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

State Demonstrations Group

May 23, 2022

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

Dear Ms. Johnson:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC#36, of Colorado's section 1115 demonstration, "Expanding the Substance Use Disorder Continuum of Care" (Project No: 11-W-00336/8), effective through December 31, 2025. CMS determined that the Evaluation Design, which was submitted on September 30, 2021 and revised on April 29, 2022, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state's SUD Evaluation Design.

CMS has added the approved SUD Evaluation Design to the demonstration's STCs as Attachment E. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state's Medicaid website within thirty days. CMS will also post the approved Evaluation Design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an Interim Evaluation Report, consistent with the approved Evaluation Design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the state chooses to extend the demonstration. Likewise, a Summative Evaluation Report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

We appreciate our continued partnership with Colorado on the Expanding the Substance Use Disorder Continuum of Care section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S

Digitally signed by Danielle Daly -S
Date: 2022.05.23 13:54:47 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Michala Walker, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

Mercer

Substance Use Disorder 1115 Waiver

Evaluation Design

State of Colorado
April 29, 2022

Services provided by Mercer Health & Benefits LLC
Mercer Proprietary and Confidential
©Mercer 2022

welcome to brighter

Contents

1. General Background Information 1
   - History and Overview 1
   - Colorado's Medicaid Behavioral Health Delivery System 3
   - Residential Substance Use Disorder Treatment in Colorado 6
   - Demonstration Approval 11
   - Description of the Demonstration 11

2. Evaluation Questions and Hypotheses 14
   - Targets for Improvement 15
   - Driver Diagrams, Research Questions and Hypotheses 16

3. Methodology 21
   - Evaluation Design 21
   - Evaluation Period 23
   - Evaluation Measures and Data Sources 23

- Analytic Methods 42

4. Methodological Limitations 50

5. Attachments 54

6. Attachment A 56

- Conflict of Interest Statement 56

7. Attachment B 58

- Evaluation Budget 58

8. Attachment C 62

- Potential Timeline and Major Deliverables 62

1

General Background Information

History and Overview

Over the past 20 years, the State of Colorado (Colorado or State), like the rest of the country, has felt the impact of the opioid epidemic and has experienced an increase in the rate of substance use disorder (SUD) diagnosis. Data collected by the Colorado Department of Public Health and Environment between 1999–2017 show that:

- An estimated half a million Coloradans are dependent on alcohol or have used illicit drugs. Nearly 30% (142,000) are Medicaid members.[1]
- Between 2000–2017, 12,821 Coloradans died due to a drug overdose.
- The number of overdose deaths has increased from 7.8 deaths per 100,000 in 2000 to 17.6 deaths per 100,000 in 2017.
- Opioid use is leading the overdose epidemic, accounting for over half of the overdose deaths between 2013 and 2017, two-thirds of which are attributable to prescription opioids.[2]

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

[2] Bol K. Colorado Department of Public Health and Environment. *Drug Overdose Deaths in Colorado. Final Data. 1999-2017.* December 2018.

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

Colorado Medicaid members are particularly affected by SUDs, impacting the health outcomes and cost of this population:

- An estimated 11% of Medicaid members have an SUD diagnosis.[4]
- Twenty-nine percent of those who die from an overdose in Colorado are Medicaid members.
- The most prevalent substances abused among Medicaid members are alcohol and methamphetamine.[5]

The costs to the health care system are clear:

- Though 11% of the Medicaid population, the cost of care for members with a SUD diagnosis accounts for nearly 19% of the total cost of care to the system.
- On average, the annual cost of care for a Medicaid member with an SUD diagnosis is nearly double the cost for one without ($10,445 versus $5,646).
- Members with an SUD diagnosis account for 20% of the State's non-SUD related pharmacy spending.[6]

---

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

[4] Ibid.

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

[6] Colorado Substance Use Disorder Data Fiscal Year 2017-2018. Colorado Department of Health Care Policy & Financing, Pharmacy and Behavioral Health Data Division. 2019.

Additionally, according to the 2017 Colorado Health Access Survey (CHAS), despite the State's efforts to date, Colorado continues to have an unmet need for SUD treatment.[7] The survey shows that more than 67,000 Coloradans need some type of treatment for drug or alcohol use but do not receive it. Many more Coloradans need treatment but are not ready to seek it.

Although these numbers reflect all Coloradans, given the higher prevalence of SUD among Medicaid members, it is clear that there is a need for more access to services.

Colorado's Medicaid Behavioral Health Delivery System

In 1995, the State implemented the Colorado Medicaid Mental Health Capitation and Managed Care Program in 51 counties, and expanded it to the remaining 12 counties in 1998. Through the program, the State was divided into eight geographic areas and the program was administered by Mental Health Assessment and Service Agencies (MHASAs). In 2004, program operations were transferred to the Department of Health Care Policy and Financing (HCPF) from the Department of Human Services, allowing for more cohesive management.

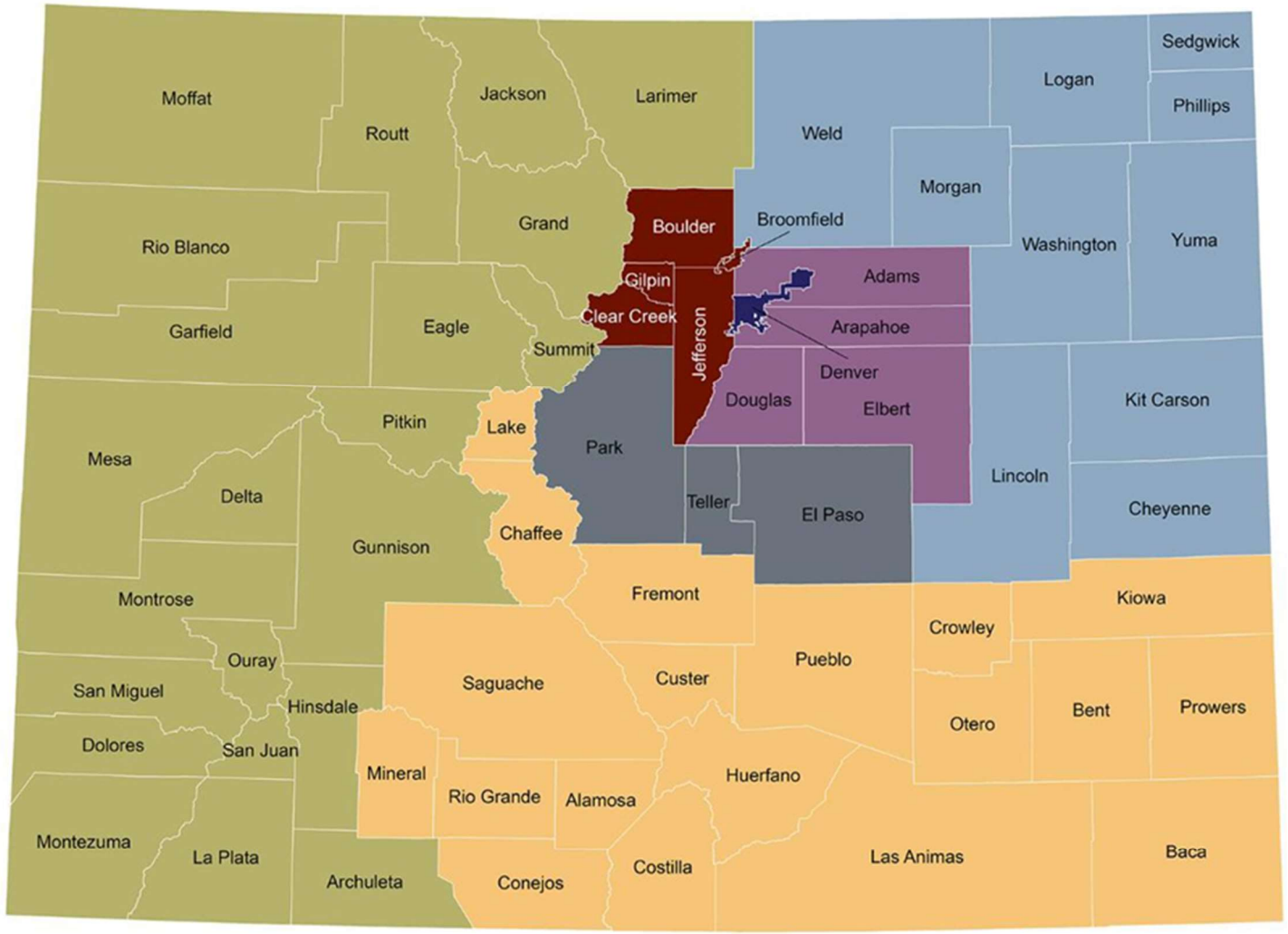
The waiver for the Mental Health Capitation and Managed Care Program was amended several times. A 2013 amendment — effective from January 1, 2014 through June 30, 2015 — included coverage of SUD treatment services and provided the authority to serve the Medicaid expansion population. In 2015, the Centers for Medicare & Medicaid Services (CMS) approved a waiver renewal from January 1, 2016 to June 30, 2017 incorporating former foster care children, expansion parents, and children age six through 19 with incomes above 100% but at or below 133% of the federal poverty level. The waiver was renewed again from July 1, 2017 to June 30, 2018.

Colorado Medicaid divided the State into seven geographic regions for the ACC. Each region is served by one Regional Accountable Entity (RAE). The RAEs are responsible for promoting physical and behavioral health in each of the seven regions. The RAEs manage a network of primary care physical health providers and specialty behavioral health providers to ensure access to appropriate care for Medicaid members in their region. A critical function of the RAEs is to create a cohesive network of providers that work together seamlessly and effectively to provide coordinated health care services to members.

[7] Colorado Health Institute. *2017 Colorado Health Access Survey: The New Normal*. https://www.coloradohealthinstitute.org/research/colorado-health-access-survey-2017

In January 2020, at the direction of the legislature and the governor, the State of Colorado entered into a contract with an additional managed care organization (MCO) to serve the Denver area. This MCO functions similarly to the seven RAEs in rest of the state, but its administrative structure differs from the RAEs. The seven RAEs and the Denver Health MCO will each provide services under this demonstration and data collected from these organizations will be used in the demonstration evaluation. For the remainder of this document the RAEs and the Denver Health MCO will be collectively referred to as Managed Care Entities (MCEs).

Regional Accountable Entity Regions in ACC Phase 2



Residential Substance Use Disorder Treatment in Colorado

In addition to the capitated behavioral health system, which provides services to Medicaid members, the Colorado Office of Behavioral Health (OBH) contracts with four Managed Service Organizations (MSOs) to deliver a continuum of SUD services that includes inpatient and residential treatment services. MSOs are funded through a combination of state and federal Substance Abuse and Mental Health Services Administration (SAMHSA) block grant dollars, but do not pay for services otherwise covered by Medicaid.

