

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

July 28, 2021

Cynthia MacDonald
Director
Minnesota Department of Human Services
540 Cedar Street
P.O. Box 64983
St. Paul, MN 55167-0983

Dear Ms. MacDonald:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder System Reform 1115 Demonstration Evaluation Design, which is required by the Special Terms and Conditions (STC), specifically, STC 39, of Minnesota's section 1115 demonstration, "Minnesota Substance Use Disorder System Reform 1115 Demonstration" (Project No: 11-W-00320/5), effective through June 30, 2024. CMS determined that the evaluation design, which was submitted on April 2, 2020 and subsequently revised on February 17, 2021 and May 14, 2021, 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 C. 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 Minnesota on the Minnesota SUD System Reform 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

**Danielle
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cc: Ashtan Mitchell, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W-00320/5

TITLE: Minnesota Substance Use Disorder System Reform

AWARDEE: Minnesota Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Minnesota for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from July 1, 2019, through June 30, 2024, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. Residential Treatment for Individuals with Substance Use Disorder (SUD).

Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an Institution for Mental Diseases (IMD). This authority is limited to participating residential treatment providers that meet nationally recognized SUD program standards used by the state.

2. Certified Community Behavioral Health Clinic (CCBHC) Services. Expenditures for CCBHC services furnished by CCBHCs as described in STC 22.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W-00320/5

TITLE: Minnesota Substance Use Disorder System Reform

AWARDEE: Minnesota Department of Human Services

I. PREFACE

The following are the special terms and conditions (STC) for the “Minnesota Substance Use Disorder System Reform” (Minnesota SUD System Reform) section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the Minnesota Department of Human Services (hereinafter “state”), to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

These STCs are effective from July 1, 2019, through June 30, 2024, unless otherwise specified.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Demonstration Programs and Benefits
- VI. Cost Sharing
- VII. Delivery System
- VIII. General Reporting Requirements
- IX. Monitoring
- X. Evaluation of the Demonstration
- XI. General Financial Requirements Under Title XIX
- XII. Monitoring Budget Neutrality for the Demonstration
- XIII. Schedule of Deliverables for the Demonstration Approval Period

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports

- Attachment C: Reserved for Evaluation Design
- Attachment D: Reserved for Substance Use Disorder (SUD) Implementation Plan Protocol
- Attachment E: Reserved for SUD Monitoring Protocol
- Attachment F: CCBHC Criteria
- Attachment G: CCBHC Payment Methodology

II. PROGRAM DESCRIPTION AND OBJECTIVES

In this demonstration, the state will test new ways to maintain and enhance access to opioid use disorder (OUD) and other SUD services and continue delivery system improvements for these services to provide more coordinated and comprehensive treatment of Medicaid beneficiaries with SUD. This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with SUD while they are short-term residents in residential and inpatient treatment settings that qualify as IMDs. It will also support state efforts to implement models of care focused on increasing support for individuals in the community and home, outside of institutions, and improve access to a continuum of SUD evidence-based services at varied levels of intensity. This continuum of care shall be based on the American Society of Addiction Medicine (ASAM) criteria and/or other nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

Section 223 of the Protecting Access to Medicare Act (P.L. 113-93) authorized states to test new strategies for delivering an enhanced set of behavioral and mental health services to Medicaid beneficiaries through innovative payment models. Minnesota was one of eight states to receive a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide these enhanced services in Certified Community Behavioral Health Clinics (CCBHCs). The focus of the demonstration project was to improve the availability, quality, and outcomes of ambulatory services provided and to provide coordinated care that addresses both behavioral and physical health conditions that affect individuals in Minnesota's healthcare system. Services provided at these facilities are not only available to beneficiaries with SUD but are accessible to all Medicaid beneficiaries. The CCBHC demonstration project is set to expire on June 30, 2019. Granting Minnesota temporary expenditure authority for CCBHC services is not supplanting any other services or funding, but merely prevents the state from having a lapse in service delivery to its beneficiaries while it works to bring the appropriate authority for these services into its Medicaid state plan.

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

1. Increased rates of identification, initiation, and engagement in treatment for SUD.
2. Increased adherence to and retention in treatment.
3. Fewer readmissions to the same or higher levels of care where the readmission is preventable or medically inappropriate.
4. Improved access to care for physical health conditions among Medicaid beneficiaries.
5. To reduce the number of opioid related overdoses and deaths within the state of Minnesota.
6. To allow for patients to receive a wider array of evidence based services that are focused on a holistic approach to treatment.

7. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.
8. Utilizing its CCBHC providers to integrate community mental health care providers into an ASAM-based provider referral network with SUD providers or other health care professionals as needed.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
2. **Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of

the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

- 5. State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

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

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

- 8. Extension of the Demonstration.** States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 9.

- 9. Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
 - a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
 - b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
 - c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
 - d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and

as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

- e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of dis-enrolling beneficiaries.

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

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

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

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved

Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

- 13. Federal Financial Participation.** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- 14. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the single state Medicaid agency must maintain authority, accountability, and oversight of the program. The state Medicaid agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The single state Medicaid agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 15. Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

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

V. DEMONSTRATION PROGRAMS AND BENEFITS

- 17. Opioid Use Disorder/Substance Use Disorder Program.** Effective upon CMS' approval of the OUD/SUD Implementation Protocol, the demonstration benefit package for Minnesota Medicaid recipients will include OUD/SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Minnesota Medicaid recipients who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Minnesota will aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Plan as outlined in STC 18 below, to ensure short-term residential treatment stays. Under this demonstration, beneficiaries will have access to high quality, evidence-

based OUD and other SUD treatment services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The extension of coverage to services for all recipients while they are in short-term residential treatment for OUD/SUD will expand the available settings and allow the state to offer a full continuum of care for recipients with OUD/SUD (see Table 1). Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Table 1: Minnesota OUD/SUD Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Expenditure Authority
Outpatient Services	State plan (Individual services covered)	
Intensive Outpatient Services	Not currently covered in state plan; will be addressed in Implementation Plan	
Residential Treatment	State plan (Individual services covered)	Services provided to individuals in an IMD
Medically Monitored Withdrawal Management	State plan	Services provided to individuals in an IMD
Clinically Managed Withdrawal Management	State plan amendment pending	Services provided to individuals in an IMD
Screening, Brief Intervention, and Referral to Treatment (SBIRT)	State plan	
Medication Assisted Treatment (MAT)	State Plan	Services provided to individuals in an IMD

Recovery Peer Support Services	State plan	Services provided to individuals in an IMD.
Comprehensive Assessment	State plan	Services provided to individuals in an IMD
SUD Treatment Coordination	State plan	Services provided to individuals in an IMD

The state attests that the services indicated in Table 1, above, as being covered under the Medicaid state plan authority are currently covered in the Minnesota Medicaid state plan.

18. SUD Implementation Plan. The state must submit the OUD/SUD Implementation Plan within 90 calendar days after approval of this demonstration. The state may not claim FFP for services provided in IMDs to beneficiaries until CMS has approved the OUD/SUD Implementation Plan. Once approved, the Implementation Plan will be incorporated into the STCs as Attachment D and, once incorporated, may be altered only with CMS approval. Failure to submit a Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the OUD/SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 25.

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

- a. **Access to Critical Levels of Care for SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;
- b. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the ASAM Criteria or other comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of SUD program demonstration approval;
- c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;
- d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service

provider qualifications described under Minnesota Statutes section 245G.02. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other comparable, nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

- e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;
- f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;
- g. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT, within 12 months of SUD program demonstration approval;
- h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
- i. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.
- j. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 20 and Attachment D.

19. SUD Monitoring Protocol. The state must submit a separate Monitoring Protocol for the SUD programs authorized by this demonstration within 150 calendar days after approval of the demonstration. However, more time may be allotted to the state for the submission subject to CMS approval. The SUD Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

- a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18 and reporting relevant information to the state's Health IT plan described in STC 20;

- b. A description of the methods of data collection and timeframes for reporting on the state’s progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
- c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

20. SUD Health Information Technology Plan (“SUD Health IT Plan”). The state must provide CMS with an assurance that it has a sufficient health IT infrastructure “ecosystem” at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration – or it must submit to CMS a plan to develop the infrastructure/capabilities. This “SUD Health IT Plan”, or assurance, must be included as a section of the state’s SUD Monitoring Protocol (see STC 19) to be approved by CMS.

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

- a. The state will include in its Monitoring Protocol (see STC 19) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
- b. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 26).
- c. As applicable, the state should advance the standards identified in the ‘Interoperability Standards Advisory—Best Available Standards and Implementation Specifications’ (ISA) in developing and implementing the state’s SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
- d. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.
- e. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.
- f. Components of the SUD Health IT Plan include:
 - i. The SUD Health IT Plan must describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program (PDMP).¹

¹ Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance

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

prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the “opioid” epidemic and facilitate a nimble and targeted response.

