable.

c. A description of the process by which clinical criteria will be applied, including a description of the documented process wherein a provider, using their professional judgment, may determine the service to be medically appropriate.

    i. Plan to identify medical appropriateness based on clinical and social risk factors.

    ii. Plan to publicly maintain these clinical and social risk criteria to ensure transparency for beneficiaries and other interested parties.

d. A description of the process for developing care plans based on assessment of need.

    i. Plan to initiate care plans and closed-loop referrals to social services and community providers based on the outcomes of screening.

    ii. Description of how the state will ensure that HRSN screening and service delivery are provided to beneficiaries in ways that are culturally responsive and/or trauma informed, as appropriate.

e. A plan to avoid duplication/displacement of existing food assistance/nutrition services, including how the state will prioritize and wrap around Supplemental Nutrition Assistance Program (SNAP) and/or Women Infants and Children (WIC) enrollment, appropriately adjust HRSN demonstration initiative benefits for individuals also receiving SNAP and/or WIC services, and ensure eligible beneficiaries are enrolled to receive SNAP and/or WIC services.

f. An affirmation that the state agrees to meet the enhanced monitoring and evaluation requirements stipulated in STC 12.6(b) and STC 13.6, which require the state to monitor and evaluate how the renewals of recurring nutrition services under STC 10.3.b affect care utilization and beneficiary physical and mental health outcomes, as well as the cost of providing such services. As required in STCs 12.5 and 13.3, the Monitoring Protocol and Evaluation Design are subject to CMS approval.

10.8. **Updates to the Protocol for Assessment of Beneficiary Eligibility and Needs and Provider Qualifications for HRSN Services:**

a. The state may choose to cover a subset of the HRSN services and/or beneficiary qualifying criteria specified in Attachment's L and M. Certain changes to the state's service offerings and qualifying criteria, within what CMS has approved in Attachments L and M, do not require additional CMS approval. The state must follow the following process to notify CMS of any such HRSN service or qualifying criteria change:

    i. The state must follow the same beneficiary notification procedures as apply in the case of changes to coverage and/or beneficiary service qualification criteria for state plan services, including with respect to beneficiaries who currently qualify for and/or are receiving services who may receive a lesser amount, duration, or scope of coverage as a result of the changes.

ii. The state must provide public notice.

iii. The state must submit a letter to CMS no less than 30 days prior to implementation describing the changes, which will be incorporated in the demonstration's administrative record.

b. In addition to the requirements in a. above, if the state seeks to implement additional clinical and/or social risk factors than what are included in approved Attachment M, the state must follow the process below to update the protocol:

i. The state must provide a budget neutrality analysis demonstrating the state's expected cost for the additional population(s). The state may only add additional clinical and/or social risk factors through the protocol process described in this STC if CMS determines the criteria are allowable and doing so would not require an increase to the amount of the state's HRSN expenditure authority in Table 11.

ii. The state must receive CMS approval for the updated protocol prior to implementation of changes under this STC 10.8(b).

iii. The state is limited to submitting to CMS one update to its protocol per demonstration year as part of this process outlined in this STC 10.8(b). This restriction is not applicable to the process and scope of changes outlined in STC 10.8(a).

10.9. **HRSN Infrastructure Protocol.** The state must submit, for CMS approval, an HRSN Infrastructure Protocol to CMS no later than 90 days after approval of the expenditure authority for HRSN infrastructure expenditures. The protocol must include the state's proposed uses of HRSN infrastructure funds. The state must resubmit the revised protocol as may be required by CMS feedback on the initial submission. The protocol may be updated as details are changed or added. The state may not claim FFP for HRSN infrastructure expenditures until CMS approves the protocol. Once the protocol is approved, the state can claim FFP in HRSN infrastructure expenditures retrospectively to the date of approval of the expenditure authority for HRSN infrastructure. The approved protocol will be appended to the STCs as Attachment N: HRSN Infrastructure Protocol. If the state adds new HRSN services through a demonstration amendment, the state must submit revisions to the Protocol to CMS no later than 90 days after approval, if required based on changes to expenditures for HRSN infrastructure to support the newly added HRSN services. The revisions must include a list of proposed uses of HRSN infrastructure funds, if different than previously submitted.

a. Specifically, the protocol(s) must include the following information: Proposed uses of HRSN infrastructure expenditures, including the type of entities to receive funding, the intended purpose of the funding, the projected expenditure amounts, and an implementation timeline.

10.10. **Service Delivery.** HRSN services will be delivered through the fee-for-service (FFS) delivery system.

a. HRSN services will be paid on a FFS basis when those HRSN services are provided to beneficiaries through the Medicaid FFS.

b. In accordance with STC 10.1, CMS expects the state to have appropriate claims data associated with each HRSN service. This is necessary to ensure appropriate fiscal oversight for HRSN services as well as monitoring and evaluation. This is also critical to ensure appropriate documentation for claims payment. Therefore, CMS requires that, for HRSN services delivered in a FFS delivery system, the state must clearly document the name and definition of each HRSN service as well as the coding used on claims data. For example, the state must note specific Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology codes that identify each HRSN service. CMS will also consider this documentation necessary for approval of any rate methodologies per STC 10.21. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports on the delivery of HRSN services through FFS.

10.11. **Service Delivery.** HRSN services will be provided in the managed care delivery system(s) and delivered by HRSN service providers. Terms applicable to all HRSN services:

a. When HRSN services are provided to beneficiaries enrolled in Medicaid managed care, the following terms will apply:

i. HRSN services can be provided by managed care plans and paid on a non-risk basis and must be appropriately included in contracts. This can be accomplished by either a separate non-risk contract with a prepaid inpatient health plan (PIHP) or a prepaid ambulatory health plan (PAHP) (see the definition of "non-risk contract" at 42 CFR § 438.2) or as an amendment to a state's existing risk-based managed care plan contract to include a non-risk payment. The state must take measures to ensure there is no duplication of payments for either the delivery of such service or the administrative costs of delivering such services.

ii. For a non-risk contract or a non-risk payment, the managed care plan is not at financial risk for changes in utilization or for costs incurred under the contract or payment that do not exceed the upper payment limits specified in 42 CFR 447.362 and may be reimbursed by the state at the end of the contract period on the basis of the incurred costs, subject to the specified limits. For the purposes of this demonstration, fee-for-service as defined in 42 CFR 447.362 is the fee-for-service authorized in this demonstration for HRSN services paid on a fee-for-service basis by the state. The managed care plan contracts must clearly document the process and methodology for non-risk payments.

iii. When the state includes non-risk payments in a risk-based contract, the state must ensure all non-risk payments are separate and apart from risk-based payments and clearly define what services/populations are covered under non-risk payments versus included in risk-based capitation rates. All of the costs of delivering services under a non-risk payment must be excluded from the

development of the risk-based capitation rates for the risk-based contracts. Specifically, the costs of delivery the services as well as any costs of administering the non-risk payment must be excluded from the development of the risk-based capitation rates.

iv. Prior written CMS approval pursuant to STC 10.12 is required before the state moves to incorporate the HRSN services into the risk-based capitation rates in Medicaid managed care. When the state incorporates the HRSN services into the risk-based capitation rates in Medicaid managed care, the state must comply with all applicable federal requirements, including but not limited to 42 CFR 438.4, 438.5, 438.6, and 438.7, and may no longer utilize non-risk payments for the services included in risk-based capitation rates.

v. Any applicable HRSN services that are delivered by managed care plans in a risk arrangement, must be included in the risk-based managed care contracts and rate certifications submitted to CMS for review and approval in accordance with 42 CFR 438.3(a) and 438.7(a).

vi. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports on the inclusion of HRSN services in managed care programs.

vii. All expenditures for HRSN services delivered under non-risk contracts must be excluded from MLR reporting. When HRSN services (i.e., HRSN services defined in STC 10.2 for the covered populations outlined in STC 10.6) are included in capitation rates paid to managed care plans under risk-based contracts, and only then, should HRSN services be reported in the medical loss ratio (MLR) reporting as incurred claims.

viii. The state must develop an MLR monitoring and oversight process specific to HRSN services. This process must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in risk-based managed care contracts and capitation rates. The state should submit this process to CMS at DMCPMLR@cms.hhs.gov. This process must specify how HRSN services will be identified for inclusion in capitation rate setting and in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and infrastructure, as applicable, will be identified and reported in the MLR as non-claims costs.

b. CMS expects the state to have appropriate encounter data associated with each HRSN service. This is necessary to ensure appropriate fiscal oversight for HRSN services as well as monitoring and evaluation. This is also critical to ensure appropriate base data for Medicaid managed care rate development purposes as well as appropriate documentation for claims payment in managed care. Therefore, CMS requires that for HRSN services provided in a managed care delivery system, the state must include the name and definition of each HRSN service as well as the coding to be used on claims and encounter data in the managed care plan contracts. For example, the state must note specific Healthcare Common Procedure Coding

System (HCPCS) or Current Procedural Terminology costs that identify each HRSN service. CMS will also consider this documentation necessary for approval of any rate methodologies per STC 10.21.

10.12. **Requirements for HRSN Services prior to being delivered in risk-based managed care.** The state's plan to incorporate HRSN into risk-based managed care contracts must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in risk-based managed care contracts and capitation rates. At least 6 months prior to moving HRSN services approved under these STCs into risk-based Medicaid managed care contracts, the state must submit to CMS, for review and written prior approval, documentation that details the following information:

a. Each HRSN service defined in STC 10.2 and each covered population that will receive each HRSN service defined in STC 10.6 where the state is seeking CMS written approval to deliver services to populations through one or more risk-based managed care program(s). The applicable managed care program(s) for each service and population should also be specified.

b. If the HRSN service will be offered in all regions under each risk-based managed care program or if the offerings will be limited geographically.

c. The first rating period the state is seeking to start offering the HRSN service(s) through risk-based managed care. If the HRSN services will be delivered through risk-based managed care on a rolling basis, provide the timeline for each service and/or population.

d. The state's timeline to complete a readiness review pursuant to 438.66(d). Implementation may only begin when each managed care plan has been determined by the state to meet certain readiness and network requirements, including providing any documentation specified by CMS.

e. A transition of care plan that provide continuity of care for beneficiaries transitioning from another delivery system (e.g. FFS) or non-risk contracts into risk-based contracts.

f. A description of base data that the state and its actuary plan to use for capitation rate setting process to develop both the benefit and non-benefit costs, including the types of data used (FFS claims data, managed care encounter data, managed care plan financial data, etc.), and the data source(s) that will be used for capitation rate development. Consistent with Medicaid managed care rate development requirements under 42 CFR 438.5(c), CMS requires at least 3 years of encounter data or similar data (e.g. cost reports, claims data) for the HRSN services defined in STC 10.2 for the covered populations defined in STC 10.6 that will be incorporated into risk-based managed care. CMS will consider exceptions to the requirement for 3 years of base data for periods impacted by COVID-19.

g. The methodology the state's actuary will use in the capitation rate setting process. This includes, but is not limited to, any trend factors and adjustments to the data the state and its actuary will apply to the base data in the capitation rate setting process. The methodology should also include information on the approach the actuary will take to incorporating the HRSN service(s) into capitation rate development (for example, if the actuary will create an add-on that will be applied to some or all existing rates cells, creating a separate rate cell, or some other method) and any changes to or new risk adjustments or acuity adjustments applied due to the inclusion of the HRSN services defined in STC 10.2 for the covered populations defined in STC 10.6.

h. If the state is planning to delegate risk for the delivery of HRSN services to clinical providers, community organizations, and/or subcontractors for specific HRSN services, the capitation rate setting plan should include a description of these proposed delegated arrangements and/or sub-capitated payment arrangements that the state intends to use in the delivery of any HRSN services defined in STC 10.2 for covered populations defined in STC 10.6.

i. Identification of any in lieu of services or settings (ILOSs) the state currently offers through its managed care programs and if there will be changes to those ILOSs as a result of the state moving these HRSN service(s) into risk-based managed care contracts.

j. Because of the uncertainty associated with HRSN services and in alignment with past guidance about situations with high levels of uncertainty, CMS is requiring the state to implement a 2-sided risk mitigation strategy (such as a 2-sided risk corridor) to provide protection for state and federal governments, as well as managed care plans. The HRSN capitation rate setting plan should provide a description of the risk mitigation mechanism(s) that will be used in the transition of HRSN services to risk-based managed care. As part of plan to incorporate HRSN into risk-based managed care, the State will also need to develop an MLR monitoring and oversight process specific to HRSN services. This process must specify how HRSN services will be identified for inclusion in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and HRSN infrastructure, as applicable, will be identified and reported by managed care plans as non-claims costs.

k. All state directed payments the state plans to implement for any HRSN services defined in STC 10.2 for the covered populations defined in STC 10.6 that will be provided under risk-based contracts must comply with all applicable federal requirements, including but not limited to 438.6(c). The state should submit information to establish compliance for any state-directed payments for HRSN services to CMS at statedirectedpayment@cms.hhs.gov.

10.13. **Contracted Providers.** Managed care plan contracts must provide, applicable to all HRSN services:

a. Managed care plans will contract with providers to deliver the HRSN services authorized under the demonstration and included in the managed care contract.

b. Managed care plans must establish a network of providers and ensure the HRSN service providers have sufficient experience and training in the provision of the HRSN services being offered. HRSN service providers do not need to be licensed, however, staff offering services through HRSN service providers must be licensed when applicable (i.e., when the staff member is performing activities for which a licensure requirement applies in the state).

c. The managed care plan and contracted providers will use rates set by the state for the provision of applicable HRSN services, consistent with state guidance for these services, and in compliance with all related federal requirements. Any state direction of managed care plan expenditures under risk-based contract(s) and risk-based payments would be considered a state directed payment subject to the requirements in 42 CFR 438.6(c).

10.14. **Provider Network Capacity.** Managed care plan contracts must ensure the HRSN services authorized under the demonstration are provided to qualifying beneficiaries in a timely manner and shall develop policies and procedures outlining the managed care plan's approach to managing provider shortages or other barriers to timely provision of the HRSN services, in accordance with the managed care plan contracts and other state Medicaid/operating agency guidance.

10.15. **Compliance with Federal Requirements.** The state shall ensure HRSN services are delivered in accordance with all applicable federal statutes and regulation.

10.16. **Person Centered Plan.** The state shall ensure there is a person-centered service plan for each beneficiary receiving HRSN services that is person-centered, identifies the beneficiary's needs and individualized strategies and interventions for meeting those needs, and developed in consultation with the beneficiary and the beneficiary's chosen support network, as appropriate. The service plan must be reviewed and revised as appropriate at least every 12 months, when the beneficiary's circumstances or needs change significantly, or at the beneficiary's request.

10.17. **Conflict of Interest.** The state shall ensure appropriate protections against conflicts of interest in HRSN service planning and delivery, including by ensuring that appropriate separation of service planning and service provision functions is incorporated into the state's conflict of interest policies.

10.18. **CMS Approval of Managed Care Contracts.** As part of the state's submission of associated managed care plan contracts to implement HRSN services through managed care, the state must include contract requirements including, but not limited to:

a. Beneficiary and plan protections, including but not limited to:

i. HRSN services must not be used to reduce, discourage, or jeopardize beneficiaries' access to covered services.

ii. Beneficiaries always retain their right to receive covered service on the same terms as would apply if HRSN services were not an option.

iii. Beneficiaries who are offered or who utilize an HRSN service retain all rights and protections afforded under 42 CFR Part 438.

iv. Managed care plans are not permitted to deny a beneficiary a covered service on the basis that the beneficiary is currently receiving HRSN services, has requested those services, has previously qualified for or received those services, or currently qualifies or may qualify in the future for those services.

v. Managed care plans are prohibited from requiring a beneficiary to receive HRSN services.

b. Managed care plans must timely submit data requested by the state or CMS, including, but not limited to:

i. Data to evaluate the utilization and effectiveness of the HRSN services.

ii. Any data necessary to monitor health outcomes and quality of care metrics at the individual and aggregate level through encounter data and supplemental reporting on health outcomes and equity of care. When possible, metrics must be stratified by age, sex (including sexual orientation and gender identify), race, ethnicity, disability status and preferred language to inform health quality improvement efforts, which may thereby mitigate health disparities.

iii. Any data necessary to monitor appeals and grievances for beneficiaries.

iv. Documentation to ensure appropriate clinical support for the medical appropriateness of HRSN services.

v. Any data determined necessary by the state or CMS to monitor and oversee the HRSN services initiative.

c. All data and related documentation necessary to monitor and evaluate the HRSN services initiative, including cost assessment, including but not limited to:

i. The managed care plans must submit timely and accurate encounter data to the state for beneficiaries who qualify for HRSN services. When possible, these encounter data must include data necessary for the state to stratify analyses by age, sex (including sexual orientation and gender identity), race, ethnicity, disability status and preferred language to inform health quality improvement efforts and subsequent efforts to mitigate health disparities undertaken by the state.

ii. Any additional information requested by CMS, the state, or another legally authorized oversight body to aid in ongoing evaluation of the HRSN services

initiative or any independent assessment or analysis conducted by the state, CMS, or another legally authorized entity.

iii. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports its progress in building and sustaining its partnership with existing housing agencies and nutrition agencies to utilize their expertise and existing housing and nutrition resources and to avoid duplication of efforts.

iv. Any additional information determined reasonable, appropriate and necessary by CMS.

10.19. **HRSN Rate Methodologies.** For FFS payment methodologies and/or rates, the state must comply with the payment rate-setting requirements in 42 CFR Part 447, as though a state plan amendment were required, to establish any payment rate and/or methodology for HRSN services as approved under (demonstration expenditure authority 2). The state must conduct state-level public notice under 42 CFR 447.205 prior to the implementation of the applicable FFS payment rates or methodologies for HRSN and maintain documentation of these FFP payment rates or methodologies on its website described in 42 CFR 447.203. The state may receive FFP for HRSN service expenditures authorized under this demonstration upon implementation of the FFS payment rates and/or methodologies for which it has conducted prior public notice and may begin claiming for this FFP (for dates of service no earlier than the effective date of approval for the relevant expenditure authority) no earlier than the date of submission of the payment rates and/or methodology to CMS for approval. However, any FFS payments to providers or claims for FFP prior to CMS approval of the payment rate or methodology must be reconciled to the ultimately approved FFS payment rate and/or methodology within one year of CMS's approval. All requirements for timely filing of claims for FFP continue to apply.

a. For managed care payments and rates (including capitation rates, non-risk payments, and state directed payments), the state must comply with all federal requirements, including those in 42 CFR Part 438 and these STCs. As applicable, the state must also notify CMS at least 60 days prior to intended implementation if it intends to direct its managed care plans on how to pay for HRSN services (i.e., state directed payments).

b. All rates/payment methodologies for HRSN services, for both FFS and managed care delivery systems, must be submitted to CMS for review and approval, including but not limited to fee-for-service payments as well as managed care capitation rates, any state directed payments that require prior written approval, and non-risk payments, as outlined in the STCs. For all payment methodologies and/or rates, for both FFS and managed care delivery systems, in addition to submitting the payment rates and/or methodology, the state must also submit all supporting documentation requested by CMS, including but not limited to how the rates and/or methodology were developed, state responses to any public comments on the rates and/or methodology (when applicable), and information about Medicaid non-federal share financing.

10.20. **Maintenance of Effort (MOE).** The state must maintain a baseline level of state funding for ongoing social services related to housing and housing transition supports and nutrition supports for the duration of the demonstration, not including one-time or non-recurring funding. Within 90 days of demonstration approval, the state will submit a plan to CMS as part of the HRSN Implementation Plan required by STC 10.22 that specifies how the state will determine baseline spending on these services throughout the state. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 12.6 with any justifications, including declines in available state resources, necessary to describe the findings, if the level of state funding is less than the comparable amount of the pre-demonstration baseline.

10.21. **Partnerships with State and Local Entities.** To ensure that expenditures for HRSN services under this demonstration do not supplant any other available funding sources available to the beneficiary through other local, state, or federal programs, the state must have in place partnerships with other state and local entities (e.g., HUD Continuum of Care Program, local housing authorities) to assist beneficiaries in obtaining non-Medicaid funded housing supports, if available, upon the conclusion of temporary demonstration payment for such supports, in alignment with beneficiary needs identified in the beneficiary's care plan, as appropriate. The state will submit a plan to CMS as part of the HRSN Implementation Plan that outlines how it will put into place the necessary arrangements with other state and local entities and also work with those entities to assist beneficiaries in obtaining available non-Medicaid funded housing and/or nutrition supports upon conclusion of temporary Medicaid payment as stated above. The plan must provide a timeline for the activities outlined. As part of the Monitoring Reports described in STC 12.6, the state will provide the status of the state's fulfillment of its plan and progress relative to the timeline, and whether and to what extent the non-Medicaid funded supports are being accessed by beneficiaries as planned. Once the state's plan is fully implemented, the state may conclude its status updates in the Monitoring Reports.

10.22. **HRSN Implementation Plan**

a. The state is required to submit a HRSN Implementation Plan that will elaborate upon and further specify requirements for the provision of HRSN services and will be expected to provide additional details not captured in the STCs regarding implementation of demonstration policies that are outlined in the STCs. The state must submit the MOE information required by (STC 10.19) no later than 90 calendar days after approval of demonstration expenditure authority for HRSN services. All other Implementation Plan requirements outlined in this STC must be submitted no later than 9 months after the approval of demonstration expenditure authority for HRSN services. The Implementation Plan shall be submitted to CMS but does not require CMS approval. CMS will ensure it is complete and contains sufficient detail for purposes of on-going monitoring. The state may update the implementation plan as initiatives are changed or added, with notification to CMS. The Implementation Plan will be appended as Attachment O.

b. At a minimum, the Implementation Plan must provide a description of the state's strategic approach to implementing the policy, including timelines for meeting critical implementation stages or milestones, as applicable, to support successful implementation. The Implementation Plan does not need to repeat any information submitted to CMS under the Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for HRSN services; however, as applicable, the information provided in the two deliverables must be aligned and consistent.

c. The Implementation Plan must include information on, but not limited to, the following:

    i. A plan for establishing and/or improving data sharing and partnerships with an array of health system and social services interested parties to the extent those entities are vital to provide needed administrative and HRSN-related data on screenings, referrals, and provision of services, which are critical for understanding program implementation and conducting demonstration monitoring and evaluation;

    ii. Information about key partnerships related to HRSN service delivery, including plans for capacity building for community partners and for soliciting and incorporating input from impacted groups (e.g., community partners, health care delivery system partners, and beneficiaries);

    iii. Plans for changes to IT infrastructure that will support HRSN-related data exchange, including development and implementation of data systems necessary to support program implementation, monitoring, and evaluation. These existing or new data systems should, at a minimum, collect data on beneficiary characteristics, qualification and consent to receive HRSN services, screening, referrals, and service provision;

    iv. A plan for tracking and improving the share of demonstration beneficiaries in the state who are eligible and enrolled in SNAP, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), Temporary Assistance for Needy Families (TANF), and/or federal, state, and local housing and/or other nutrition assistance programs, relative to the number of total eligible demonstration beneficiaries in the state (including those who are eligible but unenrolled);

    v. An implementation timeline and considerations for demonstration evaluation that may be impacted by the timeline (e.g., in the case of a phased rollout of HRSN services), to facilitate robust evaluation designs;

    vi. Information as required per STC 10.19 (MOE); and

    vii. Information as required per STC 10.20 (Partnerships with State and Local Entities).

11. MONITORING AND REPORTING REQUIREMENTS

11.1. **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.

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

11.3. **Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs, unless CMS and the state mutually agree to another timeline.

11.4. **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.

11.5. **Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after the approval of the demonstration amendment. The state must submit a revised Monitoring Protocol within 60 calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated in the STCs as Attachment K. In addition, as applicable, the state must submit an updated or a separate Monitoring Protocol for any amendments to the demonstration no later than 150 calendar days after the approval of the corresponding amendment. Such amendment Monitoring Protocols are subject to the same requirement of revisions and CMS approval, as described above.

At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, as applicable and relevant for different policies. Any proposed deviations from CMS's guidance should be documented in the Monitoring Protocol. The Monitoring Protocol must describe the quantitative and qualitative elements on which the state will report through Quarterly and Annual Monitoring Reports. For the overall demonstration as well as specific policies

where CMS provides states with a suite of quantitative monitoring metrics (e.g., those described under the performance metrics section in STC 12.6(b), the state is required to calculate and report such metrics leveraging the technical specifications provided by CMS, as applicable. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography) and demonstration component.

For the SMI/SED initiative authorized through this demonstration amendment, the Monitoring Protocol requires three components:

a. An assurance of the state's commitment and ability to report information relevant to each of the initiative implementation areas listed in STC 5.2, along with reporting information relevant to the state's SMI/SED Financing Plan described in Attachment F, and information relevant to the state's Health IT Plan(s) described in STC 5.2;

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 STC 12.6 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.

For the HRSN services and the reentry initiative authorized through this demonstration amendment, the Monitoring Protocol requires specifying a selection of quality of care and health outcomes metrics and population stratifications based on CMS's upcoming guidance on the Disparities Sensitive Measure Set, and outlining the corresponding data sources and reporting timelines, as applicable to the demonstration initiatives and populations. This set of measures consists of metrics known to be important for addressing disparities in Medicaid/CHIP (e.g., the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizes key outcome measures and their clinical and non-clinical (i.e., social) drivers. The Monitoring Protocol must also outline the state's planned approaches and parameters to track implementation progress and performance relative to the goals and milestones, as provided in the HRSN Infrastructure Protocol and Implementation Plan.

The state will also be expected to set up its HRSN service delivery system to allow screening of beneficiaries for identified needs, and to develop an appropriate closed-loop referral system or other feedback loop to ensure beneficiaries receive service referrals and provisions, and provide any applicable update on this process via the Monitoring Reports, in alignment with information provided in the Monitoring Protocol.

In addition, the state must describe in the Monitoring Protocol methods and the timeline to

collect and analyze relevant non-Medicaid administrative data to help calculate applicable monitoring metrics. These sources may include but are not limited to data related to carceral status, Medicaid eligibility, and the health care needs of individuals who are incarcerated and returning to the community. Across data sources, the state must make efforts to consult with relevant non-Medicaid agencies to collect and use data in ways that support analyses of data on demonstration beneficiaries and subgroups of beneficiaries, in accordance with all applicable requirements concerning privacy and the protection of personal information.

For the qualitative elements (e.g., operational updates as described in STC 12.6(a), CMS will provide the state with guidance on narrative and descriptive information, which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's Quarterly and Annual Monitoring Reports.

11.6. **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 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 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, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. **Performance Metrics.** Per applicable CMS guidance and technical assistance, the performance metrics will provide data to demonstrate how the state is progressing toward meeting the goals and milestones – including relative to their projected timelines – of the demonstration's program and policy implementation and infrastructure investments, and transitional non-service expenditures, as applicable and must cover all key policies under this demonstration. Additionally, per 42 CFR

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

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

i. For the SUD and/or SMI/SED component(s), the state's monitoring must align with the CMS approved SUD and/or SMI/SED Monitoring Protocol(s) (see STC 12.5) and will cover metrics in alignment with assessment of need and qualification for SUD and/or SMI/SED treatment services and the demonstration's milestones as outlined in the SUD State Medicaid Director Letter (SMDL) Dated November 1, 2017 (SMDL #17-003) and/or SMI SMDL dated November 13, 2018 (SMDL #18-011).

ii. For the continuous eligibility policy, monitoring metrics must support tracking enrollment and ex parte renewals. The state must describe successes and challenges related to annual attempts to update beneficiary contact information, provide reminders of continued eligibility, verify residency, and confirm the beneficiary is not deceased, for all beneficiaries who qualify for a continuous eligibility period that exceeds 12 months.

iii. For HRSN components, in addition to reporting on the metrics described above, the state must track beneficiary participation, screening, receipt of referrals and social services over time, as well as narratively report on the adoption of information technology infrastructure to support data sharing between the state or partner entities assisting in the administration of the demonstration and social services organizations, and the contracted providers of applicable services (e.g., managed care plans and their contracted HRSN providers). In alignment with STC 10.14 the state must additionally monitor and provide narrative updates on its progress in building and sustaining its partnership with existing housing agencies, leverage their expertise and existing housing resources instead of duplicating services. Furthermore, the state's enrollment and renewal metrics must also capture baseline data and

track progress via Monitoring Reports for the percent of Medicaid renewals completed ex parte (administratively), as well as the percentage of Medicaid beneficiaries enrolled in other public benefit programs (such as SNAP and WIC) for which they are eligible. The Monitoring Reports must also provide status updates in accordance with the Monitoring Protocol on the implementation of infrastructure investments tied to the HRSN initiatives.

iv. The state's selection and reporting of quality of care and health outcome metrics outlined above must also accommodate the Reentry Demonstration Initiative. In addition, the state is required to report on metrics aligned with tracking progress with implementation and toward meeting the milestones of the Reentry Demonstration Initiative. CMS expects such metrics to include, but not be limited to: administration of screenings to identify individuals who qualify for pre-release services, utilization of applicable pre-release and post-release services as defined in STC 10.9, provision of health or social service referral pre-release, participants who received case management pre-release and were enrolled in case management post-release, and take-up of data system enhancements among participating correctional facility settings. In addition, the state is expected to monitor the number of individuals served and types of services rendered under the demonstration. Also, in alignment with the state's Reentry Initiative Implementation Plan, the state must also provide in its Monitoring Reports narrative details outlining its progress with implementing the initiative, including any challenges encountered and how the state has addressed them or plans to address them. This information must also capture the transitional, non-service expenditures, including enhancements in the data infrastructure and information technology.

v. As applicable, if the state, health plans, or health care providers will contract or partner with organizations to implement the demonstration, the state must use monitoring metrics that track the number and characteristics of contracted or participating organizations in specific demonstration programs and corresponding payment-related metrics; these metrics are specifically relevant for the state's HRSN initiatives.

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

d. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of

evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

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

11.7. **SUD Mid-Point Assessment.** The state must conduct an independent mid-point assessment by July 1, 2023. 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 MCOs, RAEs, 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 July 1, 2023. 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 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 Plans 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.

11.8. **SMI/SED Mid-Point Assessment.** The state must contract with an independent entity to conduct an independent Mid-Point Assessment by the end of the third full year of the

program approval. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of demonstration initiative data, accounting for data run-out and data completeness. If the demonstration is not extended or is extended for a term that ends on or before this date, then this Mid-Point Assessment must address the entire term for which the SMI/SED initiative under this demonstration was authorized as is possible given the necessary time for metrics calculation. In the design, planning and conduct of the Mid-Point Assessment, the state must require that the independent assessor consult with key interested parties including, but not limited to: representatives of managed care organizations (MCOs), health care providers (including SMI/SED treatment providers), and beneficiaries, community groups, and other key partners.

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

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

Elements of the Mid-Point Assessment must include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SMI/SED Implementation Plan, the SMI/SED Financing Plan, if applicable, and toward meeting the targets for performance metrics as approved in the SMI/SED Monitoring Protocol;

b. A determination of factors that affected achievement on the milestones and performance metric 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 identified by the independent assessor as at medium to high risk of not being met, recommendations for adjustments in the state's SMI/SED Implementation Plans and/or SMI/SED Financing Plan or to other 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 SMI/SED budget neutrality requirements in these STCs.

11.9. **Reentry Demonstration Initiative Mid-Point Assessment.** The state must contract with an independent entity to conduct a mid-point assessment of the Reentry Demonstration Initiative and complete a Reentry Demonstration Initiative Mid-Point Assessment by the end of the third full year of the program approval. The state must provide a copy of the report to CMS no later than 60 calendar days after third full year of the program approval.

The Mid-Point Assessment must integrate all applicable implementation and performance data from the first 2.5 years of implementation of the Reentry Demonstration Initiative. In the event that the Reentry Demonstration Initiative is implemented at a timeline within the demonstration approval period to not enable capturing 2.5 years of data, the state and CMS will agree to an alternative timeline for submission of the Mid-Point Assessment. The state must submit a revised Mid-Point Assessment within 60 calendar days after receipt of CMS's comments, if any. If requested, the state must brief CMS on the report.

The Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies used, the findings on demonstration progress and performance, including identifying any risks of not meeting milestones and other operational vulnerabilities, and recommendations for overcoming those challenges and vulnerabilities. In the design, planning, and execution of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: provider participation in the state's Reentry Demonstration Initiative, eligible individuals, and other key partners in correctional facility and community settings.

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

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

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

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

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

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

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

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

11.11. **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. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 13.7 and 13.8, respectively.

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

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

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

f. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 12.1.

11.12. **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.

11.13. **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 Report.

12. EVALUATION OF THE DEMONSTRATION

12.1. **Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state's participation—including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable—in a federal learning collaborative aimed at cross state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring, and evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 12.1.

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

12.3. **Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) calendar days after the approval of the demonstration amendment. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs, and any applicable evaluation guidance and technical assistance for the demonstration's policy components. The draft Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic)—as these implementation strategies help create strong comparison groups and facilitate robust evaluation.

The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 13.7 and 13.8.

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

12.4. **Evaluation Budget.** A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations 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 designs are not sufficiently developed, or if the estimates appear to be excessive.

12.5. **Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design*s*, 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 designs 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 designs, 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.

12.6. **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 deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

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

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with the various demonstration policy components, including but not limited to the HRSN demonstration components, the continuous eligibility demonstration components, housing related support services, premiums, the waiver of retroactive eligibility; the reentry demonstration initiative, and beneficiary experiences with access to and quality of care In addition, the state is strongly encouraged to evaluate the implementation of the demonstration components in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. Implementation research questions can also focus

on beneficiary and provider experience with the demonstration. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

Hypotheses must cover all policies and goals of the demonstration and should be crafted not only to evaluate whether overall demonstration goals were achieved but also the extent to which each component contributed to outcomes. Where demonstration components offer tailored service to specific populations, evaluation hypotheses must include an assessment of whether these programs improved quality of care outcomes and access to health care for the targeted population while also promoting the desired administrative and fiscal efficiencies.

a. The state must assess the objectives of the SUD component of this section 1115 demonstration. Examples include (but are not limited to): initiation and compliance with treatment, utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes, such as deaths due to overdose.

b. The state must assess the objectives of the SMI/SED component of this 1115 demonstration. Examples include (but are not limited to): utilization and length of stay in emergency departments, reductions in preventable readmissions to acute care hospitals and residential settings, availability of crisis stabilization services, and care coordination.

c. For the continuous eligibility policy, the state must evaluate the impact of the policy on all relevant populations, appropriately tailored for the specific time span of eligibility. Evaluation hypotheses must focus on, but may not be limited to, enrollment continuity, utilization of age-appropriate preventive care, inpatient admissions and avoidable emergency care, and health disparities.

d. Evaluation hypotheses for the HRSN demonstration components must focus on areas such as assessing the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such assessment is expected to use applicable demonstration monitoring and other data on prevalence and severity of beneficiaries' HRSNs and the provision of beneficiary utilization of HRSN services. Furthermore, the HRSN evaluation must include analysis of how the initiatives affect utilization of preventive and routine care; utilization of and costs associated with potentially avoidable, high-acuity health care; utilization of hospital and institutional care; and beneficiary physical and mental health outcomes.

   In addition, the state must coordinate with its managed care plans to secure necessary data—for a representative beneficiary population eligible for the HRSN services—to conduct a robust evaluation of the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such an assessment will require setting up a data infrastructure and/or data sharing arrangement to collect data on beneficiary screening and rescreening and prevalence and severity of beneficiaries'

HRSNs, among others. If the data system is not operational to capture necessary data for a quantitative evaluation by the time the state's evaluation activities must be conducted, the state must provide applicable qualitative assessment to this effect leveraging suitable primary data collections efforts (e.g., beneficiary surveys).