For some Medicaid members, the MSOs provide inpatient residential treatment services, prioritizing injection drug users, parents, and pregnant women. Aside from providing inpatient and residential treatment to priority Medicaid members, the MSOs are required to ensure that people who have no other means of paying for treatment (i.e., based on insurance status or income) receive services funded under their contract with OBH.[8]

The MSOs contract with providers to deliver transitional residential treatment for adults (American Society of Addiction Medicine [ASAM] Level 3.1), Clinically Managed Residential Services (ASAM Level 3.5), Intensive Residential Treatment for adults and adolescents (ASAM Level 3.7), and Strategic Individualized Remediation Treatment (STIRT).

Through this Medicaid Section 1115 waiver, the MCEs will provide residential and inpatient SUD services to Medicaid members. The role of the MSOs will evolve as the new Medicaid benefits take effect and the State looks at options for using SAMHSA grant dollars and MSO infrastructure to enhance the State's overall delivery system.

Federal Grant Efforts to Combat SUDs

To date, Colorado has received three grants from SAMHSA for purposes of combatting the SUD crisis:[9]

[8] JSI Research and Training Institute, Inc. *A Statewide Evaluation of the effectiveness of Intensive Residential Substance Use Disorder Treatment Provided through Managed Service Organizations.* December 2018.

[9] https://www.colorado.gov/pacific/cHCPF/colorado-state-targeted-response-opioid-crisis

Medication-Assisted Treatment Prescription Drug and Opioid Addiction (MAT-PDOA) Grant

SAMHSA provided $950,000 to the State from September 2016–September 2019. The State used the MAT-PDOA grant to:

- Enhance and expand treatment service systems to increase capacity and provide accessible, effective, comprehensive, coordinated care, and medication-assisted treatment (MAT) to individuals with OUD.
- Enhanced a "hub and spoke" model for the delivery of MAT services and ancillary wraparound services (mental health supports, transportation, childcare, housing, family services).
- Provide MAT services to 763 individuals.

State Targeted Response (STR) Grant

SAMHSA provided $15.7 million to the State from May 2017–April 2019. The State used the STR grant to:

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

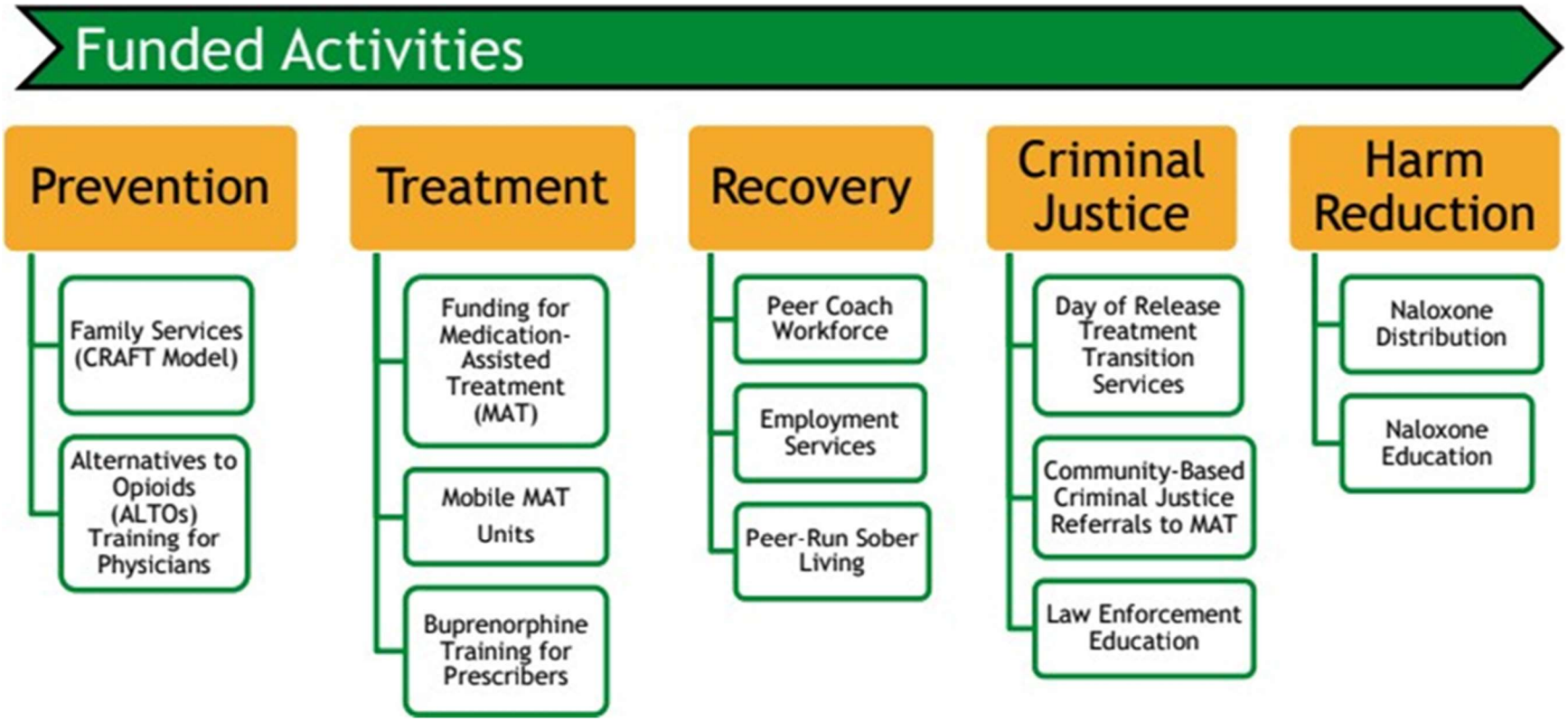
State Opioid Response (SOR) Grant

SAMHSA provided $38 million to the State to extend and expand efforts undertaken through the STR grant until 2020. By the end of the SOR grant period, the State also plans to:

- Connect at least an additional 900 individuals to MAT through mobile MAT units in rural communities.

- Train 400 individuals in the Community Reinforcement and Family Training with Prevention (CRAFT-P) and Celebrating Families models (models focused on supporting family members of individuals struggling with SUDs and how to encourage and motivate loved ones into treatment and/or maintain recovery).
- Hire 18 more Peer Recovery Coaches.
- Train 425 more prescribers with a focus on rural areas.
- Distribute 18,000 more naloxone kits.

A visual summarizing SAMHSA grant-funded activities is below:



Other Efforts to Combat SUDs

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

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

In addition to the activities above, Colorado is working to continue to reduce opioid prescriptions and reduce stigma. One of the first changes the State made was to develop the Colorado Consortium for Prescription Drug Abuse Prevention in 2013. The Consortium is a statewide organization with a wide range of participating stakeholders that has numerous workgroups designed to address the opioid crisis, with topics including: provider education; public awareness; use of the Prescription Drug Monitoring Program (PDMP); naloxone; and support for affected friends and families.

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

Lastly, Colorado's Lift the Label campaign has set a goal of reducing the stigma that prevents those with opioid use disorder (OUD) from getting treatment.

Demonstration Approval

On November 13, 2020, Colorado received approval for its application for a section 1115(a) demonstration titled "Expanding the Substance Use Disorder Continuum of Care" (Project Number 11-W-00336/8) effective January 1, 2021 through December 31, 2025.

Description of the Demonstration

This waiver will provide access to residential and inpatient treatment settings, expand the availability of withdrawal management (WM) services, and increase access to MAT for members with SUD or alcohol use disorder (AUD). These changes will ensure that the most appropriate levels of care are available for patients and improve treatment outcomes.

Colorado will add ASAM levels 3.1 (Clinically Managed Low-intensity Residential Services), 3.3 (Clinically Managed Population-specific High-intensity Residential Services), 3.5 (Clinically Managed High-intensity Residential Services) and 3.7 (Medically Monitored Intensive Inpatient Services), and 3.7-WM (Medically Managed Inpatient Withdrawal Management) as Medicaid-covered services.

We anticipate that this demonstration will accomplish the following goals and objectives, which make up our demonstration hypothesis. This waiver demonstration will:

1. Promote increased access to care for members with SUD.
2. Improve the quality of care for members with SUD.
3. Improve outcomes for members using SUD services and maintain costs.

Capacity Assessment for Expanded Inpatient and Residential Services

In order to implement the new SUD benefit, the State has begun efforts to assess and expand Colorado's existing network of inpatient and residential SUD services, currently managed by MSOs.

The State has been collecting information about availability of inpatient and residential bed capacity, including engaging with a contractor to conduct a provider assessment throughout the State.

The 2015 National Survey of Substance Abuse Treatment Services (N-SAATS) results[10] found that Colorado has between 826–1,276 residential beds, 127–216 of which are designated for inpatient SUD treatment. The Colorado Health Institute, in a report prepared for the Department and submitted to the Colorado General Assembly, estimated that this number of beds can serve between 3,090–5,256 people a year with an average 15-day inpatient average length of stay and 10,050–15,525 people with a 30-day residential average length of stay.[11]

Workforce Development and Training

The State will develop a plan and materials to train all providers working within the continuum of care on utilization management and ASAM-based assessment to ensure that the continuum of care is applied appropriately and to reduce the under- and/or overutilization of any of the levels of care. The Department understands the importance of developing and preparing the workforce to meet the growing demands on the system. Planned activities include:

- Ensuring appropriate licensure levels of all sites in the system.
- Defining and training providers on treatment terms to ensure consistency.
- Training providers on evidence-based practices for patient assessment and placement.
- Addressing provider shortages, specifically in rural areas.
- Recruiting providers not currently enrolled as Medicaid providers.

[10] Substance Abuse and Mental Health Services Administration (SAMHSA). *National Survey of Substance Abuse Treatment Facilities (N-SSATS): 2015, Data on Substance Abuse Treatment Facilities.* 2015. Available at: https://www.samhsa.gov/data/report/national-survey-substance-abuse-treatment-facilities-n-ssats-2015-data-substance-abuse

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

Other Implementation Planning Activities

The State is aware of the CMS SUD Implementation Plan requirements and is already planning activities that will support successful waiver implementation. The State has conducted a series of robust stakeholder engagement sessions dating back to October of 2018, culminating in the formal public notice and comment process required for this waiver application. The stakeholder engagement process will continue throughout the waiver negotiation period, which we anticipate will facilitate further discussion of waiver details and inform Department planning for any necessary:

- State regulation changes.
- Provider standards and billing manual updates.
- Provider engagement and training needs.
- MCE contract policy and payment rate changes.

Population Impacted

There will be no changes to the Medicaid eligibility criteria included as part of this waiver. The demonstration will be open to all Medicaid members with a covered SUD diagnosis. The demonstration will have no enrollment limits.