² *Ibid.*

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

with regards to *PDMP* interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

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

22. Certified Community Behavioral Health Clinics. Under this demonstration, the state will provide a set of mental health services (CCBHC services) furnished by CCBHCs to Medicaid eligible individuals under expenditure authority as set forth below. The table below details the CCBHC services that differ from the state plan.

The state must submit all necessary SPAs to include CCBHC services in the Medicaid state plan within one year of the approval date of this demonstration. This includes a SPA to pay the CCBHCs the established prospective payment system rate (PPS-1) rate through its fee-for-service system (FFS) and a directed PrePrint payment for payments made to CCBHCs from managed care organizations. If the state wishes to change its payment methodology, a written request must be submitted to and approved by CMS.

If the state fails to submit all necessary SPAs by this deadline, this expenditure authority will be withdrawn effective as of the date that is one year after the effective date of this demonstration unless the state submits a justifiable reason, subject to CMS approval, to allow the state more time to submit the necessary SPAs and other documentation. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If the expenditure authority is withdrawn, STC 9 will apply to the CCBHC component of this demonstration. If the state submits all necessary SPAs in a timely manner, this expenditure authority expires as of the date the approved SPAs become effective and STC 9 will not apply.

CCBHC expenditures authorized under this 1115 demonstration shall not include payments for CCBHC services to beneficiaries provided within an approved CCBHC demonstration program under Section 223 of the Protecting Access to Medicare Act of 2014, including expenditures on or after July 1, 2019, related to any congressional extension of section 223 authority.

Description of Eligibility

All Medicaid beneficiaries are eligible for CCBHC services.

Description of Enhanced CCBHC Services

CCBHC Service	Service Description
<u>Comprehensive evaluation</u>	The comprehensive evaluation is completed for all CCBHC recipients, regardless of age. It includes a face-to-face interview and a

	review and synthesis of existing information obtained by CCBHC and external sources, including screenings, assessments, and services received.
<u>Comprehensive evaluation update</u>	The comprehensive evaluation update is completed only with adults over 18 years old. It includes a face-to-face interview and a review and synthesis of existing information obtained from external sources, internal staff, preliminary screening and risk assessment, crisis assessment, initial evaluation, previous comprehensive evaluations or other services the person receives at the CCBHC.
<u>Mental Health Clinical Care Consultation</u>	Mental health clinical care consultation is communication between a treating mental health professional and other providers or educators, who are working with the same recipient. These professionals use the consultation to discuss issues about the recipient's symptoms; strategies for effective engagement, care and intervention needs; treatment expectations across service settings; and clinical service components provided to the recipient and family.
<u>Family psychoeducation</u>	Family psychoeducation services are planned, structured and face-to-face interventions that involve presenting or demonstrating information. The goal of family psychoeducation is to help prevent relapse or development of comorbid disorders and to achieve optimal mental health and long-term resilience.
<u>Functional assessment and level-of-care determination</u>	A comprehensive functional assessment is a narrative that describes how the person's mental health symptoms impact their day-to-day functioning in a variety of roles and settings.
<u>Integrated treatment plan</u>	The integrated treatment plan (ITP) is the result of a person and family-centered planning process in which the member, any family or member- defined natural supports, CCBHC service providers, external service providers as appropriate, and care coordination staff are engaged in creation of the integrated treatment plan. ITP

	<p>development should include the member and all interested parties; however, at minimum, the ITP must be completed in a face-to face interaction with the member. It must be reviewed and signed by a qualified mental health professional or by a mental health practitioner working as a clinical trainee.</p> <p>An individualized plan integrating prevention, medical and behavioral health needs and service delivery is developed by the CCBHC in collaboration with and endorsed by the consumer, the adult consumer’s family to the extent the consumer so wishes, or family/caregivers of youth and children, and is coordinated with staff or programs necessary to carry out the plan.</p> <p>The treatment plan is comprehensive, addressing all services required, with provision for monitoring of progress towards goals. The treatment plan is built upon a shared decision- making approach.</p>
<p><u>Initial evaluation</u></p>	<p>The initial evaluation must: Include the reason the CCBHC recipient is presenting for assistance, a preliminary diagnosis, referrals to services within the CCBHC (specifically: outpatient SUD services, ARMHS, TCM, CTSS, peer services and psychotherapy) and medical necessity for those services Be administered to any new CCBHC recipient age five and older include a face-to-face interview with the CCBHC recipient and a written evaluation completed by a mental health professional or practitioner working under a licensed professional as a clinical trainee</p>
<p><u>Outpatient withdrawal management – level 2(Services not currently covered in the state plan)</u></p>	<p>Outpatient Withdrawal Management (level 2- WM) is a time-limited service delivered in an office setting, an outpatient behavioral health clinic, or in a person’s home by staff who provide medically supervised evaluation and detoxification services to achieve safe</p>