Hypotheses must be designed to help understand, in particular, the impacts of housing and/or nutrition on beneficiary health outcomes and experience. More specifically, the evaluation must analyze—among other outcomes—health care utilization and access for individuals in the HRSN demonstration components. In alignment with the demonstration's objectives to improve outcomes for the state's overall beneficiary populations eligible for the HRSN initiatives, the state must also include research questions and hypotheses focused on understanding the impact of the HRSN initiatives on advancing health quality, including through the reduction of health disparities, for example, by assessing the effects of the initiatives in reducing disparities in health care access to and quality of care, or health outcomes at the individual, population, and/or community level.

The evaluation must also assess the effectiveness of the infrastructure investments authorized through the demonstration to support the development and implementation of the HRSN initiatives. The state must also examine whether and how local investments in housing and nutrition services change over time in concert with new Medicaid funding toward those services. In addition, in light of how demonstration HRSN expenditures are being treated for purposes of budget neutrality, the evaluation of the HRSN initiative must include a cost analysis to support developing comprehensive and accurate cost estimates of providing such services. Evaluation of the HRSN initiative is also required to include a robust assessment of potential improvements in the quality and effectiveness of downstream services that can be provided under the state plan authority, and associated cost implications.

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

   The state must also provide a comprehensive analysis of the distribution of services rendered by type of service over the duration of up to 90-days coverage period before the individual's expected date of release—to the extent feasible—and discuss in the evaluation any relationship identified between the provision and timing of particular services with salient post-release outcomes, including: utilization of acute

care services for chronic and other serious conditions, overdose, and overdose- and suicide-related and all-cause deaths in the period soon after release. In addition, the state is expected to assess the extent to which this coverage timeline facilitated providing more coordinated, efficient, and effective reentry planning; enabled pre-release management and stabilization of clinical, physical, and behavioral health conditions; and helped mitigate any potential operational challenges the state might have otherwise encountered in a more compressed timeline for coverage of pre-release services.

The demonstration's evaluation efforts will be expected to include the experiences of correctional and community providers, including challenges encountered, as they develop relationships and coordinate to facilitate transition of individuals into the community. Finally, the state must conduct a comprehensive cost analysis to support developing estimates of implementing the Reentry Demonstration Initiative, including covering associated services.

f. As part of its evaluation efforts, the state must conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation, Medicaid health services expenditures, and provider uncompensated care costs. The state must analyze the budgetary effects of the HRSN and reentry initiatives. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

   Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes, and help inform how the demonstration's various policies might support reducing such disparities.

12.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for each evaluation design, as applicable, and 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 Reports 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 extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. If the state is not requesting an extension for the demonstration, the draft Interim Evaluation Report is due one (1) year prior to the end of the demonstration.

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

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

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

12.8. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs. The state must submit the 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 the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.

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

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

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

12.11. **Public Access**. The state shall post the final documents (e.g., Implementation Plans, Monitoring Protocols, Monitoring Reports, Mid-Point Assessments, Close Out Report, the approved Evaluation Designs, Interim Evaluation Reports, and Summative Evaluation Reports) on the state's website within thirty (30) calendar days of approval by CMS.

12.12. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given 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.

13. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

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

13.2. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures 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 matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 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.

13.3. **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 for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 15:

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13.8. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 12.1. This report must include:

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

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

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

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

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

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

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

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

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

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

Table 4: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
SUD IMD Legacy	Hypo 1	X		X	Expenditures for medical assistance provided during an SUD IMD month for non-Expansion beneficiaries.
SUD IMD Expansion	Hypo 1	X		X	Expenditures for medical assistance provided during an SUD IMD month for Adult Group/Expansion beneficiaries.
CE – Children Under 3	Hypo 2	X		X	All expenditures for continued benefits for children who have been determined eligible for the continuous eligibility period who would otherwise lose coverage during an eligibility determination
CE – Formerly Incarcerated Youth	Hypo 2	X		X	All expenditures for continued benefits for beneficiaries leaving incarceration in the youth group during the continuous eligibility period and who would otherwise lose coverage during an eligibility determination
CE – Formerly Incarcerated Non-Expansion	Hypo 2	X		X	All expenditures for continued benefits for beneficiaries leaving incarceration in the non-expansion adult group during the continuous

Table 4: Master MEG Chart					
MEG	**To Which BN Test Does This Apply?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
Adults					eligibility period and who would otherwise lose coverage during an eligibility determination
CE – Formerly Incarcerated Expansion Adults	Hypo 2	X		X	All expenditures for continued benefits for beneficiaries leaving incarceration in the expansion adult group during the continuous eligibility period and who would otherwise lose coverage during an eligibility determination
SMI/SED IMD Legacy	Hypo 3	X		X	Expenditures for medical assistance provided during an SMI/SED IMD month for non-Expansion beneficiaries.
SMI/SED IMD Expansion	Hypo 3	X		X	Expenditures for medical assistance provided during an SMI/SED IMD month for Adult Group/Expansion beneficiaries.
Reentry Services	Hypo 4	X		X	Expenditures for reentry services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 90 days immediately prior to release from participating facilities.
Reentry Non-Services	Hypo 4		X	X	Expenditures for allowable planning and non-services for the reentry demonstration initiative.
HRSN Services	Capped Hypo		X	X	All expenditures for certain HRSN initiatives.
HRSN Infrastructure	Capped Hypo		X	X	All infrastructure expenditures for certain HRSN initiatives.

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

13.11. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00339/10). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

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

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

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

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table and in the STCs in section 15, 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 12, 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.

i. For CE MEGs, states will report a calculated number, or percentage, of the actual member months and expenditures of the corresponding non-CE MEG. As applicable, the corresponding non-CE MEG member months and expenditures will then be reduced by the same percentage. For the Children CE MEGs, this percentage will be 0.11 percent. For Formerly Incarcerated Non-Expansion Adults and Expansion Adults CE MEGs, this percentage will be 2.6 percent. For example, the actual member months and expenditures for the Formerly Incarcerated Non-Expansion Adults in the All Adults MEG will be reduced by 2.6 percent and the equivalent member months and expenditures will be reported on the CE Non- Expansion Adults MEG so that the total calculated member months and expenditures between the two MEGs are equal to the actual member months and expenditures for the Non-Expansion Adults group.

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 5: 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**
SUD IMD Legacy	Non- expansion adult Medicaid beneficiaries diagnosed with a SUD	See STC 5.5	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025
SUD IMD Expansion	Expansion adult Medicaid beneficiaries diagnosed with a SUD	See STC 5.5	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025
CE – Children Under 3	Children who are eligible via CE, equaling 0.11% of total Medicaid expenditure for Children 0- 3		Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 0.11% of total member months for children aged 0-3	11/14/2024	12/31/2025
CE – Formerly Incarcerated Youth	Formerly incarcerated youth who are eligible via CE, equaling 2.6% of total Medicaid expenditure for formerly incarcerated youth		Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 2.6% of total member months for formerly incarcerated Youth	11/14/2024	12/31/2025

Table 5: 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**
CE – Formerly Incarcerated Non-Expansion Adults	Formerly incarcerated Non- Expansion Adults who are eligible via CE, equaling 2.6% of total Medicaid expenditure for formerly incarcerated Non- Expansion Adults		Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 2.6% of total member months for formerly incarcerated Youth	11/14/2024	12/31/2025
CE – Formerly Incarcerated Expansion Adults	Formerly incarcerated ACA Expansion Adults who are eligible via CE, equaling 2.6% of total Medicaid expenditure for formerly incarcerated Expansion Adults		Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y – 2.6% of total member months for formerly incarcerated Expansion adults	11/14/2024	12/31/2025
SMI/SED IMD Legacy	Expenditures for medical assistance provided during an SMI/SED IMD month for non-Expansion beneficiaries.	STC 8.5	Follow CMS-64.9 Based Category of Service Definition	Date of Service	MAP	Y	01/13/2025	12/31/2025

Table 5: 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**
SMI/SED IMD Expansion	Expenditures for medical assistance provided during an SMI/SED IMD month for Expansion beneficiaries	STC 8.5	Follow CMS-64.9 Based Category of Service Definition	Date of Service	MAP	Y	01/13/2025	12/31/2025
Reentry Services	Expenditures for reentry services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 90 days immediately prior to release from participating facilities.	STC 8.5	Follow CMS-64.9 Based Category of Service Definition	Date of Service	MAP	Y	01/13/2025	12/31/2025
Reentry Non-Services	Expenditures for allowable planning and non-services for the reentry demonstration initiative.	None	Follow CMS-Based Category of Service Definition	Date of payment	ADM	N	01/13/2025	12/31/2025

Table 5: 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**
HRSN Services	Report all expenditures for approved HRSN initiatives	None	Follow standard CMS 64.9 or 64.10 Category of Service Definitions	Date of service/Date of payment	MAP/ ADM	N	01/13/2025	12/31/2025
HRSN Infrastructure	Report all infrastructure expenditures for approved HRSN initiatives	None	Follow standard CMS 64.10 Category of Service Definitions	Date of service/Date of payment	ADM	N	01/13/2025	12/31/2025

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

Table 6: Demonstration Years		
Demonstration Year 1	January 1, 2021 to December 31, 2021	12 months
Demonstration Year 2	January 1, 2022 to December 31, 2022	12 months
Demonstration Year 3	January 1, 2023 to December 31, 2023	12 months
Demonstration Year 4	January 1, 2024 to December 31, 2024	12 months
Demonstration Year 5	January 1, 2025 to December 31, 2025	12 months

13.13. **Calculating the Federal Medical Assistance Percentage (FMAP) for Continuous Eligibility for the Adult Group**: Because not all "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) would be eligible for the entire continuous eligibility period if the state conducted redeterminations, CMS has determined that 97.4 percent of expenditures for individuals defined in 42 CFR 433.204(a)(1) will be matched at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6) and 2.6 percent will be matched at the state's regular title XIX FMAP rate.

13.14. **State Reporting for the Continuous Eligibility FMAP Adjustment**: 97.4 percent of expenditures for "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) shall be claimed at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6), unless otherwise adjusted as described in STC 62 above. The state must make adjustments on the applicable CMS-64 waiver forms to claim the remaining 2.6 percent or other applicable percentage of expenditures for individuals defined in 42 CFR 433.204(a)(1) at the state's regular title XIX FMAP rate.

13.15. **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 15. CMS will provide technical assistance, upon request.[4]

[4] Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS'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

13.16. **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.

13.17. **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.

13.18. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are

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the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 14.18(c). If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

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

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

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

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

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

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

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

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

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

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

14. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

14.1. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of a Main Budget Neutrality Test, one or more Hypothetical Budget Neutrality Tests, and a Supplemental HRSN Aggregate Ceiling (SHAC) Test, if applicable, 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.

14.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 4, Master MEG Chart and Table 5 MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

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

14.4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests, including "capped hypotheticals". Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

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

14.6. **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 7: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend Rate	DY 1 CY 2021	DY 2 CY 2022	DY 3 CY 2023	DY 4 CY 2024	DY 5 CY 2025
Legacy SUD IMD	PC	Both	4.9%	$2,421	$2,539	$2,664	$2,794	$2,931

Expansion SUD IMD	PC	Both	5.6%	$2,199	$2,322	$2,452	$2,589	$2,734

14.7. **Hypothetical Budget Neutrality Test 2: Continuous Eligibility**: The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditure in excess of the limit from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 8: Hypothetical Budget Neutrality Test 2

MEG	PC or AGG	WOW Only, WW Only, or Both	Trend Rate	DY 1 CY 2021	DY 2 CY 2022	DY 3 CY 2023	DY 4 CY 2024	DY 5 CY 2025
CE – Children Under 3	PC	Both	5.1%	$0	$0	$0	$0	$336.69
CE - Formerly incarcerated Youth	PC	Both	5.2%	$0	$ 0	$ 0	$ 0	$1,224.55
CE - Formerly incarcerated aged Non-Expansion Adults	PC	Both	5.2%	$0	$0	$0	$0	$1,758.74
CE - Formerly incarcerated Expansion Adults	PC	Both	5.6%	$0	$0	$0	$0	$1,675.89

14.8. **Hypothetical Budget Neutrality Test 3: SMI/SED Expenditures.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.”

MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 3 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 9: Hypothetical Budget Neutrality Test 3								
MEG	**PC or Agg**	**WOW Only, WW Only, or Both**	**Trend Rate**	**DY 1 CY 2021**	**DY 2 CY 2022**	**DY 3 CY 2023**	**DY 4 CY 2024**	**DY 5 CY 2025**
SMI/SED IMD Legacy	PC	Both	7.9%	n/a	n/a	n/a	n/a	$3,757
SMI/SED IMD Expansion	PC	Both	5.3%	n/a	n/a	n/a	n/a	$3,446

14.9. **Hypothetical Budget Neutrality Test 4: Reentry Demonstration Initiative Expenditures.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 4. 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 4 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 10: Hypothetical Budget Neutrality Test 4							
MEG	**PC or Agg**	**WOW Only, WW Only, or Both**	**DY 1 CY 2021**	**DY 2 CY 2022**	**DY 3 CY 2023**	**DY 4 CY 2024**	**DY 5 CY 2025**
Reentry Services	PC	Both	n/a	n/a	n/a	n/a	$882.96
Reentry Non-Services	Agg	Both	n/a	n/a	n/a	n/a	$4,400,000

14.10. **Capped Hypothetical Budget Neutrality for Evidence-Based HRSN Initiatives.** When expenditure authority is provided for specified HRSN initiatives in the demonstration (in

this approval, as specified in section 10), CMS considers these expenditures to be "capped hypothetical" expenditures; that is, the expenditures are eligible to receive FFP up to a specific aggregate spending cap per demonstration year, based on the state's expected expenditures. States can also receive FFP for capacity-building, infrastructure, and operational costs for the HRSN initiatives; this FFP is limited by a sub-cap of the aggregate spending cap and is determined by CMS based on the amount the state expects to spend. Like all hypothetical expenditures, capped hypothetical expenditures do not need to be offset by savings, and cannot produce savings; however, unspent expenditure authority allocated for HRSN infrastructure in a given demonstration year can be applied to HRSN services in the same demonstration year. Any unspent HRSN services expenditure authority may not be used to fund HRSN infrastructure. To allow for capped hypothetical expenditures and to prevent them from resulting in savings that would apply to the rest of the demonstration, CMS currently applies a separate, independent Capped Hypothetical Budget Neutrality Test, which subjects capped hypothetical expenditures to pre-determined aggregate limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If actual HRSN initiative spending is less than the Capped Hypothetical Budget Neutrality Test's expenditure limit for a given demonstration year, the difference is not considered demonstration savings. Unspent HRSN expenditure authority under the cap for each demonstration year can be carried, shifted, or transferred across future demonstration years. However, unspent HRSN expenditure authority cannot roll over to the next demonstration approval period. If the state's capped hypothetical spending exceeds the Capped Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to refund any FFP in excess of the cap to CMS. Demonstration savings from the Main Budget Neutrality Test cannot be used to offset excess spending for the capped hypothetical.

14.11. **Capped Hypothetical Budget Neutrality Test: HRSN.** The table below identifies the MEGs that are used for the Capped Hypothetical Budget Neutrality Test. 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 Capped 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 the Capped Hypothetical Budget Neutrality Test cannot be offset by savings under the Main Budget Neutrality Test or the Hypothetical Budget Neutrality Tests.

Table 11: Capped Hypothetical Budget Neutrality Test

MEG	Agg	WOW Only, WW Only, or Both	DY 1 CY 2021	DY 2 CY 2022	DY 3 CY 2023	DY 4 CY 2024	DY 5 CY 2025
HRSN Services	Agg	Both	$0M	$0M	$0M	$0M	$39,968,436

HRSN Infrastructure	Agg	Both	$0M	$0M	$0M	$0M	$6,915,303

14.12. **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.

14.13. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2021 to December 31, 2025. 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.

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

Table 12: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

15. MONITORING ALLOTTMENT NEUTRALITY

15.1. **Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement.** The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

a. **Tracking Expenditures:** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 and CMS 64 reporting instructions as outlined in section 2115 of the State Medicaid Manual.

b. **Use of Waiver Forms:** Title XXI demonstration expenditures will be reported on the following separate forms designated for Medicaid-expansion CHIP (M-CHIP) (i.e., Forms 64.21U Waiver and/or CMS-64.21UP Waiver) and S-CHIP (i.e., Forms CMS-21 Waiver and/or CMS-21P Waiver), identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The state must submit separate CMS-21 and CMS-64.21U waiver forms for each title XXI demonstration population.

c. **Claiming Period:** All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the CMS-21 and CMS-64.21U waiver forms, net expenditures related to dates of service during the operation of the demonstration.

15.2. **Standard CHIP Funding Process.** The standard CHIP funding process will be used during the demonstration. The state will continue to estimate matchable CHIP expenditures on the quarterly Forms CMS-21B for S-CHIP and CMS-37 for M-CHIP. On these forms estimating expenditures for the title XXI funded demonstration populations, the state shall separately identify estimates of expenditures for each applicable title XXI demonstration population. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must report demonstration expenditures through Form CMS-21W and/or CMS-21P Waiver for the S-CHIP population and report demonstration expenditures for the M-CHIP population through Form 64.21U Waiver and/or CMS-64.21UP Waiver. Expenditures reported on the waiver forms must be identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). CMS will reconcile expenditures reported on the CMS-21W/CMS-21P Waiver and the CMS 64.21U Waiver/CMS-64.21UP Waiver forms with federal funding previously made

available to the state and include the reconciling adjustment in the finalization of the grant award to the state.

15.3. **Title XXI Administrative Costs.** Administrative costs will not be included in the allotment neutrality limit. All administrative costs (i.e., costs associated with the title XXI state plan and the title XXI funded demonstration populations identified in these STCs) are subject to the title XXI 10 percent administrative cap described in section 2105(c)(2)(A) of the Act.

15.4. **Limit on Title XXI Funding.** Colorado will be subject to a limit on the amount of federal title XXI funding that the state may receive on eligible CHIP state plan populations and the CHIP demonstration populations described in STC XX during the demonstration period. Federal title XXI funds for the state's CHIP program are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Expenditures only allowable through the demonstration are limited to remaining title XXI funds.

15.5. **Exhaustion of Title XXI Funds for S-CHIP Population.** If the state exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the state must continue to provide coverage to the approved title XXI separate state plan population.

15.6. **Exhaustion of Title XXI Funds for M-CHIP Population.** If the state has exhausted title XXI funds, expenditures for this population as approved within the CHIP state plan, may be claimed as title XIX expenditures, as approved in the Medicaid state plan. The state must notify CMS in writing at least 90 days prior to an expected change in claiming of expenditures for the M-CHIP population. The state shall report demonstration expenditures for these individuals, identified as "M-CHIP," on the Forms CMS 64.9W and/or CMS 64.9P W.

16. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Due	Deliverable	STC
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after approval date	SUD Implementation Plan (including Health IT Plan)	STC 5.2
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 5.2
90 calendar days after approval date	SMI/SED Implementation Plan (including Health IT Plan)	STC 8.2
60 calendar days after receipt of CMS comments	Revised SMI/SED Implementation Plan (including Health IT Plan)	STC 8.2

Due	Deliverable	STC
120 calendar days after approval date	Reentry Demonstration Initiative Implementation Plan	STC 9.10
6 months after approval date	Reentry Demonstration Initiative Reinvestment Plan	STC 9.11
150 calendar days after approval date	Monitoring Protocol(s)	STC 12.5
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol(s)	STC 12.5
180 calendar days after approval date	Draft Evaluation Design(s)	STC 13.3
60 days after receipt of CMS comments	Revised Draft Evaluation Design(s)	STC 13.5
No later than 60 calendar days after July 1, 2023	SUD Mid-Point Assessment	STC 12.7
60 days after the third year of the program approval	SMI/SED Mid-Point Assessment	STC 12.8
60 days after the third year of the program approval	Reentry Mid-Point Assessment	STC 12.9
One year prior to the expiration of the demonstration	Draft Interim Evaluation Report	STC 13.7
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 13.7
Within 18 months after approval period ends	Draft Summative Evaluation Report	STC 13.8
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 13.8
60 calendar days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 12.6
90 calendar days after end of demonstration year	Annual Monitoring Reports	STC 12.6
90 calendar days after end of each demonstration year	Annual Budget Neutrality Reports	STC 11.6(c)
30 calendar days after the end of each quarter	Quarterly Budget Neutrality Reports	STC 14.11
If applicable, due 120 calendar days after the end of the demonstration/program	Close-out Report	STC 12.11

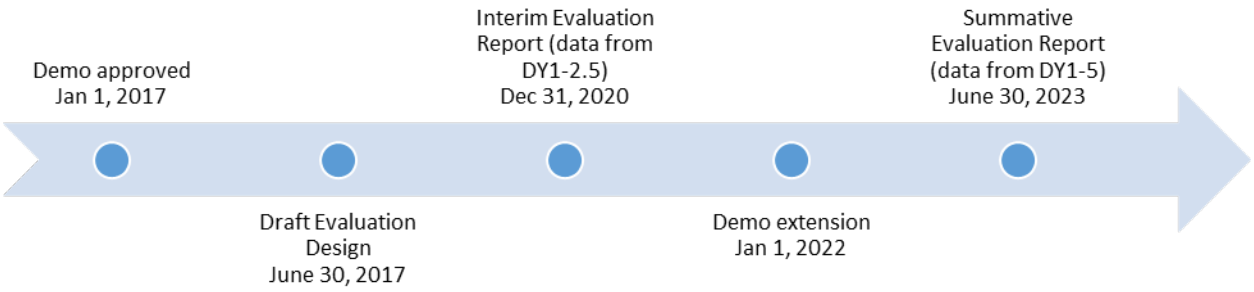
ATTACHMENT A
Developing the Evaluation Design

Introduction

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

Submission Timelines

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



Expectations for Evaluation Designs

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

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. The roadmap begins with the stated goals for the demonstration, followed by the measurable

evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

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

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

1. The issues that the state is trying to address with the approved section 1115 demonstration waivers and expenditure authorities, the potential magnitude of the issues, and why the state selected this course of action to address the issues (e.g., a narrative on why the state submitted a section 1115 demonstration application).

2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.

3. A description of the population groups impacted by the demonstration.

4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, or expansion of, the demonstration.

5. For extensions, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.

2. Address how the hypotheses and research questions promote the objectives of Titles XIX and XXI.

3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.

4. Include a Logic Model or Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended

outcomes. A driver diagram, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the goal, the primary drivers that contribute directly to achieving the goal, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

5. Include implementation evaluation questions to inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

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

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

Specifically, this section establishes:

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

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

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

4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators.

Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

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

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	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
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

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

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

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

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

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

d. No Corrective Action Plans for the demonstration.

E. Attachments

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

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

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

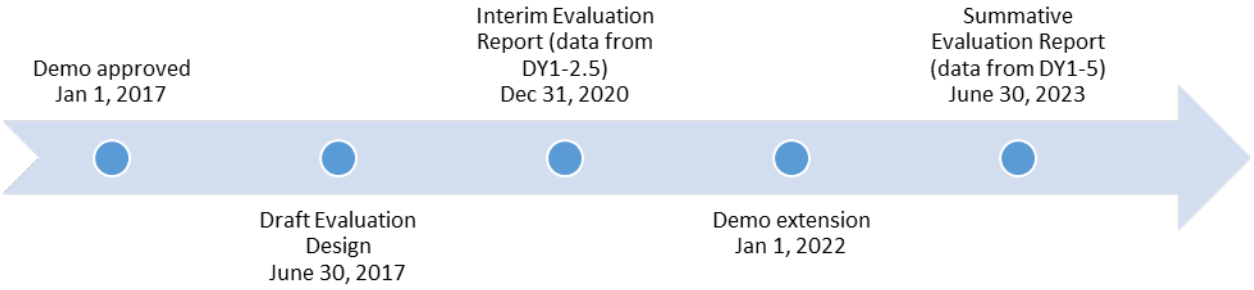
ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

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



Expectations for Evaluation Reports

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

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

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

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

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

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

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

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

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

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

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

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

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

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

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make appropriate adjustments for the limitations of the data and their

effects on results, and 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. *Focus and Comparison Populations* – Describe the focus and comparison populations, describing inclusion and exclusion criteria.

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

4. *Evaluation Measures* – List the measures used to evaluate the demonstration and their respective measure stewards.

5. *Data Sources* – Explain from where the data were obtained, and efforts to validate and clean the data.

6. *Analytic Methods* – Identify specific statistical testing which was undertaken for each measure (t–tests, chi–square, odds ratio, ANOVA, regression, etc.).

7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

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

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

G. **Conclusions** – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:
   1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
   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. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

I. **Lessons Learned and Recommendations** – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
    1. What lessons were learned as a result of the demonstration?
    2. What would you recommend to other states which may be interested in implementing a similar approach?

COLORADO
Department of Health Care Policy & Financing

Colorado Substance Use Disorder Section 1115 Waiver Implementation Plan

Submitted to the Centers for Medicare & Medicaid Services on November 2, 2020

COLORADO
Department of Health Care Policy & Financing

Table of Contents

Introduction

Over the past two decades, Colorado, like the rest of the country, has felt the impact of the opioid epidemic and has experienced an increase in the rate of SUD diagnoses. Data collected by the Colorado Department of Public Health and Environment between 1999-2017 show that:

- An estimated 500,000 Coloradans are dependent on alcohol or have used illicit drugs, defined as cocaine (including crack), marijuana, heroin, hallucinogens, inhalants, and prescription drugs used non-medically. Nearly 30 percent (142,000) are Medicaid members[1];
- Between 2000-2019, 14,512 Coloradans died due to a drug overdose[2];
- The number of overdose deaths has increased from 351 deaths in 2000 to 1,062 deaths in 2019[2]; and
- Opioid use is leading the overdose epidemic, accounting for over half of the overdose deaths in 2019.[2]

While opioid overdoses in Colorado rose between 2000 and 2019, other drugs including alcohol and methamphetamine also drive the rate of admissions for addiction treatment in the state. In 2017, alcohol was responsible for the majority of treatment admissions, followed by methamphetamine. From 2013 to 2017, methamphetamine-related admissions increased by 63%.[3]

In order to address this crisis, the State of Colorado enacted legislation in 2018 that directed the Department of Health Care Policy and Financing (Department) to seek all necessary federal authority to ensure coverage of the full continuum of Substance Use Disorder (SUD) services for Coloradans covered by Medicaid. In response, the Department submitted an 1115 demonstration application in 2019 to authorize federal financial participation for payment of residential and inpatient SUD treatment and withdrawal management services in Institutes for Mental Disease (IMDs). The state is also in the process of adding residential and inpatient treatment and withdrawal management as covered services under the State Plan. This Implementation Plan is being submitted in conjunction with the state's 1115 demonstration to

[1] Colorado Health Institute. Exploring Options for Residential and Inpatient Treatment of Substance Use Disorder in Health First Colorado. November 2017. https://www.colorado.gov/pacific/sites/default/files/HCPF%202017%20Inpatient%20SUD%20Treatment%20Report.pdf

[2] Colorado Drug Overdose Data Dashboard. https://cohealthviz.dphe.state.co.us/t/PSDVIP-MHPPUBLIC/views/DrugOverdoseDashboard/PoisoningDeathFrequencies?iframeSizedToWindow=true&%3Aembed=y&%3AshowAppBanner=false&%3Adisplay_count=no&%3AshowVizHome=no&%3Aorigin=viz_share_link

[3] Russell, S. "Colorado Drug Trends." Drug/Alcohol Coordinated Data System (DACODS), Colorado Department of Human Services Office of Behavioral Health. 2018.

detail how coverage of the full continuum of SUD services, including residential and inpatient services authorized under the 1115 demonstration, will be implemented.

This Implementation Plan describes the Department's strategies to ensure access to care, utilize the American Society of Addiction Medicine (ASAM) Criteria for patient placement and provider qualifications, address capacity, conduct prevention efforts and improve care coordination. The Implementation Plan that follows also discusses efforts to gather information from the public through stakeholder outreach and regional meetings. This information influenced the plans and actions that address each of the six milestones included in this plan.

Goals and Milestones to be addressed in Colorado's Implementation Plan Protocols

CMS is committed to working with states to provide a full continuum of care for people with opioid use disorder (OUD) and other SUDs and in supporting state-proposed solutions for expanding access and improving outcomes in the most cost-effective manner possible.

Goals:

1. Increased rates of identification, initiation and engagement in treatment for OUD and other SUDs;
2. Increased adherence to and retention in treatment for OUD and other SUDs;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for OUD and other SUD 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 readmissions is preventable or medically inappropriate for OUD and other SUD; and
6. Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs.

Milestones:

1. Access to critical levels of care for substance use disorders;

2. Widespread use of evidence-based, SUD-specific patient placement criteria;

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

4. Sufficient provider capacity at each level of care, including medication assisted treatment (MAT);

5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and opioid use disorder (OUD); and

6. Improved care coordination and transitions between levels of care.

Partners

These plans were developed collaboratively with other state agencies and stakeholders. State agencies that participated actively include the Colorado Department of Human Services Office of Behavioral Health, Department of Regulatory Agencies and Department of Public Health and Environment. In addition, this plan describes ongoing work conducted by two workgroups comprised of state agency, Regional Accountable Entity, and Managed Service Organization representatives. As discussed in the state's 1115 demonstration application, Regional Accountable Entities (RAEs) administer the Department's Accountable Care Collaborative Program and are responsible for promoting physical and behavioral health of Medicaid members in each of the regions of the state that they serve. The Managed Service Organizations (MSOs) contract with the Office of Behavioral Health to deliver a continuum of SUD care that includes residential and inpatient services through state and federal block grant funding.

Milestone #1: Access to Critical Levels of Care for SUD Treatment

CMS Specifications:

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

Colorado's Response:

Colorado currently covers outpatient SUD treatment services under the Medicaid state plan. The state plan includes coverage of early intervention, outpatient, medically acute inpatient, and some withdrawal management services. State Plan Amendments (SPAs) are in process to add new services and modify current service definitions as detailed below.

Table 1 below identifies each ASAM level of care, the service and service description, whether the service is currently Medicaid-covered, the authority used to cover it, and any changes that are being proposed under the state plan or this demonstration.

Table 1

ASAM	Service	ASAM Service Definition	Current Coverage	Future coverage

Level of Care			Authority	under Waiver or State Plan
.5	Early Intervention	Full screening, brief intervention and referral to treatment	State Plan Attachment 3.1-A, Item 13.c Preventative Services	Continuation of current state plan coverage
1	Outpatient Services	Substance abuse assessment, individual and family therapy, group therapy, alcohol/drug screening counseling, medication assisted treatment	State plan Attachment 3.1-A, Item 13-d Rehabilitative Services	Continuation of current state plan coverage
2.1	Intensive Outpatient Services	The Colorado state plan does not distinguish between outpatient and intensive outpatient.	State plan Attachment 3.1-A, Item 13-d Rehabilitative Services	Currently covered as "outpatient services;" the state submitted a SPA for this change in October 2020.
3.1	Clinically Managed Low-Intensity Residential Services	Supportive living environments (SLE) with 24-hour staff and close integration with clinical services provided when determined to be medically necessary and in accordance with an individualized treatment plan. Program services of five or more hours of services weekly may be offered in a (usually) free-standing, appropriately licensed facility located in a community setting.	Not covered	The state submitted a SPA in October 2020 to add this service and requests 1115 demonstration authority for provision of services in IMDs.
3.3	Clinically Managed Population-	Clinically managed therapeutic rehabilitation facilities for adults with	Not covered	The state submitted a SPA in October 2020

	Specific High Intensity Residential Services	cognitive impairment including developmental delay or traumatic brain injury that provides rehabilitation services to recipients with an SUD when determined to be medically necessary and in accordance with an individualized treatment plan. High intensity clinical services are provided in a manner to meet the functional limitations of patients with cognitive impairment so significant and the resulting level of functional impairment so great that outpatient motivational strategies and/or relapse prevention strategies are not feasible or effective. Staffed by credentialed addiction professionals, physicians/physician extenders, credentialed mental health professionals.		to add this service and requests 1115 demonstration authority for provision of services in IMDs.
3.5	Clinically Managed High Intensity Residential Services	Clinically managed therapeutic community or residential treatment facilities providing high intensity services for recipients with an SUD when determined to be medically necessary and in accordance with an individualized treatment plan. Staffed by	Not covered	The state submitted a SPA in October 2020 to add this service and requests 1115 demonstration authority for provision of services in IMDs.

		licensed/credentialed clinical staff, including licensed addiction professionals, licensed social workers, licensed professional counselors, physicians/physician extenders, and credentialed mental health professionals.		
3.7	Medically Monitored Intensive Inpatient Services	Medically monitored inpatient services provided in a freestanding residential facility or inpatient unit of an acute care hospital or psychiatric unit when determined to be medically necessary and in accordance with an individualized treatment plan. Includes 24-hour clinical supervision including physicians, nurses, addiction counselors, and behavioral health specialists.	Not covered	The state submitted a SPA in October 2020 to add this service and requests 1115 demonstration authority for provision of services in IMDs.
4	Medically Managed Intensive Inpatient Services	Acute care in a general hospital setting, with 24/7 medical management and nursing supervision, and counseling services (16 hours per day). Managed by addiction specialist physician with interdisciplinary team of credentialed clinical staff knowledgeable of biopsychosocial dimensions of addictions.	State plan for acute medical diagnosis only	Continuation of current state plan coverage

3.2-WM	Clinically Managed Residential Withdrawal Management	"Social detox" addressing intoxication or withdrawal in a setting that emphasizes peer and social support in a 24-hour setting.	State plan and 1915(b) waiver	The state currently covers ASAM level 3.2WM which is identified as "social detoxification." It will remain a covered service in the state plan and will be described in a new section titled "Withdrawal Management" on the 13.d Rehabilitative Services page.
3.7-WM	Medically Managed Inpatient Withdrawal Management	Severe withdrawal and needs 24-hour nursing care and physician visits as necessary; unlikely to complete withdrawal management without medical, nursing monitoring	Not covered	The state submitted a SPA in October 2020 to add this service (see above) and requests 1115 demonstration authority for provision of services in IMDs.
4-WM	Medically Managed Intensive Inpatient	Medical benefit	State plan	Continuation of current state plan coverage

Summary of Future Coverage Changes

As outlined in the table above, several SUD services are currently covered under the state plan, but new services are being added and updated through SPAs. Specifically, as illustrated in Table 1 above, the state is in the process of modifying the state plan for services at the ASAM level 2.1 and 3.2WM and is adding ASAM levels 3.1, 3.3, 3.5, and 3.7, and 3.7WM as benefits in the

Colorado Medicaid state plan. The state is working closely with the provider community to ensure that they are fully prepared to provide services based on the ASAM Criteria.

The following section summarizes the service coverage changes that will be made under the state plan and 1115 demonstration.

Level of Care: 2.1 Intensive OP SUD Services
Current State: Colorado's state plan does not currently differentiate between outpatient and intensive outpatient (IOP) services. All outpatient SUD services in the state are billed as outpatient services rather than differentiating between outpatient and IOP.
Future State: The state has submitted a SPA that will define IOP services as a distinct service.

Level of Care: 3.1 Clinically Managed Low-Intensity Residential Services
Current State: No coverage.
Future State: The state has submitted a SPA to CMS that adds clinically managed low-intensity residential services as a state plan service. This service meets the requirements of ASAM Level 3.1 by providing at least five hours of low-intensity treatment services per week, including medication management, recovery skills, relapse prevention, and other similar services. This level of care is designed to improve the patient's ability to structure and organize the tasks of daily living, stabilize and maintain the stability of the individual's substance use disorder symptoms, and to help them develop and apply recovery skills. Services are provided by allied health professional staff including counselors, group living workers, and some clinical staff knowledgeable about biological and psychosocial dimensions of SUD and psychiatric conditions.