Please see the budget neutrality narrative and worksheets in Section 5 of the waiver application for the projected eligible member months for those members who are expected to participate. Table 2, in Section 5 of the application, presents the Without and With Waiver Projections for covering SUD Institution for Mental Disease (IMD) Adults within the Colorado Medicaid program. The member months included in Table 2 reflect the estimated member months for individuals who use SUD IMD. A 2% growth assumption is applied to the member months, which is based on the average rate of enrollment growth estimated for the Medicaid program. The demonstration is not expected to have an impact on the total Medicaid enrollment for the program beyond the typical Medicaid program enrollment growth.

2

Evaluation Questions and Hypotheses

Evaluation questions and hypotheses to be addressed were derived from and organized based on the Driver Diagrams below. The overall aims of the project are to: 1) Promote increased access to care for members with SUD; 2) Improve the quality of care for members with SUD; and 3) Improve outcomes for members using SUD services and maintain costs. To accomplish these aims, the demonstration includes several key activities, organized primary drivers of change:

- Increased rates of identification, initiation, and engagement in treatment.
- Improved access to physical health care.
- Increased adherence to and retention in treatment.
- Reduction in overdose deaths.
- Fewer readmissions to the same or higher level of care
- Reduced emergency department (ED) and hospital admissions for SUD or OUD.

The specific evaluation questions to be addressed were selected based on the following criteria:

1. Potential for improvement, consistent with the key milestones of the demonstration listed above.
2. Potential for measurement, including (where possible and relevant) baseline measures that can help to isolate the effects of Demonstration initiatives and activities over time.
3. Potential to coordinate with ongoing performance evaluation and monitoring efforts.

Research questions were selected to address the demonstration's major program goals, to be accomplished by demonstration activities associated with each of the primary drivers. Specific hypotheses regarding the demonstration's impact are posed for each of these evaluation questions. These are linked to the primary drivers in the diagrams and tables beginning in Section 2 "Driver Diagrams, Research Questions and Hypotheses," directly following the next section "Targets for Improvement".

Targets for Improvement

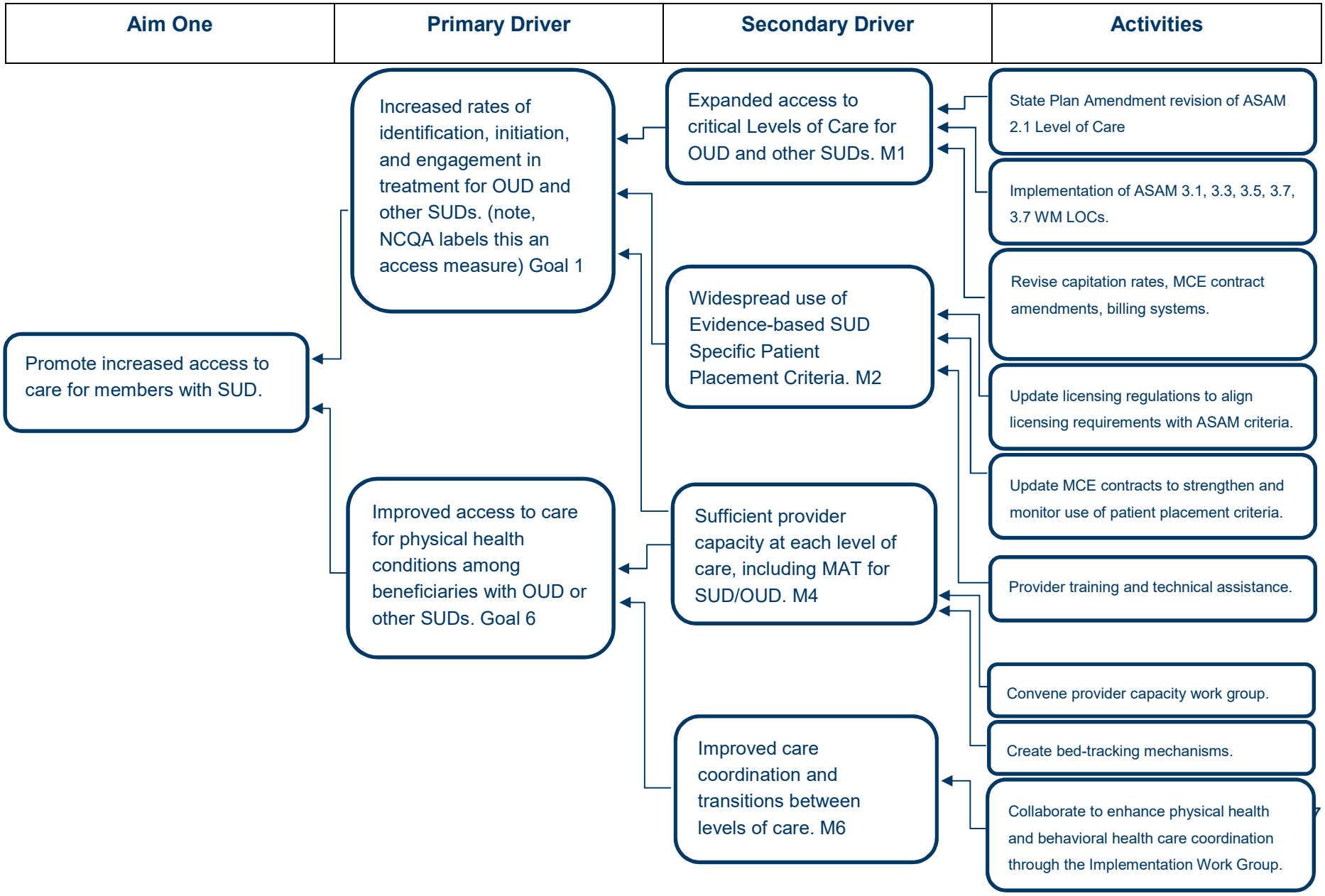
The six goals of the SUD waiver with Targets for Improvement are listed in the table below.

Targets for Improvement

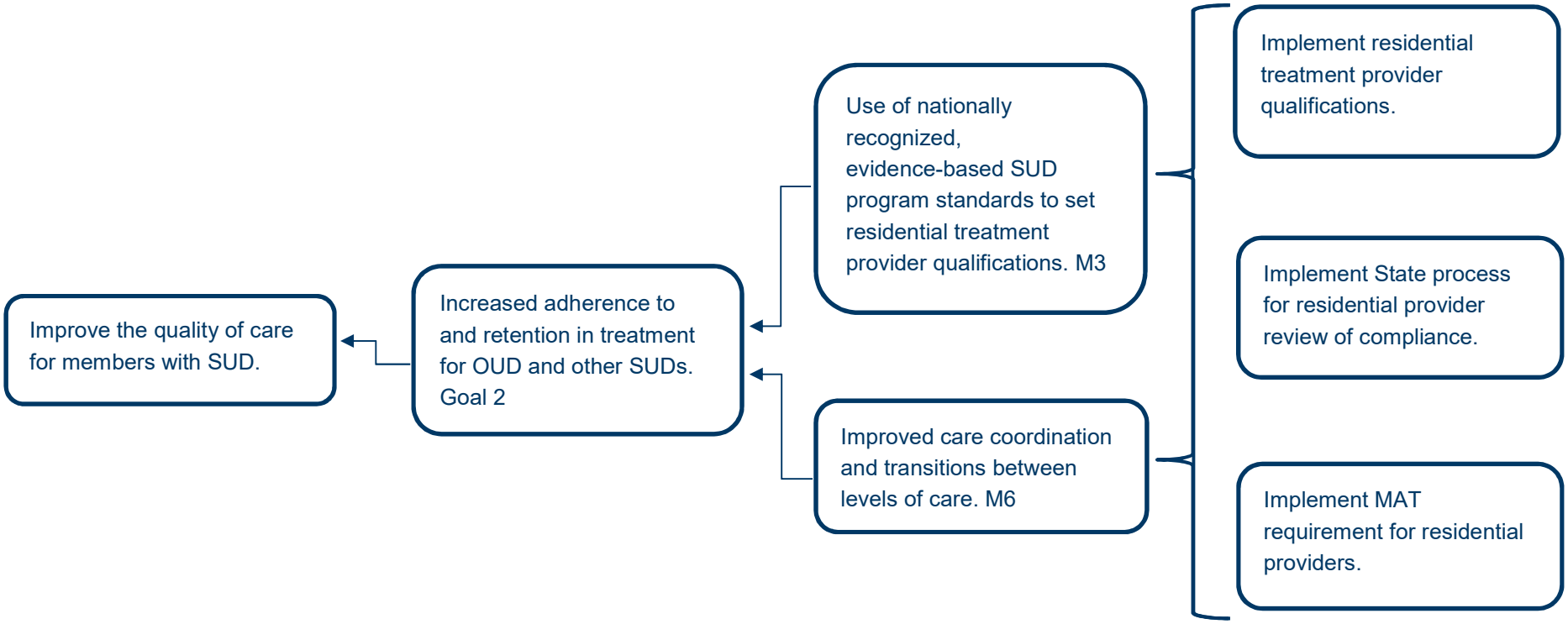
Program Goals (Primary Drivers)	Targets
Increased rates of identification, initiation, and engagement in treatment	• Increased access to critical levels of care for OUD and other SUDs. • Increased use of Evidence-based SUD Specific Patient Placement Criteria.
Increased adherence to and retention in treatment	• Increased use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications. • Improved care coordination and transitions between levels of care.
Reductions in overdose deaths, particularly those due to opioids	• Increased use of comprehensive treatment and prevention strategies to address opioid abuse and OUD. • Increased provider capacity at each level of care, including MAT for SUD/OUD.
Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	• Increased use of Evidence-based SUD Specific Patient Placement Criteria. • Increased provider capacity at each level of care, including MAT for SUD/OUD.
Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	• Increased use of Evidence-based SUD Specific Patient Placement Criteria. • Improved care coordination and transitions between levels of care.
Improved access to care for physical health conditions among beneficiaries	• Improved care coordination and transitions between levels of care for physical care. • Increased use of comprehensive treatment and prevention strategies to address opioid abuse and OUD.