	<p>and comfortable withdrawal from substances and to facilitate the person’s transition into ongoing treatment and recovery. Services include: Withdrawal management assessment, withdrawal management plan, trained observation of withdrawal symptoms and supportive services to encourage the person’s recovery.</p>
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CCBHC Payment

CCBHC services must be paid for pursuant to PPS-1 as defined in attachment G of these STCs.

VI. COST SHARING

23. Cost sharing under the demonstration remains the same as what is included in the approved state plan.

VII. DELIVERY SYSTEM

24. Minnesota currently utilizes both FFS and managed care systems as specified under its state plan for delivering SUD services, both of which currently operate statewide. The state has authority to mandatorily enroll certain special populations, otherwise exempt under federal law, into managed care through its Minnesota Senior Care Plus (MSC+) § 1915(b) Waiver. This waiver is in effect for the period of July 1, 2016 through June 30, 2021.

VIII. GENERAL REPORTING REQUIREMENTS

25. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described subsection (b) below; or 2) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

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

- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

26. Deferral of Federal Financial Participation from IMD Claiming for Insufficient Progress Toward Milestones. Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones as evidenced by reporting on the milestones in the SUD Implementation Plan and the required performance measures in the Monitoring Plan agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

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

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

- a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

29. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90 calendar days) following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

- a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c. Budget Neutrality and Financial Reporting Requirements- Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
- d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
- e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 20.

30. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by December 31, 2022. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after the Mid-Point Assessment due date. The state must brief CMS on the report.

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

Elements of the mid-point assessment include:

- a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
- b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
- c. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement; and
- d. An assessment of whether the state is on track to meet the budget neutrality requirements.

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

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

- a. The draft report must comply with the most current guidance from CMS.
- b. The state will present to and participate in a discussion with CMS on the close-out report.
- c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
- d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 25.

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

- a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
- c. The state and CMS will jointly develop the agenda for the calls.

34. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement.

Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

X. EVALUATION OF THE DEMONSTRATION

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

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

37. Draft Evaluation Design. The draft Evaluation Design must be developed in accord with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. However, additional time may be allotted for this submission with CMS approval. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

- a. All applicable Evaluation Design guidance, including guidance about SUD Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).
- b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

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

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

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

Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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

- a. The Interim Evaluation Reports will discuss evaluation progress and present findings to date as per the approved evaluation design.
- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Reports must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to renew or extend the demonstration, draft Interim Evaluation Reports is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, Interim Evaluation reports are due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, draft Interim Evaluation Reports are due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit final Interim Evaluation Reports 60 calendar days after receiving CMS comments on the draft Interim Evaluation Reports and post the document to the state's website.
- e. The Interim Evaluation Reports must comply with Attachment B of these STCs.

42. Summative Evaluation Report. The draft Summative Evaluation Reports must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit draft Summative Evaluation Reports for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Reports must include the information in the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
- b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

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

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

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

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

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

47. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS.

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

- a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
- b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
- c. Costs for services provided to inmates of a public institution, as defined in 42 CFR 435.1010 and clause A after section 1905(a), except if the individual is admitted for at least a 24 hour stay in a medical institution.

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

payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

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

- a. Administrative costs, including those associated with the administration of the demonstration;
- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

51. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this section 1115 demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time.

