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

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

State Demonstrations Group

December 18, 2020

Tracy Johnson
Medicaid Director
Colorado Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

Dear Ms. Johnson:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of Colorado's Substance Use Disorder (SUD) Implementation Plan (IP) for the state's approved section 1115(a) demonstration, titled "Expanding the Substance Use Disorder Continuum of Care" (Project Number 11-W-00336/8). With the state's submission received on November 2, 2020, CMS has now determined that the revised IP is consistent with the requirements outlined in the Special Terms and Conditions (STC); therefore, CMS is approving the SUD demonstration's IP. With this approval, the state may begin receiving federal financial participation as of the demonstration's effective date for the provision of inpatient, residential and other services provided to otherwise-eligible Medicaid beneficiaries while residing in institutions for mental diseases for primary diagnoses of SUD. A copy of the approved SUD IP is enclosed and, hereby, incorporated into the STCs as Attachment C.

If you have any questions, please do not hesitate to contact your project officer, Mr. Jack Nocito. Mr. Nocito can be reached at (410) 786-0199 or Jack.Nocito@cms.hhs.gov.

Sincerely,

Angela D. Garner -S

Digitally signed by Angela D. Garner -S
Date: 2020.12.18 15:13:07 -05'00'

Angela D. Garner
Director
Division of System Reform Demonstrations

Enclosure

cc: Curtis Volesky, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 11-W-00336/8

TITLE: Expanding the Substance Use Disorder Continuum of Care

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 1, 2021 through December 31, 2025, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00336/8

TITLE: Expanding the Substance Use Disorder Continuum of Care

AWARDEE: Colorado Department of Health Care Policy and Financing

I. 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:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Demonstration Programs and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. Monitoring
X. Evaluation of the Demonstration
XI. General Financial Requirements Under Title XIX
XII. Monitoring Budget Neutrality for the Demonstration
XIII. 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: Reserved for SUD Implementation Plan and Health IT Plan
Attachment D: Reserved for SUD Monitoring Protocol
Attachment E: Reserved for SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

This 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.

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

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

III. GENERAL PROGRAM REQUIREMENTS

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

2. **Compliance with Medicaid and Children's Health Insurance Program (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. **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 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

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

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit

required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
d. An up-to-date CHIP allotment worksheet, if necessary;
e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor 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 9.

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

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct 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.

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.

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

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

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. **Federal Financial Participation (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.

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

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

IV. ELIGIBILITY AND ENROLLMENT

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

V. DEMONSTRATION PROGRAMS AND BENEFITS

17. **SUD Program Benefits.** Effective upon CMS' 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 19, to ensure short-term residential stays. Under this demonstration beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

18. **SUD Implementation Plan and Health 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 25.
    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.

x. SUD Health IT Plan. Implementation of the milestones and metrics as detailed in STC 18(d) [or Attachment C].

d. 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 18(a) and 18(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

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

i. The state must include in its Monitoring Protocol (see STC 18(d)) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

ii. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 28).

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

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

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

vi. Components of the Health IT Plan include:

1) The Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program (PDMP).[1]
2) The Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
3) The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
4) The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]
5) The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
6) In developing the Health IT Plan, states should use the following resources:
    1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at

[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.

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.

3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

19. 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 18(a) and (c) and reporting relevant information to the state's Health IT plan described in STC 18(d);
b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

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

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

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

VI. COST SHARING

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

VII. DELIVERY SYSTEM

23. 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.

VIII. GENERAL REPORTING REQUIREMENTS

24. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days (30) after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits

the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.

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

25. **Deferral of Federal Financial Participation (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.

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

27. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
    a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
    b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
    c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

28. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual 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. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. 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.

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

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

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

29. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by 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.

30. **Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

31. **Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.
    a. The draft close-out report must comply with the most current guidance from CMS.
    b. The state will present to and participate in a discussion with CMS on the close-out report.
    c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
    d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
    e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 24.

32. **Monitoring Calls**. CMS will convene periodic conference calls with the state.
    a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
    b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
    c. The state and CMS will jointly develop the agenda for the calls.

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

X. EVALUATION OF THE DEMONSTRATION

34. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 25.

35. **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.

36. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. 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 the following CMS guidance (including but not limited to):
    a. All applicable Evaluation Design guidance, including guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies

referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).

b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

37. **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.