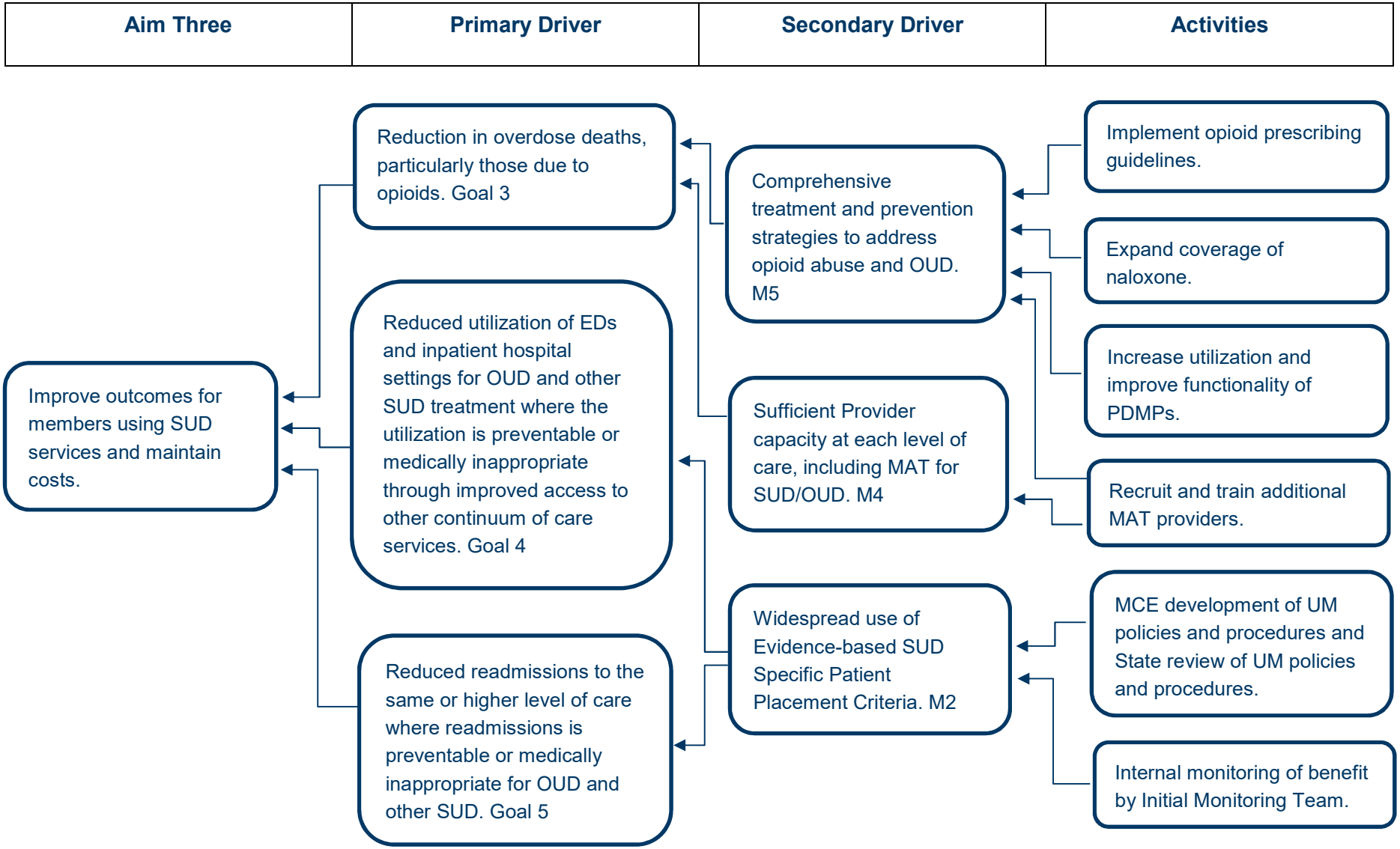
Driver Diagrams, Research Questions and Hypotheses

The three program aims represent the ultimate intentions of the waiver. The primary drivers are strategic improvements or goals to achieve the program aims. The secondary drivers are the interventions (milestones) that will need to be reached in order achieve the strategic improvements. The performance measures outlined with the research question and hypothesis for each milestone describe specific activities completed as part of the implementation. The driver diagrams below present the connections between the program activities, milestones, strategic improvements, and aims.


Aim One
Primary Driver
Secondary Driver
Activities
Promote increased access to care for members with SUD.
Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (note, NCQA labels this an access measure) Goal 1
Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs. Goal 6
Expanded access to critical Levels of Care for OUD and other SUDs. M1
Widespread use of Evidence-based SUD Specific Patient Placement Criteria. M2
Sufficient provider capacity at each level of care, including MAT for SUD/OUD. M4
Improved care coordination and transitions between levels of care. M6
State Plan Amendment revision of ASAM 2.1 Level of Care
Implementation of ASAM 3.1, 3.3, 3.5, 3.7, 3.7 WM LOCs.
Revise capitation rates, MCE contract amendments, billing systems.
Update licensing regulations to align licensing requirements with ASAM criteria.
Update MCE contracts to strengthen and monitor use of patient placement criteria.
Provider training and technical assistance.
Convene provider capacity work group.
Create bed-tracking mechanisms.
Collaborate to enhance physical health and behavioral health care coordination through the Implementation Work Group.

Aim Two	Primary Driver	Secondary Driver	Activities




Aim Three
Primary Driver
Secondary Driver
Activities
Improve outcomes for members using SUD services and maintain costs.
Reduction in overdose deaths, particularly those due to opioids. Goal 3
Reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. Goal 4
Reduced readmissions to the same or higher level of care where readmissions is preventable or medically inappropriate for OUD and other SUD. Goal 5
Comprehensive treatment and prevention strategies to address opioid abuse and OUD. M5
Sufficient Provider capacity at each level of care, including MAT for SUD/OUD. M4
Widespread use of Evidence-based SUD Specific Patient Placement Criteria. M2
Implement opioid prescribing guidelines.
Expand coverage of naloxone.
Increase utilization and improve functionality of PDMPs.
Recruit and train additional MAT providers.
MCE development of UM policies and procedures and State review of UM policies and procedures.
Internal monitoring of benefit by Initial Monitoring Team.

Measuring Effects on the Three Aims

CMS has established milestones and performance measures associated with those milestones to achieve the goals of the waiver. Some of those performance measures being used to monitor progress of the activities can also be used to indicate that the program aims have been met. Ultimately, the activities and milestones organized under the six primary drivers (goals) of:

- Increased rates of identification, initiation, and engagement in treatment.
- Improved access to physical health care.
- Increased adherence to and retention in treatment.
- Reduction in overdose deaths.
- Reduced admissions to higher levels of care.
- Reduced ED and hospital admissions for SUD or OUD.

The activities and milestones are designed to further the three main project aims:

- Promote increased access to care for members with SUD.
- Improve the quality of care for members with SUD.
- Improve outcomes for members using SUD services and maintain costs.

For the outcome evaluation, select performance measures will be used to demonstrate observed changes in outcomes, using an interrupted time-series (ITS) design where sufficient pre-demonstration data is available, or with pre-post comparisons or comparisons to national benchmarks where sufficient pre-demonstration data is not available. Additional performance measures will be collected to monitor progress on meeting the milestones and project goals. These performance measures are grouped and described under the related primary drivers.

The research design table in Section 3, outlines the research questions and hypotheses of the evaluation, organized by each primary driver.

3 Methodology

Evaluation Design

The evaluation of the Colorado SUD 1115 waiver will utilize a mixed-methods evaluation design with three main goals:

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

A combination of qualitative and quantitative approaches will be used throughout the evaluation. Qualitative methods will include key informant interviews with Department and provider staff, MSOs, and other identified stakeholders regarding waiver activities, as well as document reviews of contracts, policy guides, and manuals. Quantitative methods will include descriptive statistics and time series analyses showing change over time in both counts and rates for specific metrics and ITS analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome measures.

Qualitative analysis will include document review and interviews with key informants. It will identify and describe the SUD service delivery system and changes occurring during the demonstration for Medicaid enrollees in the eligible population. Each of the milestones will be discussed and documented. This will allow identification of key elements Colorado intends to modify through the demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, telephone interviews, and face-to-face meetings, a descriptive analysis of the key Colorado demonstration features will be conducted.

The evaluation will analyze how the State is carrying out its implementation plan and track any changes it makes to its initial design as implementation proceeds. Both planned changes that are part of the demonstration design (e.g., expansion of ASAM) and operational and

policy modifications the State makes based on changing circumstances will be identified. Finally, it is possible that, in some instances, changes in the policy environment in the State will trigger alterations to the original demonstration implementation plan.

During ongoing communication with the State, detailed information on how Colorado has implemented each milestone, including how it has structured the ASAM expansion, identified providers at each ASAM level, implemented PDMP[12] and other Health Information Technology (HIT) changes, and structured care coordination between levels of care for beneficiaries enrolled in the demonstration, will be collected. The evaluation will analyze the scope of each of these milestones as implemented, the extent to which they conduct these functions directly or through contract, and internal structures established to promote implementation of the milestones.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written, and prior to the final summative evaluation report being finalized.

The key informant interviews will be conducted with staff members in the following departments who are directly responsible for SUD 1115 implementation and operations: HCPF, OBH, MSOs, MCEs, and service providers.

To maximize efficiency in the evaluation, most outcome measures align with performance measures being reported to CMS for each of the six milestones. As the independent evaluator/contractor, Mercer Government Human Services Consulting (Mercer) will calculate the quantitative performance measures, according to metrics specifications, and based on data provided by both HCPF and OBH, along with other State agencies, as needed. Mercer is currently receiving monthly transfers of Colorado's Medicaid Management Information System (MMIS) data, and quarterly transfers of MCE behavioral health data, from IBM through a Health Insurance Portability and Accountability Act (HIPAA)-compliant secure portal. Mercer is also arranging to receive pre-demonstration detailed claims data on inpatient and residential SUD services from OBH, which coordinated residential and inpatient services with block grant funding prior to implementation of the demonstration in 2021. Mercer will calculate all performance measures using the period of time specified in the CMS technical manual (e.g., monthly, quarterly, or annually).

The demonstration is open to all adult non-expansion and expansion members, so a concurrent comparison group of Colorado Medicaid members is not available. Outcomes will be assessed, where possible, using an ITS quasi-experimental design. The ITS analysis projects

[12] In Colorado, State staff are statutorily barred from accessing PDMP data. Evaluations requiring PDMP data will be limited to the annual report that is made public.

metrics derived from a pre-demonstration time period into the post-demonstration implementation time period as a comparison for actual post-demonstration implementation metrics. In cases where there are not enough data points for reliable projects (e.g., annual measures) we will use a basic time series analysis, or pre-post analyses, to describe changes over time.

Target and Comparison Populations

Because there is not an available comparison population, the "comparison population groups" in this design will be a projection of each measure, based on historical data, of what the group would look like in the absence of the demonstration.

The Target population includes non-expansion and expansion adult Colorado Medicaid beneficiaries with an SUD diagnosis. Based on demonstration goals and activities, we do not anticipate that the demonstration will have ***intentional*** differential impacts on specific subgroups. However, to account for known long-term disparities in access to care, engagement, and outcomes, we will use some demographic categories as covariates in our analyses. Additionally, some covariates based on OUD diagnosis will be used in examining changes in specific SUD utilization metrics. Other specified subpopulations (dual eligible, pregnant women, and the criminal justice population) will likely have insufficient data to provide reliable analysis. However, if the sample size permits, we will split the sample by subpopulations and will run interrupted time series or regression analyses. This will allow for an examination of the trend/slopes of the estimated effects to see if there are differences across subpopulations. All members who are eligible for and/or receive services will be included in all descriptive time series and ITS analysis, so no sampling strategy is needed.