- a. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
- b. The state acknowledges that any amendments that impact the financial status of this section 1115 demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

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

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR §433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR

- §433.51(c). The entities that incurred the cost must also provide cost documentation to support the state’s claim for federal match.
- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
 - e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR §447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

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

Table 2: Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Fee for Service IMD Services	Hypo	X		X	See Expenditure Authority #1
Capitated IMD Services	Hypo	x		x	See Expenditure Authority #1

CCBHC Services	Hypo	x		x	See Expenditure Authority #2
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55. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS. Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, the state must report the actual number of “eligible member months”

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

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

Table 3: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Fee for services IMD Services	SUD IMD spending: Expenditures for otherwise covered services furnished to otherwise eligible individuals provided during a SUD IMD month. See Expenditure Authority#1	N/A	Report on customary lines by category of service	Date of service	MAP	Y	7/1/19	6/30/2024
Capitated IMD services	SUD IMD spending: Expenditures for otherwise covered services furnished to otherwise eligible individuals provided during a SUD IMD month. See Expenditure Authority#1	N/A	Report on customary lines by category of service	Date of service	MAP	Y	7/1/19	6/30/2024

CCBHC services	Expenditures for CCBHC services as described in STC 22	N/A	Report on customary lines by category of service	Date of service	MAP	Y	7/1/19	6/30/2024
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56. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the table below.

Table 4: Demonstration Years		
Demonstration Year 1	July 1, 2019 to June 30, 2020	12 months
Demonstration Year 2	July 1, 2020 to June 30, 2021	12 months
Demonstration Year 3	July 1, 2021 to June 30, 2022	12 months
Demonstration Year 4	July 1, 2022 to June 30, 2023	12 months
Demonstration Year 5	July 1, 2023 to June 30, 2024	12 months

57. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.⁴

58. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration

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

period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

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

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. If, after review and/or audit, the data supplied by the state to set the budget neutrality expenditure limit is found to be inaccurate. The state certifies that the data it provided is accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

60. Limit on Title XIX Funding. The state will be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STCs 60 and 61, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in Section XI. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS'

assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

61. Risk. The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregation method is used, the state accepts risks for both enrollment and per capita costs.

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

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

64. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's WW hypothetical

spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by t refunding the FFP to CMS.

MEG	PC or Agg*	WOW Only, WW Only, or Both	TREND RATE	DY 1	DY 2	DY 3	DY 4	DY5
Fee for service IMD services	PC	Both	4.4%	\$4,196	\$4,381	\$4,574	\$4,775	\$4,985
Capitated IMD services	PC	Both	4.4%	\$1,174	\$1,225	\$1,279	\$1,335	\$1,394
CCBHC Services	PC	Both	4.3%	\$1,010	\$1,054	\$1,099	\$1,146	\$1,196

*PC = Per Capita, Agg = Aggregate

65. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

66. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from 2019-2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

67. Mid-Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and

approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Hypothetical Budget Neutrality Test

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XIII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date	Deliverable	STC
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Protocol	STC 18
150 days after SUD program approval date	SUD Monitoring Protocol	STC 19
180 days after approval date	Draft Evaluation Design	STC 37
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 39
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 39
December 31, 2021	Mid-Point Assessment	STC 30
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 41(c)

60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 41(d)
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 42
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 42(a)
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 42(b)
Monthly Deliverables	Monitoring Calls	STC 33
Quarterly Deliverables	Quarterly Monitoring Reports	STC 29
Due 60 days after end of each quarter, except 4 th quarter	Quarterly Expenditure Reports	STC 55(e)
Annual Deliverables - Due 90 days after end of each 4 th quarter	Annual Reports	STC 29
Within 120 calendar days prior to the expiration of the demonstration	Draft Close-out Operational Report	STC 32
30 calendar days after receipt of CMS comments	Final Close-out Operational Report	STC 32(d)

ATTACHMENT A

Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

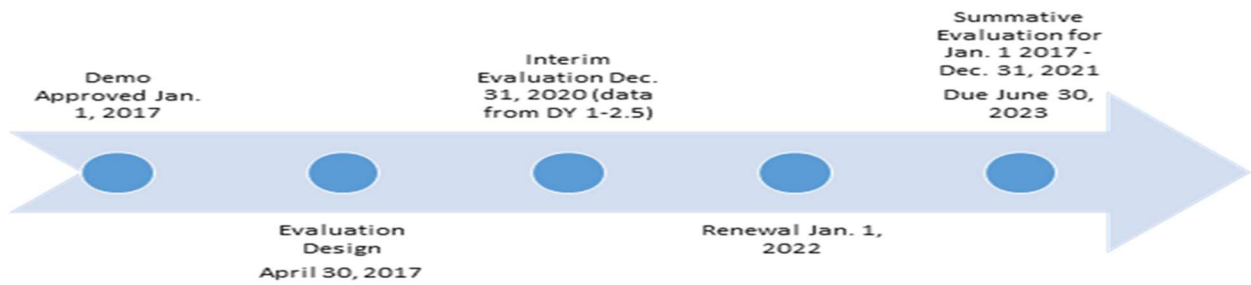
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals.