38. **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.

39. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

40. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for 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 renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for the demonstration, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit the final Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
e. The Interim Evaluation Report must comply with Attachment B of these STCs.

41. **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. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

42. **Corrective Action Plan Related to Evaluation**. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10

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

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

45. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

46. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.[4]

47. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate 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.

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

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

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.

49. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

50. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

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

health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

51. 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.

52. 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 2: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Legacy	Hypo 1	**X**		**X**	Non-expansion adult Medicaid beneficiaries diagnosed with a SUD
Expansion	Hypo 1	X		X	Expansion adult Medicaid beneficiaries diagnosed with a SUD

53. 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. 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, 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 IX, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member

months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3: 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**
Legacy	Non-expansion adult Medicaid beneficiaries diagnosed with a SUD	See STC 21	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025
Expansion	Expansion adult Medicaid beneficiaries diagnosed with a SUD	See STC 21	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025

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

Table 4: Demonstration Years		
Demonstration Year 1	January 1, 2021 to December 31, 2025	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

55. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing

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

56. 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.

57. 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,

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

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

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

59. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment 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.

60. 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.

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

62. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been

eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by refunding the FFP to CMS.

63. Hypothetical Budget Neutrality Test 1: SUD Services (see Expenditure Authority #1). The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 5: Hypothetical Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only, or Both	Base Year	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
Legacy	PC	Both	2020	4.9%	$1,088	$1,141	1,197	$1,256	$1,317
Expansion	PC	Both	2020	5.6%	$501	$529	$559	$590	$623

64. 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.

65. **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.

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

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

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

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

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

ATTACHMENT A
DEVELOPING THE EVALUATION DESIGN

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about 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 on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

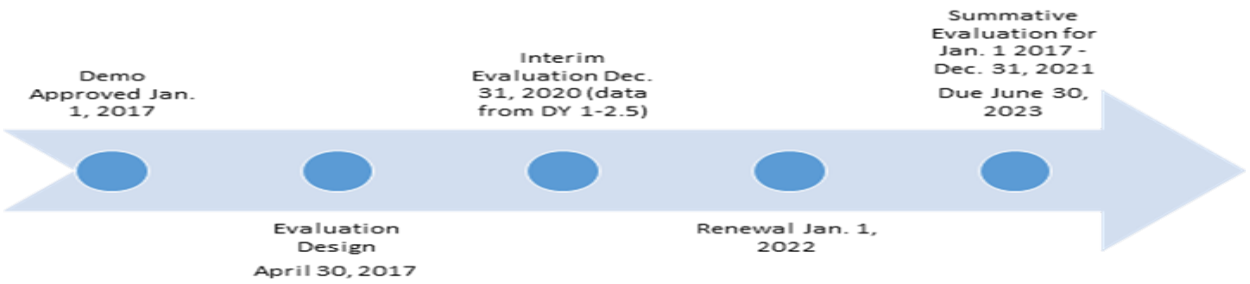
Expectations for Evaluation Designs

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. 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**.**

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

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



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

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

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

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

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

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

5) Describe the population groups impacted by the demonstration.

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

1) 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 could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

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, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes 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 will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include 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. 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.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. 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 (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

    If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to 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). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the 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. For example:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. 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; and
b. No or minimal appeals and grievances; and
c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) 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, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" 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 cost, 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 or if CMS finds that the draft Evaluation Design is not sufficiently developed.

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 an Interim and Summative Evaluation. 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

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. 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 provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is 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). To this end, 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. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. 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.

Intent of this Guidance

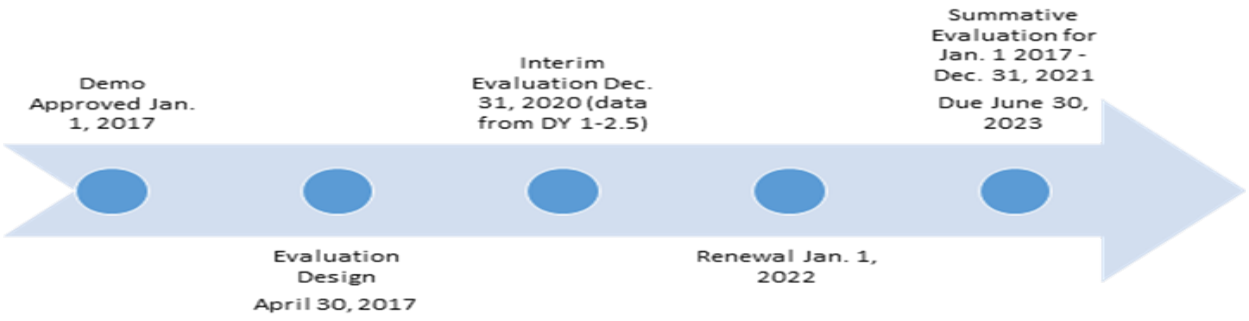
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance 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.