Evaluation Period

The evaluation period is January 1, 2021 through December 31, 2025. The Draft Summative Evaluation Report analysis will allow for a three-month run out of encounter data. Results across this time period will be included in the Draft Summative Evaluation Report due to CMS by June 30, 2027. Draft interim results derived from a portion of this evaluation period, January 1, 2021 through June 30, 2023 (with three months run out of encounter data) will be reported in the Draft Interim Evaluation Report due to CMS on June 30, 2024.

Evaluation Measures and Data Sources

The evaluation design and evaluation measures are based on sources that provide valid and reliable data that will be readily available throughout the demonstration and final evaluation. To determine if data to be used for the evaluation are complete and accurate, the independent evaluator will review the quality and completeness of data sources (including but not limited to claims and encounters for

pharmacy, professional, and facility services as well as eligibility data). Example analyses the independent evaluator will use to determine reliability and accuracy of encounter data include, but are not limited to: frequency reports, valid values, missing values, date and numerical distributions, duplicates (part of adjustment logic), and encounter to cost report comparisons.

As often as possible, measures in the evaluation have been selected from nationally recognized measure stewards for which there are strict data collection processes and audited results. Information from additional data sources, such as the Department of Health and Environment, OBH, and Pharmacy Boards will be assessed for completeness and accuracy to the best of the ability of the independent evaluator and based on State knowledge of the provider community and experience in Colorado.

The following tables summarize: the primary drivers and hypotheses, process (implementation) and outcome measures for the evaluation, measure steward (if applicable), numerator and denominator definitions where appropriate, types of data (quantitative or qualitative), and data sources.

Mercer will calculate all performance measures for the demonstration period using claims/encounters data from IBM and encounter data from the MCEs, except for overdose deaths, which is calculated using vital statistics data maintained by the Colorado Department of Health and Environment. The period before the waiver demonstration will also include encounter data obtained from OBH, which was providing inpatient and residential SUD services for most of the Medicaid population (with the exception of pregnant women and young adults up to age 21, who were eligible for some inpatient and residential services through Medicaid) with block grant funding prior to the demonstration implementation. This data is important to provide a full picture of the services Medicaid members were receiving prior to the waiver, even though those services were not paid by Medicaid and will therefore not be in the data sets provided by IBM. Mercer will use similar methods of data testing and validation of for both the OBH and IBM data sets where possible, as discussed on page 23 and 47 of this document. We will also conduct qualitative interviews of OBH and HCPF staff once preliminary forecasts of trends are complete to provide a face validity check of the OBH data.

The State considered the possibility of using Transformed Medicaid Statistical Information System (T-MSIS) Analytical Files (TAF) Research Identifiable Files (RIF) for baseline comparisons, but feels that pursuing the OBH data will provide a more accurate description of the pre-demonstration landscape for SUD services in Colorado. The majority of inpatient and residential SUD services provided to Colorado Medicaid members would not be captured in the TAF-RIF data prior to the start of the demonstration in 2021.

HCPF is working closely with OBH to determine data quality and utility. While this analysis is not yet complete, it will be well in advance of the evaluation analysis. HCPF will notify CMS once we have a full assessment complete. In the case that the OBH data is unavailable or un-

useable, the evaluation will add comparisons of select outcome measures with questions from the National Survey on Drug Use and Health (NSDUH) or the CMS Medicaid Adult Core Set to provide context to Colorado's demonstration within the national trends.

AIM ONE: Promote increased access to care for members with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
	Primary Driver: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. **Hypothesis 1: The Demonstration will expand access to critical levels of care for OUD and other SUDs, resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M1)**						
Research Question 1: Have critical levels of care been revised and expanded to align with ASAM standards? **(Process Question)**	Revision of ASAM level 2.1 Intensive outpatient SUD services and implementation of ASAM Levels of Care: 3.1, 3.3, 3.5, 3.7, and 3.7 WM, including access to MAT.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant Interviews (HCPF, OBH staff, MCE representatives; Document Review (MCE policies and procedures, provider contracts)	Thematic analysis of interviews, policies, and contracts
	Develop MCE rate methodology and update MCE contracts with capitation rates, which include revised continuum of services.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant Interviews; Document Review (MCE policies and procedures, provider contracts)	Thematic analysis of interviews and contracts, policies, and contracts
Research Question 2: Has increased access to critical levels of care resulted in increased rates	Number/percent of beneficiaries who receive prevention or early intervention services (CMS #7).	CMS	Monthly	Number of unique members in the denominator with a service claim for early intervention services	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
of identification, initiation, and engagement in treatment for OUDs and other SUDs as measured by utilization?				(e.g., procedure codes associated with SBIRT).			
	Number/percent of beneficiaries who use outpatient services (CMS #8).	CMS	Monthly	Number of unique members in the denominator with a claim for outpatient services for SUD (e.g., outpatient recovery or motivational enhancement therapies, step-down care, and monitoring for stable patients).	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups
	Number/percent of beneficiaries who use intensive outpatient and partial hospitalization services (CMS #9).	CMS	Monthly	Number of unique members in the denominator with a service or pharmacy claim for intensive outpatient and/or partial hospitalization services for SUD (e.g., specialized outpatient SUD	Members with a SUD diagnosis (CMS #3) for percentage	Claims/ encounters	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				therapy and other clinical services).			
	Number/percent of beneficiaries who use residential and/or inpatient services for SUD (CMS #10).	CMS	Monthly	Number of unique members in the denominator with a service for residential and/or inpatient services for SUD.	Members with a SUD diagnosis (CMS #3) for percentage Include OBH data in numerator for baseline years	Claims/ encounters	ITS; controlling for demographic subgroups
	Number/percent of beneficiaries who use WM services (CMS #11).	CMS	Monthly	Number of unique members in the denominator with a service or pharmacy claim for withdrawal management services.	Members with a SUD diagnosis (CMS #3) for percentage	Claims/Encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups
	Number and length of IMD stays for SUD (CMS #36).	CMS	Yearly	Total number of days in an IMD for inpatient/ residential discharges for SUD.	Total number of discharges from an IMD for beneficiaries with an inpatient or residential treatment stay for SUD.	Claims/Encounters Include OBH data in numerator for baseline years	Descriptive Time Series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Hypothesis 2: The demonstration will promote widespread use of evidence-based SUD specific patient placement criteria resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M2)							
Research Question 1: Has widespread use of ASAM patient placement criteria been implemented? **(Process Question)**	Number/percent of providers licensed at each level of care.	Evaluator, with input from the agency collecting the data	Yearly	Number of providers in the denominator licensed at each level of care.	Total number of SUD providers (CMS #13) for percentage	OBH licensing records	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each level of care)
	Description of activities to monitor MCE use of ASAM criteria for patient placement.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant interviews and document review from MCEs; OBH monitoring records	Thematic analysis of interviews and documents
	Description of training and technical assistance activities to align providers with ASAM standards.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key Informant interviews and document review with SUD providers	Thematic analysis of interviews and documents
Research Question 2: Has the widespread use of ASAM patient	Number/percent of beneficiaries receiving any SUD treatment service (CMS #6).	CMS	Monthly	Number of unique members in the denominator receiving at least one SUD	Number of unique members enrolled in the measurement period (for percentage)	Claims/ Encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups Compare to NSDUH "Received Any

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
placement criteria resulted in increased rates of identification, initiation, and engagement in treatment for members with SUD diagnoses?				treatment service or pharmacy claim during the measurement period.	Subpopulations: OUD, Age, Dual, Pregnant, Criminal Justice		Substance Use Treatment in the Past Year" as benchmark if OBH data is not available/useable for ITS
	Initiation of Alcohol and Other Drug (AOD) Abuse or Dependence Treatment (IET-AD) (CMS #15)	NCQA NQF #0004	Yearly	Number of unique members in the denominator who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis.	Number of unique members with a new episode of AOD abuse or dependence	Claims/ Encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Compare to CMS Medicaid Adult Core Set national median as benchmark if OBH data is not available/ useable
	Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET-AD) (CMS #15).	NCQA NQF #0004	Yearly	Number of unique members in the denominator who were engaged in	Number of unique members with a new episode of AOD abuse or dependence and	Claims/ Encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				ongoing AOD treatment within 34 days of the initiation visit.	initiated treatment		post-demonstration period proportion Compare to CMS Medicaid Adult Core Set national median as benchmark if OBH data is not available/ useable
Hypothesis 3: The demonstration will promote sufficient provider capacity at each level of care, including MAT, for SUD/OUD, resulting in increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. (IP M4)							
Research Question 1: Is there sufficient provider capacity at each level of care, including MAT? **(Process Question)**	Description of Provider Capacity Workgroup activities.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews; document review	Thematic analysis of interviews and documents
	Number/percent of providers participating in IT MATTRs forums.	Evaluator, with input from the agency collecting the data	Yearly	Number unique providers in the denominator who are participating in IT MATTRs forums.	Number of SUD providers that can deliver MAT (CMS #14) for percentage	HCPF	Descriptive statistics (counts); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 2: Has the availability of providers in Medicaid accepting new patients, including MAT, improved under the demonstration?	Number of eligible SUD providers. (CMS #13).	CMS	Yearly	Number of providers who were enrolled in Medicaid and qualified to deliver SUD services.	None	HCPF	Descriptive time series
	Number/percent of eligible SUD providers that can deliver MAT (CMS #14).	CMS	Yearly	Number of providers who were enrolled in Medicaid and qualified to deliver SUD services and who meet the standards to provide MAT services.	Number of SUD Providers (CMS #13) for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Total number of beds available (Bed capacity)	Evaluator, with input from the agency collecting the data	Yearly	Total number of beds available in residential and inpatient facilities.	None	OBH electronic bed tracking system HCPF	Descriptive time series
Primary Driver: Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs							
Hypothesis 4: The demonstration will improve care coordination for physical care, resulting in improved access to care for physical health conditions among beneficiaries with OUD or other SUDs. (IP M6)							

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 1: Has the demonstration implemented changes that improve care coordination for physical care? **(Process Question)**	Description of MCE Care Coordination activities determined by SUD Implementation Workgroup.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	SUD Implementation Workgroup member interview; document review	Thematic analysis of interviews and documents
Research Question 2: Has improving care coordination resulted in increased utilization of physical health services for members with SUD diagnoses?	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD (AAP) [Adjusted HEDIS measure] (CMS #32).	NCQA	Yearly	Number of unique members with SUD with an ambulatory or preventative care visit.	Number of unique members with a SUD diagnosis (CMS #4)	Claims	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