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

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



Required Core Components of All Evaluation Designs

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

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

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

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

1. Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:
<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
3. Identify the state’s hypotheses about the outcomes of the demonstration:
4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

- 3) *Evaluation Period* – Describe the time periods for which data will be included.
- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
 - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
 - a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
 - b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
 - c. A discussion of how propensity score matching and difference in differences

design may be used to adjust for differences in comparison populations over time (if applicable).

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

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

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

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

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

- 1) When the state demonstration is:
 - a. Long-standing, non-complex, unchanged, or
 - b. Has previously been rigorously evaluated and found to be successful, or
 - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

- 2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:

- a. Operating smoothly without administrative changes; and
- b. No or minimal appeals and grievances; and
- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include “No Conflict of Interest” signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B

Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

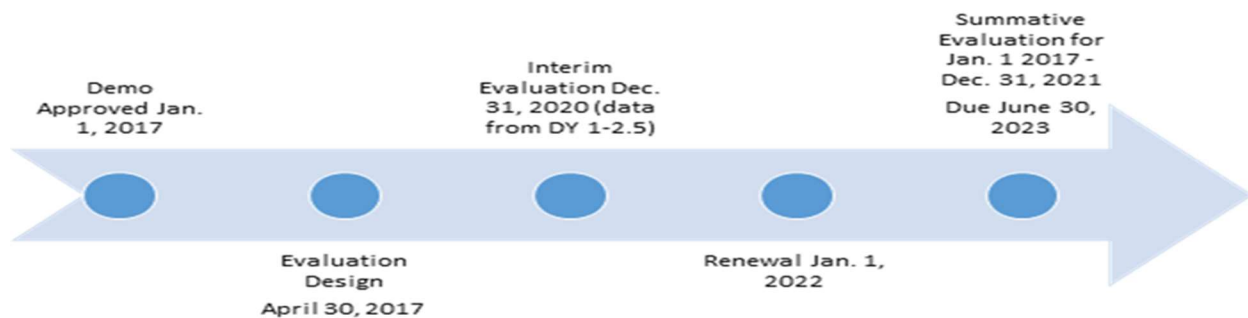
The Act requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design.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

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

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

Submission Timelines

There is a specified timeline for the state’s submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration STCs. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state’s website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state’s Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the

implications on future Medicaid policy. Therefore, the state's submission must include:

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
- 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
- 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
 - 2) Identify the state's hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

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

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

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

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
 - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives –

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

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

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

F. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

**Attachment C:
Evaluation Design**

Evaluation Design Plan

**Minnesota Substance Use Disorder System
Reform Section 1115(a) Demonstration
Project Evaluation**

MAY 14, 2021

PRESENTED TO:
CMS

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General Background Information

Effective and evidence-based substance use disorder (SUD) treatments exist, but fewer than 1 in 5 individuals in need of treatment in the United States has access to them. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, 21.2 million people age 12 or older needed substance use treatment in 2018, but only 17.5 percent of those who needed treatment received any.¹ In Minnesota, 6.5 percent of residents (about 301,000 individuals) age 12 and older had an SUD between 2015 and 2017.² Between 2012 and 2016, Minnesota's total Medicaid spending on SUD treatment increased by 37.8 percent from roughly \$160 million to almost \$220 million.³ This increase is partially due to the increase in enrollees utilizing SUD treatment services (about 24,332 in 2012 and 32,015 in 2016); however, per-enrollee spending also increased by 4.7 percent.⁴

On May 31, 2016, the governor of Minnesota signed Minn. Stat. § 254B.15 that directed a commission to design a reform of Minnesota's SUD treatment system in order to ensure a full continuum of care is available for individuals with SUDs.⁵ In fulfilling this statute, the Minnesota Substance Use Disorder System Reform Section 1115(a) Demonstration Project from the Minnesota Department of Human Services (MN DHS) Behavioral Health Division, a new approach to SUD treatment, was approved by CMS on June 28, 2019 and supports access to a full continuum of care with a focus on ensuring that individuals are matched to an appropriate level of care. The implementation plan was approved on July 22, 2020. With Minnesota's ASAM (American Society of Addiction Medicine) levels of care requirements published in October of 2020 and the monitoring protocol approved on January 5, 2020, Minnesota officially began the rollout of training and technical assistance to participating providers on January 14, 2021. This new treatment assignment is hypothesized to lead to lower costs.⁶