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).

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 this timeline). 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 to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report 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. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report 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. Therefore, the state's submission must include:

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 its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

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

3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) 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. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

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 (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim 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.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made 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. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be 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.

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

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

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) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

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

D. 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 interpretation 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.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

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?

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

COLORADO
Department of Health Care Policy & Financing

Attachment C

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.

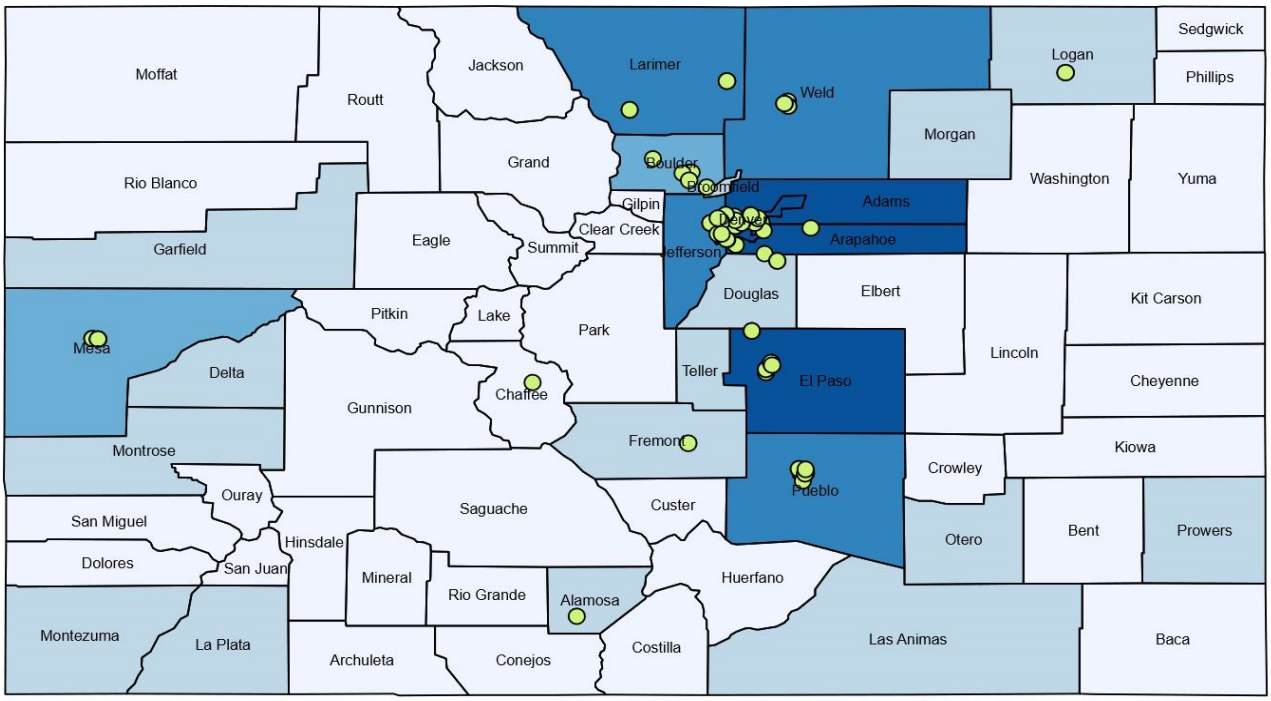
In 2019, the State:

- 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.

Are

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.