Level of Care: 3.3 Clinically Managed Population-Specific High-Intensity Residential Services
Current State: No coverage.
Future State: The state has submitted a SPA to CMS that adds clinically managed population-specific high-intensity residential services as a state plan service. This service meets the requirements of ASAM Level 3.3 by providing services for individuals with temporary or permanent cognitive limitations that make it unlikely for them to benefit from other residential levels of care that offer group therapy and other cognitive-based relapse prevention strategies. This level of care is designed to improve the patient's ability to structure and organize the tasks of daily living and recovery, to stabilize and maintain the stability of the individual's substance use disorder symptoms, and to help them develop and apply recovery skills. Services are provided by 24-hour allied health professional staff who supervise the residential component with access to clinicians competent in SUD treatment.

Level of Care: 3.5 Clinically Managed High-Intensity Residential Services
Current State: No coverage.
Future State: The state has submitted a SPA to CMS that adds clinically managed high-intensity residential services as a state plan service. This service meets the requirements of ASAM Level 3.5 by providing comprehensive, multifaceted treatment to individuals with psychological problems, chaotic or unsupportive interpersonal relationships, criminal justice histories, and

antisocial value systems. Services will include a range of cognitive, behavioral and other therapies administered on an individual and group basis and provided by an interdisciplinary team comprised of appropriately credentialed clinical staff including addiction counselors, social workers, and licensed professional counselors, and allied health professionals who provide residential oversight.

Level of Care: 3.7 Medically Monitored Intensive Inpatient Services
Current State: No coverage.
Future State: The state has submitted a SPA to CMS that adds medically monitored intensive inpatient services as a state plan service. This service meets the requirements of ASAM Level 3.7 by providing services to patients with biomedical, emotional, behavioral and/or cognitive conditions that require highly structured 24-hour services including direct evaluation, observation, and medically monitored addiction treatment. Medically monitored treatment is provided through a combination of direct patient contact, record review, team meetings and quality assurance programming. These services are differentiated from Level 4.0 (which is currently covered by Colorado Medicaid) in that the population served does not have conditions severe enough to warrant medically managed inpatient services or acute care in a general hospital where daily treatment decisions are managed by a physician. The care team will include physicians credentialed in addiction who are available on-site 24 hours daily, registered nurses, and additional appropriately credentialed nurses, addiction counselors, behavioral health specialists, and other clinical staff.

Level of Care: 3.2 WM Clinically Managed Residential Withdrawal Management
Current State: This service is currently covered through 1915(b) authority and under the state plan.
Future State: The state has submitted a SPA that outlines withdrawal management as a covered service at both the 3.2 WM and 3.7 WM levels of care. This service will continue to meet the ASAM 3.2 WM level of care criteria by providing 24-hour structure, support, supervision, and observation for individuals who are intoxicated or experiencing withdrawal symptoms. Services are supervised by a qualified medical professional who must be available by telephone or in person 24 hours per day. These facilities will be required to demonstrate that they are licensed to provide this level of care by the Colorado Office of Behavioral Health (OBH).

Level of Care: 3.7 WM Medically Managed Residential Withdrawal Management
Current State: Not covered.
Future State: The state has submitted a SPA to CMS that adds medically managed residential withdrawal management as a state plan service. This service meets the ASAM 3.7 level of care criteria by providing 24-hour medically supervised evaluation and withdrawal management. This level of care is for individuals whose withdrawal signs and symptoms are sufficiently severe to require care by medical professionals but not an inpatient hospital level of care. Services are supervised by a medical director who must be on site seven days a week and available for consultation or onsite recipient monitoring 24 hours per day.

Actions Needed to Achieve Milestone #1 Across All Service Levels

Action Needed	Timeline
SPA revision of 2.1 Intensive OP SUD Services	Pending approval of SPA; proposed effective date January 1, 2021
Implementation of 3.1 Clinically Managed Low-Intensity Residential Services	Pending approval of SPA; proposed effective date January 1, 2021
Implementation of 3.3 Clinically Managed Population-Specific High-Intensity Residential Services	Pending approval of SPA; proposed effective date January 1, 2021
Implementation of 3.5 Clinically Managed High-Intensity Residential Services	Pending approval of SPA; proposed effective date January 1, 2021
Implementation of 3.7 Medically Monitored Intensive Inpatient Services	Pending approval of SPA; proposed effective date January 1, 2021
Implementation of 3.7 WM Medically Managed Residential Withdrawal Management	Pending approval of state plan amendment; proposed effective date January 1, 2021
Develop and implement Regional Accountable Entity (RAE) rate methodology that reflects continuum of additional and modified services	October 2019 – Current; anticipated contract updates in effect prior to January 1, 2021
Execute RAE contract amendments that reflect updated capitation rates that include new and modified services	By January 1, 2021
Billing system changes to allow for claim submission for new services (residential and inpatient) and changes to existing service billing rules (IOP)	November 2020

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

CMS Specifications:

- Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g. the ASAM Criteria or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines; and
- Implementation of a utilization management approach such that a) beneficiaries have access to SUD services at the appropriate level of care, b) interventions are appropriate for the diagnosis and level of care, and c) there is an independent process for reviewing placement in residential treatment settings.

Colorado's Response:
Colorado Medicaid requires evidence-based level of care determinations that utilize the ASAM Criteria.

The state will require treatment providers to conduct assessments that allow them to gather information about the patient that allows for rating of the six ASAM dimensions, and the use of the ASAM Criteria for matching to an appropriate level of care. For residential treatment admissions, the RAEs will review those recommendations through a prior authorization process to ensure that medical necessity exists for the level of care recommended. RAE contracts that will be effective January 1, 2021 contain language pertaining to utilization management of residential and inpatient SUD services. The RAEs have submitted draft utilization management policies and procedures to the Department that are aligned with the Department's requirements related to the management of these services.

Colorado will require the RAEs to conduct a utilization review process to ensure that beneficiaries have access to the most appropriate level of care depending on their individual needs. RAEs will also be responsible for ensuring that the continuum of care is surrounded by recovery supports that promote sustained recovery and minimize readmissions.

The state will also conduct monitoring activities when the benefit is in place to review prior authorization documentation of medical necessity and level of care decision making.

A. Patient Placement Assessment

Current State: The state requires that ASAM Criteria be used for SUD-related assessments. Specifically, Office of Behavioral Health licensing requirements state that SUD providers at all levels of care, including outpatient, intensive outpatient and residential levels, conduct assessments in accordance with the following requirements:

- Use the ASAM Criteria as a guide for assessing and placing individuals in the appropriate level of care;

- Assessments shall include information gathered on all six (6) dimensions outlined in the ASAM criteria; and,

- Level of care shall be determined utilizing the decisional flow process as outlined in the ASAM criteria.

During site visits to SUD provider facilities, the Office of Behavioral Health reviews patient charts to verify that the ASAM criteria was used to appropriately place the client in the level of care.

Contracts with RAEs direct the RAEs to conduct evaluations that are "designed to determine the most appropriate level of care, based on criteria established by ASAM, the extent of drug/alcohol use, abuse or dependence and related problems, and the comprehensive treatment needs of a member with a drug or alcohol diagnosis."

In addition, in its role as regulator, the Colorado Office of Behavioral Health (OBH) licenses all SUD providers in the state. In August 2020, OBH completed the rule revision process to fully align its licensure requirements with the ASAM Criteria. The new licensure rules distinguish providers by ASAM level and describe the levels of care in detail. Providers receiving reimbursement for SUD services by Medicaid must be licensed for the level of care which they are offering.

Future State: The state is updating its contract language with RAEs to strengthen requirements and monitor the RAEs' use of the ASAM Criteria for patient placement. Contract changes include a requirement that the ASAM Criteria be used for level of care determination and to document medical necessity for the level of care the provider is recommending. Contracts with RAEs will also provide guidance on other expectations for RAE relationships with SUD providers. The state is working with the RAEs to develop policies and procedures for aspects of utilization management such as prior authorization and reauthorization practices.

In addition to aligning its licensure rules with the ASAM Criteria, Colorado is also in the process of procuring ASAM-based technology that will facilitate state-of-the-science assessments. Once the technology is made accessible to all residential and inpatient SUD providers, they will be required to use it to assess patients and make level of care determinations. The use of a standardized tool would improve communication between RAEs and providers and increase consistency in the application of ASAM criteria for level of care decision making. Until that system is accessible to providers, the state will require providers to use ASAM-consistent screening and assessment tools that collect data to allow providers to develop risk ratings on

the six dimensions of care and then manually map to an appropriate level of care based on those ratings.

B. Utilization Management

Current State: The OBH licensure process aims to ensure that Coloradans have access to SUD care that is consistent with the levels of care described by the ASAM Criteria. Expectations regarding utilization management practices are set forth in RAE contract requirements.

Future State: The state is strengthening the utilization management requirements for SUD services by the RAEs. The state has convened an Implementation Work Group (comprised of key stakeholders and partners from the Department, OBH, RAEs, and Managed Service Organizations, or MSOs), which is charged with working through the details of 1115 demonstration implementation. RAE representatives on the work group include staff who are focused on utilization management. The State has communicated requirements that pertain to prior authorizations and timeframes for prior authorization reviews that will be implemented uniformly across RAEs. RAEs incorporated those uniform standards into their policies and have operationalized them. The Department has also convened an Initial Monitoring Team that is developing plans to monitor utilization of residential and inpatient services in the early weeks and months after implementation. This team is developing plans for independent tracking of residential and inpatient SUD service utilization across RAE regions and identifying outliers or utilization trends that require management.

Actions Needed to Achieve Milestone #2

Action Needed	Timeline
Update OBH licensing regulations	Completed August 2020
Update RAE contracts to include new services and UM of services	December 2020
Implement training and technical assistance to align providers with ASAM standards	February 2020 and ongoing
RAE development of UM policies and procedures	August 2020
State review of UM policies and procedures and provision of feedback to the RAEs	October 2020
Begin UM process for residential placements	January 2021
Begin internal monitoring of benefit according to initial monitoring plan currently in development	January 2021

Communicate changes to providers	Ongoing

Milestone #3: Use of Nationally-Recognized SUD-Specific Program Standards for Residential Treatment Facility Provider Qualifications

CMS Specifications:

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

Colorado's Response:

The state recently updated licensure regulations for residential treatment providers to fully align with ASAM standards. Regional Accountable Entities (RAEs), Managed Service Organizations (MSOs), and the state will work together to ensure residential treatment provider compliance with the newly updated regulations and contract requirements, including providing onsite, or facilitating offsite, access to MAT services.

A. Implementation of Residential Treatment Provider Qualifications (in Licensure Requirements, Policy Manuals, Managed Care Contracts, or Other Guidance)

Current State:

Licensure Requirements

The Colorado Office of Behavioral Health (OBH) is responsible for licensing residential treatment providers in the state. Licensing regulations include standards on staffing, admissions, data collection and reporting, quality improvement, application and revocation of a license, license expiration, background checks for staff, use of records, service plans, type of care provided, and rules specific to special populations such as adolescents. These regulations were revised in August 2020 to directly align with ASAM levels of care. Under the new rules, providers are being issued licenses associated with each ASAM level of care they provide.

Managed Care Contracts

Managed care contracts between the state and the RAEs currently include the following provisions:

- RAEs may only enter into written contracts with behavioral health providers that are enrolled as Colorado Medicaid Providers. Note: Providers must be licensed by the OBH in order to enroll as a Colorado Medicaid Provider.

- RAEs shall ensure that all network behavioral health providers are credentialed and that the credentialing process follows NCQA credentialing and re-credentialing standards.
- RAEs must re-credential all contracted providers every three years.

Policy Manuals
The department maintains a Uniform Services Coding Standards Manual, which provides guidance on coding, documenting and reporting on services covered by Medicaid in Colorado. It also aligns coding requirements with those of the OBH for services paid through other funding sources. The manual includes instructions for providers on billing for all behavioral health services including the outpatient SUD services currently covered by Medicaid.

Future State:
Licensure Requirements
The OBH is currently requiring providers to reapply for licenses as they are defined under the new regulations. Providers must be licensed in accordance with the recently ratified rules prior to billing Medicaid for services. RAEs are aware of the rule changes and are in conversation with providers regarding any plans to relicense at a different level of care if a program is not aligned with the current licensing standards.

Policy Manuals
The SUD Residential Provider Manual, released in October 2020, covers: member eligibility, provider requirements, provider enrollment procedures, SUD benefit policies, and the roles of MSOs and RAEs in benefit management. Additionally, an update to the Uniform Service Coding Standards Manual will be published on its regular cycle in January 2021 and will include pages outlining coding instructions for the newly covered SUD services. In order to ensure that providers are informed of the appropriate coding practices for the new services prior to the benefit go-live date, the billing and coding instruction pages for the new SUD services are included in the SUD Residential Provider Manual.

Prior to residential services going live on January 1, 2021, the state will require providers to enroll with Colorado Medicaid based on their licensing level. In November, providers will enroll with the Department's Medicaid Management Information System (MMIS). In order to do so, they will submit their license and enroll under a specialty provider type associated with each level of care they are licensed to provide. Billing rules require providers to code services by level of care which must match the specialty provider type for that level of care.

Other Guidance
In addition to communicating provider requirements through policy manuals, the Department conducted two provider trainings in October 2020. The trainings included content on: Medicaid coverage across the SUD continuum, ASAM Criteria and medical necessity, utilization management procedures, provider requirements, SUD provider licensing, provider enrollment, the roles of the RAEs and MSOs and MAT requirements. These trainings were recorded and are being made available online to providers to reference in the future.

Managed Care Contracts
Managed care contracts currently only allow RAEs to contract with providers enrolled with Medicaid. In order to enroll with Medicaid, providers must be licensed under the current rules. With the recently ratified OBH rules for SUD providers, RAEs will only be contracting with providers that are licensed according to rules that align with the levels of care as defined by ASAM.

B. Implementation of State Process for Reviewing Residential Treatment Provider Compliance with Standards

Current State: In order to license as an SUD Provider, providers submit an application to the OBH. After review of the application, the OBH conducts a site visit, which involves review of policies and procedures, touring the facility, reviewing local fire inspections to assure compliance with fire and safety codes, and examining local zoning ordinances to ensure compliance.

Licensure of facilities by the OBH also involves verification of credentialing for individual medical or counseling practitioners who work in these facilities. Colorado uses federal standards for screenings based on provider type risk level. The OBH verifies licenses and conducts site visits for moderate- and high-risk providers. The state also requires a fingerprinting process for provider owners with more than 5% ownership.

SUD Provider licenses are valid for two years. The OBH investigates critical incident reports and complaints, which can result in licensure status changes such as revocation or probation. Provider compliance with current regulations is enforced through the OBH, that takes appropriate actions when residential treatment providers have complaints filed against them or fall short of meeting requirements.

Future State: Since the ratification of licensing rules that align with ASAM Criteria, the OBH licensure process will ensure that providers are offering services consistent with the levels of care. Programs will be further reviewed for compliance with those licensure standards through the RAE credentialing process. Contracts between RAEs and providers will include specifics pertaining to ASAM requirements.

C. Implementation of Requirement that Residential Treatment Facilities Offer MAT Onsite or Facilitate Access Offsite

Current State: The state currently has 26 opioid treatment programs (OTPs) that offer methadone, with most also offering buprenorphine. This is an increase of 15 providers compared to four years ago. The state also has 1,200 new X-waivered providers and is working to create more. There are roughly 7,000 people receiving MAT through a state licensed OTP and another 9,300 people receiving MAT through an X-waivered provider. The OTP statewide

census and those receiving MAT through X-waivered providers have both increased more than 50% since January 2017.

MSOs currently direct residential treatment providers to be "MAT-friendly." RAEs do not have any requirements regarding residential treatment providers and MAT services, as residential treatment is not a covered service at this time.

Future State: Contract language effective January 1, 2021 pertaining to MAT in residential facilities requires RAEs to review policies and procedures of inpatient SUD services and residential SUD services programs to ensure that they provide onsite access, or facilitate offsite access to medication assisted treatment services. The state is currently developing a toolkit to support providers in facilitating access to MAT.

Actions Needed to Achieve Milestone #3

Action Needed	Timeline
Relicensing of providers based on updated OBH regulations; OBH responsible	December 2020
Implement training and technical assistance to align providers with ASAM standards	October - December 2020
Update RAE contracts to reflect residential provider requirement changes, including requirements related to providing access to MAT.	Draft revisions complete. Contracts will be in place by November 2020.
MMIS system changes to allow for enrollment of providers by ASAM level	Complete
Colorado Medicaid enrollment portal opens for SUD providers	Complete (Opened November 5, 2020)
Publish SUD Residential Provider Manual	Complete (October 2020)
Publish updated Uniform Services Coding Standards Manual with billing and coding requirements for new services	January 2021

Milestone #4: Sufficient Provider Capacity at Critical Levels of Care, Including MAT

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

Colorado's Response:
The State has completed a provider capacity assessment and is actively developing strategies to further expand provider capacity in the state.

Current State: In preparation for submission of the state's 1115 SUD demonstration application, the Department undertook a provider capacity assessment in 2018 to assess the availability of providers across the state to deliver the expanded set of SUD treatment services. The surveys helped inform state planning and preliminary discussions of the waiver.

In 2019, the State:

- Developed a series of maps depicting the current demand for SUD services, represented by SUD diagnoses among Medicaid members and the existing treatment programs across the state. Those maps appear on the following pages.
- Conducted 12 regional meetings across the state to gather qualitative data about the accessibility of SUD treatment in various regions.
- Convened the SUD Capacity Workgroup comprised of RAEs, MSOs, OBH, and Department representatives to review the available information on SUD service capacity and develop a plan for addressing capacity deficiencies where they exist across the SUD continuum.

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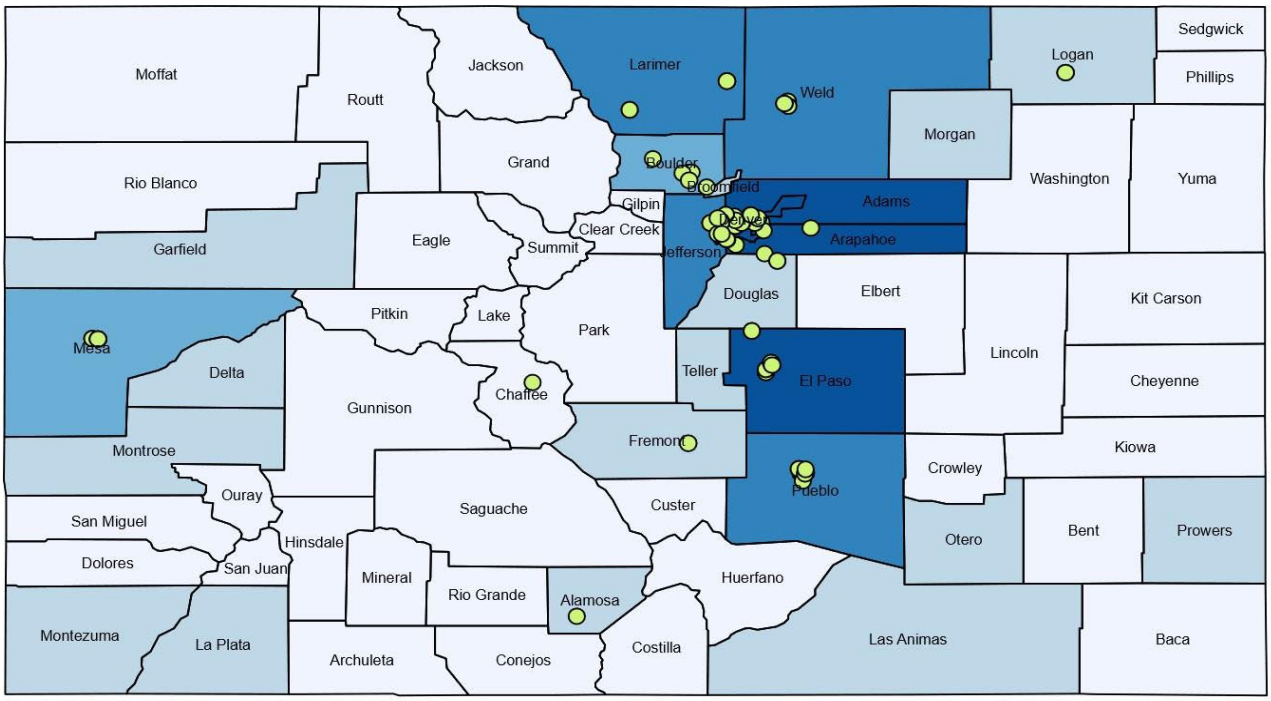
COLORADO
Department of Health Care Policy & Financing

Number of Unique SUD Clients by County and All SUD Providers for Levels 3.1, 3.5 and 3.7 State Fiscal Year 2018-2019



The client data represented in this map was retrieved from the Department of Health Care Policy and Financing Department Decision Support System. SUD Clients are defined by the presence of an SUD related Primary or Secondary Diagnosis code on a claim at least once during the 2018 - 2019 State Fiscal Year.

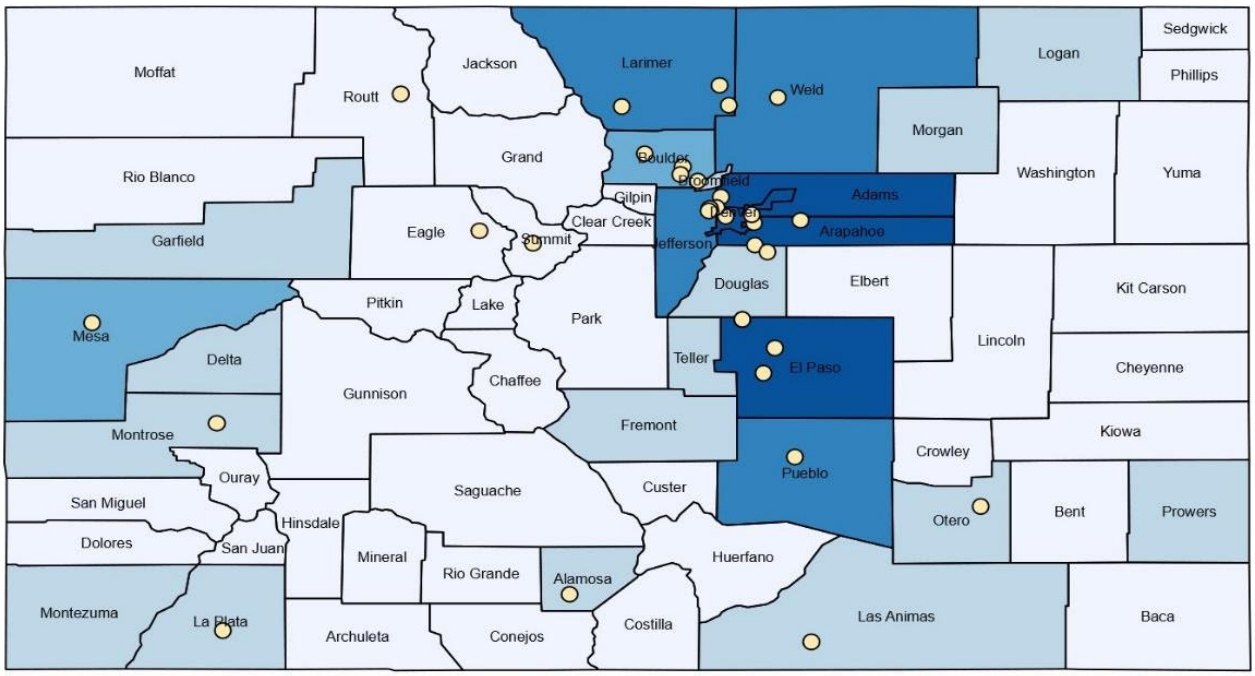
Project Tracking #: 8555 Map Created on: 6/3/2020

In Colorado, there are approximately 1,180 community-based residential substance use treatment beds and another 416 correctional beds. That estimate equates to one bed per 2,750 individuals. In addition, there are another 629 withdrawal management, or detox, beds. Treatment provider facilities are represented as yellow dots on the map above.

	Treatment Capacity by ASAM Level						
ASAM Level	**3.1**	**3.3**	**3.5**	**3.7**	**3.2 WM**	**3.7 WM**	**Correctional**
Number of Beds	323	0	603	252	423	206	416

COLORADO
Department of Health Care Policy & Financing

Number of Unique SUD Clients by County and All SUD Providers for Levels 3.2WM and 3.7WM State Fiscal Year 2018-2019



The client data represented in this map was retrieved from the Department of Health Care Policy and Financing Department Decision Support System. SUD Clients are defined by the presence of an SUD related Primary or Secondary Diagnosis code on a claim at least once during the 2018 - 2019 State Fiscal Year.

Number of SUD Clients

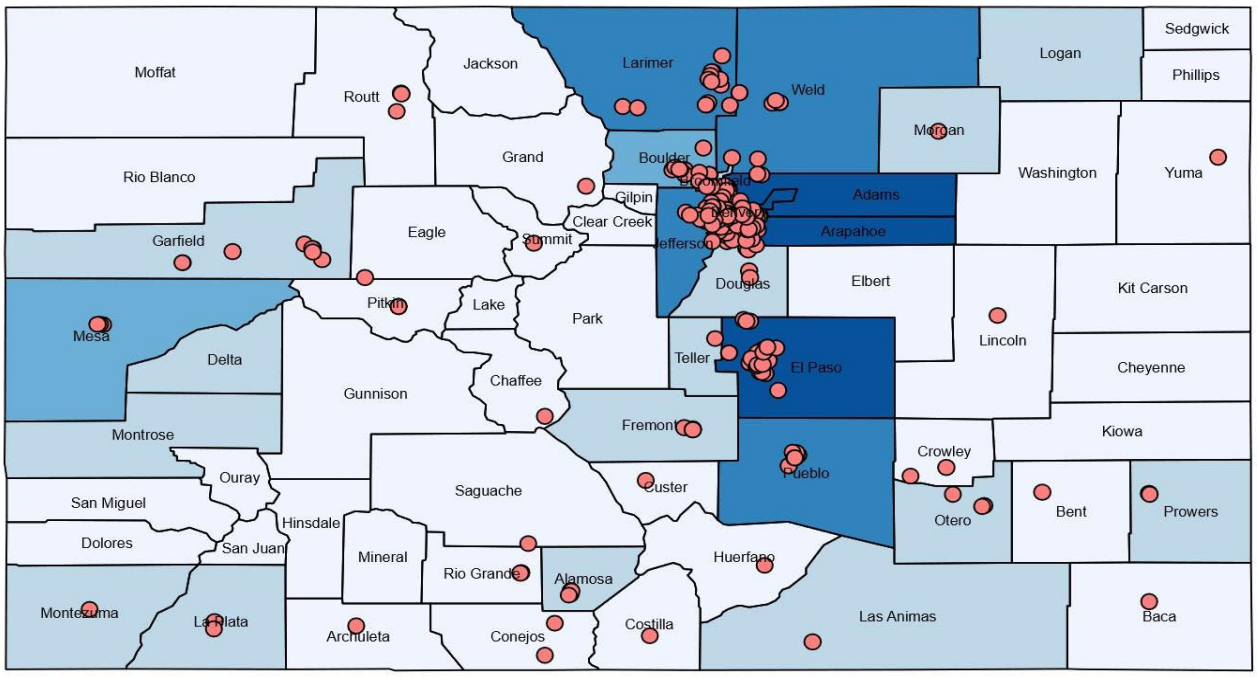
0 - 500
501 - 2,500
2,501 - 5,000
5,001 - 10,000
10,001 - 20,000

Project Tracking #: 8555 Map Created on: 6/3/2020

Colorado has 629 withdrawal management beds, with a 2:1 ratio of 3.2 WM to 3.7 WM. The majority of these Level 3.2 WM beds, about 380, are available to Colorado Medicaid members. Of the 23 Level 3.2 WM facilities, ten facilities comprising almost 100 beds lie outside the Front Range. While there are facilities outside of the I-25 corridor, access to those facilities is limited for several reasons including: several programs do not accept Medicaid members, several do not accept unscheduled admissions, the facility in Frisco has operated intermittently.

COLORADO
Department of Health Care Policy & Financing

Number of Unique SUD Clients by County and NonCorrectional SUD Providers for Level 2.1 State Fiscal Year 2018-2019



The client data represented in this map was retrieved from the Department of Health Care Policy and Financing Department Decision Support System. SUD Clients are defined by the presence of an SUD related Primary or Secondary Diagnosis code on a claim at least once during the 2018 - 2019 State Fiscal Year.

Project Tracking #: 8555 Map Created on: 6/3/2020

The map of IOP providers shows that they are more evenly distributed across the state than residential providers. While the map demonstrates this, stakeholders reported during regional meetings that IOP capacity is lacking throughout the state, even in populated areas. Stakeholders noted that maintaining IOP programs in less populated areas is a challenge due to workforce shortages.

Future State:

The State and its SUD Capacity Workgroup are currently in the process of reviewing findings and developing a plan to facilitate capacity expansion where needed. RAEs will be a critical part of the effort to expand provider networks and grow capacity. The Department's contracts with the RAEs require them to comply with network adequacy requirements, and those requirements are independently audited through a contract with Health Services Advisory Group (HSAG). These requirements will include having a complete continuum of SUD care, across all ASAM levels, for members attributed to their region. We also anticipate that a new, sustainable payor for these services will drive existing providers to increase available beds and new providers to enroll in Medicaid. In addition to Medicaid payments for residential and

inpatient SUD care driving expansion of capacity for these services, several other resources may be utilized to support capacity expansion. These are discussed below.

First, the state has an initiative underway to improve bed tracking capabilities. The 2019 legislature passed HB 19-1287, a bill that creates an electronic bed tracking system which will allow for real-time bed availability in the state. The system will initially be updated through provider self-reporting, and site visit audits will validate alignment with reported bed numbers and revised rules. HB 19-1287 also created a Care Navigation Program and assigns OBH and the Department the responsibility for ensuring care transitions.

Second, this same state bill also appropriated $5 million in funding for OBH to support rural and frontier SUD capacity expansion. While funding was disbursed in 2019 to awardees for expansion of treatment services, the program was suspended for fiscal year 2020-21 because of state budget shortfalls resulting from COVID-19. Budget assumptions pertaining to the Medicaid SUD benefit were adjusted at the same time to account for a slower ramp-up of capacity.

Third, through the state's Hospital Transformation Program, a rural hospital fund has been created. One of the allowable uses of funds is to expand bed capacity specifically for SUD services, especially in areas where there are no services available at a particular level of care. HTP will begin in February 2021, coincident with the SUD benefit program launch.

Fourth, the state has undertaken an X-waiver provider recruitment program entitled "IT MATTTRs." Colorado used SAMHSA State Targeted Response (STR) to the Opioid Crisis and State Opioid Response (SOR) grant funding to expand the MAT capacity of the state. The program has provided X-waiver training at no cost to providers. Funds also support onsite practice implementation training at participating health clinics. Nationally, a barrier that impedes MAT expansion is provider apprehension about initiating MAT in their practice. In order to address this issue, IT MATTRSs offers regular telephonic training forums where an experienced MAT provider offers real time support to newly waivered providers across the state. To date, there have been 244 participants in these forums.

Finally, in addition, legislation passed in 2019 will expand MAT access. HB 19-001 provides grant funding for MAT expansion pilot programs specifically targeted in communities with limited access, targeting the 15 out of 64 counties in the state that do not currently have a MAT provider.

Actions Needed to Achieve Milestone #4

Action Needed	Timeline
Convenings of the Provider Capacity Work Group	September 2019 – Ongoing

OBH go-live of electronic bed tracking system	January 2021
Hospital Transformation Program bed capacity expansion	Application opens February 2021
IT MATTrs (X-waiver training)	Ongoing

Milestone #5: Implementation of Comprehensive Treatment and Prevention Strategies

CMS Specifications:

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

Colorado's Response:

Colorado has numerous efforts underway to address opioid abuse and OUDs, including state and federal partnerships and the state's Consortium for Prescription Drug Abuse Prevention (the Consortium), which facilitates a robust public/private partnership centered around a variety of prevention and treatment strategies. The Department leverages its sister agencies and other statewide community organizations to achieve the goals and milestones of this section.

Colorado's efforts that are most relevant to Milestone #5 are summarized below.

A. Implementation of Opioid Prescribing Guidelines Along with other Interventions to Prevent Opioid Abuse

Current State:

Opioid Prescribing Guidelines

Colorado Medicaid has taken a number of steps over the past five years that have resulted in a more than 50% reduction in the number of opioid pills prescribed and a 44% reduction in the number of Medicaid members taking opioids. Those policy initiatives have been aimed at reducing the number of opioids prescribed to members, tightening criteria when requesting refills, and reducing the daily Morphine Milligram Equivalents (MME) members can take – all while continually ensuring members receive necessary medications for adequate pain management.

Other state efforts to prevent opioid abuse include:

- A helpful guide containing research and a list of resources is maintained by the OBH and can be found here.
- Colorado's Lift the Label campaign has set a goal of reducing the stigma that prevents those with opioid use disorder from seeking treatment.
- The state's Prescription Drug List (PDL) provides guidelines for all Medicaid-related prescription drugs, including those that require prior authorization.

- A Drug Utilizations Review (DUR) board serves in an advisory role to the Department and makes recommendations on drug utilization, provider education, and application of standards. A pain specialist sitting on the DUR board determines the prior authorization criteria for drugs with special prescribing guidelines such as those that don't make the state's PDL.[4]

One of the recent initiatives of the DUR was to inform providers of how they compare in Medicaid opioid prescribing patterns to those of their peers.

Other Interventions to Combat SUDs
To date, Colorado has received two grants from SAMHSA for purposes of combatting the SUD crisis:[5]

State Targeted Response (STR) Grant
SAMHSA provided $15.7 million to the state for the period May 2017 - April 2019. The state used the STR grant to:

- Conduct a state SUD needs assessment that identified areas where opioid misuse and its harms are most prevalent, what existing activities and funding sources are in place to address the opioid crisis, and gaps in the existing system that need to be addressed;
- Provide MAT services to 1,947 individuals, 481 of whom received MAT before or upon release from jail;
- Train 530 prescribers to provide buprenorphine;
- Connect 596 individuals to Peer Recovery Coaches; and
- Distribute 27,027 naloxone kits throughout the state.