AIM TWO: Improve the quality of care for members with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Primary Driver: Increased adherence to and retention in treatment for OUD and other SUDs							
Hypothesis 1: The 1115 SUD demonstration will implement use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications resulting in increased adherence to and retention in treatment for OUD and other SUDs.							
Research Question 1: Have evidence-based SUD program standards been used in evaluating residential treatment provider qualifications? **(Process Question)**	Number/percent of providers licensed for each ASAM level of care they provide.	Evaluator, with input from the agency collecting the data	Yearly	Number of providers licensed for each ASAM level of care they provide.	Number of SUD providers (CMS #13) for percentage	OBH	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each level of care)
	Number and rate of providers reviewed for compliance.	Evaluator, with input from the agency collecting the data	Yearly	Number of unique SUD providers reviewed for compliance.	Number of SUD providers (CMS #13) for rate	MCE credentialing records/HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of residential and inpatient providers who provide onsite access, or who facilitate access to MAT.	Evaluator, with input from the agency collecting the data	Yearly	Number of residential and inpatient SUD providers who provide onsite access, or who facilitate access to MAT.	Number of unique SUD residential and inpatient providers for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Research Question 2: Has increased utilization of SUD program standards for SUD residential treatment resulted in increased adherence and retention in treatment?	Continuity of Pharmacotherapy for OUD (CMS #22).	USC	Yearly	Number of unique members in the denominator who have at least 180 days of continuous treatment.	Number of unique members with OUD diagnosis and at least one claim for an OUD medication. Stratify on residential/ inpatient versus outpatient services	Claims/encounters Include OBH data in numerator for baseline years	Descriptive time series; pre-post chi square test of significance comparing baseline proportion of members initiating treatment to post-demonstration period
	Number/percent of beneficiaries who have a claim for MAT for SUD during the measurement period (CMS #12).	CMS	Monthly	The number of unique members in the denominator who have a claim for a MAT dispensing event for SUD.	Members with a SUD diagnosis (CMS #3) for percentage Stratify on residential/ inpatient versus outpatient services	Claims/encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups Compare to NSDUH "Received Medication-Assisted Treatment for Opioid Misuse in the Past Year" as benchmark if OBH data is not available/useable for ITS
Hypothesis 2: The 1115 SUD demonstration will improve care coordination and transitions between levels of care qualifications resulting in increased adherence to and retention in treatment for OUD and other SUDs.							
Research Question 1: Have the MCEs	Description of activities to enhance care	N/A	Cumulative for interim reporting	None	None	Key informant interviews of SUD Implementation	Thematic analysis of interviews and contracts

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
implemented policies to enhance care coordination?	coordination through the Implementation Work Group.		period, and for summative reporting period.			Workgroup members; document review (e.g. contracts)	
	MCE policy development to ensure adequate care coordination across the SUD continuum.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews of SUD Implementation Workgroup members; document review (e.g. contracts)	Thematic analysis of interviews and contracts
	Number/rate of licensed residential care facilities.	Evaluator, with input from the agency collecting the data	Yearly	Number of licensed residential care facilities.	Number of licensed residential care facilities	OBH	Descriptive statistics (counts); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
Research Question 2: Has enhanced care coordination across the SUD continuum of care resulted in increased follow up after an ED visit?	Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA-AD) (CMS #17-1).	NCQA	Yearly	Number of ED visits for members in the denominator who had a follow-up visit for AOD abuse or dependence within: • 30 days • 7 days	Number of ED visits for members with a principal diagnosis of AOD abuse or dependence.	Claims/encounters	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups Also compare to CMS Medicaid Adult Core

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
							Set national median as benchmark
	Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD) (CMS #17-2).	NCQA	Yearly	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness within: • 30 days • 7 days	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm	Claims/encounters	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups Also compare to CMS Medicaid Adult Core Set national median as benchmark

AIM THREE: Improve outcomes for members using SUD services and maintain costs.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
Primary Driver: Reduction in overdose deaths, particularly those due to opioids. G3							
Hypothesis 1: The demonstration will implement comprehensive treatment and prevention strategies to address opioid abuse and OUD as well as recruit and train more providers to provide MAT, resulting in a reduction in overdose deaths.							
Research Question 1: Have comprehensive treatment and	Key informant reports on Implementation of opioid prescribing guidelines.	N/A	Cumulative for interim reporting period, and for summative	None	None	Key Informant interviews from MCEs and SUD providers; document review	Descriptive narrative, Thematic analysis

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
prevention strategies been implemented and is MAT more accessible? **(Process Question)**			reporting period.				
	Number/percent of State organizations who distribute naloxone.	Evaluator, with input from the agency collecting the data	Yearly	Number of State organizations who distribute naloxone.	Number of State organizations	HCPF	Descriptive statistics (count) or time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of MAT providers at all LOCs (CMS #14).	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid MAT providers at all LOCs.	Number of SUD providers at all LOCs (CMS #13) for percentage	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
	Number/percent of providers using the PDMPs.	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid providers using PDMPs.	Number of Medicaid Providers	HCPF	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
Research question 2: Have comprehensive treatment and prevention strategies been	Use of opioids at high dosage in persons without cancer (OHD-AD) (CMS#18).	PQA	Yearly	Number of members in the denominator who received prescriptions for opioids with an average daily	Number of members with at least two opioid prescriptions with at least 15 days' supply. Members with a	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
effective in addressing opioid abuse and OUD?				dosage greater than or equal to 90 MMEs over a period of 90 days or more.	cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.		Also compare to CMS Medicaid Adult Core Set national median as benchmark
	Concurrent use of opioids and benzodiazepines (COB-AD) (CMS#21).	PQA	Yearly	Number of members in the denominator with concurrent use of prescription opioids and benzodiazepines.	Number of members with at least two opioid prescriptions with at least 15 days' supply. Members with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Also compare to CMS Medicaid Adult Core Set national median as benchmark
Research question 3: Did comprehensive treatment and prevention strategies correspond to a reduction in overdose deaths and activities that support	Overdose Deaths (rate) (CMS#27)	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid members with overdose as cause of death.	All Medicaid members	State data on cause of death	Descriptive time series (data ID's Medicaid members? Possible ITS); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Also compare to National Center for Health Statistics

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
overdose death reduction?							national drug overdose death rate as benchmark
Primary Driver: Reduced readmissions to the same or higher level of care where readmission is preventable or medically inappropriate for OUD and other SUD. G5							
Hypothesis 2: The demonstration will lead to widespread use of Evidence-based SUD specific Patient Placement Criteria resulting in reduced readmissions to the same or higher level of care where readmission is preventable or medically inappropriate for OUD and other SUD. M2							
Research question 1: Were utilization management policies and procedures, based upon patient placement criteria, fully implemented?	MCE development of utilization management policies and procedures and State review of utilization management policies and procedures. Internal monitoring of benefit by Initial Monitoring Team.	N/A	Cumulative for interim reporting period, and for summative reporting period.	None	None	Key informant interviews from MCEs and State reviewers Internal monitoring team	Descriptive narrative and thematic analysis
Research question 2: Did readmissions to the same or higher level of care, where readmission is preventable or medically inappropriate for OUD and	Readmissions Among Beneficiaries with SUD (CMS #25).	CMS	Yearly	Acute hospital admissions from the denominator with at least one acute readmission for any diagnosis within 30 days of discharge.	Acute hospital admissions for members with SUD diagnosis	Claims/encounters	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
other SUD, decrease?							
Primary Driver: Reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. G4							
Hypothesis 3: The Demonstration will lead to widespread use of Evidence-based SUD specific Patient Placement Criteria resulting in reduced utilization of EDs and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate. M2							
Research Question 1: Did ED utilization decrease after implementation of utilization management?	ED Utilization for SUD per 1,000 Medicaid Beneficiaries (CMS #23).	CMS	Monthly	Number of ED visits for SUD.	All Medicaid members	Claims/encounters	ITS; controlling for demographic subgroups
Research Question 2: Did inpatient stays decrease after implementation of utilization management?	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries (CMS #24).	CMS	Monthly	Number of inpatient stays for SUD.	All Medicaid members	Claims/encounters Include OBH data in numerator for baseline years	ITS; controlling for demographic subgroups
Hypothesis 4: The demonstration will improve outcomes for members using SUD services with similar or lower service costs.							
Research Question 1: Have increasing trends in total cost of care	SUD Spending (CMS #28)	CMS	Yearly	The sum of all Medicaid spending on SUD treatment services	None	Claims/encounters Use provider paid amounts	Descriptive time series

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
been slowed for individuals with SUD diagnoses?	SUD Spending within IMDs (CMS #29).	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs.	None	Claims/encounters Use provider paid amounts	Descriptive time series
	Per Capita SUD Spending (CMS #30)	CMS	Yearly	The sum of all Medicaid spending on SUD treatment services (CMS #28).	Members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	Per Capital SUD Spending within IMDs (CMS #31)	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs (CMS #29).	Number of members with a claim for inpatient/ residential treatment for SUD in an IMD	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	Total Cost PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending (Inpatient, Outpatient, Pharmacy, Long Term Care,	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
				Capitation payments, Administrative Costs, Federal Costs) for members with a SUD diagnosis		CMS #64 for Federal Costs	
	SUD Cost Drivers - Total SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services (CMS #28).	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	SUD Cost Drivers - IMD SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services within an IMD (CMS #29).	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups
	SUD Cost Drivers - Non-IMD SUD Spending PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on SUD treatment services not within an IMD	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	SUD Cost Drivers - Non-SUD Spending PMPM	CMS SUD Evaluation Design	Quarterly	The sum of all Medicaid spending on non-SUD treatment	Member months per quarter for members with a SUD diagnosis	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
		Guidance, Appendix C		for members with a SUD diagnosis			
	Source of treatment cost drivers for members with SUD – Inpatient services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on inpatient treatment for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – Emergency Department services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on emergency department services for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – non-ED Outpatient services PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on non-ED Outpatient services for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups
	Source of treatment cost drivers for members with SUD – Pharmacy PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on Pharmacy for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator[a]	Data Sources	Analytic Method
	Source of treatment cost drivers for members with SUD – Long Term Care PMPM	CMS SUD Evaluation Design Guidance, Appendix C	Quarterly	The sum of all Medicaid spending on Long Term Care for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis (CMS #4)	Claims/encounters Use provider paid amounts	ITS; controlling for demographic subgroups

Analytic Methods

Multiple analytic techniques will be used, depending on the type of data for the measure and the use of the measure in the evaluation design (e.g., process measure versus outcome measures). Descriptive, content analysis will be used to present data related to process evaluation measures gathered from document reviews, key informant interviews, etc., as discussed previously. Qualitative analysis software (R Qualitative, ATLAS, or similar) will be used to organize documentation, including key informant interview transcripts. Analysis will identify common themes across interviews and documents. In some cases, checklists may be used to analyze documentation (e.g., licensure) for compliance with standards. These data will be summarized in order to describe the activities undertaken for each project milestone, including highlighting specific successes and challenges.

Descriptive statistics including frequency distributions and time series (presentation of rates over time) will be used for quantitative process measures in order to describe the output of specific waiver activities. These analysis techniques will also be used for some short-term outcome measures in cases where the role of the measure is to describe changes in the population, but not to show specific effects of the waiver demonstration. Where pre-demonstration and post-demonstration rates are comparable, pre-post distributional test will be made to quantify statistical differences in process measures before and after the demonstration.