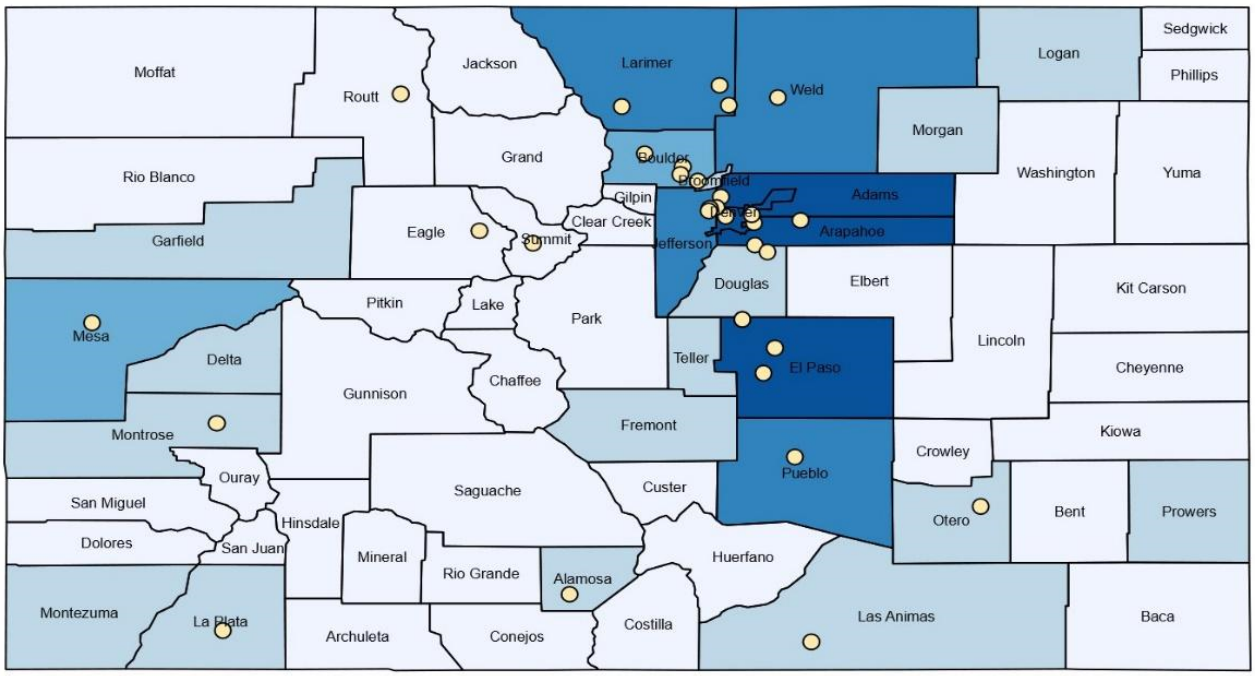
Project Tracking #: 8555 Map Created on: 6/3/2020

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

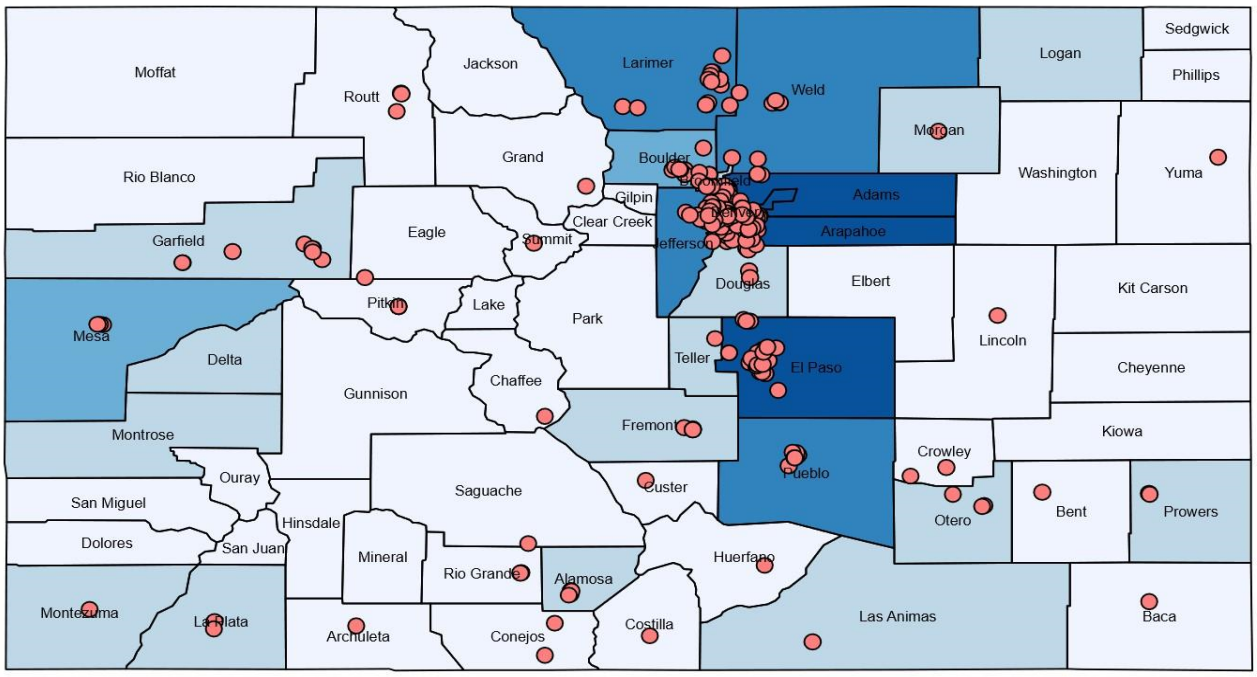
0 - 500
501 - 2,500
2,501 - 5,000
5,001 - 10,000
10,001 - 20,000