Of all individuals receiving SUD treatment in Minnesota, 7 out of 10 have their services paid for with public funds, and that proportion—particularly Medicaid's share—is increasing. Medicaid paid for about a quarter of all 2016 SUD treatment admissions, up from 13 percent in 2011.⁷ About two-thirds of Medical Assistance enrollees receiving SUD treatment are in the Medicaid expansion group and eligible

¹ Lipari RN. (2019). *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*. Washington, DC: Substance Abuse and Mental Health Services Administration. [https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNNationalFindingsReport2018/NSDUHNNationalFindingsReport2018.pdf](https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNNationalFindingsReport2018.pdf)

² Substance Abuse and Mental Health Services Administration. (2019). *Behavioral Health Barometer: Minnesota, 5*. <https://store.samhsa.gov/sites/default/files/d7/priv/sma19-baro-17-us.pdf>

³ Minnesota Department of Human Services. (2018). Medicaid Matters. <https://mn.gov/dhs/medicaid-matters/>

⁴ Ibid.

⁵ Minnesota Legislature. (2016). Chapter 170--S.F.No. 2378, Pub. L. No. 254B.15. <https://www.revisor.mn.gov/laws/2016/0/170/>

⁶ Stallvik M, Gastfriend DR, Nordahl HM. (2015). Matching patients with substance use disorder to optimal level of care with the ASAM Criteria software. *Journal of Substance Use*, 20(6):389-398. <https://doi.org/10.3109/14659891.2014.934305>

⁷ Minnesota Department of Human Services. (2019). *Minnesota Substance Use Disorder Section 1115 Waiver Implementation Plan (DRAFT)*. Submitted to the Centers for Medicare & Medicaid Services on September 27, 2019.

for an enhanced federal match rate of 93 percent.⁸ Under the waiver, MN DHS anticipates that about three-quarters of treatment costs for individuals residing in participating residential facilities will be covered by federal funds.⁹

Aspects of existing national Medicaid regulations and state-specific reimbursement policies have limited Minnesota's ability to adequately match patients to treatment options based on ASAM criteria and assure they can access the full SUD continuum of care. The first of these policies is a federal rule that excludes institutions for mental disease (IMD) from Medicaid payments. When Medicaid was enacted in 1965, states still operated large-scale psychiatric institutions or IMDs. The intent of the exclusion was to prevent states from shifting the financial burden of these institutions to the federal government without providing any additional services. The IMD exclusion defined an IMD as any psychiatric institution with more than 16 beds.¹⁰ The issues and challenges with the IMD exclusion are well-known and are a focus of the Centers for Medicaid & Medicare Services (CMS) in its efforts to combat the nation's opioid crisis. Many states assert that the IMD exclusion has undermined their ability to provide sufficient access to care for enrollees with SUDs, particularly the increasing number seeking treatment for opioid use disorders (OUD). States also argue that the IMD exclusion means Medicaid enrollees suffering from mental health conditions and SUDs experience a lack of continuity in care.¹¹ Recent work by the Medicaid and CHIP Payment and Access Commission (MACPAC) described similar concerns with the current behavioral health care delivery system, such as limited access to inpatient psychiatric services and gaps in the continuum of care associated with both restrictive coverage policies and the IMD payment exclusion.¹²

Minnesota is pursuing a multi-agency strategy to make SUD treatment more accessible and integrated with the larger health care system. In 2018, Minnesota Medicaid fee-for-service (FFS) reimbursement rates were the same as or lower than Medicaid managed care fees, almost all of which were the same as or lower than commercial managed care rates.¹³ Earlier this year, the state approved a 15 percent rate increase for the treatment portion of residential services and a 10 percent increase for outpatient services delivered through the demonstration.¹⁴ These additional funds should help encourage more providers to provide a full continuum of care for SUD, including OUD. The state plan includes coverage of outpatient services (i.e., treatment coordination and peer support), counseling, withdrawal management, intensive levels of care in residential and inpatient settings, and medication-assisted treatment (MAT). A state plan amendment to cover screening, brief intervention, and referral to treatment (SBIRT) was approved by CMS in October 2019. MAT is currently provided in conjunction with outpatient and residential

⁸ Minnesota Management and Budget. (2019). *Human Services 2020-21 Governor's Revised Biennial Budget Proposal*. <https://www.leg.state.mn.us/docs/2019/mandated/190516/human-services.pdf>

⁹ Ibid.