State Opioid Response (SOR) Grant
SAMHSA provided $41 million to the state in a second round of funding for the period September 30, 2020 - September 29, 2021. The state will utilize these funds for the following purposes:

Prevention

- Implement family services utilizing the Community Reinforcement and Family Training (CRAFT) model
- Implement culturally responsive prevention programming for American Indian/Alaska Native students

Treatment

- Increase MAT access for uninsured and underinsured Coloradans
- Expand evidence-based treatment program for stimulant use disorder

[4] https://www.colorado.gov/pacific/hcpf/drug-utilization-review-board
[5] https://www.colorado.gov/pacific/cdhs/colorado-state-targeted-response-opioid-crisis

- Place mobile health units for MAT induction in rural areas
- Fund residential treatment services for underinsured and uninsured
- Employ peer navigators to connect clients to treatment
- Provide tools to Colorado hospitals to support MAT initiation within emergency departments as well as disseminate protocols to reduce the use of opioids for treatment of pain
- Implement Practice Improvement Program to support X-waivered prescribers
- Support staff for the Colorado Crisis Hotline
- Implement services identified through a needs assessment for three tribal communities
- Implement MAT in jails

Recovery

- Implement employment services utilizing Individual Placement and Support (IPS) model
- Increase access to peer recovery services at Recovery Community Organizations
- Expand Recovery Housing funding
- Incorporate recovery-based questions on the Behavioral Risk Factor Surveillance System

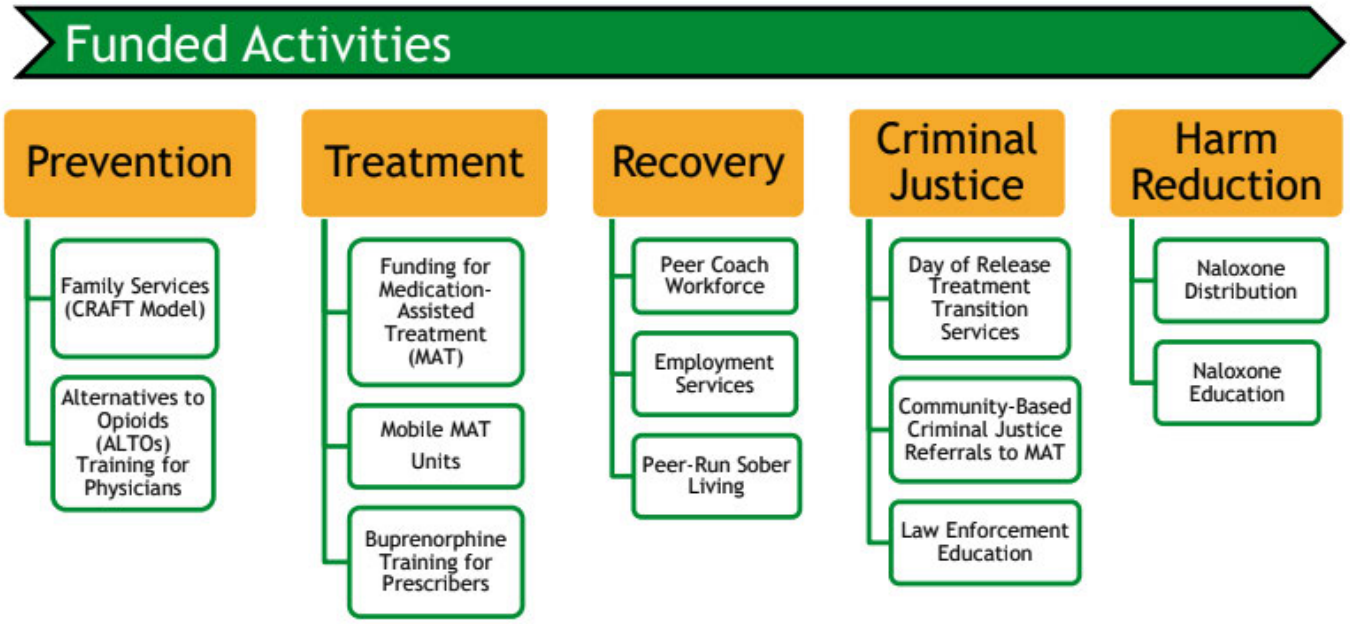
Harm Reduction

- Naloxone distribution
- Increase access to STI/HIV/HCV testing and syringe exchange for people who inject drugs

Communications and Outreach

- Lift the Label and Colorado Crisis Line marketing campaigns to refer people to treatment
- Community outreach about resources available to address the opioid crisis and community concerns

A visual summarizing SAMHSA grant-funded activity is below:



Marijuana Tax Revenue

Since authorizing medical marijuana use in 2000 and personal marijuana use in 2012, Colorado has collected three types of taxes on marijuana: the state sales tax, a special sales tax, and an excise tax. The taxes generate millions of dollars in revenue for the state, which is used for a variety of health, human services, public safety, and higher education programs and initiatives. Some funds are specifically dedicated to SUD treatment and services, including:

- Training for health professionals who provide Screening, Brief Intervention, and Referral for Treatment (SBIRT) services for individuals at risk of substance abuse;
- Increasing access to effective SUD services, including evaluation of intensive residential treatment (the study conducted in conjunction with the authorizing legislation for this demonstration);
- Implementing programs for adults with co-occurring mental health conditions and SUDs;
- Providing behavioral health services for individuals in rural areas with co-occurring mental health conditions and SUDs;
- Implementing community prevention and treatment for alcohol and drug abuse;
- Providing SUD services at mental health facilities; and
- Promoting substance abuse prevention through public awareness campaigns.

Colorado Consortium for Prescription Drug Abuse Prevention

In addition to the activities above, Colorado is working to continue to reduce opioid prescriptions and reduce stigma. During his tenure as governor, Governor John Hickenlooper led an effort to create a workgroup focused on cross-agency ways to address the opioid epidemic. The resulting Colorado Consortium for Prescription Drug Abuse Prevention (Consortium) has grown with a wide range of stakeholders participating in numerous work

groups designed to address the opioid crisis. The Consortium's 2019 Annual Report outlines the accomplishments and future projects which include the placement of 162 safe medication disposal boxes throughout the state, training medical providers on safe opioid prescribing, tracking prescriptions through the PDMP and increasing access to naloxone and MAT.

Future State: The Department has contracted with OpiSafe to provide the opioid risk metric tool for Medicaid providers, which includes:

- Easy access to Prescription Drug Monitoring Program (PDMP) data,
- Identification of Opioid Use Disorders (OUD),
- Educational tools with access to evidence-based treatment,
- Tools for overdose prevention, and
- Provides tracking for health systems and states.

The opioid module will be operational in January 2021. Additionally the Department is initiating a subsidy program where 5,000 user licenses will be provided free of charge to qualified Medicaid prescribers. In collaboration with OpiSafe, HCPF will identify and reach out to high impact prescribers for the subsidy program. HCPF is also partnering with external stakeholders, such the Colorado Pain Society and the Colorado Hospital Association to further identify high impact prescribers suitable for the subsidy program. Any Medicaid prescriber will be able to apply for a subsidized license via an online request form which will be activated by the end of December 2020.

In addition, the state will continue to build on all activities described in the current state section, with an emphasis on monitoring and improving prescribing guidelines based on the latest science and informed by the state's DUR.

B. Expanded Coverage of, and Access to, Naloxone for Overdose Reversal

Current State: In April 2015, Colorado passed Senate Bill 15-053, expanding access to the life-saving drug naloxone, which is used to reverse overdoses to narcotic drugs, such as certain prescription medications and heroin. As a result of the 2015 law, a physician — or any medical professional with prescriptive authority — can write a standing order for naloxone that can be dispensed by other designated individuals (such as pharmacists and harm reduction organizations).

With these standing orders, pharmacists and harm reduction organizations can provide naloxone to those who might benefit from it the most, including:

- A family member, friend, or other person in a position to assist a person at risk of overdose
- An employee or volunteer of a harm reduction organization
- A first responder
- An individual at risk of overdose

Pharmacies can contact the Colorado Department of Public Health & Environment (CDPHE) to request a standing order for naloxone prescriptions. These standing orders are intended for pharmacies that do not have their own medical providers. Those who do have affiliated medical providers should use their prescriptive authority and signature to create their own standing orders.[6]

Colorado has other efforts underway that facilitate access to overdose reversal medications, led by the Consortium, who:

- Through a partnership with OBH, purchased 6,500 naloxone kits with nearly 3,600 kits distributed through October of 2018;
- Facilitated reporting of 439 successful naloxone reversals through the OpiRescue smartphone app since May 1, 2017;
- Trained and equipped 183 law enforcement departments in Colorado to administer naloxone;
- Equipped five county jails to dispense naloxone to inmates upon release;
- Increased the number of pharmacies with standing orders to distribute naloxone;
- Increased collaboration with Walmart, King Soopers, and Walgreens pharmacies;
- Trained AmeriCorps members to become trainers to provide overdose awareness and naloxone education and distribution in their assigned regions;
- Travelled extensively around state for community coalition building and overdose awareness education; and
- Received $335,000 from the Colorado Legislature to expand community-based naloxone education and expand programs for law enforcement.

In addition, the OBH provides Community Reinforcement and Family Training (CRAFT) “train the trainer” classes to help spread this model of support for family members which emphasizes building resilience and teaching treatment strategies. At the end of the training, newly-trained facilitators are issued naloxone kits.

As part of the state’s SOR grant, the OBH also facilitates naloxone distribution programs in jails and schools. OBH has supported the distribution of naloxone in various ways for the past four years. Initially, OBH dedicated state funding aimed at jail-based SUD treatment services to provide naloxone training and medication to at-risk people upon release from incarceration. SAMHSA STR and now SOR funds have been used to expand this to many other high-risk populations. Colorado has standing orders laws that are operationalized through the Colorado Department of Public Health and Environment (CDPHE). The OBH worked with their MSOs to make Narcan Nasal Spray available to all syringe access programs, withdrawal management providers, and treatment programs serving those with opioid use histories. Other organizations, such as first responders or schools, and even public libraries have also utilized this program. More recently, the Naloxone for Life program that was established in 2017 by the State Attorney General Cynthia Coffman, has been supported with OBH funding. This program

[6] https://www.colorado.gov/pacific/dora-pdmp/resources-pdmp

provides Narcan Nasal Spray to law enforcement agencies throughout Colorado. The initial supply of naloxone was from the Attorney General's office, but since the Spring of 2019, OBH has supported replacement doses, or initial supplies for newly adopting law enforcement agencies. Since the beginning of the STR grant, OBH has distributed nearly 40,000 naloxone kits, and had over 1,500 overdose reversals reported using naloxone purchased with SAMHSA grant funds.

Future State: The Consortium's Harm Reduction Work Group has several initiatives underway in 2020, related to developing naloxone training videos, planning educational trainings for pharmacists around safe opioid prescribing, overdose awareness, and naloxone dispensing, and broadening syringe access throughout Colorado.

In addition, the 2019 Colorado legislature created a statewide naloxone bulk purchasing program through SB 19-227. This fund established by CDPHE will allow organizations to buy naloxone at discounted rates. The legislation also appropriated funding to defer the cost for most organizations, such as syringe access programs, law enforcement, or treatment programs. The OBH will dedicate future SAMHSA grant funds into this program to streamline the process for organizations looking to distribute naloxone to at risk people.

C. Strategies to Increase Utilization and Improve Functionality of Prescription Drug Monitoring Programs

Current State: The states' Prescription Drug Monitoring Program (PDMP) is a program run through the Department of Regulatory Agencies (DORA) and governed by the Board of Pharmacy. The PDMP helps prescribers and dispensers reduce prescription drug misuse by allowing them to make more informed decisions when considering prescribing or dispensing a controlled substance to a patient. The PDMP is comprised of controlled substance prescription data uploaded every regular business day through pharmacies across the state.

Historically, access to the state's PDMP has been limited to prescribers and pharmacists with registered accounts. More recently, the Colorado Department of Public Health and Environment (CDPHE) has been granted authority to access information in the PDMP to pilot provider report cards showing prescribers' opioid prescribing practices and comparing them to their peers. The report care pilot has been successful: 83% of prescribers felt that the information was new and 81% found it useful.

Future State: Enhancements and improved participation in the PDMP continues with new pharmacies and medical systems added each year and increased rates of prescriber and pharmacy use. Data from the PDMP will continue to be utilized to inform prescribing guidelines. The Board of Pharmacy is also interested in improving PDMP capabilities and participation to include state-to-state connections to the PDMP. Currently, Colorado's PDMP is connected to all contiguous states except NE and WY. The board also employs surveys and key informant interviews soliciting ideas for improving the PDMP.

Summary of Actions Needed to Achieve Milestone #5

Action Needed	Timeline
Identify opportunities for expanding PDMP functionality and use; DORA responsible	Ongoing
Increase the use of PDMP by providers and pharmacists; DORA responsible	Ongoing
Continue implementing SOR grant activities; OBH responsible	Ongoing
Continue implementing marijuana tax revenue SUD prevention-related activities; OBH responsible	Ongoing
Consortium work groups; Consortium responsible	Ongoing
Statewide naloxone bulk purchasing program; CDPHE responsible	Ongoing

Milestone #6: Improved Care Coordination and Transitions between Levels of Care

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

Colorado's Response:
Colorado is working to ensure that there is a full continuum of care in place in order to effectively serve beneficiaries with SUDs. The Department is working closely with the RAEs and other state agencies to ensure that members receive services along the continuum that are appropriate to their needs and that transitions between levels of care are supported through care coordination.

Current State: The RAEs administer a continuum of outpatient SUD services and facilitate care coordination for members receiving SUD treatment services. Care coordination is overseen by the RAEs and MSOs utilizing a variety of care providers and support services.

Managed Care Contracts and Policies
Current RAE contracts require coordination of services for members between transitions of care and collaboration with MSOs and other agencies to reduce duplication of services and improve member experience.

Under the current system, even though RAEs are not responsible for coverage of residential or inpatient SUD services, they are responsible for facilitating care coordination for members as they leave those levels of care. These services may include:

- Outreach while still in placement or immediately after;
- Arranging for follow-up appointment within seven days of discharge;
- Establishing an initial connection with care coordination staff at community-based facility;
- Medication reconciliation to prevent errors; and
- Provision of clinical information to care coordinator for follow-up and continuity of care.

Other care coordination services provided by RAEs varies by region, though all RAEs report to the state on their specific activities. Generally speaking, RAE care coordination activities include:

- Co-location of care coordinators in behavioral health facilities;

- Availability of coordinators via phone (call and text), email, mail, or in-person;
- Facilitation of needs assessment and individualized goal-setting;
- Referral to health providers and community resources addressing social determinants of health;
- Appointment reminders;
- Medication follow-up;
- Education about navigating systems, coping skills, crisis management, etc.;
- Attending appointments (health and non-health) with members when necessary;
- Safety planning with high-risk members;
- Attending operations meetings at provider locations to talk through complex cases; and
- Care managers that work with individual care coordinators.

Other State Efforts
In addition, both the Medicaid benefit and the OBH-funded services for uninsured include coverage for Peer Recovery Support Services. Peer support services provide needed support to individuals working to maintain their recovery and can be especially helpful to those transitioning between levels of care.

Future State:
Managed Care Contracts and Policies
As the RAEs transition to managing the full continuum of SUD services for all members, they will be in an optimal position to coordinate care during transitions from one level to another. In addition to current RAE contract language that outlines expectations for care coordination, the state has also directed the RAEs to develop policies that outline how they will conduct care coordination for the following:

- Members discharging from residential or inpatient SUD services receive comprehensive support as they transition to lower levels of care and;
- Members awaiting treatment at a facility where no bed is available at the time of referral are provided with interim services.

RAE care coordination policy drafts are currently under review by the Department. The Department has an existing process for monitoring the RAEs care coordination activities through deliverables. The Department is in the process of ensuring that the population of members receiving SUD services are incorporated into that monitoring strategy.

Additionally, the SUD Implementation Workgroup is exploring opportunities for care coordination activities to address gaps and needs in treatment and recovery support.

Other State Efforts
Legislation enacted in 2019 specifically addresses the need for improved care coordination and navigation services for individuals with SUD. HB 19-1287 creates a Care Navigation Program and assigns OBH and HCPF responsibility for ensuring care transitions, including the hiring of a staff person to facilitate implementation of the law. Legislation includes a requirement for a 24/7

crisis hotline, encourages the use of peer support specialists, and creates mechanisms for ensuring that individuals receive care coordination through the staff person hired to implement the initiative. Due to state budget impacts related to COVID-19, implementation of HB19-1287 is subject to available appropriations.

Additionally, the state will be implementing a new care coordination program through the OBH, the Hospital Follow-Up Program. This program will work with hospitals across the state to identify individuals who have experienced a mental health or substance use crisis involving suicidal ideation and could benefit from additional support. Individuals will be paired with a trained crisis or peer support specialist to ensure they continue care, begin outpatient treatment and receive support during a period of heightened risk.

Summary of Actions Needed to Achieve Milestone #6

Action Needed	Timeline
Collaboration with the RAEs to enhance care coordination activities through the Implementation Work Group	January 2021 – Ongoing
RAE policy development to ensure adequate care coordination across the SUD continuum	October - December 2020
Certify recovery residences; Office of Behavioral Health	January 2020 – Ongoing

Attachment A – Template for SUD Health Information Technology (IT) Plan

The following table is a component of Milestone 5, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP.

Prescription Drug Monitoring Program (PDMP) Functionalities			
Milestone Criteria	**Current State**	**Future State**	**Summary of Actions Needed**
Enhanced interstate data sharing to better track patient specific prescription data	Colorado shares data with 33 states through the PMP InterConnect hub, including contiguous states Kansas, Oklahoma, New Mexico, Arizona, Utah and Wyoming. Colorado also shares data through the RxCheck hub with Kentucky, Utah (both hubs), Washington (both hubs) and is in progress with Nebraska. Currently, healthcare organizations with an integrated (API using PMP Gateway) connection to the PDMP have more limited interstate access. Each integrated entity must be approved by other states' PDMPs for access.	Data sharing with additional states will be pursued, but data sharing agreements are contingent on other states' processes and policies for interstate data sharing.	Security enhancements for Colorado's integrated users are being pursued, which will require all integrated users to be validated against the CO PDMP (PMP AWARE) user account list to successfully access the PDMP through an integrated connection (direct EHR connection, e-prescribing software, HIE connection). Expanded interstate access for integrated healthcare entities leveraging reciprocal agreements with other states to approve out of state healthcare entities for PMP Gateway access will be pursued once the security enhancements are implemented.
Enhanced "ease of use" for prescribers and other state and federal stakeholders	Direct PDMP integrations with EHRs, pharmacy management systems and e-prescribing software allow the user to query the PDMP directly within their workflow. All major Colorado pharmacies and approximately 5,000	Prescribers and pharmacies will continue to integrate their electronic health technology with the PDMP.	Integration mini-grants will be offered in fall 2020 to cover the planning and/or implementation costs of PDMP integration, funded by Overdose Data to Action grant (CDPHE is recipient,

	prescribers currently have integrated access through the PMP Gateway. Those without an integrated connection must log in to the PMP AWARE website to query the PDMP. Prescribers and pharmacists can authorize up to three delegates to search the PDMP on their behalf. Delegate access is only in place for the PMP AWARE website.		DORA is sub-recipient through an interagency agreement). The exact number of integration grants is dependent upon available funding with awards anticipated to be at the $5,000, $15,000 and $30,00 level. Organizations in rural or high-burden counties will receive higher priority in the application scoring process.
Enhanced connectivity between the state's PDMP and statewide, regional or local health information exchanges	Pilot projects for QHN and CORHIO funded by CDPHE completed an integrated PDMP connection through PMP Gateway within the HIE portals in March 2018 for CORHIO and in May 2018 for QHN. CORHIO integrated the PatientCare 360 portal for urgent care facilities, QHN implemented an integrated PDMP connection through PMP Gateway for St. Mary's Hospital, which offers single sign-on access to the QHN portal and PDMP can be accessed through the QHN portal. Colorado is sharing data with Nebraska, which operates its PDMP through the state HIE. Access to Colorado PDMP data for Nebraska is currently limited to	Other state HIEs may be considered for interstate access, subject to other states' HIEs requesting access, confirmation that other state HIEs do not download or store PDMP data, and the development of a reciprocal framework for approval of out of state integrated healthcare entities once Colorado implements the aforementioned security enhancements for PMP Gateway integrations.	See "future state" response.

	pharmacists and their delegates because Nebraska law varies from Colorado for prescribers.		
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns (see also “Use of PDMP” #2 below)	Colorado sends prescriber scorecards, which compare a prescriber’s controlled substance prescribing habits to their peers in the same healthcare specialty as well as Patient Alerts, triggered by patients meeting the state’s confidential multiple provider/multiple pharmacy threshold. Section 12-280-404(9), C.R.S. states: Reports generated by the program and provided to prescribing practitioners for purposes of information, education, and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion are: 1. Not public records under the "Colorado Open Records Act", part 2 of article 72 of title 24; 2. Not discoverable in any criminal or administrative proceeding against a prescribing practitioner; and 3. Not admissible in any civil, criminal, or administrative proceeding against a	Additional enhancements may require legislative or rule changes.	

	prescribing practitioner.		

Current and Future PDMP Query Capabilities			
Milestone Criteria	**Current State**	**Future State**	**Summary of Actions Needed**
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)	The PDMP vendor is Appriss, who has shared the patient matching algorithm has a 99.5% success rate.	Further enhancements are not being considered at this time.	

Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			
Milestone Criteria	**Current State**	**Future State**	**Summary of Actions Needed**
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	HB 14-1283 expanded authorized access to allow a prescriber or pharmacist to authorize up to three delegates to search the PDMP on the prescriber's or pharmacist's behalf. Direct EHR integrations, integrations with electronic prescribing software and integrations with HIEs that also offer single sign-on access to PDMP data, which are dependent on specific	Further enhancements are not being considered at this time, however, PDMP integration mini-grants will reimburse approximately 25-30 healthcare organizations with integration implementation costs.	

issues which follow	businesses/facilities, often allow providers to access the PDMP in a single click within the patient's chart.		
Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	This is dependent on the PDMP access method/facility or practice setting for prescribers as described above.	Further enhancements are not being considered at this time; however, expanding PDMP access to delegates allows staff working for prescribers to access PDMP reports on the provider's behalf and competitive PDMP integration mini-grants will reimburse healthcare organizations with integration implementation costs in the near future. Additionally, the Board has approved over 230 PMP Gateway licenses for Colorado healthcare organizations, covering over 700 facilities in their requests for integration, which continues to increase depending on facility/practice needs and funding.	

Master Patient Index / Identity Management			
Milestone Criteria	**Current State**	**Future State**	**Summary of Actions Needed**
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery	Prescriptions for SUD (suboxone, etc.) dispensed by a pharmacy are reported to the PDMP. SUD drugs dispensed by an entity governed by 42 CFR Part 2 are not required to report dispensations to the PDMP. Any DEA-licensed practitioner or their delegate can search the PDMP for any current patient. Clinical	The Board and Division are committed to enhancing the PDMP to best meet the needs of the state. Additional	

	decision support tools can leverage PDMP data with other data sources if connected to the PDMP and other data sets.	enhancements may require legislative or other changes.	

Overall Objective for Enhancing PDMP Functionality & Interoperability			
Milestone Criteria	**Current State**	**Future State**	**Summary of Actions Needed**
Leverage the above functionalities, capabilities, and supports (in concert with any other state health IT, TA 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 Colorado legislature is currently contemplating House Bill 20-1085, which aims to curb inappropriate opioid prescribing, amongst other efforts.	The Board and Division are committed to enhancing the PDMP to best meet the needs of the state. Additional enhancements may require legislative or other changes.	

Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) - Planned Metrics (Version 5.0)
State: Colorado
Demonstration Name: Extending the Substance Use Disorder Continuum of Care

Substance Use Disorder (SUD) Planned Metrics

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specification manual		Phased-in metrics reporting		
#	Metric name	Metric description	Milestone or reporting topic*	Metric type	Reporting frequency	Data source	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Aztext that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data source, definition, codes, target population, etc.)	State plans to phase in (reporting X/N)	Report in which metric will be phased in (Format SUD DY1); ex. DY1#333	Explanation of any plans to phase in retroactive 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 metric*	*EXAMPLE: Medical record review or claims*	*EXAMPLE: Month*	*EXAMPLE: Quarterly*	*EXAMPLE: Recommended*	*EXAMPLE: Y*	*EXAMPLE: 07/1/2018-06/30/2019*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: N*	*EXAMPLE: The Department will use state-defined procedure codes / rate specific codes to calculate this metric.*	*EXAMPLE: Y*	*EXAMPLE: DY2*	*EXAMPLE: This measure requires an update to the Adult Needs and Strengths Assessment tool that reflects an 4SAM 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 metric	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 metric	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Detoxification Value Set: codes not covered by Colorado include H0009, H0012, H0013, H0014, HZZZZZZ, due to the lookback period, codes S3005, T1007, T1019, and T1023 need to be included since they were replaced with H0010 after implementation. • Emergency Department Value Set: 4525898 is not covered by Colorado. • IET Stand Alone Visits Value Set: codes not covered by Colorado include G0155, G0396, G0397, G0409, G0410, G0411, G0463, G0463, H0007, H0016, H0022, H0047, H2010, H2013, H2020, H2035, M0064, S0201, S9484, T1006, T1012, T1015 • Inpatient Value Set: codes not covered by Colorado include 0190, 0191, 0192, 0193, 0194, 0199, 1001. • Telephone Visits Value Set: no codes are covered by Colorado (11797002, 185317003, 314049005, 386472008, 386473003, 386479004). • IET Visits Group 1 Value Set: 90845 is not covered by Colorado. • Online Assessments: Value Set: no codes are covered by Colorado (98970, 98971, 98972, 99421, 99422, 99423).	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 metric	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	Same as metric #3.	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 metric	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• HCPCS Value Set: codes not covered by Colorado include: H0050, G0396 , G0397. • UB Revenue Value Set: 1001 is not covered by Colorado.	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Detoxification Value Set: codes not covered by Colorado include H0009, H0012, H0013, H0014, HZZZZZZ, due to the lookback period, codes S3005, T1007, T1019, and T1023 need to be included since they were replaced with H0010 after implementation. • Emergency Department Value Set: 4525898 is not covered by Colorado. • IAD Stand Alone Outpatient Value Set: codes not covered by Colorado include: 96101, 96102, 96103, 96111, 96118, 96119, 96120, 98960, 98961, 98962, 99078, G0155, G0396, G0397, G0409, G0442, G0443, G0463, H0007, H0012, H0013, H0014, H0016, H0022, H0047, H0050, H2010, H2013, H2020, M0064, S9475, T1006, T1012, T1015, S9483, 99510, 0527, 0528, 0902, 0903, 0904, 0916, 0917, 0918, 0919, 0983 • Inpatient Value Set: codes not covered by Colorado include 0190, 0191, 0192, 0193, 0194, 0199, 1001. • Telephone Visits Value Set: no codes are covered by Colorado (11797002, 185317003, 314049005, 386472008, 386473003, 386479004). • Early Intervention Value Set: codes not covered by Colorado include: H0050, G0396, G0397, H0050, G0396, G0397. • HCPCS Value Set: codes not covered by Colorado include: H0050, G0396 , G0397. • IAD Stand Alone IOP/PH Value Set: codes not covered by Colorado include: G0410, G0411, S0201, S9484, 0905, 0906, 0907. • IAD Stand Alone Outpatient Value Set: codes not covered by Colorado include: 96101, 96102, 96103, 96111, 96118, 96119, 96120, 98960, 98961, 98962, 99078, G0155, G0396, G0397, G0409, G0442, G0443, G0463, H0007, H0012, H0013, H0014, H0016, H0022, H0047, H0050, H2010, H2013, H2020, M0064, S9475, T1006, T1012, T1015, S9483, 99510, 0527, 0528, 0902, 0903, 0904, 0916, 0917, 0918, 0919, 0983 • Telephone Visits Value Set: no codes are covered by Colorado (11797002, 185317003, 314049005, 386472008, 386473003, 386479004). • Online Assessments: Value Set: no codes are covered by Colorado (98970, 98971, 98972, 99421, 99422, 99423). • Visit Setting Unspecified: 90845 is not covered by Colorado.	N		
7	Early Intervention	Number of beneficiaries who used early intervention services (such as precedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Early Intervention Value Set: codes not covered by Colorado include: H0050, G0396, G0397, H0050, G0396, G0397. • Telephone Visits Value Set: no codes are covered by Colorado (11797002, 185317003, 314049005, 386472008, 386473003, 386479004).	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• IAD Stand Alone Outpatient Value Set: codes not covered by Colorado include: 96101, 96102, 96103, 96111, 96118, 96119, 96120, 98960, 98961, 98962, 99078, G0155, G0396, G0397, G0409, G0442, G0443, G0463, H0007, H0012, H0013, H0014, H0016, H0022, H0047, H0050, H2010, H2013, H2020, M0064, S9475, T1006, T1012, T1015, S9483, 99510, 0527, 0528, 0902, 0903, 0904, 0916, 0917, 0918, 0919, 0983 • Telephone Visits Value Set: no codes are covered by Colorado (11797002, 185317003, 314049005, 386472008, 386473003, 386479004). • Online Assessments: Value Set: no codes are covered by Colorado (98970, 98971, 98972, 99421, 99422, 99423). • Visit Setting Unspecified: 90845 is not covered by Colorado.	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Visit Setting Unspecified: 90845 is not covered by Colorado. • IAD Stand Alone IOP/PH Value Set: codes not covered by Colorado include: G0410, G0411, S0201, S9484, 0905, 0906, 0907.	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Inpatient Value Set: codes not covered by Colorado include 0190, 0191, 0192, 0193, 0194, 0199, 1001. • HCPCS Value Set: codes not covered by Colorado include: H0050, G0396 , G0397. • UB Revenue Value Set: 1001 is not covered by Colorado.	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	• Detoxification Value Set: codes not covered by Colorado include H0009, H0012, H0013, H0014, HZZZZZZ, due to the lookback period, codes S3005, T1007, T1019, and T1023 need to be included since they were replaced with H0010 after implementation.	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	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 metric	Provider enrollment database; Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		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 metric	Provider enrollment database; Claims; SAMHSA datasets	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		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 metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		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 addiction treatment.	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Medical record review or claims	Year	Annually	Recommended	N								
17(1)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence (FUA-AD) [NCQA; NQF #3400; Medicaid Adult Core Set; Adjusted HEDIS measure][8]	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of 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 metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
17(2)	Follow-up after Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF #0576; Medicaid Adult Core Set; Adjusted HEDIS measure][8]	Percentage of 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 metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		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 are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
19	Use of Opioids from Multiple Providers in Persons without Cancer (OMP) [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 metric that is an established quality measure	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 metric that is an established quality measure	Claims	Year	Annually	Recommended	N								

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 reporting topic[a]	Metric type	Reporting cadence	Data source	Measurement method	Reporting frequency	Reporting subsets	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data source, definition, codes, target escalation, etc.)	State plans to phase in a metric (Y/N)	Report in which metric will be phased in (Format SUD DY#):	Explanation of any plans to phase in a metric over time
21	Concurrent Use of Opioids and Benzodiazepines (CUB-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 are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	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 metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2020-12/31/2021	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	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 metric	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	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 metric	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	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 metric	State data on cause of death	Year	Annually	Required	Y	01/01/2021-12/31/2021	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 metric	State data on cause of death	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
28	SUD Spending	Total Medicaid SUD spending during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metric	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 metric	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 metric	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 metric	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 metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		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	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		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	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		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 metric	Claims; State-specific IMD database	Year	Annually	Required	Y	01/01/2021-12/31/2021	Stabilize	No more than 30 days	Y		N		
Q1	Total Number of PDMP Users	Annual review of the number of unique prescribers and pharmacies enrolled in the PDMP for noserius.	Health IT	State-specific	Other annual metric	State-specific database	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase			N		
Q2	Number of Opioid Prescriptions in PDMP	Number of opioid prescriptions reported in PDMP	Health IT	State-specific	Other annual metric	State-specific database	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease			N		
Q3	Tracking MAT with Use of Counseling and Behavioral Therapies	Number of individuals receiving both MAT and any other ASAM levels of care through telehealth appointments and other virtual or electronic services.	Health IT	State-specific	Other annual metric	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase			N		
State-Specific Metrics																		
Add rows for any additional state-specific metrics																		

[a]There are no CMS-provided metrics related to milestone 3

[b] Rates 1 and 2 reported for Metric #17(1) correspond to rates 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

[c] Rates 1 and 2 reported for Metric #17(2) correspond to rates 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

Medicaid Section 1115 SUD Demonstrations Protocol (Part A) - Planned Subpopulations (Version 5.0)
State: Colorado
Demonstration Name: Expanding the Substance Use Disorder Continuum of Care

Substance Use Disorder (SUD) Planned Subpopulations

Planned subpopulation reporting						Alignment with CMS-provided technical specifications manual			
						Subpopulations		Relevant metrics	
Subpopulation category	Subpopulations	Reporting priority	Relevant metrics	Subpopulation type	State will report (Y/N)	Attest that planned subpopulation reporting within each category matches the description in the CMS-provided technical specifications manual (Y/N)	If the planned reporting of subpopulations does not match (i.e., column G = "N"), list the subpopulations state plans to report (Format: comma separated)	Attest that metrics reporting for subpopulation category matches CMS-provided technical specifications manual (Y/N)	If the planned reporting of relevant metrics does not match (i.e., column I = "N"), list the metrics for which state plans to report for each subpopulation category (Format: metric number, comma separated)
EXAMPLE: *Age group* ***(Do not delete or edit this row)***	*EXAMPLE:* *Children <18, adults 18–64, and older adults 65+*	*EXAMPLE:* *Required*	*EXAMPLE:* *Metrics #1-3, 6-12, 23, 24, 26, 27*	*EXAMPLE:* *CMS-provided*	*EXAMPLE:* *Y*	*EXAMPLE:* *N*	*EXAMPLE:* *Children/Young adults 12-21, Adults 21-65*	*EXAMPLE:* *N*	*EXAMPLE:* *1, 2, 3*
Age group	Children <18, adults 18–64, and older adults 65+	Required	Metrics #1-3, 6-12, 23, 24, 26, 27	CMS-provided	Y	Y		Y	
Dual–eligible status	Dual-eligible (Medicare-Medicaid eligible), Medicaid only	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y		Y	
Pregnancy status	Pregnant, Not pregnant	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y		Y	
Criminal justice status	Criminally involved, Not criminally involved	Required	Metrics #1-3, 6-12	CMS-provided	Y	N	Data sent directly from the Department of Corrections that flags members in prison being released with release dates. Date of release will be used for the subpopulation flag.	Y	
OUD population	Opioid diagnosis	Recommended	Metrics #2-12, 23, 24, 26, 27, 36	CMS-provided	Y	Y		Y	
[Insert row(s) for any state-specific subpopulation(s)]									

Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) - Reporting Schedule (Version 5.0)

State	Colorado
Demonstration Name	Expanding the Substance Use Disorder Continuum of Care

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 report names and reporting periods should use the format DY#Q# 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 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 E, select Y or N in column G, "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 G= "Y"), the state should describe these deviations in column H, "Explanation for deviations (if column G="Y")" and use column I, "Proposed deviations from standard reporting schedule," to indicate the SUD measurement periods with which it wishes to overwrite the standard schedule (column F). All other columns are locked for editing and should not be altered by the state.