An ITS will be used to describe the effects of waiver implementation in metrics that are measured on a monthly or quarterly basis. Specific outcome measure(s) will be collected for multiple time periods both before and after start of intervention. Segmented regression analysis will be used to measure statistically the changes in level and slope in the post-intervention period (after the waiver) compared to the pre-intervention period (before the waiver). The ITS design will be dependent on being able to use similar historical data on specific outcome measures collected from OBH based on inpatient and residential SUD services provided prior to the demonstration and on the ability to receive data needed to produce historical data regarding outpatient SUD services, ED use, and hospitalizations using previous encounter data, (see

Methodology Limitation section for more information). The ITS design uses historical data to forecast the "counterfactual" of the evaluation, that is to say, what would happen if the demonstration did not occur. We propose using basic time series linear modeling to forecast these "counterfactual" rates for three years following the demonstration implementation.[13] The more historical data available, the better these predictions will be. ITS models are commonly used in situations where a contemporary comparison group is not available.[14] The State has considered options for a contemporary comparison group. Since the demonstration will target all adult non-expansion and expansion Medicaid members in need of SUD services, the only viable groups for comparison within the State would be those covered with private insurance, which would include a very different demographic population.

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

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

[13] E Kontopantelis (2015). Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. British Medical Journal (BMJ). Available at: https://www.bmj.com/content/350/bmj.h2750.

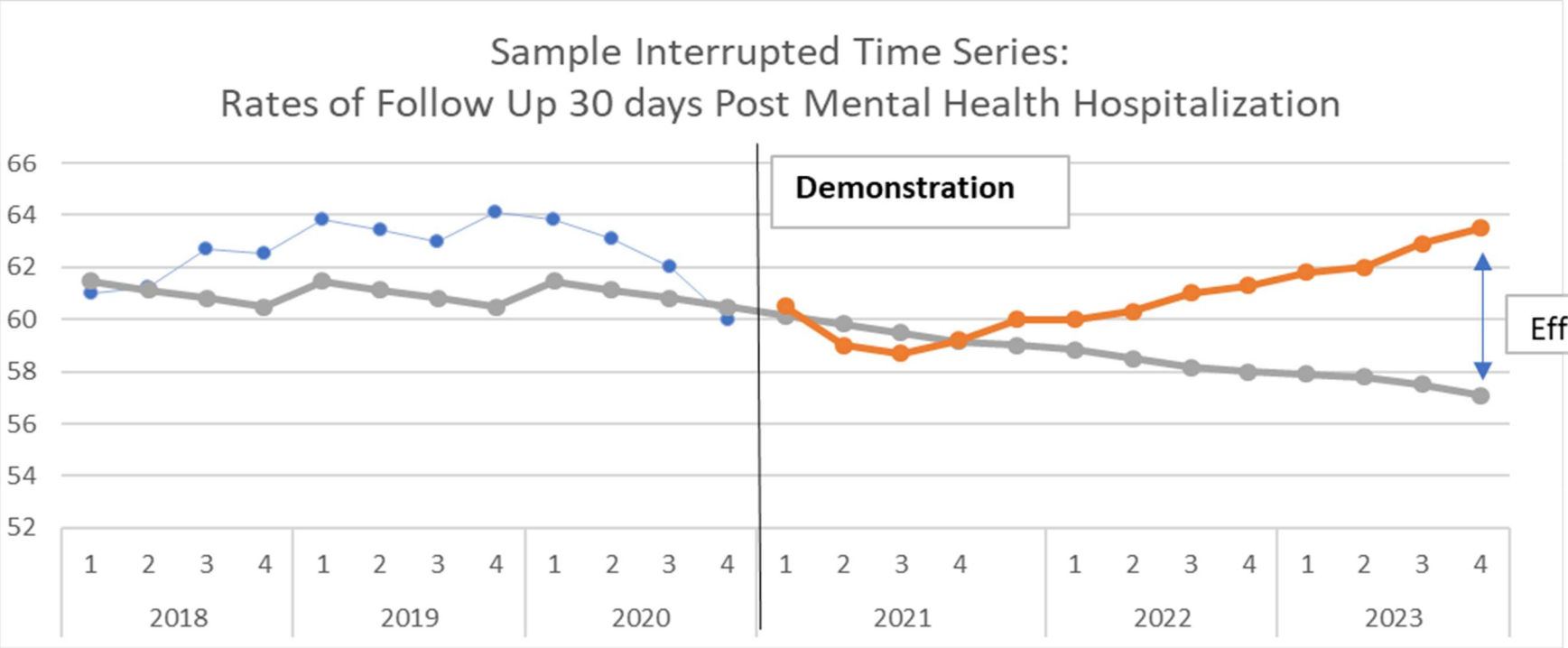
[14] Ibid.

Where β_0 represents the baseline observation, β_1 is the change in the measure associated with a time unit (quarter or year) increase (representing the underlying pre-intervention trend), β_2 is the level change following the intervention and β_3 is the slope change following the intervention (using the interaction between time and intervention: TX_t).[15]

This can be represented graphically as follows.

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

Figure 1: (SAMPLE data only) Rates of Follow Up Post Mental Health Hospitalization



Pre-demonstration data from January 1, 2018 to December 31, 2020 will be calculated using the monthly, quarterly, or annual period of time as specified in the CMS technical specifications for each metric. Trends in these data for each measure will be used to predict the counterfactual (what would have happened without the demonstration). Outcomes measures will be calculated beginning January 1, 2021 through the end of the waiver demonstration project (December 31, 2025). A discussion of including confounding variables (e.g., COVID-19, other SUD efforts) is included in the next section.

Quantitative outcome measures with yearly measurement periods that are expressed as averages or proportions will be analyzed with pre-post tests and may be compared with national benchmark statistics from the National Survey on Drug Use and Health, the CMS Medicaid Adult

Core Set, and the National Center for Health Statistics. While two or three pre-demonstration measurement periods for yearly metrics may not be enough information to establish a trend for the ITS analysis, pre-post analyses may reveal differences in outcomes before and after the demonstration. One-way analysis of covariance, or t-tests will be used to compare pre-demonstration averages with post-demonstration averages, and chi-square tests will be used to compare proportions.

In the case that Mercer is not able to obtain detailed encounter data from OBH, or data validation suggests that the data should not be used, benchmark comparisons to national data will also be implemented for a limited number of metrics, as described in the preceding research design table.

Qualitative analysis will utilize data collected from three main sources: 1) key informant interviews with State staff working on implementation efforts, MCE representatives, and providers, 2) key process documentation (e.g., policy and procedure manuals, guidance documents), and 3) MCE and provider contracts. Informant sampling will be largely based on convenience/snowball sampling where key stakeholders provide initial lists of potential interviewees, based on their perspective on demonstration implementation activities. Meeting minutes listing attendees will also be reviewed to identify potential interviewees. MCE staff and provider staff will also be included. Because this likely will be a large number of people, the independent evaluator will work with the State to determine whether to conduct focus groups with these populations, or to engage in a strategic stratified sampling process. The latter will ensure representation from each MCE, and from providers stratified by geography/location, size, and services provided. Document reviews will include meeting minutes, policy and procedure documents, MCE and provider contracts, and others identified during the qualitative analysis process. Themes will be identified by multiple coders who review documents, identify initial themes, then collaborate in the creation of a central list of primary and secondary themes.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written and prior to the final summative evaluation report being finalized. Specifically, the initial qualitative analysis will occur May 2022–July 2022. The second qualitative analysis will occur May 2023–July 2023. The third qualitative analysis will occur March 2024–May 2024. The final qualitative analysis will occur March 2027–May 2027.

4 Methodological Limitations

There are two primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either: 1) are not sufficient to conduct the analysis proposed here (e.g., not enough historical data for needed prior time periods), or 2) contain errors. The second limitation is related to the design itself because this evaluation plan relies heavily on descriptive, time series analysis, and qualitative data, this evaluation will describe what happened after the demonstration was implemented, but it will be difficult to isolate why changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. Each of these limitations is discussed in greater detail within this section.

Some of the metrics being computed by Mercer will be calculated for the first time. Both Mercer and the Department are working closely with OBH and IBM to request and test extracts of pre-demonstration data. While it is unclear at this time the degree to which it will be possible to generate historical data needed to forecast the slope of the "counterfactual" trend line (what would have happened without the demonstration), HCPF is confident the independent evaluator will have access to this historical data in the near future. This historical data is an important component of the ITS design, but also supports the descriptive time series analysis. In particular, there will be a limitation in estimating the slope of what the trend line would be without the demonstration if we do not have data to model what would have happened without implementation.

In addition to any issues with historical data, the Department's data systems may have current issues that contribute to data errors. Combining data from separate sources can prove challenging, and Mercer is working through the process carefully to minimize any data errors, including performing various data validations and duplicate record checks.

Behavioral health data for the evaluation is received in separate files for the various MCEs. There are currently eight MCEs and an additional five historical RAEs. Mercer has noted several data issues so far. For example, some of the MCEs reuse claim numbers, which impacts claim adjustment logic. In addition, some fields with the same name are populated with different field types, so special care is required when combining the data from different MCEs, so data is not inadvertently dropped. Mercer is currently working through adjustment logic for the behavioral health data, including creating and testing unique claim identifiers.

There have also been some import issues with the MMIS data due to misplaced carriage returns, which will be monitored going forward. Adjustment logic will also be applied to the MMIS data, but at this time looks to be a more standardized process.

After the behavioral health data and the MMIS data are received, imported, adjusted, and validated, they will be combined with the available pre-demonstration OBH data, which will be subject to similar processes, to comprise the base data for measure calculation. Further, the current system has a runout of six months, and will need to take into account timing around pulling data to calculate numerators and denominators for the measures.

While the ITS design is the strongest available research method, in the absence of a randomized trial or matched control group, there are some threats to the validity of results in the design.[16] The primary threat is that of history, or other changes over time happening during the waiver period. This ITS design is only valid to the extent that the waiver program was the only thing that changed during the evaluation period. Other changes to policies or programs could affect the outcomes being measured under the demonstration. We will attempt to control this threat by considering other policy and program changes happening concurrent to the waiver period interventions. At a minimum, we will use qualitative methods, in the form of key informant interviews, to identify other initiatives or events may have occurred during the demonstration that might influence demonstration effects. We will conduct a qualitative assessment of these likely impacts and will use time series analysis to show how trends may have changed at these critical time periods. In order to isolate the effects of these efforts, we will also conduct additional iterations of the ITS. Using identified critical time points as additional variables, we will test whether other major efforts had a statistically significant impact in the post-demonstration waiver trend. The analysis will note the dates of other changes and analyze the degree to which the slope of the trend line changes after implementation of other interventions are made.