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

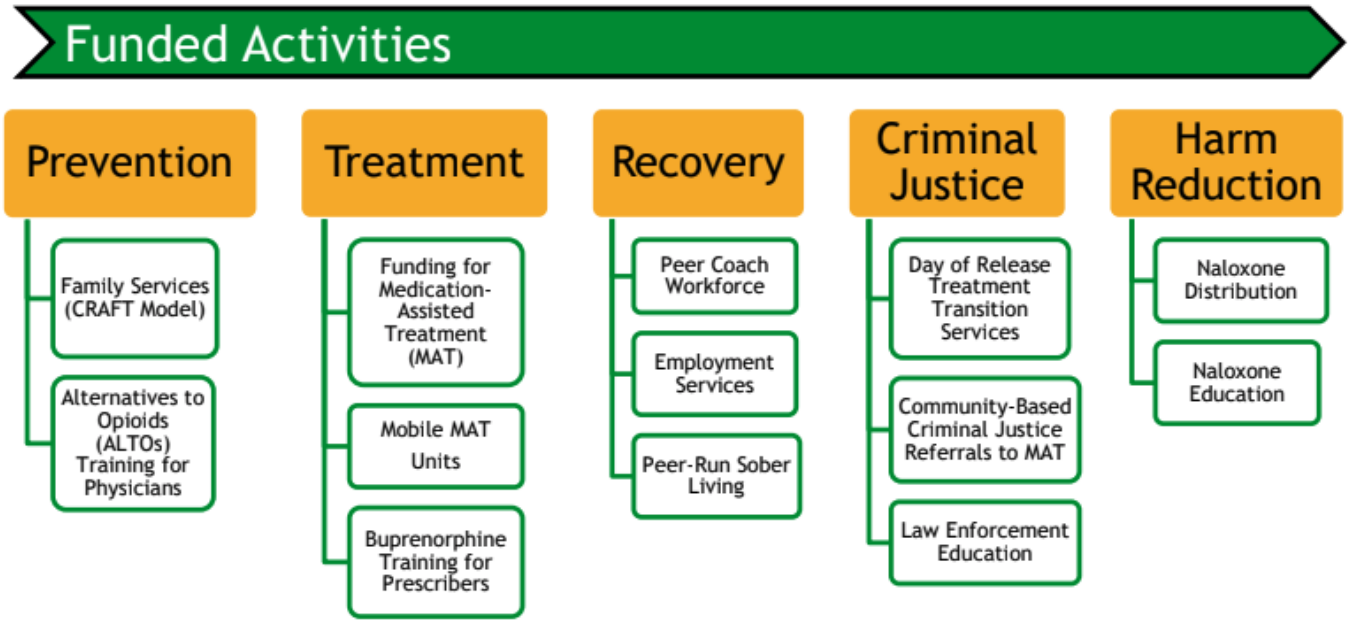
Harm Reduction

- 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.	

ATTACHMENT D
Reserved for SUD Monitoring Protocol

ATTACHMENT E
Reserved for SUD Evaluation Design