Table 1. Reporting Periods Input Table

	Demonstration reporting periods/dates
Dates of first SUD reporting quarter:	
Reporting period (Format SUD DYQ; Ex. DY1Q1)	DY1Q1
Start date (MM/DD/YYYY)[a]	1/1/2021
End date (MM/DD/YYYY)	3/31/2021
Broader section 1115 demonstration reporting period correponding with the first SUD reporting quarter, if applicable. If there is no broader demonstration, fill in the first SUD reporting period. (Format DYQ; Ex. DY3Q1)	DY1Q1
First SUD report due date (per STC) (MM/DD/YYYY)	5/30/2021
First SUD report in which the state plans to report annual metrics that are established quality measures (EQMs)	
Baseline period for EQMs (Format CY; Ex. CY2019)	CY2021
SUD DY and Q associated with report (Format SUD DYQ; Ex. DY1Q1)	DY2Q3
Start date (MM/DD/YYYY)	7/1/2022
End date (MM/DD/YYYY)	9/30/2022
Dates of last SUD reporting quarter:	
Start date (MM/DD/YYYY)	10/1/2025
End date (MM/DD/YYYY)	12/31/2025

Table 2. SUD Demonstration Reporting Schedule

Dates of SUD reporting quarter (MM/DD/YYYY - MM/DD/YYYY) Start date	End date	Report due (per STC) (MM/DD/YYYY)	Broader section 1115 reporting period, if applicable; else SUD reporting period (Format DYQ; Ex. DY1Q3)	Reporting category	For each reporting category, measurement period for which information is captured in monitoring report per standard reporting schedule (Format DYQ; Ex. DY1Q3)[b] SUD	Deviation from standard reporting schedule (Y/N)	Explanation for deviations (if column G="Y")	Proposed deviations from standard reporting schedule (Format DYQ; Ex. DY1Q3)
1/1/2021	3/31/2021	5/30/2021	DY1Q1	Narrative information	DY1Q1	N		
				Grievances and appeals	DY1Q1	N		
				Other monthly and quarterly metrics		N		
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
4/1/2021	6/30/2021	8/29/2021	DY1Q2	Narrative information	DY1Q2	N		
				Grievances and appeals	DY1Q2	N		
				Other monthly and quarterly metrics	DY1Q1	N		
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
7/1/2021	9/30/2021	11/29/2021	DY1Q3	Narrative information	DY1Q3	N		
				Grievances and appeals	DY1Q3	N		
				Other monthly and quarterly metrics	DY1Q2	N		
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
10/1/2021	12/31/2021	3/31/2022	DY1Q4	Narrative information	DY1Q4	N		
				Grievances and appeals	DY1Q4	N		
				Other monthly and quarterly metrics	DY1Q3	N		
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
1/1/2022	3/31/2022	5/30/2022	DY2Q1	Narrative information	DY2Q1	N		
				Grievances and appeals	DY2Q1	N		
				Other monthly and quarterly metrics	DY1Q4	N		
				Annual metrics that are established quality measures		N		
				Other annual metrics	DY1	N		
4/1/2022	6/30/2022	8/29/2022	DY2Q2	Narrative information	DY2Q2	Y	Report due 9/28 based on State reporting	
				Grievances and appeals	DY2Q2	Y	Report due 9/28 based on State reporting	
				Other monthly and quarterly metrics	DY2Q1	Y	6 month lag needed; Report due 9/28 based on State reporting; Consistent 3-month claims runout for all data will be used	DY1Q4
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
7/1/2022	9/30/2022	11/29/2022	DY2Q3	Narrative information	DY2Q3	Y	Report due 12/29 based on State reporting	
				Grievances and appeals	DY2Q3	Y	Report due 12/29 based on State reporting	
				Other monthly and quarterly metrics	DY2Q2	Y	6 month lag needed; Report due 12/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY2Q1
				Annual metrics that are established quality measures	CY2021	Y	Report due 12/29 based on State reporting	
				Other annual metrics		N		
10/1/2022	12/31/2022	3/31/2023	DY2Q4	Narrative information	DY2Q4	Y	Report due 4/30 based on State reporting	
				Grievances and appeals	DY2Q4	Y	Report due 4/30 based on State reporting	
				Other monthly and quarterly metrics	DY2Q3	Y	6 month lag needed; Report due 4/30 based on State reporting; Consistent 3-month claims runout for all data will be used	DY2Q2
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
1/1/2023	3/31/2023	5/30/2023	DY3Q1	Narrative information	DY3Q1	Y	Report due 6/29 based on State reporting	
				Grievances and appeals	DY3Q1	Y	Report due 6/29 based on State reporting	
				Other monthly and quarterly metrics	DY2Q4	Y	6 month lag needed; Report due 6/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY2Q3
				Annual metrics that are established quality measures		N		
				Other annual metrics	DY2	Y	6 month lag needed; Report due 6/29 based on State reporting; Consistent 3-month claims runout for all data will be used	Reported DY3Q3

Start date	End date	(MM/DD/YYYY)	(Format DYQ; Ex. DY1Q3)	Reporting category	SUD	(Y/N)	(if column G="Y")	(Format DYQ; Ex. DY1Q3)
4/1/2023	6/30/2023	8/29/2023	DY3Q2	Narrative information	DY3Q2	Y	Report due 9/28 based on State reporting	
				Grievances and appeals	DY3Q2	Y	Report due 9/28 based on State reporting	
				Other monthly and quarterly metrics	DY3Q1	Y	6 month lag needed; Report due 9/28 based on State reporting; Consistent 3-month claims runout for all data will be used	DY2Q4
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
7/1/2023	9/30/2023	11/29/2023	DY3Q3	Narrative information	DY3Q3	Y	Report due 12/29 based on State reporting	
				Grievances and appeals	DY3Q3	Y	Report due 12/29 based on State reporting	
				Other monthly and quarterly metrics	DY3Q2	Y	6 month lag needed; Report due 12/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY3Q1
				Annual metrics that are established quality measures	CY2022	Y	Report due 12/29 based on State reporting	
				Other annual metrics		N		
10/1/2023	12/31/2023	3/30/2024	DY3Q4	Narrative information	DY3Q4	Y	Report due 4/29 based on State reporting	
				Grievances and appeals	DY3Q4	Y	Report due 4/29 based on State reporting	
				Other monthly and quarterly metrics	DY3Q3	Y	6 month lag needed; Report due 4/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY3Q2
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
1/1/2024	3/31/2024	5/30/2024	DY4Q1	Narrative information	DY4Q1	Y	Report due 6/29 based on State reporting	
				Grievances and appeals	DY4Q1	Y	Report due 6/29 based on State reporting	
				Other monthly and quarterly metrics	DY3Q4	Y	6 month lag needed; Report due 6/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY3Q3
				Annual metrics that are established quality measures		N		
				Other annual metrics	DY3	Y	6 month lag needed; Report due 6/29 based on State reporting	Reported DY4Q3
4/1/2024	6/30/2024	8/29/2024	DY4Q2	Narrative information	DY4Q2	Y	Report due 9/28 based on State reporting	
				Grievances and appeals	DY4Q2	Y	Report due 9/28 based on State reporting	
				Other monthly and quarterly metrics	DY4Q1	Y	6 month lag needed; Report due 9/28 based on State reporting; Consistent 3-month claims runout for all data will be used	DY3Q4
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
7/1/2024	9/30/2024	11/29/2024	DY4Q3	Narrative information	DY4Q3	Y	Report due 12/29 based on State reporting	
				Grievances and appeals	DY4Q3	Y	Report due 12/29 based on State reporting	
				Other monthly and quarterly metrics	DY4Q2	Y	6 month lag needed; Report due 12/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY4Q1
				Annual metrics that are established quality measures	CY2023	N	Report due 12/29 based on State reporting	
				Other annual metrics		N		
10/1/2024	12/31/2024	3/31/2025	DY4Q4	Narrative information	DY4Q4	Y	Report due 4/30 based on State reporting	
				Grievances and appeals	DY4Q4	Y	Report due 4/30 based on State reporting	
				Other monthly and quarterly metrics	DY4Q3	Y	6 month lag needed; Report due 4/30 based on State reporting; Consistent 3-month claims runout for all data will be used	DY4Q2
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
1/1/2025	3/31/2025	5/30/2025	DY5Q1	Narrative information	DY5Q1	Y	Report due 6/29 based on State reporting	
				Grievances and appeals	DY5Q1	Y	Report due 6/29 based on State reporting	
				Other monthly and quarterly metrics	DY4Q4	Y	6 month lag needed; Report due 6/29 based	DY4Q3

Start date	End date	(MM/DD/YYYY)	(Format DYQ; Ex. DY1Q3)	Reporting category	SUD	(Y/N)	(if column G="Y")	(Format DYQ; Ex. DY1Q3)
				Annual metrics that are established quality measures		N		
				Other annual metrics	DY4	Y	6 month lag needed; Report due 6/29 based on State reporting	Reported DY5Q3
4/1/2025	6/30/2025	8/29/2025	DY5Q2	Narrative information	DY5Q2	Y	Report due 9/28 based on State reporting	
				Grievances and appeals	DY5Q2	Y	Report due 9/28 based on State reporting	
				Other monthly and quarterly metrics	DY5Q1	Y	6 month lag needed; Report due 9/28 based on State reporting; Consistent 3-month claims runout for all data will be used	DY4Q4
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
7/1/2025	9/30/2025	11/29/2025	DY5Q3	Narrative information	DY5Q3	Y	Report due 12/29 based on State reporting	
				Grievances and appeals	DY5Q3	Y	Report due 12/29 based on State reporting	
				Other monthly and quarterly metrics	DY5Q2	Y	6 month lag needed; Report due 12/29 based on State reporting; Consistent 3-month claims runout for all data will be used	DY5Q1
				Annual metrics that are established quality measures	CY2024	Y	Report due 12/29 based on State reporting	
				Other annual metrics		N		
10/1/2025	12/31/2025	3/31/2026	DY5Q4	Narrative information	DY5Q4	Y	Report due 4/30 based on State reporting	
				Grievances and appeals	DY5Q4	Y	Report due 4/30 based on State reporting	
				Other monthly and quarterly metrics	DY5Q3	Y	6 month lag needed; Report due 4/30 based on State reporting; Consistent 3-month claims runout for all data will be used	DY5Q2
				Annual metrics that are established quality measures		N		
				Other annual metrics		N		
Add rows for all additional demonstration reporting quarters								

Notes:

[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 12/15/2020, with an effective date of 1/1/2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration. Please see Appendix A of the Monitoring Protocol Instructions for more information on determining demonstration quarter timing.

[b] The auto-populated reporting schedule in Table 2 outlines the data 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 protocol approval. The state should see Section B of the Monitoring Report Instructions for more information on retrospective reporting of data following protocol approval.

Mercer

Substance Use Disorder 1115 Waiver

Evaluation Design

State of Colorado
April 29, 2022

welcome to brighter

Contents

1

General Background Information

History and Overview

Over the past 20 years, the State of Colorado (Colorado or State), like the rest of the country, has felt the impact of the opioid epidemic and has experienced an increase in the rate of substance use disorder (SUD) diagnosis. Data collected by the Colorado Department of Public Health and Environment between 1999–2017 show that:

- An estimated half a million Coloradans are dependent on alcohol or have used illicit drugs. Nearly 30% (142,000) are Medicaid members.[1]
- Between 2000–2017, 12,821 Coloradans died due to a drug overdose.
- The number of overdose deaths has increased from 7.8 deaths per 100,000 in 2000 to 17.6 deaths per 100,000 in 2017.
- Opioid use is leading the overdose epidemic, accounting for over half of the overdose deaths between 2013 and 2017, two-thirds of which are attributable to prescription opioids.[2]

[1] Colorado Health Institute. *Exploring Options for Residential and Inpatient Treatment of Substance Use Disorder in Health First Colorado.* November 2017. Available at: https://www.colorado.gov/pacific/sites/default/files/HCPF%202017%20Inpatient%20SUD%20Treatment%20Report.pdf

[2] Bol K. Colorado Department of Public Health and Environment. *Drug Overdose Deaths in Colorado. Final Data. 1999-2017.* December 2018.

While opioid overdoses in Colorado rose between 2000 and 2017, other drugs including alcohol and methamphetamine drive the rate of admissions for addiction treatment in the State. In 2017, alcohol was responsible for the majority of treatment admissions, followed by methamphetamine. From 2013 to 2017, methamphetamine-related admissions increased by 63%.[3]

Colorado Medicaid members are particularly affected by SUDs, impacting the health outcomes and cost of this population:

- An estimated 11% of Medicaid members have an SUD diagnosis.[4]
- Twenty-nine percent of those who die from an overdose in Colorado are Medicaid members.
- The most prevalent substances abused among Medicaid members are alcohol and methamphetamine.[5]

The costs to the health care system are clear:

- Though 11% of the Medicaid population, the cost of care for members with a SUD diagnosis accounts for nearly 19% of the total cost of care to the system.
- On average, the annual cost of care for a Medicaid member with an SUD diagnosis is nearly double the cost for one without ($10,445 versus $5,646).
- Members with an SUD diagnosis account for 20% of the State's non-SUD related pharmacy spending.[6]

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[3] Russell S. "Colorado Drug Trends." Drug/Alcohol Coordinated Data System (DACODS), Colorado Department of Human Services Office of Behavioral Health. 2018.

[4] Ibid.

[5] Colorado Health Institute. *Exploring Options for Residential and Inpatient Treatment of Substance Use Disorder in Health First Colorado.* November 2017. Available at: https://www.colorado.gov/pacific/sites/default/files/HCPF%202017%20Inpatient%20SUD%20Treatment%20Repor t.pdf

[6] Colorado Substance Use Disorder Data Fiscal Year 2017-2018. Colorado Department of Health Care Policy & Financing, Pharmacy and Behavioral Health Data Division. 2019.

Additionally, according to the 2017 Colorado Health Access Survey (CHAS), despite the State's efforts to date, Colorado continues to have an unmet need for SUD treatment.[7] The survey shows that more than 67,000 Coloradans need some type of treatment for drug or alcohol use but do not receive it. Many more Coloradans need treatment but are not ready to seek it.

Although these numbers reflect all Coloradans, given the higher prevalence of SUD among Medicaid members, it is clear that there is a need for more access to services.

Colorado's Medicaid Behavioral Health Delivery System

In 1995, the State implemented the Colorado Medicaid Mental Health Capitation and Managed Care Program in 51 counties, and expanded it to the remaining 12 counties in 1998. Through the program, the State was divided into eight geographic areas and the program was administered by Mental Health Assessment and Service Agencies (MHASAs). In 2004, program operations were transferred to the Department of Health Care Policy and Financing (HCPF) from the Department of Human Services, allowing for more cohesive management.

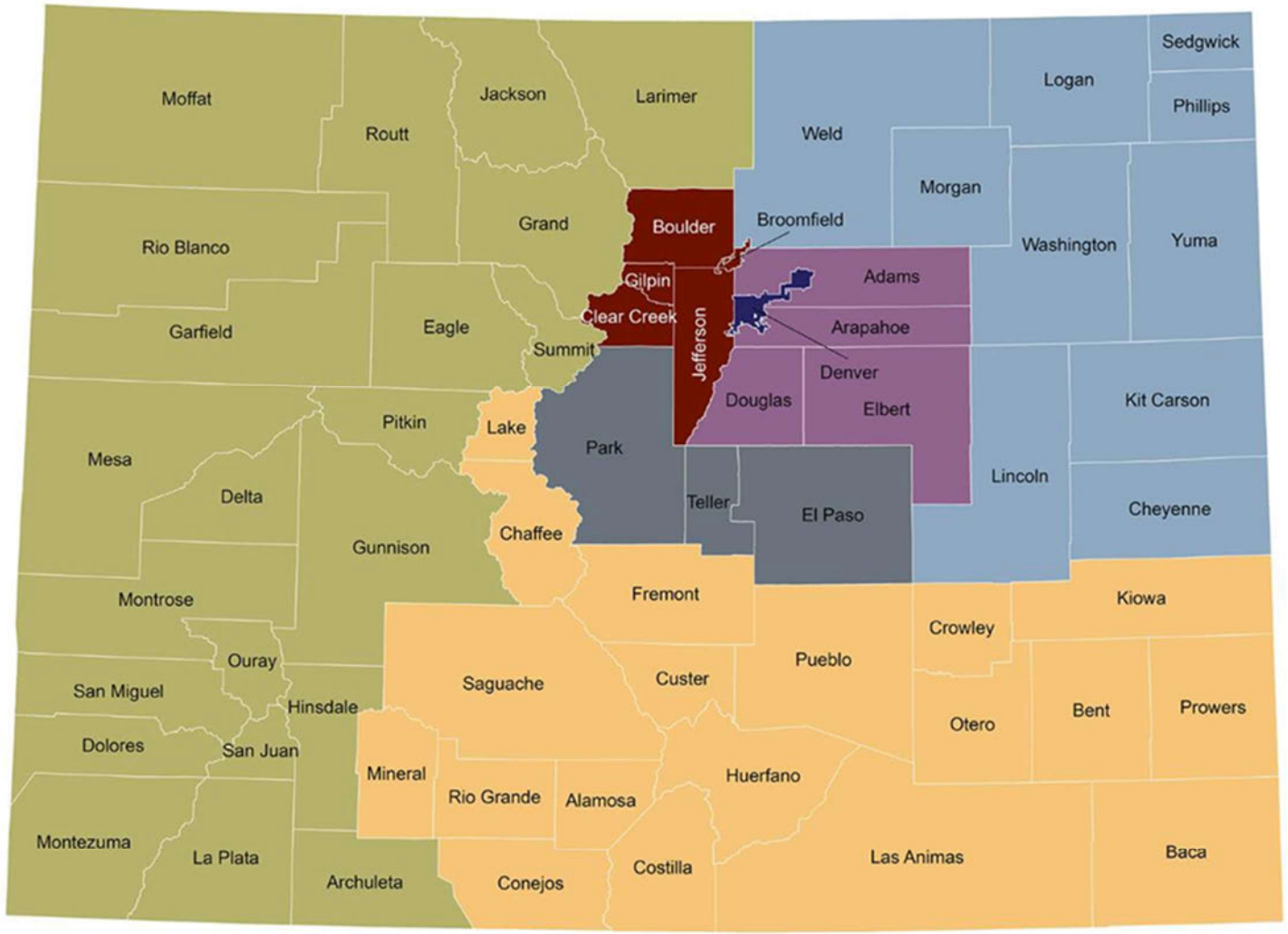
The waiver for the Mental Health Capitation and Managed Care Program was amended several times. A 2013 amendment — effective from January 1, 2014 through June 30, 2015 — included coverage of SUD treatment services and provided the authority to serve the Medicaid expansion population. In 2015, the Centers for Medicare & Medicaid Services (CMS) approved a waiver renewal from January 1, 2016 to June 30, 2017 incorporating former foster care children, expansion parents, and children age six through 19 with incomes above 100% but at or below 133% of the federal poverty level. The waiver was renewed again from July 1, 2017 to June 30, 2018.

Colorado Medicaid divided the State into seven geographic regions for the ACC. Each region is served by one Regional Accountable Entity (RAE). The RAEs are responsible for promoting physical and behavioral health in each of the seven regions. The RAEs manage a network of primary care physical health providers and specialty behavioral health providers to ensure access to appropriate care for Medicaid members in their region. A critical function of the RAEs is to create a cohesive network of providers that work together seamlessly and effectively to provide coordinated health care services to members.

[7] Colorado Health Institute. *2017 Colorado Health Access Survey: The New Normal*. https://www.coloradohealthinstitute.org/research/colorado-health-access-survey-2017

In January 2020, at the direction of the legislature and the governor, the State of Colorado entered into a contract with an additional managed care organization (MCO) to serve the Denver area. This MCO functions similarly to the seven RAEs in rest of the state, but its administrative structure differs from the RAEs. The seven RAEs and the Denver Health MCO will each provide services under this demonstration and data collected from these organizations will be used in the demonstration evaluation. For the remainder of this document the RAEs and the Denver Health MCO will be collectively referred to as Managed Care Entities (MCEs).

Regional Accountable Entity Regions in ACC Phase 2



Residential Substance Use Disorder Treatment in Colorado

In addition to the capitated behavioral health system, which provides services to Medicaid members, the Colorado Office of Behavioral Health (OBH) contracts with four Managed Service Organizations (MSOs) to deliver a continuum of SUD services that includes inpatient and residential treatment services. MSOs are funded through a combination of state and federal Substance Abuse and Mental Health Services Administration (SAMHSA) block grant dollars, but do not pay for services otherwise covered by Medicaid.

For some Medicaid members, the MSOs provide inpatient residential treatment services, prioritizing injection drug users, parents, and pregnant women. Aside from providing inpatient and residential treatment to priority Medicaid members, the MSOs are required to ensure that people who have no other means of paying for treatment (i.e., based on insurance status or income) receive services funded under their contract with OBH.[8]

The MSOs contract with providers to deliver transitional residential treatment for adults (American Society of Addiction Medicine [ASAM] Level 3.1), Clinically Managed Residential Services (ASAM Level 3.5), Intensive Residential Treatment for adults and adolescents (ASAM Level 3.7), and Strategic Individualized Remediation Treatment (STIRT).

Through this Medicaid Section 1115 waiver, the MCEs will provide residential and inpatient SUD services to Medicaid members. The role of the MSOs will evolve as the new Medicaid benefits take effect and the State looks at options for using SAMHSA grant dollars and MSO infrastructure to enhance the State's overall delivery system.

Federal Grant Efforts to Combat SUDs

To date, Colorado has received three grants from SAMHSA for purposes of combatting the SUD crisis:[9]

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[8] JSI Research and Training Institute, Inc. *A Statewide Evaluation of the effectiveness of Intensive Residential Substance Use Disorder Treatment Provided through Managed Service Organizations.* December 2018.

[9] https://www.colorado.gov/pacific/cHCPF/colorado-state-targeted-response-opioid-crisis

Medication-Assisted Treatment Prescription Drug and Opioid Addiction (MAT-PDOA) Grant

SAMHSA provided $950,000 to the State from September 2016–September 2019. The State used the MAT-PDOA grant to:

- Enhance and expand treatment service systems to increase capacity and provide accessible, effective, comprehensive, coordinated care, and medication-assisted treatment (MAT) to individuals with OUD.
- Enhanced a "hub and spoke" model for the delivery of MAT services and ancillary wraparound services (mental health supports, transportation, childcare, housing, family services).
- Provide MAT services to 763 individuals.

State Targeted Response (STR) Grant

SAMHSA provided $15.7 million to the State from May 2017–April 2019. The State used the STR grant to:

- Conduct a State SUD needs assessment that identified areas where opioid misuse and its harms are most prevalent, what existing activities and funding sources are in place to address the opioid crisis, and gaps in the existing system that need to be addressed.
- Provide medication-assisted treatment (MAT) services to 1,947 individuals, 481 of whom received MAT before or upon release from jail.
- Train 530 prescribers to provide buprenorphine.
- Connect 596 individuals to Peer Recovery Coaches.
- Distribute 27,027 naloxone kits throughout the State.

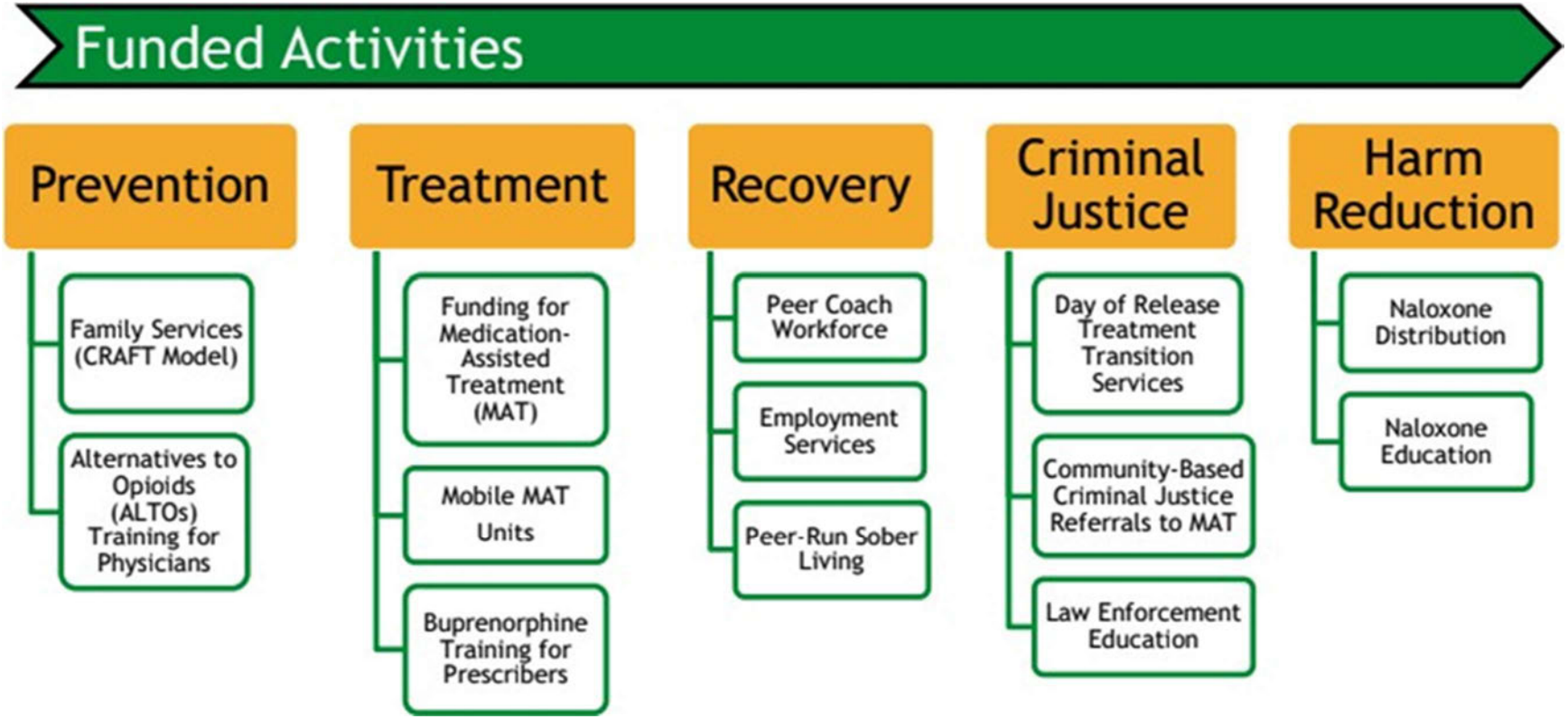
State Opioid Response (SOR) Grant

SAMHSA provided $38 million to the State to extend and expand efforts undertaken through the STR grant until 2020. By the end of the SOR grant period, the State also plans to:

- Connect at least an additional 900 individuals to MAT through mobile MAT units in rural communities.

- Train 400 individuals in the Community Reinforcement and Family Training with Prevention (CRAFT-P) and Celebrating Families models (models focused on supporting family members of individuals struggling with SUDs and how to encourage and motivate loved ones into treatment and/or maintain recovery).
- Hire 18 more Peer Recovery Coaches.
- Train 425 more prescribers with a focus on rural areas.
- Distribute 18,000 more naloxone kits.

A visual summarizing SAMHSA grant-funded activities is below:



Other Efforts to Combat SUDs

Since authorizing medical marijuana use in 2000 and personal marijuana use in 2012, Colorado has collected three types of taxes on marijuana: the State sales tax, a special sales tax, and an excise tax. The taxes generate millions of dollars in revenue for the State, which is used for a variety of health, human services, public safety, and higher education programs and initiatives. Some funds are specific to SUD treatment and services, including:

- Training for health professionals to provide Screening, Brief Intervention, and Referral for Treatment (SBIRT) services for Medicaid clients at risk for substance abuse.
- Increasing access to effective SUD services, including evaluation of intensive residential treatment (the study conducted in conjunction with authorizing legislation for this waiver).
- Implementing programs for adults with co-occurring mental health and SUDs.
- Providing behavioral health services for individuals in rural areas with co-occurring mental health and SUDs.
- Implementing community prevention and treatment for alcohol and drug abuse.
- Providing SUD services at mental health institutes.
- Promoting substance abuse prevention through public awareness campaigns.

In addition to the activities above, Colorado is working to continue to reduce opioid prescriptions and reduce stigma. One of the first changes the State made was to develop the Colorado Consortium for Prescription Drug Abuse Prevention in 2013. The Consortium is a statewide organization with a wide range of participating stakeholders that has numerous workgroups designed to address the opioid crisis, with topics including: provider education; public awareness; use of the Prescription Drug Monitoring Program (PDMP); naloxone; and support for affected friends and families.

Colorado Medicaid has also taken a number of steps over the past five years that have resulted in a more than 50% reduction in the number of pills prescribed and a 44% reduction in the number of Medicaid members taking opioids. Those policy initiatives have been aimed at reducing the number of opioids prescribed to members, tightening criteria when requesting refills, and reducing the daily Morphine Milligram Equivalents (MME) members can take — all while continually ensuring members receive necessary medications for adequate pain management.

Lastly, Colorado's Lift the Label campaign has set a goal of reducing the stigma that prevents those with opioid use disorder (OUD) from getting treatment.

Demonstration Approval

On November 13, 2020, Colorado received approval for its application for a section 1115(a) demonstration titled "Expanding the Substance Use Disorder Continuum of Care" (Project Number 11-W-00336/8) effective January 1, 2021 through December 31, 2025.

Description of the Demonstration

This waiver will provide access to residential and inpatient treatment settings, expand the availability of withdrawal management (WM) services, and increase access to MAT for members with SUD or alcohol use disorder (AUD). These changes will ensure that the most appropriate levels of care are available for patients and improve treatment outcomes.

Colorado will add ASAM levels 3.1 (Clinically Managed Low-intensity Residential Services), 3.3 (Clinically Managed Population-specific High-intensity Residential Services), 3.5 (Clinically Managed High-intensity Residential Services) and 3.7 (Medically Monitored Intensive Inpatient Services), and 3.7-WM (Medically Managed Inpatient Withdrawal Management) as Medicaid-covered services.

We anticipate that this demonstration will accomplish the following goals and objectives, which make up our demonstration hypothesis. This waiver demonstration will:

1. Promote increased access to care for members with SUD.
2. Improve the quality of care for members with SUD.
3. Improve outcomes for members using SUD services and maintain costs.

Capacity Assessment for Expanded Inpatient and Residential Services

In order to implement the new SUD benefit, the State has begun efforts to assess and expand Colorado's existing network of inpatient and residential SUD services, currently managed by MSOs.

The State has been collecting information about availability of inpatient and residential bed capacity, including engaging with a contractor to conduct a provider assessment throughout the State.

The 2015 National Survey of Substance Abuse Treatment Services (N-SAATS) results[10] found that Colorado has between 826–1,276 residential beds, 127–216 of which are designated for inpatient SUD treatment. The Colorado Health Institute, in a report prepared for the Department and submitted to the Colorado General Assembly, estimated that this number of beds can serve between 3,090–5,256 people a year with an average 15-day inpatient average length of stay and 10,050–15,525 people with a 30-day residential average length of stay.[11]

Workforce Development and Training

The State will develop a plan and materials to train all providers working within the continuum of care on utilization management and ASAM-based assessment to ensure that the continuum of care is applied appropriately and to reduce the under- and/or overutilization of any of the levels of care. The Department understands the importance of developing and preparing the workforce to meet the growing demands on the system. Planned activities include:

- Ensuring appropriate licensure levels of all sites in the system.
- Defining and training providers on treatment terms to ensure consistency.
- Training providers on evidence-based practices for patient assessment and placement.
- Addressing provider shortages, specifically in rural areas.
- Recruiting providers not currently enrolled as Medicaid providers.

[10] Substance Abuse and Mental Health Services Administration (SAMHSA). *National Survey of Substance Abuse Treatment Facilities (N-SSATS): 2015, Data on Substance Abuse Treatment Facilities.* 2015. Available at: https://www.samhsa.gov/data/report/national-survey-substance-abuse-treatment-facilities-n-ssats-2015-data-substance-abuse

[11] Colorado Health Institute. *Exploring Options for Residential and Inpatient Treatment of Substance Use Disorder in Health First Colorado.* November 2017. Available at: https://www.colorado.gov/pacific/sites/default/files/HCPF%202017%20Inpatient%20SUD%20Treatment%20Report.pdf

Other Implementation Planning Activities

The State is aware of the CMS SUD Implementation Plan requirements and is already planning activities that will support successful waiver implementation. The State has conducted a series of robust stakeholder engagement sessions dating back to October of 2018, culminating in the formal public notice and comment process required for this waiver application. The stakeholder engagement process will continue throughout the waiver negotiation period, which we anticipate will facilitate further discussion of waiver details and inform Department planning for any necessary:

- State regulation changes.
- Provider standards and billing manual updates.
- Provider engagement and training needs.
- MCE contract policy and payment rate changes.

Population Impacted

There will be no changes to the Medicaid eligibility criteria included as part of this waiver. The demonstration will be open to all Medicaid members with a covered SUD diagnosis. The demonstration will have no enrollment limits.

Please see the budget neutrality narrative and worksheets in Section 5 of the waiver application for the projected eligible member months for those members who are expected to participate. Table 2, in Section 5 of the application, presents the Without and With Waiver Projections for covering SUD Institution for Mental Disease (IMD) Adults within the Colorado Medicaid program. The member months included in Table 2 reflect the estimated member months for individuals who use SUD IMD. A 2% growth assumption is applied to the member months, which is based on the average rate of enrollment growth estimated for the Medicaid program. The demonstration is not expected to have an impact on the total Medicaid enrollment for the program beyond the typical Medicaid program enrollment growth.

2

Evaluation Questions and Hypotheses

Evaluation questions and hypotheses to be addressed were derived from and organized based on the Driver Diagrams below. The overall aims of the project are to: 1) Promote increased access to care for members with SUD; 2) Improve the quality of care for members with SUD; and 3) Improve outcomes for members using SUD services and maintain costs. To accomplish these aims, the demonstration includes several key activities, organized primary drivers of change:

- Increased rates of identification, initiation, and engagement in treatment.
- Improved access to physical health care.
- Increased adherence to and retention in treatment.
- Reduction in overdose deaths.
- Fewer readmissions to the same or higher level of care
- Reduced emergency department (ED) and hospital admissions for SUD or OUD.

The specific evaluation questions to be addressed were selected based on the following criteria:

1. Potential for improvement, consistent with the key milestones of the demonstration listed above.
2. Potential for measurement, including (where possible and relevant) baseline measures that can help to isolate the effects of Demonstration initiatives and activities over time.
3. Potential to coordinate with ongoing performance evaluation and monitoring efforts.

Research questions were selected to address the demonstration's major program goals, to be accomplished by demonstration activities associated with each of the primary drivers. Specific hypotheses regarding the demonstration's impact are posed for each of these evaluation questions. These are linked to the primary drivers in the diagrams and tables beginning in Section 2 "Driver Diagrams, Research Questions and Hypotheses," directly following the next section "Targets for Improvement".

Targets for Improvement

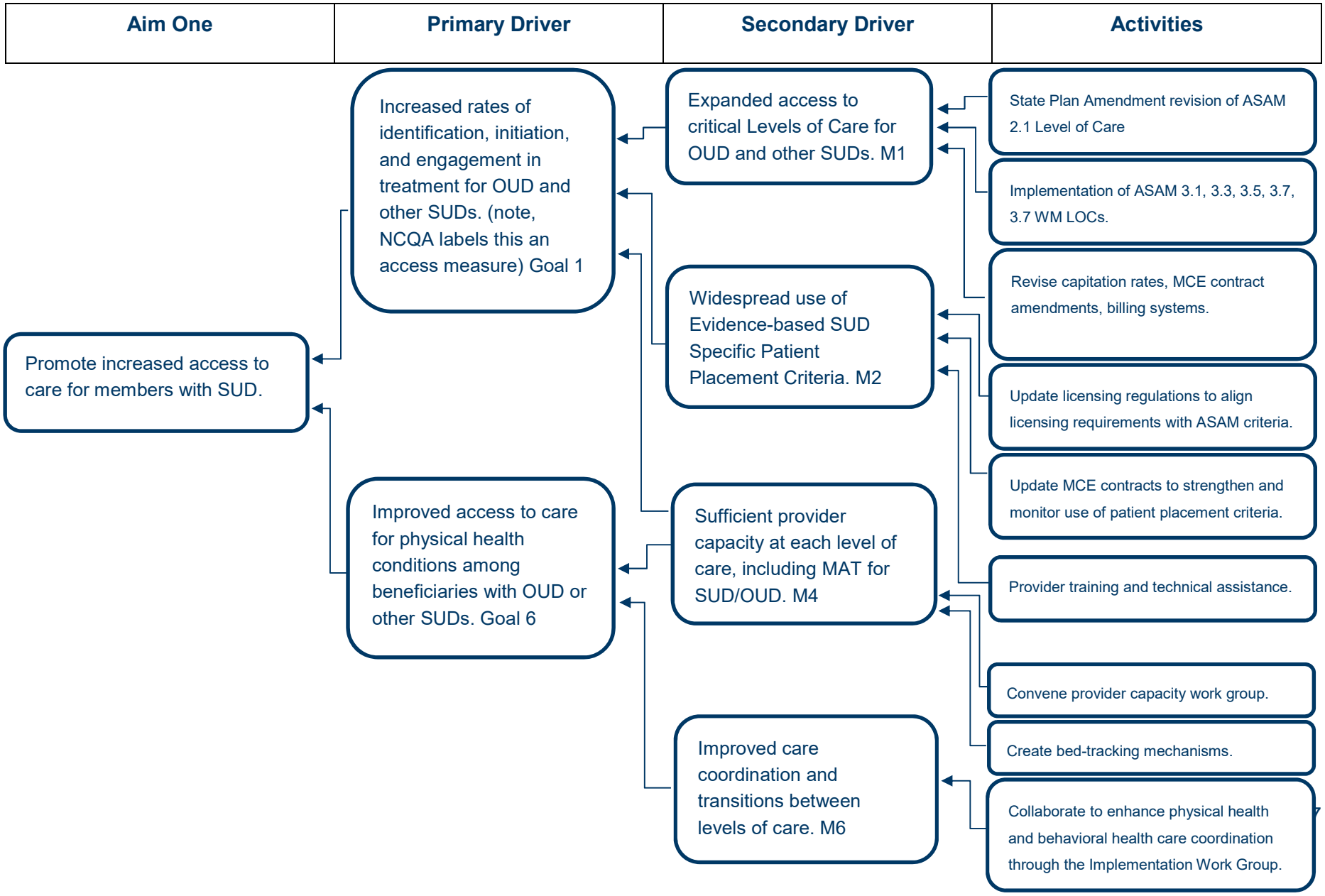
The six goals of the SUD waiver with Targets for Improvement are listed in the table below.