The demonstration waiver application lists three main efforts that likely impact SUD services in the State: Implementation of the ACC program (Phase 2) in July, 2018, the STR, which began in May 2017 and the SOR grant, which extended the STR grant activities through 2020. Because most of these activities took place during the pre-demonstration period, their impacts will be reflected in the historical data (January 2018–December 2020) and will therefore impact the predicted trend line. It is possible that effects of these efforts may mute the hypothesized impacts of the demonstration. The ACC continues into the demonstration period, so accounting for this in the pre-demonstration predicted trend is reasonable, as any measurable effects should be due to the demonstration. The STR and SOR, which ended prior to the demonstration and included expanding MAT and increasing availability of naloxone, would likely have the largest impact on the predicted trend

[16] Penfold RB, Zhang F. “Use of interrupted time series analysis in evaluating heath care quality improvements.” Academic Pediatrics, 2013 Nov-Dec, 13(6Suppl): S38-44.

lines for metrics measuring MAT usage and opioid deaths. These metrics may show only muted or no detectable demonstration impacts. We will discuss the impact of the STR and SOR in the interpretation of relevant metrics in the evaluation reports.

The impact of COVID-19 most likely affected the pre-demonstration period, and we anticipate a statically significant impact on most metrics. Therefore, in the initial forecasting within the ITS model, the independent evaluator will include a COVID-19 covariant for the start of the pandemic in the forecast model. Essentially, the ITS for this evaluation will create two counterfactual scenarios using historical data. We will create a "without" COVID-19 forecast using historical data only prior to March of 2020 as one potential counterfactual to compare against actual trends. If we can establish sufficient data points between March 2020 and the waiver start date of January 2021, we can estimate the COVID-19 impact on the forecast. We will also create a forecast with data through the pre-demonstration period (up to January 2021) that includes data during the times COVID-19 was prevalent in the State. As long as COVID-19 remains prevalent during the demonstration period, we anticipate that using the "with COVID-19" model as the counterfactual will be more accurate. Additional covariate time periods can be added to the model if there are significant shifts in either COVID-19 prevalence numbers or policy shifts (e.g., new stay at home orders) in the State. We will also qualitatively explore how COVID-19 impacted the implementation of the waiver, based on data from key informant interviews.

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

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

We will also attempt to limit this threat to validity by triangulating our data. Encounter data trends across multiple time periods will be compared to trends happening at other points in time (other large policy or program shifts that might influence the slope of the trend in addition to the demonstration). Also, key informant interviews will be used to inform the quantitative findings and explain the degree to which individuals are seeing demonstration impacts. We will also attempt to seek out national and other State data for benchmarking, that will allow us to determine whether Colorado is performing in a similar fashion to other demonstration states, non-demonstration states, or national benchmarks overall.

According to the literature on ITS analysis, estimating the level and slope parameters requires a minimum of eight observations before and after implementation in order to have sufficient power to estimate the regression coefficients.[17] Evaluators will need to work closely with the Department, OBH, and their respective data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

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

Qualitative data, while useful in confirming quantitative data and providing rich detail, can be compromised by individual biases or perceptions. Key informant interviews, for example, represent a needed perspective around context for demonstration activities and outcomes. However, individuals may be limited in their insight or understanding of specific programmatic components, meaning that the data reflects perceptions, rather than objective program realities. The evaluation will work to address these limitations by collecting data from a variety of different perspectives to help validate individuals' reports. In addition, standardized data collection protocols will be used in interviews and interviewers will be trained to avoid "leading" the interviewee or inappropriately biasing the interview. It will also utilize multiple "coders" to analyze data and will create a structured analysis framework, based on research questions that analysts will use to organize the data and to check interpretations across analysts. Finally, results will be reviewed with stakeholders to confirm findings.

[17] Ibid.

5
Attachments

As part of the Standard Terms and Conditions (STCs), as set forth by CMS, the demonstration project is required to arrange with an independent party to conduct an evaluation of the SUD demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. Mercer, through a request for proposal (RFP) process, contracts to provide technical assistance to HCPF.

Mercer was selected as the technical assistance vendor. One of the scopes of work in the technical assistance work plan is the waiver evaluation. Mercer will develop the evaluation design, calculate the results of the study, evaluate the results for conclusions, and write the Interim and Summative Evaluation Reports.

Mercer has over 25 years of experience assisting state governments with the design, implementation, and evaluation of publicly sponsored health care programs. Mercer currently has over 25 states under contract and has worked with over 35 different states in total. They have assisted states like Arizona, Connecticut, Missouri, and New Jersey in performing independent evaluations of their Medicaid programs; many of which include 1115 Demonstration waiver evaluation experience. Given their extensive experience, the Mercer team is well equipped to work effectively as the external evaluator for the demonstration project. The table below includes contact information for the lead coordinators from Mercer for the evaluation:

NAME	POSITION	EMAIL ADDRESS
Kate Goergen	Engagement Leader	kate.goergen@mercer.com
Tonya Aultman-Bettridge, PhD	Evaluation Lead	taultman-bettridge@triwestgroup.net
Jeanie Aspiras, MBA	Program Manager	jeanie.aspiras@mercer.com
Carissa Cramer	Project Manager	carissa.cramer@mercer.com
Brenda Jenney, PhD	Statistician	brenda.jenney@mercer.com
Brenda Jackson, MPP	Policy and Operations Sector	brenda.jackson@mercer.com

6

Attachment A

Conflict of Interest Statement

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

Mercer's Government specialty practice does not have any conflicts of interest, such as providing services to any MSOs or health care providers doing business in Colorado under the Health First Colorado program or to providing direct services to individual recipients. One of the byproducts of being a nationally operated group dedicated to the public sector is the ability to identify and avoid potential conflicts of interest with our firm's multitude of clients. To accomplish this, market space lines have been agreed to by our senior leadership. Mercer's Government group is the designated primary operating group in the Medicaid space.

Before signing a contract to work in the Medicaid market, either at the state-level or otherwise, we require any Mercer entity to discuss the potential work with Mercer's Government group. If there is a potential conflict (i.e., work for a Medicaid health plan or provider), the engagement is not accepted. If there is a potential for a perceived conflict of interest, Mercer's Government group will ask our state client if they approve of this engagement, and we develop appropriate safeguards such as keeping separate teams, restricting access to files, and establish process firewalls to avoid the perception of any conflict of interest. If our client does not approve, the engagement will not be accepted. Mercer has collectively turned down a multitude of potential assignments over the years to avoid a conflict of interest.

Given that Mercer is acting as both technical assistance provider and independent evaluator for this project, HCPF and Mercer have implemented measures to ensure there is no perceived conflicts of interest. This contract was awarded following a competitive bidding process that complied with all Colorado State laws, the Mercer evaluation team is functionally and physically separate from the technical assistance

team, and the contract does not include any performance incentives that would contribute to a perception of conflicted interests between technical assistance services and the independence of the evaluation process. As an additional firewall, the evaluation statistical analyses will be conducted by a subcontractor that has not had any interaction with the technical assistance team, using data that has been reviewed and accepted by CMS (through monitoring protocol submissions).

In regards to Mercer's proposed subcontractors, all have assured Mercer there will be no conflicts and that they will take any steps required by Mercer or HCPF to mitigate any perceived conflict of interest. To the extent that we need to implement a conflict mitigation plan with any of our valued subcontractors, we will do so.

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

7

Attachment B

Evaluation Budget

	DY 1	DY2	DY3	DY4	DY5	Final Evaluation	Total Evaluation Cost
	2021	2022	2023	2024	2025	6/30/2027	
State of Colorado							
HCPF & OBH	$100,000*	$50,000**	$50,000	$50,000	$50,000	$50,000	$350,000

*Estimates based on 1) Demonstration Year 1 (DY1) data infrastructure and data sharing protocol build between Departments and vendor; and 2) staff review of DY1 deliverables.
**Estimates for DY2–DY5 based on State of Colorado review of annual, ongoing deliverables.

Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours					
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours
Evaluation Activities					
Develop and draft Evaluation Design	288	72	--	30	390
Revise drafted Evaluation Design	28	7	--	--	35
Draft Interim Evaluation report	72	18	--	26	116
Finalize Interim Evaluation report	40	10	--	--	50
Draft Summative Evaluation report	92	23	--	26	141
Finalize Summative Evaluation report	40	10	--	--	50

Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours					
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours
Data Activities					
Load, validate, and scrub raw data — Evaluation measures for Annual reports.	--	250	250	10	510
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report	148	148	35	--	331
File mapping to standardize file format — Evaluation measures for Annual reports.	100	195	100	10	405
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report	--	128	128	10	266
Initial programming/validation of code for measure development — Evaluation measures (37)	88	10	88	--	186
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for annual reports. (10 measures; 40 hours/year; 10 PM)	--	100	100	10	210
Statistical measures for the evaluation: Interim and Final report (300 hours/report)	100	250	250	10	610
Final Total:					**3,300**

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
Evaluation Activities									
Develop and draft Evaluation Design	$115,140	--	--	--	--	--	--	--	$ 115,140
Revise drafted Evaluation Design	--	$10,465	--	--	--	--	--	--	$ 10,465
Draft Interim Evaluation report	--	--	--	--	$33,410	--	--	--	$ 33,410
Finalize Interim Evaluation report	--	--	--	--	--	$14,950	--	--	$ 14,950
Draft Summative Evaluation report	--	--	--	--	--	--	$40,885	--	$ 40,885
Finalize Summative Evaluation report	--	--	--	--	--	--	--	$14,950	$ 14,950
Data Activities									
Load, validate, and scrub raw data — Evaluation measures for Annual reports.	--	$27,750	$27,750	$27,750	$27,750	$27,750	--	--	$ 138,750
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report (190 hours initial	--	$52,975	--	$30,263	--	--	$30,263	--	$ 113,500
File mapping to standardize file format — Evaluation	--	$44,163	$17,650	$17,650	$17,650	$17,650	--	--	$ 114,763

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
measures for Annual reports.									
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report	--	--	--	$34,694	--	$34,694	--	--	$ 69,388
Initial programming/validation of code for measure development — Evaluation measures (37)	--	$172,744	--	--	--	--	--	--	$ 172,744
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for Annual reports.	--	$12,600	$12,600	$12,600	$12,600	$12,600	--	--	$ 63,000
Statistical measures for the evaluation: Interim and Final report	--	--	--	$78,250	--	$78,250	--	--	
Final Total:									**$ 1,058,444**

8

Attachment C

Potential Timeline and Major Deliverables

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

Deliverable	STC Reference	Date
Submit evaluation design plan to CMS	38	October 1, 2021
Final evaluation design due 60 days after comments received from CMS	38	February 4, 2022
Mid-point assessment due	29	August 30, 2023
Draft Interim Report due	40C	June 30, 2024 (or with renewal application)
Final Interim Report due 60 days after CMS comments received	40D	60 days after comments received from CMS
Draft Summative Evaluation Report due 18 months following demonstration	41	June 30, 2027
Final Summative Evaluation Report due 60 days after CMS comments received	41A	60 days after comments received from CMS

Mercer Health & Benefits LLC
2325 East Camelback Road, Suite 600
Phoenix, AZ 85016
www.mercer-government.mercer.com

A business of Marsh McLennan