Targets for Improvement

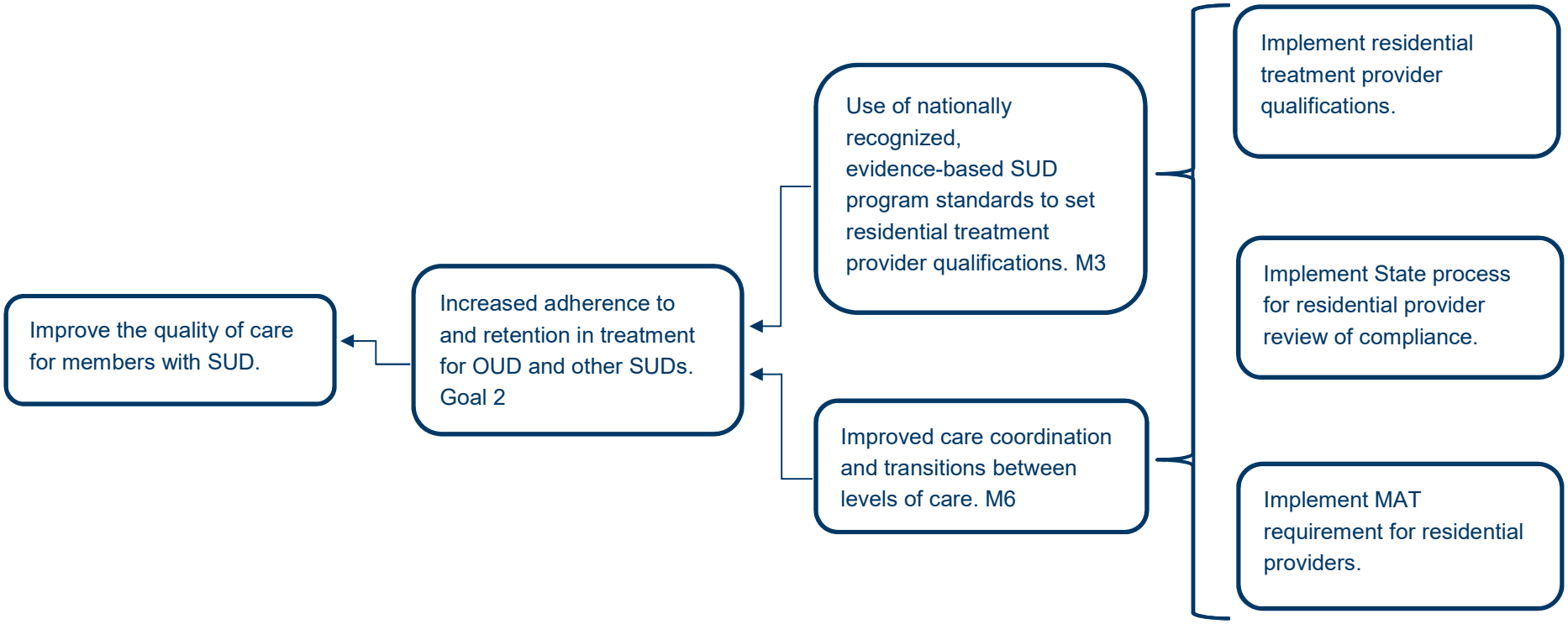
Program Goals (Primary Drivers)	Targets
Increased rates of identification, initiation, and engagement in treatment	• Increased access to critical levels of care for OUD and other SUDs. • Increased use of Evidence-based SUD Specific Patient Placement Criteria.
Increased adherence to and retention in treatment	• Increased use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications. • Improved care coordination and transitions between levels of care.
Reductions in overdose deaths, particularly those due to opioids	• Increased use of comprehensive treatment and prevention strategies to address opioid abuse and OUD. • Increased provider capacity at each level of care, including MAT for SUD/OUD.
Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	• Increased use of Evidence-based SUD Specific Patient Placement Criteria. • Increased provider capacity at each level of care, including MAT for SUD/OUD.
Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	• Increased use of Evidence-based SUD Specific Patient Placement Criteria. • Improved care coordination and transitions between levels of care.
Improved access to care for physical health conditions among beneficiaries	• Improved care coordination and transitions between levels of care for physical care. • Increased use of comprehensive treatment and prevention strategies to address opioid abuse and OUD.

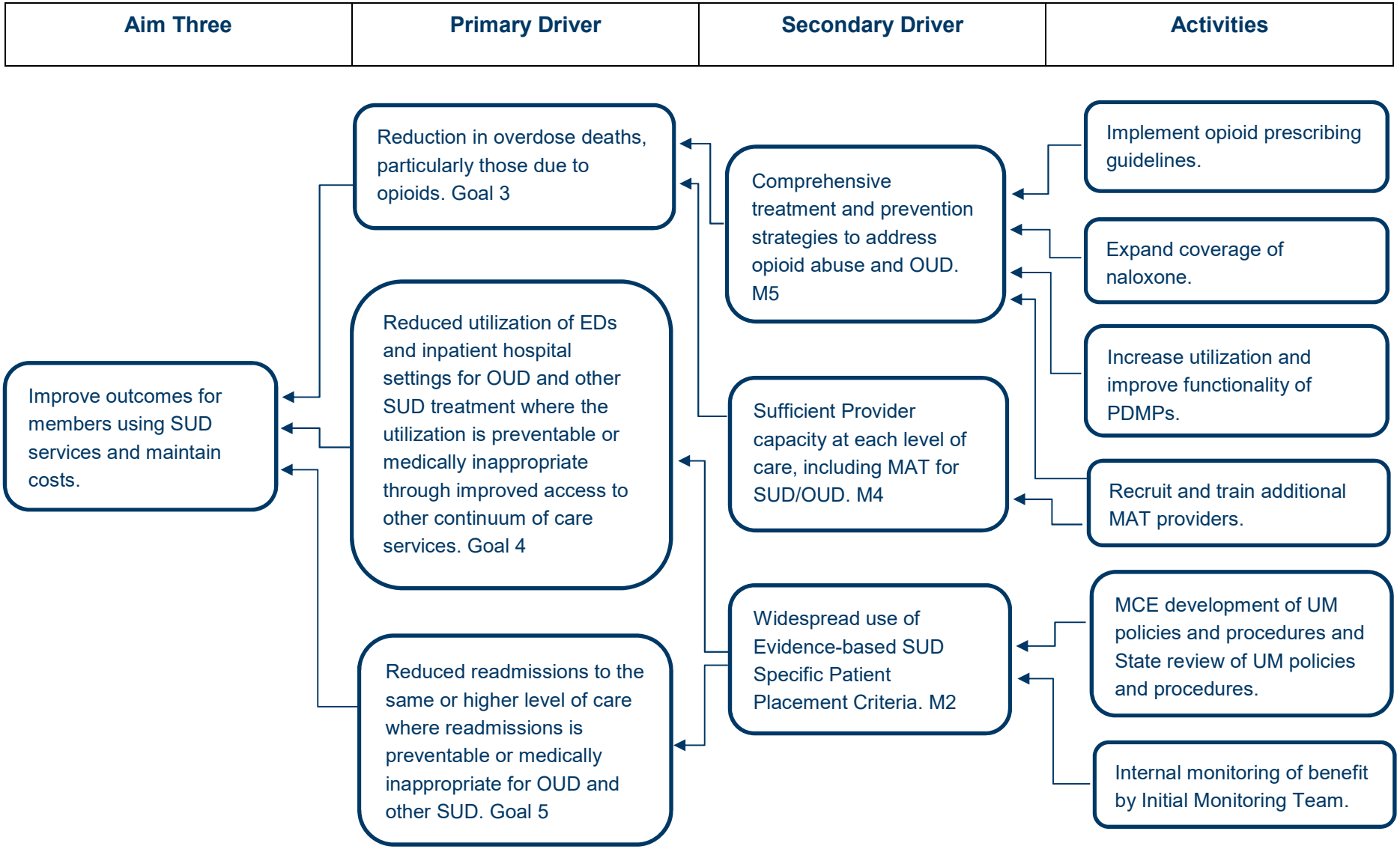
Driver Diagrams, Research Questions and Hypotheses

The three program aims represent the ultimate intentions of the waiver. The primary drivers are strategic improvements or goals to achieve the program aims. The secondary drivers are the interventions (milestones) that will need to be reached in order achieve the strategic improvements. The performance measures outlined with the research question and hypothesis for each milestone describe specific activities completed as part of the implementation. The driver diagrams below present the connections between the program activities, milestones, strategic improvements, and aims.


Aim One
Primary Driver
Secondary Driver
Activities
Promote increased access to care for members with SUD.
Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (note, NCQA labels this an access measure) Goal 1
Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs. Goal 6
Expanded access to critical Levels of Care for OUD and other SUDs. M1
Widespread use of Evidence-based SUD Specific Patient Placement Criteria. M2
Sufficient provider capacity at each level of care, including MAT for SUD/OUD. M4
Improved care coordination and transitions between levels of care. M6
State Plan Amendment revision of ASAM 2.1 Level of Care
Implementation of ASAM 3.1, 3.3, 3.5, 3.7, 3.7 WM LOCs.
Revise capitation rates, MCE contract amendments, billing systems.
Update licensing regulations to align licensing requirements with ASAM criteria.
Update MCE contracts to strengthen and monitor use of patient placement criteria.
Provider training and technical assistance.
Convene provider capacity work group.
Create bed-tracking mechanisms.
Collaborate to enhance physical health and behavioral health care coordination through the Implementation Work Group.

Aim Two	Primary Driver	Secondary Driver	Activities




Aim Three
Primary Driver
Secondary Driver
Activities
Improve outcomes for members using SUD services and maintain costs.
Reduction in overdose deaths, particularly those due to opioids. Goal 3
Reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. Goal 4
Reduced readmissions to the same or higher level of care where readmissions is preventable or medically inappropriate for OUD and other SUD. Goal 5
Comprehensive treatment and prevention strategies to address opioid abuse and OUD. M5
Sufficient Provider capacity at each level of care, including MAT for SUD/OUD. M4
Widespread use of Evidence-based SUD Specific Patient Placement Criteria. M2
Implement opioid prescribing guidelines.
Expand coverage of naloxone.
Increase utilization and improve functionality of PDMPs.
Recruit and train additional MAT providers.
MCE development of UM policies and procedures and State review of UM policies and procedures.
Internal monitoring of benefit by Initial Monitoring Team.

Measuring Effects on the Three Aims

CMS has established milestones and performance measures associated with those milestones to achieve the goals of the waiver. Some of those performance measures being used to monitor progress of the activities can also be used to indicate that the program aims have been met. Ultimately, the activities and milestones organized under the six primary drivers (goals) of:

- Increased rates of identification, initiation, and engagement in treatment.
- Improved access to physical health care.
- Increased adherence to and retention in treatment.
- Reduction in overdose deaths.
- Reduced admissions to higher levels of care.
- Reduced ED and hospital admissions for SUD or OUD.

The activities and milestones are designed to further the three main project aims:

- Promote increased access to care for members with SUD.
- Improve the quality of care for members with SUD.
- Improve outcomes for members using SUD services and maintain costs.

For the outcome evaluation, select performance measures will be used to demonstrate observed changes in outcomes, using an interrupted time-series (ITS) design where sufficient pre-demonstration data is available, or with pre-post comparisons or comparisons to national benchmarks where sufficient pre-demonstration data is not available. Additional performance measures will be collected to monitor progress on meeting the milestones and project goals. These performance measures are grouped and described under the related primary drivers.

The research design table in Section 3, outlines the research questions and hypotheses of the evaluation, organized by each primary driver.

3 Methodology

Evaluation Design

The evaluation of the Colorado SUD 1115 waiver will utilize a mixed-methods evaluation design with three main goals:

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

A combination of qualitative and quantitative approaches will be used throughout the evaluation. Qualitative methods will include key informant interviews with Department and provider staff, MSOs, and other identified stakeholders regarding waiver activities, as well as document reviews of contracts, policy guides, and manuals. Quantitative methods will include descriptive statistics and time series analyses showing change over time in both counts and rates for specific metrics and ITS analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome measures.

Qualitative analysis will include document review and interviews with key informants. It will identify and describe the SUD service delivery system and changes occurring during the demonstration for Medicaid enrollees in the eligible population. Each of the milestones will be discussed and documented. This will allow identification of key elements Colorado intends to modify through the demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, telephone interviews, and face-to-face meetings, a descriptive analysis of the key Colorado demonstration features will be conducted.

The evaluation will analyze how the State is carrying out its implementation plan and track any changes it makes to its initial design as implementation proceeds. Both planned changes that are part of the demonstration design (e.g., expansion of ASAM) and operational and

policy modifications the State makes based on changing circumstances will be identified. Finally, it is possible that, in some instances, changes in the policy environment in the State will trigger alterations to the original demonstration implementation plan.

During ongoing communication with the State, detailed information on how Colorado has implemented each milestone, including how it has structured the ASAM expansion, identified providers at each ASAM level, implemented PDMP[12] and other Health Information Technology (HIT) changes, and structured care coordination between levels of care for beneficiaries enrolled in the demonstration, will be collected. The evaluation will analyze the scope of each of these milestones as implemented, the extent to which they conduct these functions directly or through contract, and internal structures established to promote implementation of the milestones.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written, and prior to the final summative evaluation report being finalized.

The key informant interviews will be conducted with staff members in the following departments who are directly responsible for SUD 1115 implementation and operations: HCPF, OBH, MSOs, MCEs, and service providers.

To maximize efficiency in the evaluation, most outcome measures align with performance measures being reported to CMS for each of the six milestones. As the independent evaluator/contractor, Mercer Government Human Services Consulting (Mercer) will calculate the quantitative performance measures, according to metrics specifications, and based on data provided by both HCPF and OBH, along with other State agencies, as needed. Mercer is currently receiving monthly transfers of Colorado's Medicaid Management Information System (MMIS) data, and quarterly transfers of MCE behavioral health data, from IBM through a Health Insurance Portability and Accountability Act (HIPAA)-compliant secure portal. Mercer is also arranging to receive pre-demonstration detailed claims data on inpatient and residential SUD services from OBH, which coordinated residential and inpatient services with block grant funding prior to implementation of the demonstration in 2021. Mercer will calculate all performance measures using the period of time specified in the CMS technical manual (e.g., monthly, quarterly, or annually).

The demonstration is open to all adult non-expansion and expansion members, so a concurrent comparison group of Colorado Medicaid members is not available. Outcomes will be assessed, where possible, using an ITS quasi-experimental design. The ITS analysis projects

[12] In Colorado, State staff are statutorily barred from accessing PDMP data. Evaluations requiring PDMP data will be limited to the annual report that is made public.

metrics derived from a pre-demonstration time period into the post-demonstration implementation time period as a comparison for actual post-demonstration implementation metrics. In cases where there are not enough data points for reliable projects (e.g., annual measures) we will use a basic time series analysis, or pre-post analyses, to describe changes over time.

Target and Comparison Populations

Because there is not an available comparison population, the "comparison population groups" in this design will be a projection of each measure, based on historical data, of what the group would look like in the absence of the demonstration.

The Target population includes non-expansion and expansion adult Colorado Medicaid beneficiaries with an SUD diagnosis. Based on demonstration goals and activities, we do not anticipate that the demonstration will have ***intentional*** differential impacts on specific subgroups. However, to account for known long-term disparities in access to care, engagement, and outcomes, we will use some demographic categories as covariates in our analyses. Additionally, some covariates based on OUD diagnosis will be used in examining changes in specific SUD utilization metrics. Other specified subpopulations (dual eligible, pregnant women, and the criminal justice population) will likely have insufficient data to provide reliable analysis. However, if the sample size permits, we will split the sample by subpopulations and will run interrupted time series or regression analyses. This will allow for an examination of the trend/slopes of the estimated effects to see if there are differences across subpopulations. All members who are eligible for and/or receive services will be included in all descriptive time series and ITS analysis, so no sampling strategy is needed.

Evaluation Period

The evaluation period is January 1, 2021 through December 31, 2025. The Draft Summative Evaluation Report analysis will allow for a three-month run out of encounter data. Results across this time period will be included in the Draft Summative Evaluation Report due to CMS by June 30, 2027. Draft interim results derived from a portion of this evaluation period, January 1, 2021 through June 30, 2023 (with three months run out of encounter data) will be reported in the Draft Interim Evaluation Report due to CMS on June 30, 2024.

Evaluation Measures and Data Sources

The evaluation design and evaluation measures are based on sources that provide valid and reliable data that will be readily available throughout the demonstration and final evaluation. To determine if data to be used for the evaluation are complete and accurate, the independent evaluator will review the quality and completeness of data sources (including but not limited to claims and encounters for

pharmacy, professional, and facility services as well as eligibility data). Example analyses the independent evaluator will use to determine reliability and accuracy of encounter data include, but are not limited to: frequency reports, valid values, missing values, date and numerical distributions, duplicates (part of adjustment logic), and encounter to cost report comparisons.

As often as possible, measures in the evaluation have been selected from nationally recognized measure stewards for which there are strict data collection processes and audited results. Information from additional data sources, such as the Department of Health and Environment, OBH, and Pharmacy Boards will be assessed for completeness and accuracy to the best of the ability of the independent evaluator and based on State knowledge of the provider community and experience in Colorado.

The following tables summarize: the primary drivers and hypotheses, process (implementation) and outcome measures for the evaluation, measure steward (if applicable), numerator and denominator definitions where appropriate, types of data (quantitative or qualitative), and data sources.

Mercer will calculate all performance measures for the demonstration period using claims/encounters data from IBM and encounter data from the MCEs, except for overdose deaths, which is calculated using vital statistics data maintained by the Colorado Department of Health and Environment. The period before the waiver demonstration will also include encounter data obtained from OBH, which was providing inpatient and residential SUD services for most of the Medicaid population (with the exception of pregnant women and young adults up to age 21, who were eligible for some inpatient and residential services through Medicaid) with block grant funding prior to the demonstration implementation. This data is important to provide a full picture of the services Medicaid members were receiving prior to the waiver, even though those services were not paid by Medicaid and will therefore not be in the data sets provided by IBM. Mercer will use similar methods of data testing and validation of for both the OBH and IBM data sets where possible, as discussed on page 23 and 47 of this document. We will also conduct qualitative interviews of OBH and HCPF staff once preliminary forecasts of trends are complete to provide a face validity check of the OBH data.

The State considered the possibility of using Transformed Medicaid Statistical Information System (T-MSIS) Analytical Files (TAF) Research Identifiable Files (RIF) for baseline comparisons, but feels that pursuing the OBH data will provide a more accurate description of the pre-demonstration landscape for SUD services in Colorado. The majority of inpatient and residential SUD services provided to Colorado Medicaid members would not be captured in the TAF-RIF data prior to the start of the demonstration in 2021.

HCPF is working closely with OBH to determine data quality and utility. While this analysis is not yet complete, it will be well in advance of the evaluation analysis. HCPF will notify CMS once we have a full assessment complete. In the case that the OBH data is unavailable or un-

useable, the evaluation will add comparisons of select outcome measures with questions from the National Survey on Drug Use and Health (NSDUH) or the CMS Medicaid Adult Core Set to provide context to Colorado's demonstration within the national trends.

AIM ONE: Promote increased access to care for members with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
	Primary Driver: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. **Hypothesis 1: The Demonstration will expand access to critical levels of care for OUD and other SUDs, resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M1)**						
Research Question 1: Have critical levels of care been revised and expanded to align with ASAM standards? **(Process Question)**	Revision of ASAM level 2.1 Intensive outpatient SUD services and implementation of ASAM Levels of Care: 3.1, 3.3, 3.5, 3.7, and 3.7 WM, including access to MAT.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant Interviews (HCPF, OBH staff, MCE representatives; Document Review (MCE policies and procedures, provider contracts)	Thematic analysis of interviews, policies, and contracts
	Develop MCE rate methodology and update MCE contracts with capitation rates, which include revised continuum of services.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant Interviews; Document Review (MCE policies and procedures, provider contracts)	Thematic analysis of interviews and contracts, policies, and contracts
Research Question 2: Has increased access to critical levels of care resulted in increased rates	Number/percent of beneficiaries who receive prevention or early intervention services (CMS #7).	CMS	Monthly	Number of unique members in the denominator with a service claim for early intervention services	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
of identification, initiation, and engagement in treatment for OUDs and other SUDs as measured by utilization?				(e.g., procedure codes associated with SBIRT).			
	Number/percent of beneficiaries who use outpatient services (CMS #8).	CMS	Monthly	Number of unique members in the denominator with a claim for outpatient services for SUD (e.g., outpatient recovery or motivational enhancement therapies, step-down care, and monitoring for stable patients).	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups
	Number/percent of beneficiaries who use intensive outpatient and partial hospitalization services (CMS #9).	CMS	Monthly	Number of unique members in the denominator with a service or pharmacy claim for intensive outpatient and/or partial hospitalization services for SUD (e.g., specialized outpatient SUD	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				therapy and other clinical services).			
	Number/percent of beneficiaries who use residential and/or inpatient services for SUD (CMS #10).	CMS	Monthly	Number of unique members in the denominator with a service for residential and/or inpatient services for SUD.	Members with a SUD diagnosis (CMS #3) for percentage Include OBH data in numerator for baseline years	Claims/ encounters	ITS; controlling for demographic subgroups
	Number/percent of beneficiaries who use WM services (CMS #11).	CMS	Monthly	Number of unique members in the denominator with a service or pharmacy claim for withdrawal management services.	Members with a SUD diagnosis (CMS #3) for percentage	Claims/Encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups
	Number and length of IMD stays for SUD (CMS #36).	CMS	Yearly	Total number of days in an IMD for inpatient/ residential discharges for SUD.	Total number of discharges from an IMD for beneficiaries with an inpatient or residential treatment stay for SUD.	Claims/Encounters Include OBH data in numerator for baseline years	Descriptive Time Series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Hypothesis 2: The demonstration will promote widespread use of evidence-based SUD specific patient placement criteria resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M2)							
Research Question 1: Has widespread use of ASAM patient placement criteria been implemented? **(Process Question)**	Number/percent of providers licensed at each level of care.	Evaluator, with input from the agency collecting the data	Yearly	Number of providers in the denominator licensed at each level of care.	Total number of SUD providers (CMS #13) for percentage	OBH licensing records	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each level of care)
	Description of activities to monitor MCE use of ASAM criteria for patient placement.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant interviews and document review from MCEs; OBH monitoring records	Thematic analysis of interviews and documents
	Description of training and technical assistance activities to align providers with ASAM standards.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant interviews and document review with SUD providers	Thematic analysis of interviews and documents
Research Question 2: Has the widespread use of ASAM patient	Number/percent of beneficiaries receiving any SUD treatment service (CMS #6).	CMS	Monthly	Number of unique members in the denominator receiving at least one SUD	Number of unique members enrolled in the measurement period (for percentage)	Claims/ Encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups Compare to NSDUH "Received Any

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
placement criteria resulted in increased rates of identification, initiation, and engagement in treatment for members with SUD diagnoses?				treatment service or pharmacy claim during the measurement period.	Subpopulations: OUD, Age, Dual, Pregnant, Criminal Justice		Substance Use Treatment in the Past Year" as benchmark if OBH data is not available/useable for ITS
	Initiation of Alcohol and Other Drug (AOD) Abuse or Dependence Treatment (IET-AD) (CMS #15)	NCQA NQF #0004	Yearly	Number of unique members in the denominator 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.	Number of unique members with a new episode of AOD abuse or dependence	Claims/ Encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Compare to CMS Medicaid Adult Core Set national median as benchmark if OBH data is not available/ useable
	Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET-AD) (CMS #15).	NCQA NQF #0004	Yearly	Number of unique members in the denominator who were engaged in	Number of unique members with a new episode of AOD abuse or dependence and	Claims/ Encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				ongoing AOD treatment within 34 days of the initiation visit.	initiated treatment		post-demonstration period proportion Compare to CMS Medicaid Adult Core Set national median as benchmark if OBH data is not available/ useable
Hypothesis 3: The demonstration will promote sufficient provider capacity at each level of care, including MAT, for SUD/OUD, resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M4)							
Research Question 1: Is there sufficient provider capacity at each level of care, including MAT? **(Process Question)**	Description of Provider Capacity Workgroup activities.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews; document review	Thematic analysis of interviews and documents
	Number/percent of providers participating in IT MATTRs forums.	Evaluator, with input from the agency collecting the data	Yearly	Number unique providers in the denominator who are participating in IT MATTRs forums.	Number of SUD providers that can deliver MAT (CMS #14) for percentage	HCPF	Descriptive statistics (counts); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 2: Has the availability of providers in Medicaid accepting new patients, including MAT, improved under the demonstration?	Number of eligible SUD providers. (CMS #13).	CMS	Yearly	Number of providers who were enrolled in Medicaid and qualified to deliver SUD services.	None	HCPF	Descriptive time series
	Number/percent of eligible SUD providers that can deliver MAT (CMS #14).	CMS	Yearly	Number of providers who were enrolled in Medicaid and qualified to deliver SUD services and who meet the standards to provide MAT services.	Number of SUD Providers (CMS #13) for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Total number of beds available (Bed capacity)	Evaluator, with input from the agency collecting the data	Yearly	Total number of beds available in residential and inpatient facilities.	None	OBH electronic bed tracking system HCPF	Descriptive time series
Primary Driver: Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs							
Hypothesis 4: The demonstration will improve care coordination for physical care, resulting in improved access to care for physical health conditions among beneficiaries with OUD or other SUDs. (IP M6)							

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 1: Has the demonstration implemented changes that improve care coordination for physical care? **(Process Question)**	Description of MCE Care Coordination activities determined by SUD Implementation Workgroup.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	SUD Implementation Workgroup member interview; document review	Thematic analysis of interviews and documents
Research Question 2: Has improving care coordination resulted in increased utilization of physical health services for members with SUD diagnoses?	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD (AAP) [Adjusted HEDIS measure] (CMS #32).	NCQA	Yearly	Number of unique members with SUD with an ambulatory or preventative care visit.	Number of unique members with a SUD diagnosis (CMS #4)	Claims	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

AIM TWO: Improve the quality of care for members with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Primary Driver: Increased adherence to and retention in treatment for OUD and other SUDs							
Hypothesis 1: The 1115 SUD demonstration will implement use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications resulting in increased adherence to and retention in treatment for OUD and other SUDs.							
Research Question 1: Have evidence-based SUD program standards been used in evaluating residential treatment provider qualifications? **(Process Question)**	Number/percent of providers licensed for each ASAM level of care they provide.	Evaluator, with input from the agency collecting the data	Yearly	Number of providers licensed for each ASAM level of care they provide.	Number of SUD providers (CMS #13) for percentage	OBH	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each level of care)
	Number and rate of providers reviewed for compliance.	Evaluator, with input from the agency collecting the data	Yearly	Number of unique SUD providers reviewed for compliance.	Number of SUD providers (CMS #13) for rate	MCE credentialing records/HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of residential and inpatient providers who provide onsite access, or who facilitate access to MAT.	Evaluator, with input from the agency collecting the data	Yearly	Number of residential and inpatient SUD providers who provide onsite access, or who facilitate access to MAT.	Number of unique SUD residential and inpatient providers for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 2: Has increased utilization of SUD program standards for SUD residential treatment resulted in increased adherence and retention in treatment?	Continuity of Pharmacotherapy for OUD (CMS #22).	USC	Yearly	Number of unique members in the denominator who have at least 180 days of continuous treatment.	Number of unique members with OUD diagnosis and at least one claim for an OUD medication. Stratify on residential/ inpatient versus outpatient services	Claims/encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period
	Number/percent of beneficiaries who have a claim for MAT for SUD during the measurement period (CMS #12).	CMS	Monthly	The number of unique members in the denominator who have a claim for a MAT dispensing event for SUD.	Members with a SUD diagnosis (CMS #3) for percentage Stratify on residential/ inpatient versus outpatient services	Claims/encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups Compare to NSDUH "Received Medication-Assisted Treatment for Opioid Misuse in the Past Year" as benchmark if OBH data is not available/useable for ITS
Hypothesis 2: The 1115 SUD demonstration will improve care coordination and transitions between levels of care qualifications resulting in increased adherence to and retention in treatment for OUD and other SUDs.							
Research Question 1: Have the MCEs	Description of activities to enhance care	N/A	Cumulative for interim reporting	None	None	Key informant interviews of SUD Implementation	Thematic analysis of interviews and contracts

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
implemented policies to enhance care coordination?	coordination through the Implementation Work Group.		period, and for summative reporting period.			Workgroup members; document review (e.g. contracts)	
	MCE policy development to ensure adequate care coordination across the SUD continuum.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews of SUD Implementation Workgroup members; document review (e.g. contracts)	Thematic analysis of interviews and contracts
	Number/rate of licensed residential care facilities.	Evaluator, with input from the agency collecting the data	Yearly	Number of licensed residential care facilities.	Number of licensed residential care facilities	OBH	Descriptive statistics (counts); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
Research Question 2: Has enhanced care coordination across the SUD continuum of care resulted in increased follow up after an ED visit?	Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA-AD) (CMS #17-1).	NCQA	Yearly	Number of ED visits for members in the denominator who had a follow-up visit for AOD abuse or dependence within: • 30 days • 7 days	Number of ED visits for members with a principal diagnosis of AOD abuse or dependence.	Claims/encounters	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups Also compare to CMS Medicaid Adult Core

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
							Set national median as benchmark
	Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD) (CMS #17-2).	NCQA	Yearly	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness within: • 30 days • 7 days	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm	Claims/encounters	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups Also compare to CMS Medicaid Adult Core Set national median as benchmark

AIM THREE: Improve outcomes for members using SUD services and maintain costs.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Primary Driver: Reduction in overdose deaths, particularly those due to opioids. G3							
Hypothesis 1: The demonstration will implement comprehensive treatment and prevention strategies to address opioid abuse and OUD as well as recruit and train more providers to provide MAT, resulting in a reduction in overdose deaths.							
Research Question 1: Have comprehensive treatment and	Key informant reports on Implementation of opioid prescribing guidelines.	N/A	Cumulative for interim reporting period, and for summative	None	None	Key Informant interviews from MCEs and SUD providers; document review	Descriptive narrative, Thematic analysis

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
prevention strategies been implemented and is MAT more accessible? **(Process Question)**			reporting period.				
	Number/percent of State organizations who distribute naloxone.	Evaluator, with input from the agency collecting the data	Yearly	Number of State organizations who distribute naloxone.	Number of State organizations	HCPF	Descriptive statistics (count) or time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of MAT providers at all LOCs (CMS #14).	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid MAT providers at all LOCs.	Number of SUD providers at all LOCs (CMS #13) for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of providers using the PDMPs.	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid providers using PDMPs.	Number of Medicaid Providers	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
Research question 2: Have comprehensive treatment and prevention strategies been	Use of opioids at high dosage in persons without cancer (OHD-AD) (CMS#18).	PQA	Yearly	Number of members in the denominator who received prescriptions for opioids with an average daily	Number of members with at least two opioid prescriptions with at least 15 days' supply. Members with a	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
effective in addressing opioid abuse and OUD?				dosage greater than or equal to 90 MMEs over a period of 90 days or more.	cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.		Also compare to CMS Medicaid Adult Core Set national median as benchmark
	Concurrent use of opioids and benzodiazepines (COB-AD) (CMS#21).	PQA	Yearly	Number of members in the denominator with concurrent use of prescription opioids and benzodiazepines.	Number of members with at least two opioid prescriptions with at least 15 days' supply. Members with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Also compare to CMS Medicaid Adult Core Set national median as benchmark
Research question 3: Did comprehensive treatment and prevention strategies correspond to a reduction in overdose deaths and activities that support	Overdose Deaths (rate) (CMS#27)	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid members with overdose as cause of death.	All Medicaid members	State data on cause of death	Descriptive time series (data ID's Medicaid members? Possible ITS); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Also compare to National Center for Health Statistics

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
overdose death reduction?							national drug overdose death rate as benchmark
Primary Driver: Reduced readmissions to the same or higher level of care where readmission is preventable or medically inappropriate for OUD and other SUD. G5							
Hypothesis 2: The demonstration will lead to widespread use of Evidence-based SUD specific Patient Placement Criteria resulting in reduced readmissions to the same or higher level of care where readmission is preventable or medically inappropriate for OUD and other SUD. M2							
Research question 1: Were utilization management policies and procedures, based upon patient placement criteria, fully implemented?	MCE development of utilization management policies and procedures and State review of utilization management policies and procedures. Internal monitoring of benefit by Initial Monitoring Team.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews from MCEs and State reviewers Internal monitoring team	Descriptive narrative and thematic analysis
Research question 2: Did readmissions to the same or higher level of care, where readmission is preventable or medically inappropriate for OUD and	Readmissions Among Beneficiaries with SUD (CMS #25).	CMS	Yearly	Acute hospital admissions from the denominator with at least one acute readmission for any diagnosis within 30 days of discharge.	Acute hospital admissions for members with SUD diagnosis	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
other SUD, decrease?							
Primary Driver: Reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. G4							
Hypothesis 3: The Demonstration will lead to widespread use of Evidence-based SUD specific Patient Placement Criteria resulting in reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate. M2							
Research Question 1: Did ED utilization decrease after implementation of utilization management?	ED Utilization for SUD per 1,000 Medicaid Beneficiaries (CMS #23).	CMS	Monthly	Number of ED visits for SUD.	All Medicaid members	Claims/encounters	ITS; controlling for demographic subgroups
Research Question 2: Did inpatient stays decrease after implementation of utilization management?	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries (CMS #24).	CMS	Monthly	Number of inpatient stays for SUD.	All Medicaid members	Claims/encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups
Hypothesis 4: The demonstration will improve outcomes for members using SUD services with similar or lower service costs.							
Research Question 1: Have increasing trends in total cost of care	SUD Spending (CMS #28)	CMS	Yearly	The sum of all Medicaid spending on SUD treatment services	None	Claims/encounters Use provider paid amounts	Descriptive time series

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
been slowed for individuals with SUD diagnoses?	SUD Spending within IMDs (CMS #29).	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs.	None	Claims/encounters Use provider paid amounts	Descriptive time series
	Per Capita SUD Spending (CMS #30)	CMS	Yearly	The sum of all Medicaid spending on SUD treatment services (CMS #28).	Members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	Per Capital SUD Spending within IMDs (CMS #31)	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs (CMS #29).	Number of members with a claim for inpatient/ residential treatment for SUD in an IMD	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	Total Cost PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending (Inpatient, Outpatient, Pharmacy, Long Term Care,	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				Capitation payments, Administrative Costs, Federal Costs) for members with a SUD diagnosis		CMS #64 for Federal Costs	
	SUD Cost Drivers - Total SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services (CMS #28).	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	SUD Cost Drivers - IMD SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services within an IMD (CMS #29).	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	SUD Cost Drivers - Non-IMD SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services not within an IMD	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	SUD Cost Drivers - Non-SUD Spending PMPM	CMS SUD Evaluation Design	Quarterly	The sum of all Medicaid spending on non-SUD treatment	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
		Guidance, Appendix C		for members with a SUD diagnosis			
	Source of treatment cost drivers for members with SUD – Inpatient services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on inpatient treatment for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – Emergency Department services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on emergency department services for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – non-ED Outpatient services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on non-ED Outpatient services for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – Pharmacy PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on Pharmacy for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
	Source of treatment cost drivers for members with SUD – Long Term Care PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on Long Term Care for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Analytic Methods

Multiple analytic techniques will be used, depending on the type of data for the measure and the use of the measure in the evaluation design (e.g., process measure versus outcome measures). Descriptive, content analysis will be used to present data related to process evaluation measures gathered from document reviews, key informant interviews, etc., as discussed previously. Qualitative analysis software (R Qualitative, ATLAS, or similar) will be used to organize documentation, including key informant interview transcripts. Analysis will identify common themes across interviews and documents. In some cases, checklists may be used to analyze documentation (e.g., licensure) for compliance with standards. These data will be summarized in order to describe the activities undertaken for each project milestone, including highlighting specific successes and challenges.

Descriptive statistics including frequency distributions and time series (presentation of rates over time) will be used for quantitative process measures in order to describe the output of specific waiver activities. These analysis techniques will also be used for some short-term outcome measures in cases where the role of the measure is to describe changes in the population, but not to show specific effects of the waiver demonstration. Where pre-demonstration and post-demonstration rates are comparable, pre-post distributional test will be made to quantify statistical differences in process measures before and after the demonstration.

An ITS will be used to describe the effects of waiver implementation in metrics that are measured on a monthly or quarterly basis. Specific outcome measure(s) will be collected for multiple time periods both before and after start of intervention. Segmented regression analysis will be used to measure statistically the changes in level and slope in the post-intervention period (after the waiver) compared to the pre-intervention period (before the waiver). The ITS design will be dependent on being able to use similar historical data on specific outcome measures collected from OBH based on inpatient and residential SUD services provided prior to the demonstration and on the ability to receive data needed to produce historical data regarding outpatient SUD services, ED use, and hospitalizations using previous encounter data, (see

Methodology Limitation section for more information). The ITS design uses historical data to forecast the "counterfactual" of the evaluation, that is to say, what would happen if the demonstration did not occur. We propose using basic time series linear modeling to forecast these "counterfactual" rates for three years following the demonstration implementation.[13] The more historical data available, the better these predictions will be. ITS models are commonly used in situations where a contemporary comparison group is not available.[14] The State has considered options for a contemporary comparison group. Since the demonstration will target all adult non-expansion and expansion Medicaid members in need of SUD services, the only viable groups for comparison within the State would be those covered with private insurance, which would include a very different demographic population.

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

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

[13] E Kontopantelis (2015). Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. British Medical Journal (BMJ). Available at: https://www.bmj.com/content/350/bmj.h2750.

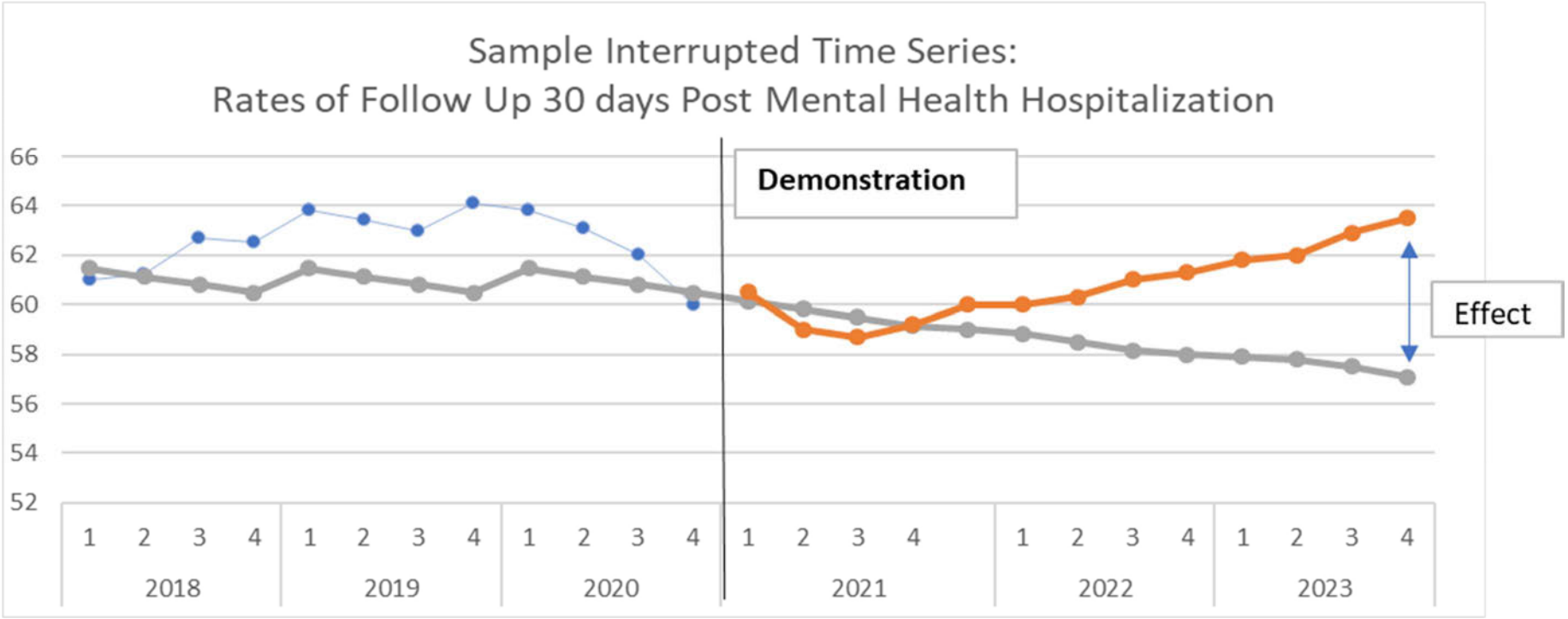
[14] Ibid.

Where β_0 represents the baseline observation, β_1 is the change in the measure associated with a time unit (quarter or year) increase (representing the underlying pre-intervention trend), β_2 is the level change following the intervention and β_3 is the slope change following the intervention (using the interaction between time and intervention: TX_t).[15]

This can be represented graphically as follows.

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

Figure 1: (SAMPLE data only) Rates of Follow Up Post Mental Health Hospitalization



Pre-demonstration data from January 1, 2018 to December 31, 2020 will be calculated using the monthly, quarterly, or annual period of time as specified in the CMS technical specifications for each metric. Trends in these data for each measure will be used to predict the counterfactual (what would have happened without the demonstration). Outcomes measures will be calculated beginning January 1, 2021 through the end of the waiver demonstration project (December 31, 2025). A discussion of including confounding variables (e.g., COVID-19, other SUD efforts) is included in the next section.

Quantitative outcome measures with yearly measurement periods that are expressed as averages or proportions will be analyzed with pre-post tests and may be compared with national benchmark statistics from the National Survey on Drug Use and Health, the CMS Medicaid Adult

Core Set, and the National Center for Health Statistics. While two or three pre-demonstration measurement periods for yearly metrics may not be enough information to establish a trend for the ITS analysis, pre-post analyses may reveal differences in outcomes before and after the demonstration. One-way analysis of covariance, or t-tests will be used to compare pre-demonstration averages with post-demonstration averages, and chi-square tests will be used to compare proportions.

In the case that Mercer is not able to obtain detailed encounter data from OBH, or data validation suggests that the data should not be used, benchmark comparisons to national data will also be implemented for a limited number of metrics, as described in the preceding research design table.

Qualitative analysis will utilize data collected from three main sources: 1) key informant interviews with State staff working on implementation efforts, MCE representatives, and providers, 2) key process documentation (e.g., policy and procedure manuals, guidance documents), and 3) MCE and provider contracts. Informant sampling will be largely based on convenience/snowball sampling where key stakeholders provide initial lists of potential interviewees, based on their perspective on demonstration implementation activities. Meeting minutes listing attendees will also be reviewed to identify potential interviewees. MCE staff and provider staff will also be included. Because this likely will be a large number of people, the independent evaluator will work with the State to determine whether to conduct focus groups with these populations, or to engage in a strategic stratified sampling process. The latter will ensure representation from each MCE, and from providers stratified by geography/location, size, and services provided. Document reviews will include meeting minutes, policy and procedure documents, MCE and provider contracts, and others identified during the qualitative analysis process. Themes will be identified by multiple coders who review documents, identify initial themes, then collaborate in the creation of a central list of primary and secondary themes.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written and prior to the final summative evaluation report being finalized. Specifically, the initial qualitative analysis will occur May 2022–July 2022. The second qualitative analysis will occur May 2023–July 2023. The third qualitative analysis will occur March 2024–May 2024. The final qualitative analysis will occur March 2027–May 2027.

4

Methodological Limitations

There are two primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either: 1) are not sufficient to conduct the analysis proposed here (e.g., not enough historical data for needed prior time periods), or 2) contain errors. The second limitation is related to the design itself because this evaluation plan relies heavily on descriptive, time series analysis, and qualitative data, this evaluation will describe what happened after the demonstration was implemented, but it will be difficult to isolate why changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. Each of these limitations is discussed in greater detail within this section.

Some of the metrics being computed by Mercer will be calculated for the first time. Both Mercer and the Department are working closely with OBH and IBM to request and test extracts of pre-demonstration data. While it is unclear at this time the degree to which it will be possible to generate historical data needed to forecast the slope of the "counterfactual" trend line (what would have happened without the demonstration), HCPF is confident the independent evaluator will have access to this historical data in the near future. This historical data is an important component of the ITS design, but also supports the descriptive time series analysis. In particular, there will be a limitation in estimating the slope of what the trend line would be without the demonstration if we do not have data to model what would have happened without implementation.

In addition to any issues with historical data, the Department's data systems may have current issues that contribute to data errors. Combining data from separate sources can prove challenging, and Mercer is working through the process carefully to minimize any data errors, including performing various data validations and duplicate record checks.

Behavioral health data for the evaluation is received in separate files for the various MCEs. There are currently eight MCEs and an additional five historical RAEs. Mercer has noted several data issues so far. For example, some of the MCEs reuse claim numbers, which impacts claim adjustment logic. In addition, some fields with the same name are populated with different field types, so special care is required when combining the data from different MCEs, so data is not inadvertently dropped. Mercer is currently working through adjustment logic for the behavioral health data, including creating and testing unique claim identifiers.

There have also been some import issues with the MMIS data due to misplaced carriage returns, which will be monitored going forward. Adjustment logic will also be applied to the MMIS data, but at this time looks to be a more standardized process.

After the behavioral health data and the MMIS data are received, imported, adjusted, and validated, they will be combined with the available pre-demonstration OBH data, which will be subject to similar processes, to comprise the base data for measure calculation. Further, the current system has a runout of six months, and will need to take into account timing around pulling data to calculate numerators and denominators for the measures.

While the ITS design is the strongest available research method, in the absence of a randomized trial or matched control group, there are some threats to the validity of results in the design.[16] The primary threat is that of history, or other changes over time happening during the waiver period. This ITS design is only valid to the extent that the waiver program was the only thing that changed during the evaluation period. Other changes to policies or programs could affect the outcomes being measured under the demonstration. We will attempt to control this threat by considering other policy and program changes happening concurrent to the waiver period interventions. At a minimum, we will use qualitative methods, in the form of key informant interviews, to identify other initiatives or events may have occurred during the demonstration that might influence demonstration effects. We will conduct a qualitative assessment of these likely impacts and will use time series analysis to show how trends may have changed at these critical time periods. In order to isolate the effects of these efforts, we will also conduct additional iterations of the ITS. Using identified critical time points as additional variables, we will test whether other major efforts had a statistically significant impact in the post-demonstration waiver trend. The analysis will note the dates of other changes and analyze the degree to which the slope of the trend line changes after implementation of other interventions are made.

The demonstration waiver application lists three main efforts that likely impact SUD services in the State: Implementation of the ACC program (Phase 2) in July, 2018, the STR, which began in May 2017 and the SOR grant, which extended the STR grant activities through 2020. Because most of these activities took place during the pre-demonstration period, their impacts will be reflected in the historical data (January 2018–December 2020) and will therefore impact the predicted trend line. It is possible that effects of these efforts may mute the hypothesized impacts of the demonstration. The ACC continues into the demonstration period, so accounting for this in the pre-demonstration predicted trend is reasonable, as any measurable effects should be due to the demonstration. The STR and SOR, which ended prior to the demonstration and included expanding MAT and increasing availability of naloxone, would likely have the largest impact on the predicted trend

[16] Penfold RB, Zhang F. “Use of interrupted time series analysis in evaluating heath care quality improvements.” Academic Pediatrics, 2013 Nov-Dec, 13(6Suppl): S38-44.

lines for metrics measuring MAT usage and opioid deaths. These metrics may show only muted or no detectable demonstration impacts. We will discuss the impact of the STR and SOR in the interpretation of relevant metrics in the evaluation reports.

The impact of COVID-19 most likely affected the pre-demonstration period, and we anticipate a statically significant impact on most metrics. Therefore, in the initial forecasting within the ITS model, the independent evaluator will include a COVID-19 covariant for the start of the pandemic in the forecast model. Essentially, the ITS for this evaluation will create two counterfactual scenarios using historical data. We will create a "without" COVID-19 forecast using historical data only prior to March of 2020 as one potential counterfactual to compare against actual trends. If we can establish sufficient data points between March 2020 and the waiver start date of January 2021, we can estimate the COVID-19 impact on the forecast. We will also create a forecast with data through the pre-demonstration period (up to January 2021) that includes data during the times COVID-19 was prevalent in the State. As long as COVID-19 remains prevalent during the demonstration period, we anticipate that using the "with COVID-19" model as the counterfactual will be more accurate. Additional covariate time periods can be added to the model if there are significant shifts in either COVID-19 prevalence numbers or policy shifts (e.g., new stay at home orders) in the State. We will also qualitatively explore how COVID-19 impacted the implementation of the waiver, based on data from key informant interviews.

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

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

We will also attempt to limit this threat to validity by triangulating our data. Encounter data trends across multiple time periods will be compared to trends happening at other points in time (other large policy or program shifts that might influence the slope of the trend in addition to the demonstration). Also, key informant interviews will be used to inform the quantitative findings and explain the degree to which individuals are seeing demonstration impacts. We will also attempt to seek out national and other State data for benchmarking, that will allow us to determine whether Colorado is performing in a similar fashion to other demonstration states, non-demonstration states, or national benchmarks overall.

According to the literature on ITS analysis, estimating the level and slope parameters requires a minimum of eight observations before and after implementation in order to have sufficient power to estimate the regression coefficients.[17] Evaluators will need to work closely with the Department, OBH, and their respective data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

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

Qualitative data, while useful in confirming quantitative data and providing rich detail, can be compromised by individual biases or perceptions. Key informant interviews, for example, represent a needed perspective around context for demonstration activities and outcomes. However, individuals may be limited in their insight or understanding of specific programmatic components, meaning that the data reflects perceptions, rather than objective program realities. The evaluation will work to address these limitations by collecting data from a variety of different perspectives to help validate individuals' reports. In addition, standardized data collection protocols will be used in interviews and interviewers will be trained to avoid "leading" the interviewee or inappropriately biasing the interview. It will also utilize multiple "coders" to analyze data and will create a structured analysis framework, based on research questions that analysts will use to organize the data and to check interpretations across analysts. Finally, results will be reviewed with stakeholders to confirm findings.

[17] Ibid.

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Attachments

As part of the Standard Terms and Conditions (STCs), as set forth by CMS, the demonstration project is required to arrange with an independent party to conduct an evaluation of the SUD demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. Mercer, through a request for proposal (RFP) process, contracts to provide technical assistance to HCPF.

Mercer was selected as the technical assistance vendor. One of the scopes of work in the technical assistance work plan is the waiver evaluation. Mercer will develop the evaluation design, calculate the results of the study, evaluate the results for conclusions, and write the Interim and Summative Evaluation Reports.

Mercer has over 25 years of experience assisting state governments with the design, implementation, and evaluation of publicly sponsored health care programs. Mercer currently has over 25 states under contract and has worked with over 35 different states in total. They have assisted states like Arizona, Connecticut, Missouri, and New Jersey in performing independent evaluations of their Medicaid programs; many of which include 1115 Demonstration waiver evaluation experience. Given their extensive experience, the Mercer team is well equipped to work effectively as the external evaluator for the demonstration project. The table below includes contact information for the lead coordinators from Mercer for the evaluation:

NAME	POSITION	EMAIL ADDRESS
Kate Goergen	Engagement Leader	kate.goergen@mercer.com
Tonya Aultman-Bettridge, PhD	Evaluation Lead	taultman-bettridge@triwestgroup.net
Jeanie Aspiras, MBA	Program Manager	jeanie.aspiras@mercer.com
Carissa Cramer	Project Manager	carissa.cramer@mercer.com
Brenda Jenney, PhD	Statistician	brenda.jenney@mercer.com
Brenda Jackson, MPP	Policy and Operations Sector	brenda.jackson@mercer.com

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Attachment A

Conflict of Interest Statement

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

Mercer's Government specialty practice does not have any conflicts of interest, such as providing services to any MSOs or health care providers doing business in Colorado under the Health First Colorado program or to providing direct services to individual recipients. One of the byproducts of being a nationally operated group dedicated to the public sector is the ability to identify and avoid potential conflicts of interest with our firm's multitude of clients. To accomplish this, market space lines have been agreed to by our senior leadership. Mercer's Government group is the designated primary operating group in the Medicaid space.

Before signing a contract to work in the Medicaid market, either at the state-level or otherwise, we require any Mercer entity to discuss the potential work with Mercer's Government group. If there is a potential conflict (i.e., work for a Medicaid health plan or provider), the engagement is not accepted. If there is a potential for a perceived conflict of interest, Mercer's Government group will ask our state client if they approve of this engagement, and we develop appropriate safeguards such as keeping separate teams, restricting access to files, and establish process firewalls to avoid the perception of any conflict of interest. If our client does not approve, the engagement will not be accepted. Mercer has collectively turned down a multitude of potential assignments over the years to avoid a conflict of interest.

Given that Mercer is acting as both technical assistance provider and independent evaluator for this project, HCPF and Mercer have implemented measures to ensure there is no perceived conflicts of interest. This contract was awarded following a competitive bidding process that complied with all Colorado State laws, the Mercer evaluation team is functionally and physically separate from the technical assistance

team, and the contract does not include any performance incentives that would contribute to a perception of conflicted interests between technical assistance services and the independence of the evaluation process. As an additional firewall, the evaluation statistical analyses will be conducted by a subcontractor that has not had any interaction with the technical assistance team, using data that has been reviewed and accepted by CMS (through monitoring protocol submissions).

In regards to Mercer's proposed subcontractors, all have assured Mercer there will be no conflicts and that they will take any steps required by Mercer or HCPF to mitigate any perceived conflict of interest. To the extent that we need to implement a conflict mitigation plan with any of our valued subcontractors, we will do so.

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

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Attachment B

Evaluation Budget

	DY 1	DY2	DY3	DY4	DY5	Final Evaluation	Total Evaluation Cost
	2021	2022	2023	2024	2025	6/30/2027	
State of Colorado							
HCPF & OBH	$100,000*	$50,000**	$50,000	$50,000	$50,000	$50,000	$350,000

*Estimates based on 1) Demonstration Year 1 (DY1) data infrastructure and data sharing protocol build between Departments and vendor; and 2) staff review of DY1 deliverables.
**Estimates for DY2–DY5 based on State of Colorado review of annual, ongoing deliverables.

Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours					
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours
Evaluation Activities					
Develop and draft Evaluation Design	288	72	--	30	390
Revise drafted Evaluation Design	28	7	--	--	35
Draft Interim Evaluation report	72	18	--	26	116
Finalize Interim Evaluation report	40	10	--	--	50
Draft Summative Evaluation report	92	23	--	26	141
Finalize Summative Evaluation report	40	10	--	--	50

Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours					
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours
Data Activities					
Load, validate, and scrub raw data — Evaluation measures for Annual reports.	--	250	250	10	510
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report	148	148	35	--	331
File mapping to standardize file format — Evaluation measures for Annual reports.	100	195	100	10	405
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report	--	128	128	10	266
Initial programming/validation of code for measure development — Evaluation measures (37)	88	10	88	--	186
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for annual reports. (10 measures; 40 hours/year; 10 PM)	--	100	100	10	210
Statistical measures for the evaluation: Interim and Final report (300 hours/report)	100	250	250	10	610
Final Total:					**3,300**

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
Evaluation Activities									
Develop and draft Evaluation Design	$115,140	--	--	--	--	--	--	--	$ 115,140
Revise drafted Evaluation Design	--	$10,465	--	--	--	--	--	--	$ 10,465
Draft Interim Evaluation report	--	--	--	--	$33,410	--	--	--	$ 33,410
Finalize Interim Evaluation report	--	--	--	--	--	$14,950	--	--	$ 14,950
Draft Summative Evaluation report	--	--	--	--	--	--	$40,885	--	$ 40,885
Finalize Summative Evaluation report	--	--	--	--	--	--	--	$14,950	$ 14,950
Data Activities									
Load, validate, and scrub raw data — Evaluation measures for Annual reports.	--	$27,750	$27,750	$27,750	$27,750	$27,750	--	--	$ 138,750
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report (190 hours initial	--	$52,975	--	$30,263	--	--	$30,263	--	$ 113,500
File mapping to standardize file format — Evaluation	--	$44,163	$17,650	$17,650	$17,650	$17,650	--	--	$ 114,763

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
measures for Annual reports.									
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report	--	--	--	$34,694	--	$34,694	--	--	$ 69,388
Initial programming/validation of code for measure development — Evaluation measures (37)	--	$172,744	--	--	--	--	--	--	$ 172,744
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for Annual reports.	--	$12,600	$12,600	$12,600	$12,600	$12,600	--	--	$ 63,000
Statistical measures for the evaluation: Interim and Final report	--	--	--	$78,250	--	$78,250	--	--	
Final Total:									**$ 1,058,444**

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Attachment C

Potential Timeline and Major Deliverables

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

Deliverable	STC Reference	Date
Submit evaluation design plan to CMS	38	October 1, 2021
Final evaluation design due 60 days after comments received from CMS	38	February 4, 2022
Mid-point assessment due	29	August 30, 2023
Draft Interim Report due	40C	June 30, 2024 (or with renewal application)
Final Interim Report due 60 days after CMS comments received	40D	60 days after comments received from CMS
Draft Summative Evaluation Report due 18 months following demonstration	41	June 30, 2027
Final Summative Evaluation Report due 60 days after CMS comments received	41A	60 days after comments received from CMS

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ATTACHMENT F
Reserved for SMI/SED Implementation Plan

ATTACHMENT G
Reserved for Reentry Demonstration Initiative Services

ATTACHMENT H
Reserved for Reentry Demonstration Initiative Implementation Plan

ATTACHMENT I
Reserved for Reentry Demonstration Initiative Reinvestment Plan

ATTACHMENT J
Reserved for SMI/SED, HRSN, and Reentry Monitoring Protocol

ATTACHMENT K
Reserved for SMI/SED, HRSN, and Reentry Evaluation Design

Attachment L: Protocol for Assessment of Beneficiary Eligibility Needs and Provider Qualifications for Health-Related Social Needs

Health-Related Social Needs Services

In accordance with the State's Section 1115 Demonstration and Special Terms and Conditions (STCs), this protocol provides additional detail on the requirements for the delivery of services for the Health-Related Social Needs (HRSN) program, as specifically required by STC 10.7. The State may claim federal financial participation (FFP) for the specified evidence-based HRSN services identified in STC 10.2, (subject to the restrictions described below and the exclusions in STC 10.4). This protocol outlines the covered HRSN services, a process for identifying eligible individuals, a process for determining the services medically appropriate, a description of the process for developing care plans based on assessment of need, and provider qualification criteria for each service. As the HRSN program matures, Colorado anticipates that this protocol will need to be edited accordingly. Updates to the HRSN services (duration, scope, and definitions) is subject to the restrictions in STCs 10.8.

The State agrees to meet the enhanced monitoring and evaluation requirements stipulated in STC 11.6(b) and STC 12.6, which require the state to monitor and evaluate how the renewals of recurring nutrition services under STC 10.3.b affect care utilization and beneficiary physical and mental health outcomes, as well as the cost of providing such services. As required in STCs 11.5 and 12.5, the Monitoring Protocol and Evaluation Design are subject to CMS approval.

1. Covered HRSN Services

A list of the covered HRSN services with associated service descriptions and service-specific provider qualification requirements.

Colorado will provide robust housing and nutrition services to eligible Medicaid beneficiaries. Please find a detailed list of the covered housing services with associated descriptions in **Table 1.**

HRSN services include housing and nutrition services delivered by enrolled providers with knowledge and skills in management and delivery of housing and support services. Housing providers will, under the oversight of Department of Local Affairs (DOLA), will manage voucher administration and ensure rental assistance and housing navigation (pre-tenancy and tenancy sustaining) are delivered by qualified and trained staff. Case management, nutrition education and counseling and all other supportive services will be provided by enrolled providers qualified and trained in accordance with Medicaid provider type roles and responsibilities.

Table 1. Services and Definitions

Service	Definition
Rent/temporary housing for up to six months (Short-term rental assistance)	Rent/short-term housing for up to six months: Rent payments for apartments, SRO units, single-family homes, multi-family homes, mobile home communities, ADUs, co-housing communities, trailers, manufactured homes, manufactured home lots, motel or hotel when it is serving as the member's primary residence, transitional and recovery housing, including bridge, site-based, population-specific, and community living programs that may or may not offer supportive services and programming. Payment will not exceed limits in the approved Services Protocols per person. The following services are included in this definition: • Reimbursement for room (without board) for a short-term period, not to exceed six total months within a five-year period. This service is subject to a cap of 6 months per household per demonstration period. Coverage may be permitted in one or more episodes, so long as the total duration remains under the cap for the demonstration period. Additionally, this service is subject to the 6 months global cap on housing services per rolling year in combination with other housing services that include room and board (i.e., short-term post-transition housing). • Allowable units for housing must provide the following for members: — Access to a clean, healthy environment that allows members to perform activities of daily living — Access to a private, semi-private, or shared independent room, with a personal bed for the entire day, with no more than three roommates (note: dormitories are not permitted) — Eligible costs include: • Rent payment (past due or forward rent) The combination of past due and forward rent cannot exceed the 6 month cap noted above. • Storage fees if necessary to secure and maintain the unit • Renter's insurance, if required by the lease Payments must only be provided in connection with dwellings that meet maintenance regulation code within the local jurisdiction for safety, sanitation, and habitability. Congregate sleeping space, facilities that have been temporarily converted to shelters (e.g., gymnasiums or convention centers), facilities in which sleeping spaces are not available to residents 24 hours a day, and facilities without private sleeping space are excluded from the demonstration.

Service	Definition
Short-term Post-transition Housing	Short-term post-transition housing (e.g., post-hospitalization), where integrated, clinically oriented rehabilitative services and supports are provided, but ongoing monitoring of the individual's condition by clinicians is not required. Coverage is permitted in one or more spans or episodes, as long as the total duration remains under the six-month cap for the rolling year or demonstration period, in combination with other housing services that include room and board (i.e., short-term rental assistance). Room and board-only interventions are limited to a combined 6 months per household per demonstration period. Congregate sleeping space, facilities that have been temporarily converted to shelters (e.g., gymnasiums or convention centers), facilities in which sleeping spaces are not available to residents 24 hours a day, and facilities without private sleeping space are excluded from the demonstration.
Pre-tenancy supports (Pre-tenancy navigation services)	• Pre-tenancy navigation services: To assist an individual in finding housing, the individual may receive: — Functional needs assessment — Assistance with social service connection — Person-centered plan including community integration • Providers of housing navigation assist enrollees experiencing homelessness to locate housing options and have materials necessary for completing housing applications • Housing search may include: — Identify housing needs and preferences — Develop and implement a housing search strategy that meets the enrollee's identified needs and preferences, and supports the stated needs of the member and/or household to achieve their stability goals — Review, update, and modify preferences with the member to reflect current needs and preferences, and address existing or recurring housing retention barriers — Apply for income supports and housing that are aligned with the enrollee's identified needs and preferences, including completing an assessment in vocational rehabilitation or other employment opportunities — Coordinate viewing of housing options — Providing information and referrals to resources in the community to address identified housing issues, such as referrals to: Legal assistance organizations, Local housing quality enforcement agencies and funding sources for home improvements • Application assistance: — Helping enrollees fill out applications, collect necessary application paperwork, and secure any needed documents (e.g., photo identification, birth certificate, social security

Service	Definition
	card), including providing funding if needed to obtain these items. — Helping submit applications for resources necessary to increase income and stabilize housing such as those below: • Helping enrollees develop a system for organizing, tracking, and following up on the status of applications, including applications for: — Income supports and financial assistance, including finding employment — Tax deferral/discount programs — Discount utility programs — Funding for payments to address rent/mortgage arrears — Housing — subsidized and market rate, including enrollment in the local Regions Coordinated Entry System — Assist in completing housing applications and payment of any housing application or inspection fees, background checks, and identification documents — Assist in coordinating transportation to ensure access to housing options prior to transition and on move-in day. The intensity of housing search services may vary over the course of service delivery as enrollees wait for housing opportunities to become available.
Tenancy and sustaining services	Providers assist enrollees with maintaining housing including: • Landlord relationships • Community relationships • Lease renewals and payments — Assist enrollees to access benefits, negotiate with landlords, seek legal assistance, apply for new housing (if needed), or take other actions to help stabilize an enrollee's housing situation. — Review, update, and modify preferences with the member to reflect current needs and preferences, and address existing or recurring housing retention barriers — Apply for income supports and housing that are aligned with the enrollee's identified needs and preferences, including completing an assessment in vocational rehabilitation or other employment opportunities — Provide information and referrals to resources in the community to address identified housing issues, such as referrals to: Legal assistance organizations, Local housing quality enforcement agencies and funding sources for home improvements • Housing stabilization: Meet with the enrollee to: — Ensure the enrollee makes timely rent payments (e.g., connect the enrollee to money management services)

Service	Definition
	— Provide coaching on life skills needed to adjust to community-based housing — Provide education and training on appropriate tenant behaviors — Provide referrals to community-based organizations, as needed, for ongoing housing stabilization services — Mediation and negotiations to sustain a tenancy such as those below: • Mediating with the landlord (or landlord's designee) • Assisting in submitting a request for a reasonable accommodation • Establishing a payment plan with the landlord (or landlord's designee) or bank
One-time transition and moving costs	Through one-time transition and moving goods, the State will pay for move-in costs (e.g., security deposits, movers) as well as furnishings and other items necessary to make new housing habitable and comfortable. One-time transition and moving costs necessary to establish a basic household such as: • Deposits needed to secure housing (i.e., security deposits). The payment for a security deposit does not count against this six-month coverage cap on room and board services offered through HRSN. • Unresolved arrearages (up to 6 months of combined arrears and prospective payments), if necessary, to set up services in new residence • Relocation expenses • Basic household goods and furniture, which may include appliances necessary for food consumption, bedding, furnishings, cribs, bathroom supplies, and cleaning supplies • Housing application fees and fees related to background checks as part of application
First month's rent, as a transitional service	• First month's rent • This service counts towards the six-month coverage cap on room and board services offered through HRSN.
Case Management	Case management support includes connecting members to services and supports to assist in maintaining the housing moving forward, such as linkages to: — Service planning and support, and participation in person-centered plan meetings — Maintaining enrollment in Colorado Program Eligibility and Application Kit (PEAK). Colorado PEAK is a secure online tool that allows Colorado residents to: • Learn about public assistance programs and benefits

Service	Definition
	• Apply for benefits like cash, food, and medical assistance • Manage their benefits online • Check the status of existing benefits — Coordinating and linking the recipient to services (e.g., primary care, health homes, SUD, mental health, medical, vision, nutritional, dental, long term services and supports, vocational, education, employment, volunteer supports, hospitals, emergency departments, probation and parole, crisis, end of life planning, and other support groups and natural supports) — Assistance accessing supports to preserve independence — Provision of supports, including development of independent living skills — Providing supports in communicating with landlords and property managers — Coordinating with tenant to review housing support and crisis plan and address barriers — Connect the individual to training and resources on good tenancy, lease compliance, and household management — Connect to services from other State agencies — Engaging the landlord, and communicating with and advocating on behalf of the member with landlords — Assist the member in communicating with the landlord and property manager — Provide training and resources to assist the member in complying with the member's lease — Establish procedures and contacts to retain housing, including developing a housing support crisis plan that includes prevention and early intervention services when housing is jeopardized — Provide supports to assist the member in the development of independent living skills needed to remain housed (e.g., skills to maintain a healthy living environment, develop and manage a household budget, interact appropriately with neighbors or roommates, reduce social isolation, utilize local transportation, etc.) — Support housing stability by facilitation of the enrollment of individuals of the household in local school and college systems — Coordinate referrals for access to other necessary medical, disability, social, educational, legal, income-related tools and resources for housing, and other services (e.g., connections to behavioral health treatment providers)
Nutrition counseling and instruction	Any combination of educational strategies designed to motivate and facilitate voluntary adoption of food choices and other food and nutrition-related behaviors conducive to health and well-being.

Service	Definition
	This service may consist of the following: • Medical nutrition therapy assessment or re-assessment • Provision of nutrition education or information to an individual or group that offers evidence-based or evidence-informed strategies on adoption of food choices and other food- and nutrition-related behaviors conducive to health and well-being and guidance on food and nutrition resources • Meal preparation education in an individual or group setting Nutrition education services may be supplemented with handouts, take-home materials, and other informational resources that support nutritional health and well-being. This service must: • Be provided in accordance with evidence-based nutrition guidelines • Follow food safety standards • Be person-centered, consider dietary preferences, and be culturally appropriate
Medically tailored meals	Meals tailored to support specific individuals for which nutrition supports would improve health outcomes. This service includes: • The preparation and provision of the prescribed meals, consistent with a nutrition care plan, up to three meals a day, for up to six months • Delivery of the meal. Meals must be provided in accordance with evidence-based nutrition guidelines. Each meal must contain sufficient food to support approximately one-third of an individual's daily nutritional need as indicated by the Dietary Reference Intakes and Dietary Guidelines. The meal may also include an accompanying fluid/drink and/or a supplementary food item to support meeting a member's nutrition needs between meals if medically appropriate (for example, to provide access to fluids and/or support taking medication accompanied by food). Meals may consist of fresh or frozen food. If a member is receiving medically tailored meals, the member may not receive home delivered meals or pantry stocking simultaneously.
Home delivered meals or pantry stocking	Home-delivered meals: Receipt of prepared hot foods, meal kits, or restaurant meals to supplement HRSN "Pantry Stocking" for members who require additional food supports, in particular, for but not limited to supporting members' engagement with healthcare or other supportive services. This service may also be provided in place of

Service	Definition
	HRSN "Pantry Stocking" for members who do not have the means to prepare or store groceries (e.g., individuals who are unhoused). Member may pick up food from food retailer or have food delivered to the member's home or private residence, if delivery service is available. This service must be consistent with the nutrition care plan and is available for up to three meals a day, for up to six months. This intervention may be renewed for additional 6-month periods if it is determined the beneficiary still meets the qualifying health-related and social-risk factors. This service may: • Take into account a member's household size when provided to the household of a pregnant individual (plus twelve months postpartum). • Be administered through, for example, a voucher or prepaid card to be used only at a food retailer for allowable purchases • Be provided in conjunction with resources on the Dietary Guidelines for Americans to encourage healthy food selection This service must: • Be provided in accordance with evidence-based nutrition guidelines • Follow food safety standards • Be person-centered, consider dietary preferences, and be culturally appropriate For all nutrition services, the member may not exceed a full nutrition regimen of 3 meals/day. Pantry stocking: This service allows a member to purchase an assortment of foods aimed at promoting improved nutrition for the member. Member may pick up food from food retailer or have food delivered to the member's home or private residence, if delivery service is available. This service must be consistent with the nutrition care plan and is available for up to three meals a day, for up to six months. This intervention may be renewed for additional 6-month periods if it is determined the beneficiary still meets the qualifying health-related and social-risk factors. Examples of allowable foods include: • Fruits and vegetables • Meat, poultry, and fish • Dairy products • Breads and cereals

Service	Definition
	• Snack foods and non-alcoholic beverages • Seeds and plants, which produce food for the household to eat This service may: • Take into account a member's household size when provided to the household of a pregnant individual (plus twelve months postpartum). • Be administered through, for example, a voucher or prepaid card to be used only at a food retailer for allowable purchases • Be provided in conjunction with resources on the Dietary Guidelines for Americans to encourage healthy food selection This service must: • Be provided in accordance with evidence-based nutrition guidelines • Follow food safety standards • Be person-centered, consider dietary preferences, and be culturally appropriate

1.1. Providing Culturally and Linguistically Appropriate Services

All HRSN services must be provided in a way that is culturally responsive and ensures meaningful access to language services. The State will require the fiscal intermediary (FI) and all services providers to provide services in support of Colorado's health equity goals, consistent with National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care to ensure language access across all services.

1.2. Nonduplication of Services

No HRSN service will be covered that is found to be duplicative of a State or federally funded service or other HRSN service the member is already receiving. To avoid the duplication or displacement of existing food assistance and nutrition services, enrolled providers delivering these services will facilitate beneficiaries understanding, applying for, and accessing other state and federal benefit programs such as Supplemental Nutrition Assistance Program (SNAP) and/or Women Infants and Children (WIC) and/or Older Americans Act Nutrition Services.

1.3. Provider Qualifications

There are several components in Colorado for delivery of HRSN services including with different provider types each with different qualification requirements.

Voucher Administrators and Housing Navigators will, under the oversight of Department of Local Affairs (DOLA), manage voucher administration and ensure rental assistance and housing navigation (pre-tenancy and tenancy sustaining) are delivered by qualified and trained staff. Housing Voucher Administrator providers will be providing rent/temporary housing for up to

six months (Short-term rental assistance) First month's rent, as a transitional service housing deposits to secure housing, including application and inspection fees and fees to secure needed identification. A description of what is required of the provider is found in the subsection 1.3.1.

Housing Program providers will be providing short-term post-transition and housing case management services. A description of what is required of the provider is found in the subsection 1.3.3.

Nutrition Program providers will be providing medically tailored meals and home delivered meals or pantry stocking. A description of what is required of the provider is found in subsection 1.3.4.

1.3.1 Housing Voucher Administrator Provider Minimum Qualifications Include

For providers managing rental assistance, the Division of Housing (DOH) within Colorado's Department of Local Affairs (DOLA) sets the standard that all voucher administrators must meet. The DOH Rental Assistance Program (RAP) Administrative plan includes minimum requirements and criteria for these providers and is updated annually.

- Experience and capacity to provide and manage the housing services proposed
- Knowledge of principles, methods and procedures of covered housing services
- Experience from across housing sectors, such as homeless services and other community-based services providers, community mental health centers, and healthcare or other systems.
- Knowledge of safety for beneficiaries who may be at risk of victimization or violence
- An understanding of housing best practices including Housing First, Trauma Informed Care, and Harm Reduction, as well as how these service delivery models apply when working with the intended population(s)
- Current DOH contracted Voucher Administrator agency or have a letter of commitment from a current DOH contracted Voucher Administrator agency
- Knowledge of Trauma-Informed Design, Safety Planning, and Security
- Knowledge and commitment to quality housing

1.3.2 Minimum Provider Qualifications for Managing Goods as Services

Acceptable Goods as outlined in the approved Services Protocol, with the caveat that use of this service must meet the test of reasonable cost, supports the goals in the Plan of Care (POC) and there is no alternative to pay/support these needs. The allowable timeframe in which goods will support a goal in the POC should be consistent (e.g., if a goal is set to be achieved in three months, then the goods or services supported should be contained to that timeframe). The POC is approved by the FI. In Colorado goods that will be provided to HRSN participants include move-in goods and moving costs, utilities assistance and pantry stocking. Providers who will be responsible for managing these resources will be required to

- Contract with a state agency or FI
- Experience in managing accounts and procurement
- Goods cannot exceed limits in the approved Services Protocol per year using a FI.
- Goods should be used as the funding source of last resort - only for those costs that cannot be covered by any other source and that are vital to the implementation of the care plan.
- This service does not duplicate other services available through the Medicaid State Plan.
- The FI ensures that suppliers of goods adhere to all Medicaid requirements.
- The FI ensures that any insurance required by state law is obtained and maintained.
- The FI ensures that any safety precautions needed to protect the population served are taken as necessary and required by state law.

1.3.3 Housing Program Provider Minimum Qualifications Include

For providers managing housing programs the following minimum qualifications apply to all housing programs.

- Housing program providers must have organizational capacity sufficient to address the estimated demand for services in their geographic area, project planning skills, community engagement, involvement of peers, persons with lived experience, and other factors that are associated with high-quality service delivery.
- Housing program providers must have knowledge of principles, methods, and procedures for effective delivery of tenancy sustaining services (TSS), or comparable services meant to support individuals in obtaining and maintaining stable housing.
- Housing program providers must enroll as a Medicaid provider and comply with staffing requirements outlined by the provider type the housing program provider is enrolled as.
- Housing program providers must provide quality services to beneficiaries as determined by agency review and oversight. Any program found deficient through monitoring or audit review must comply with an agency action plan to address deficiencies.
- Housing program providers must have experience providing housing support to persons experiencing homelessness or at risk of homelessness.

Additional Permanent Supportive Housing (PSH) program provider qualification requirements include:

- Experience with individuals who have complex barriers to housing stability, including those who are diagnosed with a mental health and/or substance use disorder (SUD), those with a physical disability, as well as persons with long lengths of homelessness, incarceration, and/or institutional settings.
- Have staff, or contractual arrangement with another organization to provide clinical care for members with behavioral health (BH) diagnoses, in addition to general staffing requirements noted above.

Additional Colorado Fostering Success (CFS) program Provider Qualification requirements

Services for the CFS population are administered through county John H. Chafee Foster Care Program for Successful Transition to Adulthood (Chafee programs), Chafee contractors, and Division of Youth Services (DYS) Regional Housing Specialists. The Chafee program provides assistance to help youth currently and formerly in foster care

successfully transition to adulthood by providing grants to States and eligible Tribes that submit an approvable plan. CFS providers must meet Colorado Department of Human Services (CDHS) requirements including:

(a) To be eligible to provide services, a case management agency must:

(I) Be a current recipient of a grant from the foster youth successful transition to adulthood grant program created in Colorado Statute Section 19-7-314; or

(II) Be currently operating a program through funding received pursuant to the federal "John H. Chafee Foster Care Program for Successful Transition to Adulthood" (Chafee program), 42 U.S.C. 677 (a).

Additional Community Access Team (CAT) program provider qualification requirements

Services for the CAT population are delivered by Home and Community Based Services (HCBS) Medicaid providers who must meet the Department of Health Care Policy and Financing (HCPF) HCBS provider requirements.

1.3.4 Nutrition Program Provider Minimum Qualifications Include

Nutrition providers must meet HCPF requirements including: providers must have knowledge of principles, methods, and procedures of the nutrition services covered under the waiver, or comparable services meant to support an individual in obtaining food security and meeting their nutritional needs. Nutrition service providers must follow best practice guidelines and industry standards for food safety.

Providers must have at least one year of experience in delivering nutrition services with an emphasis on addressing food insecurity, such as providing tailored services like medically tailored meals and fruit/vegetable prescriptions, or chronic disease management.

1.4. Use of a Fiscal Intermediary (FI)

The Department of Health Care Policy and Finance (HCPF) will contract with Colorado Department of Local Affairs (DOLA) as an FI to reimburse for and track expenditures for HRSN goods and rental assistance. Under the contract, DOLA is held to the same contractual requirements of ensuring provider qualifications of purchased goods. DOLA is monitored to ensure that they contract with providers meeting applicable requirements. DOLA will undergo a readiness review as part of the determination that it is qualified to furnish these services. Financial accountability is assured because DOLA is required to bill the Medicaid Management Information System (MMIS) only for the amount of the goods under the rate codes for each of those items and under a separate rate code for the FI.

The FI services are provided statewide through one FI, DOLA. Members will have a choice of goods vendors from among those vendors that are available in their region. If, after completing the HRSN eligibility determination and documenting all the required information, the individual meets all of the criteria for being HRSN eligible (see Section 2 below), the FI will verify authorization of goods and/or rental assistance and will reimburse the provider as expeditiously as possible. The FI will ensure that any individual eligible for HRSN waiver services receives goods in a timely manner according to the HCPF outlined requirements. The

FI will work with members, families, contractors, and vendors to promote timely service delivery.

DOLA will demonstrate cost-effectiveness and include a realistic and comprehensive budget for each purchased good. DOLA will develop and facilitate a network of vendors, contractors, and evaluators within the state and regional area; DOLA will function as an FI and the provider of record in its provider agreement with such entities. The FI may then purchase goods authorized in the service plan on the individual's behalf and bill the costs of such goods to the State. An agreement with a vendor is not required but there must be documentation to verify the purchase of the goods and the goods must meet the standards specified in the waiver.

DOLA will:

- Meet all current and future requirements, procedures and terms outlined in the approved demonstration authorizing and outlining the provision of these services upon approval by Centers for Medicare and Medicaid Services (CMS);
- Comply with current and future policies, standards and procedures, regulations, and operational policies implemented by HCPF and CMS for FIs generally and specifically with respect to the HRSN demonstration;
- Participate in related case reviews and other oversight processes conducted by HCPF;
- Establish a process to bill and be reimbursed for the goods managed and be responsible for payment to the goods vendors;
- Establish a process to bill under the MMIS, as required, only for the amount of the goods under the rate codes for each of those services and under a separate rate code for the FI

All service providers will enroll in the MMIS and submit claims. All private service providers will enroll directly with HCPF and be paid through the MMIS. For an individual to receive HRSN services, the housing program service provider, through appropriately trained and credentialed staff allowable under Medicaid enrollment type, must determine if the individual meets the eligibility and service criteria for each service. The housing program service provider will maintain eligibility documentation. The FI will need to maintain documentation of eligibility and payment of goods and rental assistance. The MMIS will enroll HRSN Providers and will reimburse for submitted claims. Client-Specific Service needs are characterized as those needs which can be anticipated. Therefore, they must be reflected in the individualized Plan of Care for payment to be approved and need to be documented in the individual's progress notes.

2. Identifying Beneficiaries with HRSN

A description of the process for identifying beneficiaries with HRSNs, including outlining beneficiary eligibility, implementation settings, screening tool selection, and rescreening approach and frequency, as applicable.

The description of the process for identifying beneficiaries with HRSNs, including outlining beneficiary eligibility, implementation settings, screening tool selection, and rescreening approach and frequency is provided below in this section.

2.1. HRSN Beneficiary Eligibility

Covered Populations

The covered populations in Colorado will dovetail with preexisting programs: individuals eligible for Permanent Supporting Housing (PSH) vouchers, individuals eligible for Colorado Fostering Success (CFS) vouchers, and individuals eligible for Community Access Team (CAT) vouchers. These covered populations will be eligible to receive HRSN services, so long as they also satisfy the applicable clinical and social risk criteria, and the HRSN service is determined to be medically appropriate:

1. Individuals eligible for PSH vouchers:

   Such individuals must:

   - Be 18 years of age or older
   - Have a disabling condition
   - Have a history of homelessness or be at risk of homelessness
   - Must be at or below 30% of the area median income

   For purposes of this Demonstration, the PSH population is further divided into three distinct eligibility groups based on the individual's status vis-à-vis a PSH voucher:

   - Individuals matched to a PSH voucher within the past 12 months (PSHa population)
   - Individuals eligible for PSH but not yet matched to a voucher (PSHb population)
   - Individuals residing in PSH for more than one year (PSHc population).

2. Individuals eligible for CFS vouchers:

   Such individuals must:

   - Be at least 18 years of age or older, but less than 26 years of age
   - Have prior foster care or kinship care involvement in at least one of the following ways:
     - Have been in foster care on or after the youth's fourteenth birthday
     - Have been in noncertified kinship care on or after the youth's fourteenth birthday and have been adjudicated dependent and neglected
     - Have turned 18 years of age when the youth was a named child or youth in a dependency and neglect case
   - Reside in Colorado
   - Have an income level at or below 50% of the area median income based on the county in which the young adult resides

3. Individuals Eligible for CAT vouchers:

Such individuals must:

- Be 18 years of age or older
- Be at or below 30% of the area median income
- Meet the Housing and Urban Development (HUD) definition of a disability
- Receive Home- and Community-Based Services (HCBS) Medicaid services, or State Plan services[1], or are eligible for such services

2.2. Demonstration Eligibility

The covered populations in 2.1 are eligible for at least some of the HRSN services (see Attachment M. HRSN Services Matrix) as long as they are Medicaid eligible and meet the social and clinical criteria.

Full demonstration eligibility criteria are listed in Table 2 below.

Table 2. Demonstration Eligibility

Eligible Population	Social Risk Factor	Clinical Criteria for the Population
Individuals eligible for PSH vouchers	"Homeless or At Risk of Homelessness" • Meets the US Department of Housing and Urban Development's (HUD's) definitions of homeless or at-risk of homelessness as codified at 24 CFR part 91.5. "Nutrition Insecurity" • Meets the USDA Definition of Low or Very Low Food Security	"Behavioral health need" means: • A diagnosed behavioral health disorder, according to the criteria of the current editions of the Diagnostic and Statistical Manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems where there is a need for improvement, stabilization, or prevention of deterioration of functioning (including ability to live independently without support) resulting from the presence of a behavioral health condition. "Chronic Health Condition" • One or more chronic conditions including but not limited to those identified in Social Security Act section1945(h)(2). Examples of conditions can include: diabetes, BMI over 25, cardiovascular disease, respiratory disease, HIV/AIDS diagnosis, hypertension, physical disability (e.g. amputation, visual impairment), cancer, hyperlipidemia, chronic obstructive pulmonary diseases, chronic kidney disease
Individuals eligible for	"Homeless or At Risk of Homelessness"	Clinical criteria, as defined above, is determined through self-disclosure of a behavioral health

[1] SPA #: 23-0040

Eligible Population	Social Risk Factor	Clinical Criteria for the Population
CFS vouchers	• Meets the US Department of Housing and Urban Development's (HUD's) definitions of homeless or at-risk of homelessness as codified at 24 CFR part 91.5. "Nutrition Insecurity" • Meets the USDA Definition of Low or Very Low Food Security	need or chronic health condition during the initial screening. While not a requirement of the CFS program, individuals who qualify for CFS may be screened for HRSN criteria, including assessment for clinical care, and if HRSN criteria is met and clinical need is determined by a clinician, the member would be eligible to enroll as an HRSN services recipient.
Individuals eligible for CAT vouchers	"Homeless or At Risk of Homelessness" • Meets the US Department of Housing and Urban Development's (HUD's) definitions of homeless or at-risk of homelessness as codified at 24 CFR part 91.5. • "Nutrition Insecurity" Meets the USDA Definition of Low or Very Low Food Security	Eligible for home- and community-based services (HCBS) or State Plan services and transitioning out of a nursing home, hospital, Intermediated Care Facility for Individuals with Intellectual and Developmental Disabilities (ICF-IDD), Regional Center, or are at risk of institutionalization as defined in Targeted Case Management Transition Coordination Services under Colorado Medicaid[1].

[1]**Colorado State Plan Amendment (SPA) #: 23-0040 (approved March 13, 2024).**

2.3. Screening Tool

To receive Housing or Nutrition services, individuals must meet criteria for one of the eligible voucher programs: PSH, CAT, CFS. Colorado will use existing infrastructure, including existing screening tools, to screen for need and eligibility for these voucher programs.

Imminent risk of homelessness for the purposes of CFS voucher program is defined as:

A youth or young adult who is currently experiencing any of the following situations:

A. An individual or family who will imminently lose their primary nighttime residence, provided that all of the following apply;
    a. Residence that may or may not be provided through a publicly funded institution or system of care (eligible placements through DYS or Child Welfare) will be lost within 90 days of the date of application for homeless assistance;
    b. No subsequent residence has been identified; and
    c. The individual or family lacks the resources (housing vouchers or placement options) or support networks needed to obtain other permanent housing.
B. Have not had a lease, ownership interest in permanent housing during the 60 days prior to the homeless assistance application;
C. Can be expected to continue in such status for an extended period of time

Individuals may also qualify as being at imminent risk of homelessness if one or both of the following apply in conjunction with the clauses A, B, and C;

- Individuals or families who are fleeing or attempting to flee intimate partner violence, dating violence, sexual assault, or stalking (or other dangerous or life-threatening conditions), and who lack resources and support networks to obtain other permanent housing.
- Individuals who have or are experiencing, or at-risk of human and/or sexual trafficking.

The Division of Child Welfare staff will utilize the CDHS Homeless Risk Assessment (HRA) tool to gauge the risk of homelessness for applicants and establish a prioritization according to the available resources in the community for the following list of eligible populations:

- Black, Indigenous, and People of Color (BIPOC)
- Qualifying diagnosis or disability
- Current or past Juvenile Justice involvement
- Youth who have been the victims of Human and/or Sex trafficking
- Parenting youth or young adults
- LGBTQ+ youth or young adults

2.3.3. CAT Population

CAT voucher members are assessed through the Targeted Case Management - Transition Coordination (TCM-TC) Community Needs Assessment completed by Transition Coordinators (TC) while the member is residing in a Skilled Nursing Facility (SNF). This assessment encompasses a review of the members' needs for successful transition back into the community including the need for a CAT voucher and other transition services that include home delivered meals, Pantry Stocking, and Pre and Post Tenancy Support services.

Members at-risk of institutionalization are identified through the use of a risk score to identify individuals at highest risk of institutionalization and, in the future, will additionally be identified through a referral process. Individuals identified through these processes that identify a need for housing are referred to Transitions Coordination where the Transition Coordinator assesses the member’s needs for housing supports like housing navigation and CAT vouchers.

Referral process for CAT vouchers

When a member has completed the TCM-TC Community Needs Assessment and housing assistance and a CAT voucher is identified as a need for the member to transition into the community, the TC initiates a referral for the CAT voucher. The TC works with the member to complete the CAT Voucher Application and submits it to DOH for approval.

If an individual’s circumstances or needs change significantly, and at the request of the individual, the individual may be rescreened. However, unless there is a change in circumstances or the individual requests the rescreen, there is no additional need for rescreening for HRSN eligibility because HRSN services under the demonstration are one-time services or limited to six months in duration for rental assistance, nutrition counseling, and medically tailored meals, with the exception of tenancy-sustaining supports.

2.4. Implementation Settings

Allowable settings under the demonstration include apartments, single room occupancy (SRO) units, single-family homes, multi-family homes, mobile home communities, accessory

dwelling units (ADUs), co-housing communities, trailers, manufactured homes, motel or hotel when it is serving as the member's primary residence, transitional and recovery UM housing, including bridge, site-based, population-specific, and community living programs that offer supportive services and programming. The units must provide the following for members:

- Access to a clean, healthy environment that allows members to perform activities of daily living
- Access to a private, semi-private, or shared independent room with a personal bed for the entire day with no more than three roommates (note: dormitories are not permitted)

Congregate sleeping space, facilities that have been temporarily converted to shelters (e.g., gymnasiums or convention centers), facilities where sleeping spaces are not available to residents 24 hours a day, and facilities without private sleeping space are excluded from the demonstration.

In addition, for a CAT voucher, participants may also lease from an Assisted Living Facility as long as the voucher is used solely for rent. Rental Assistance may not be used for board payments.

Nutrition services may not be provided in provider-owned settings in which the provider is expected to provide meals, including assisted living facilities, nursing facilities, hospitals, group homes, and other congregate care settings.

3. Application of Clinical Criteria

A description of the process by which clinical criteria will be applied, including a description of the documented process wherein a provider, using their professional judgment, may deem the service to be medically appropriate.

For the PSH population, clinical criteria are determined initially through self-disclosure of a behavioral health need or chronic health condition during the Coordinated Entry assessment. Once a member is referred to services, a licensed clinician affiliated with the supportive housing provider confirms clinical diagnosis and uses their professional judgment to deem the service to be medically appropriate and in accordance with the member's diagnosis and treatment plan.

For the CAT population, clinical criteria includes that the member must have a verified disability. A Verification of Disability must be completed by a Medical Professional willing to attest to the member's disability, including the Medical Provider's license number. Verification can also be confirmed through an SSDI letter that includes their disability.

For the CFS population, clinical criteria is determined through self-disclosure of a behavioral health need or chronic health condition during the initial screening. While not a requirement of the CFS program, individuals who qualify for CFS may be screened for HRSN criteria, including assessment for clinical care, and if HRSN criteria is met and clinical need is determined by a clinician the member would be eligible to enroll as an HRSN services recipient.

Determining Medical Appropriateness

Include the State's plan to identify medical appropriateness based on clinical and social risk factors.

The State will utilize a standard needs assessment using the existing assessment and referral process (see above in Section 2.3) and will gather information regarding the eligibility and service criteria for each service utilizing current tools and practices. The State will maintain documentation of eligibility for each individual in case of audit.

As required by the State, HRSN providers will submit results of the standard needs assessment to the state's contracted FFS utilization management (UM) vendor[1] or the FI. The state's contracted FFS UM vendor will confirm eligibility and manage requests for services that require a prior authorization (e.g. medically tailored meals). The FFS UM vendor will be required to notify the individual of approval or denial of the service including information about appeals and hearing rights. Individuals who are denied HRSN services or are authorized for HRSN services but such authorization is limited in scope, amount, or duration, will receive a notice consistent with 42 CFR 431 Subpart E and have appeal rights. The FFS UM vendor shall notify all individuals who have undergone an HRSN service authorization or denial as expeditiously as the circumstances require, not to exceed fourteen (14) calendar days from the date of, as applicable and appropriate, authorization or denial. The FFS UM vendor will follow an individual's preferred method of communication (e.g., email, phone call, etc.).

3.1. Care Plan Description

A description of the process for developing care plans based on assessment of need.

The State intends to connect and, if necessary, to procure a Case Management System with a Closed-Loop Referral System vendor(s) to support statewide HRSN screening and referral data sharing for members. Once medical appropriateness is established, the HRSN Provider will include HRSN in each individual's care plan and ensure referrals to appropriate social services and community providers are made

Each individual's care plan will include goals related to housing permanency and stability, even if HRSN is not an included service. The care plans will identify actions needed as well as any housing services that will help the member attain that goal. All care plans that include HRSN must, at a minimum:

- Be individualized for each member
- Be congruent with the State-approved HRSN screening tool
- Be developed using an individualized, person-centered planning process
- Be reviewed and revised when the individual's circumstances or needs change significantly, and at the request of the individual
- Include a housing permanency goal
- Demonstrate that the member has an informed choice of providers

PSH Population

In Colorado's Permanent Supportive Housing (PSH) programs a care plan, often called a "housing stability plan", involves a comprehensive approach. Beginning with an assessment of the individual's needs, a personalized plan is based on the Housing First model. A dedicated housing program service provider, through appropriately trained and credentialed staff allowable under Medicaid enrollment type, provides intensive support, coordinating on-site services and community resources. The housing stability plan emphasizes tenant rights, regular check-ins, and continuous evaluation to ensure effectiveness.

CAT Population

Transition Coordinators develop a Transition or Diversion Plan which are written documents that identify person-centered goals, assessed needs, and the choices and preferences of services and supports to address the identified goals and needs; appropriate services and additional community supports; outlines the process and identifies responsibilities of transition options team members; details a risk mitigation plan; and establishes a timeline that will support an individual in transitioning to or remaining in a community setting of their choosing.

CFS Population

Individualized, developmentally-appropriate case management (CM) services are a required support for all individuals accessing the Colorado Fostering Success Housing Voucher Program. CM services are administered through county Chafee programs, Chafee contractors and DYS regional Housing Specialists.

Support for CM services should be individualized to address the specific needs of each young person and should address goals and needs targeted to reach the intended outcome of successful transition to adulthood beyond the lifetime of the housing voucher and Chafee programs.

Chafee caseworkers should work with the young person to assess their long term goals and utilize assessment tools intended to identify areas of need and prioritize services as determined by the individual receiving services. Caseworkers are encouraged to maintain regular contact with voucher participants based on their preference and need. Caseworkers are expected to maintain support for annual recertification processes, which will be initiated 90 days prior to the end of the Housing Assistant Payment (HAP) contract/ Lease Agreement, and will be expected to report income changes and updates to employment and household demographics at the point of recertification for the housing voucher.

4. Public Plan for Service Eligibility and Medical Necessity Criteria

The state will maintain eligibility criteria for each HRSN program consistent with the clinical and social risk criteria detailed in this protocol on a public facing HCPF webpage. The content will be updated if the criteria is changed

Attachment M: Colorado 1115 HRSN Services Matrix

Service Category	Service	PSHa	PSHb	PSHc	CFS	CAT
Case Management	Case management for housing	X	X	X	X	X
Housing/Home Environment interventions without room and board	Pre-tenancy navigation services	X	X		X	
	Tenancy and sustaining services			X		X
	One-time transition and moving costs *other than* rent	X			X	
	Utility assistance	X			X	X
Housing interventions with Room and Board (episodic Interventions)	Short-term post-transition housing					X
Housing interventions with Room and Board (Rent Only Interventions)	First month's rent, as a transitional service	X			X	X
	Short-term rental assistance	X			X	X
Nutrition Interventions without food	Nutrition counseling and instruction	X		X	X	X
Nutrition interventions with food	Home Delivered meals/ Pantry Stocking	X			X	X
	Medically Tailored Meals	X		X	X	

Colorado 1115 HRSN Services Matrix: Housing

	Service	Population	Social Risk Factor	Clinical Criteria for the pop
Case Management	Case management for housing	PSHa, PSHb, PSHc, CFS, CAT	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition or HCBS
Housing/Home Environment interventions without room and board	Pre-tenancy navigation services	PSHa, PSHb, CFS	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition or HCBS
	Tenancy and sustaining services	PSHc, CAT	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition or HCBS
	One-time transition and moving costs *other than* rent	PSHa, CFS	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition
	Utility assistance	PSHa, CFS, CAT	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition
Housing interventions with Room and Board (episodic Interventions)	Short-term post-transition housing	CAT	Homeless or At Risk of Homelessness	HCBS
Housing interventions with Room and Board (Rent Only Interventions)	First month's rent, as a transitional service	PSHa, CFS, CAT	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition
	Short-term rental assistance	PSHa, CFS, CAT	Homeless or At Risk of Homelessness	Behavioral Health Need or Chronic Health Condition

Colorado 1115 HRSN Services Matrix: Nutrition

	Service	Population	Social Risk Factor	Clinical Criteria for the pop
Nutrition interventions with food	Nutrition counseling and instruction	PSHa, PSHc, CFS, CAT	Nutrition Insecurity	Behavioral Health Need or Chronic Health Condition or HCBS
	Home Delivered meals / Pantry stocking	PSHa, CFS, CAT	Nutrition Insecurity	Behavioral Health Need or Chronic Health Condition or HCBS
	Medically Tailored Meals	PSHa, PSHc, CFS	Nutrition Insecurity	Behavioral Health Need or Chronic Health Condition

Colorado 1115 HRSN Services Matrix: Clinical Criteria Detail

Clinical Risk Factor	Clinical Criteria Detail
Behavioral Health Need	A diagnosed behavioral health disorder, according to the criteria of the current editions of the Diagnostic and Statistical Manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems, where there is a need for improvement, stabilization, or prevention of deterioration of functioning (including ability to live independently without support) resulting from the presence of a behavioral health condition.
Chronic Health Condition	One or more chronic conditions including but not limited to those identified in Social Security Act section1945(h)(2). Examples of conditions can include: diabetes, BMI over 25, cardiovascular disease, respiratory disease, HIV/AIDS diagnosis, hypertension, physical disability (e.g. amputation, visual impairment), cancer, hyperlipidemia, chronic obstructive pulmonary diseases, chronic kidney disease
HCBS	Eligible for home- and community-based services (HCBS) or State Plan services and transitioning out of a nursing home, hospital, Intermediated Care Facility for Individuals with Intellectual and Developmental Disabilities (ICF-IDD), Regional Center, or are at risk of institutionalization as defined in Targeted Case Management Transition Coordination Services under Colorado Medicaid[1].

[1] Colorado State Plan Amendment (SPA) #: 23-0040 (approved March 13, 2024).

Colorado 1115 HRSN Services Matrix: Social Risk Factor Detail

Social Risk Factor	Social Criteria Detail
Homeless or At Risk of Homelessness	Meets the US Department of Housing and Urban Development's (HUD's) definitions of homeless or at-risk of homelessness as codified at 24 CFR part 91.5.
Nutrition Insecurity	Meets the USDA Definition of Low or Very Low Food Security

Colorado 1115 HRSN Services Matrix: Population Details

Population	Details
Permanent Supportive Housing (PSH)	**For each PSH subpopulation an indvidual must:** Be 18 years of age or older Have a disabling condition Have a history of homelessness or be at risk of homelessness; and Must be at or below 30% of the area median income.
PSHa	**In addition to general critera above for PSH:** Individuals matched to a PSH voucher within the past 12 months (PSHa population)
PSHb	**In addition to general critera above for PSH:** Individuals eligible for PSH but not yet matched to a voucher (PSHb population)
PSHc	**In addition to general critera above for PSH:** Individuals residing in PSH for more than one year (PSHc)
Colorado Fostering Success (CFS)	An individual must: Young adults transitioning out of the foster care system on or after their 18th birthday: Be at least 18 years of age or older but less than 26 years of age; and Have prior foster care or kinship care involvement in at least one of the following ways: - Have been in foster care on or after the youth's 14 birthday; - Have been in noncertified kinship care on or after the youth's 14 birthday and have been adjudicated dependent and neglected; and - Have turned 18 years of age when the youth was a named child or youth in a dependency and neglect case; - Reside in Colorado; and - Have an income level at or below 50% of the area median income based on the county where the young adult resides.
Community Access Team (CAT)	**An individual must:** Be 18 years of age or older; Be at or below 30% of the area median income; Meet the Housing and Urban Development (HUD) definition of a disability; and Receive Home and Community Based (HCBS) Medicaid services or State Plan services or are eligible for such services.

Attachment N: Health-Related Social Needs Infrastructure Protocol

Health-Related Social Needs Infrastructure

The Health-Related Social Needs (HRSN) infrastructure protocol addresses the requirements of infrastructure investments for the HRSN services program. The Colorado HRSN services program will allow certain eligible Medicaid beneficiaries to receive evidence-based services. As required in Section 10.9 of the Special Terms and Conditions (STCs), this protocol details the proposed uses of HRSN infrastructure expenditures, types of entities that will receive funding, intended purposes of funding, projected expenditure amounts, and an implementation timeline. According to the STCs, the state is authorized to spend up to $6.9 million on infrastructure investments necessary to support the development and implementation of HRSN services.

Implementation Approach and Timeline

The State may begin awarding infrastructure funds to eligible entities and contractors following approval of this infrastructure protocol document. The State will use a phased approach to disbursing infrastructure funds. Much of the initial phase of the disbursement of infrastructure funding will be for technological updates and procurements as well as business practice development.

Implementation Approach

A. The State will Develop application, distribution, or contracting processes for eligible entities seeking infrastructure funds from the State.
    i. Evaluate applications and allocate funds for activities to be performed in each of the four approved infrastructure categories.
    ii. Award infrastructure funding based on the application and disburse those funds.
B. Ensure that any HRSN fund disbursements to eligible entities and contractors are consistent with the STCs.

Monitoring and Oversight

The State will take action to address non-compliance, ensure non-duplication of funds, and perform other monitoring and technical assistance, as necessary.

The State may claim federal financial participation (FFP) in infrastructure investments to support the development and implementation of HRSN services across the following domains, in accordance with the categories specified in the STCs:

1. Technology
2. Development of business or operational practices
3. Workforce development
4. Outreach, education, and stakeholder convening

The specific activities that may be funded with infrastructure fund are as follows:

1. Technology:
    A. Procuring information technology (IT) infrastructure and data platforms needed to enable, for example:
        i. Authorization of HRSN services
        ii. Referral to HRSN services
        iii. HRSN service delivery
        iv. HRSN service billing
        v. HRSN program oversight, monitoring, and reporting
    B. Modifying existing systems to support HRSN service delivery and closed-loop referrals
    C. Developing an HRSN services eligibility screening tool
    D. Integration of data platforms, systems, and tools
    E. Supporting successful adoption of IT infrastructure and data platforms related to HRSN
2. Development of business or operational practices:
    A. Development of policies and procedures related to:
        i. HRSN referral and service delivery workflows
        ii. Billing and invoicing
        iii. Data sharing and reporting
        iv. Program oversight and monitoring
        v. Evaluation
        vi. Privacy and confidentiality
    B. Training and technical assistance on HRSN program roles and responsibilities
    C. Administrative and/or overhead costs necessary to perform HRSN duties or expand HRSN service delivery capacity, including development and implementation of community hubs
3. Workforce development:
    A. Cost of hiring staff
    B. Cost of training staff members on HRSN policies and procedures
    C. Salary and benefits for staff that will have a direct role in overseeing, designing, implementing, or executing HRSN responsibilities prior to launch of delivery of HRSN services

D. Necessary certifications, training, technical assistance, or education for staff participating in the HRSN program

E. Privacy and confidentiality training or technical assistance related to HRSN service delivery

F. Production costs for training materials or experts as it pertains to the HRSN program

4. Outreach, education, and stakeholder convening:

A. Development and production of materials necessary for marketing, outreach, training, or education

B. Translation of materials

C. Development of culturally competent materials

D. Planning for and facilitation of community-based outreach events to support awareness of HRSN services

E. Planning for and facilitation of learning collaboratives or stakeholder convenings

F. Community engagement activities necessary to support HRSN program implementation and launch

G. Administrative or overhead costs associated with outreach, education, or convening

Eligible Entities

The following entities may be eligible to apply for and receive HRSN infrastructure funding:

1. **Providers of HRSN services, including, but not limited to:**

A. Community-based organizations

B. Social-services agencies

C. Housing agencies and providers

D. Food and nutrition service providers

E. Case management providers

F. Traditional health workers

G. Child welfare providers

H. State, county, city, and local governmental agencies

I. Tribes and Indian health care providers

J. Physical and behavioral health care providers

2. Other entities supporting the infrastructure and delivery of HRSN services such as technology and technical assistance providers

3. State-contracted, third-party administrator and/or financial executor to support HRSN contracting, implementation, and service delivery

1. State and local agencies to support technology; development of business or operational practices; workforce development; and outreach, education, and stakeholder convening

Available Infrastructure Funds and Projected Amounts

Per STC 10.5b, Colorado is approved to use the following infrastructure funds:

HRSN Infrastructure

Pop Type: HRSN Infrastructure	DY 05	Total
Total Expenditure	$6,915,303	$6,915,303

Allowable Use	Percent of Infrastructure Pool	Amount
Technology	40%	$2,766,121
Development of operational or business practices	25%	$1,728,826
Workforce development	25%	$1,728,826
Outreach, education, and stakeholder convening	10%	$691,530
Total	**100%**	$6,915,303

The State provides current estimates for infrastructure expenditure amounts use category. The estimates were developed using anticipated need by category.

ATTACHMENT O
Reserved for HRSN Implementation Plan

ATTACHMENT P
Reserved for Provider Rate Increase Assessment Attestation Table