¹⁰ Priest KC, et al. (2017). Medicaid coverage for residential substance use disorder treatment: addressing the institutions for mental disease exclusion policy. *Health Affairs Blog*. <https://www.healthaffairs.org/doi/10.1377/hblog20170831.061745/full/>

¹¹ National Association of Medicaid Directors. (2015, July 27). Letter to Director, Center for Medicaid & CHIP Services.

¹² Melecki S, Weider K. (2017). The Medicaid Institutions for Mental Diseases (IMD) Exclusion, MACPAC, March 31, 2016. In MACPAC, *Report to the Congress on Medicaid and CHIP*, June 2017, Chapter 2: Medicaid and the Opioid Epidemic.

¹³ Ibid.

¹⁴ Minnesota Management and Budget. (2019). *Human Services 2020-21 Governor's Revised Biennial Budget Proposal*. <https://www.leg.state.mn.us/docs/2019/mandated/190516/human-services.pdf>

treatment services but will be expanded under the waiver. For example, the state is in the process of implementing a new provision as part of its agreements with all participating providers that MAT must be offered as part of the continuum of care and that providers have at least one medical professional with prescribing authority within their networks. Most recently, the legislature expanded the SUD treatment services covered under the state plan to include a comprehensive assessment, treatment coordination, peer recovery, and support services and residential withdrawal management.¹⁵

The adoption of the ASAM model will provide a framework for Minnesota’s SUD continuum of care. Beginning in the early 1990s, the ASAM developed, validated, and refined a six-dimension model to assess the level and intensity of treatment needed for a given individual at a specific moment in time.¹⁶ These dimensions include: 1) acute intoxication and potential for withdrawal, 2) biomedical conditions, complications, and past history, 3) emotional, behavioral, and cognitive conditions, 4) readiness to change, 5) relapse, continued use, or continued problems, and 6) recovery and living environment.

Based on measures within each of these dimensions and in combination, applying the ASAM criteria results in a clinical recommendation for treatment services ranging from early intervention (at the low end of the scale) to medically managed intensive inpatient services (at the high end).

Minnesota currently uses both FFS and managed care systems as specified under its state plan for delivering SUD services, both of which operate statewide. To meet the goal of fully aligning the Minnesota Medicaid SUD care system with the ASAM levels of care, Minnesota is using a mix of the SUD System Reform Section 1115(a) Demonstration Project, pilot programs, licensing reforms, and other regulatory tools to establish a comprehensive continuum of care. For more details on the ASAM Continuum of Care, please see Attachment 4.

Demonstration Overview

Minnesota’s SUD System Reform Section 1115(a) Demonstration Project (hereinafter referred to as “the demonstration”) will test new ways to strengthen the state’s behavioral health care system by improving access to treatment for the ASAM critical levels of care, discussed in greater detail in Attachment 4. The state aims to improve access by:

- Providing new federal Medicaid funding opportunities for SUD services provided to patients within intensive residential settings (i.e., IMDs) that have established referral arrangements with other SUD providers to create a continuum of care network.
- Establishing new provider networks to promote access to all levels of covered SUD services to meet a patient’s assessed level of need through the following activities:

¹⁵ Support services include services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovery community, and serve as a personal guide and mentor toward the achievement of goals. See Minnesota Department of Human Services. (2019). *Minnesota Substance Use Disorder Section 1115 Waiver Implementation Plan (DRAFT)*. Submitted to the Centers for Medicare & Medicaid Services on September 27, 2019.

¹⁶ American Society of Addiction Medicine. (2017). *The ASAM Criteria*. http://asamcontinuum.org/wp-content/uploads/2017/05/The-ASAM-Criteria_2017_pg1n2_PRINT_FINAL_v9_small.pdf

- Conducting a provider capacity assessment to create a baseline set of measures to assess the state’s capacity to provide each critical level of care and where gaps of care may exist in the state (see Attachment 5 for additional information on the provider capacity assessment).
- Identifying those gaps and developing measures to build capacity at those critical levels of care where the gaps exist.
- Developing measures to ensure sufficient provider capacity at, and beneficiary access to, ASAM critical levels of care.
- Updating provider and service delivery standards to increase the use of evidence-based placement assessment criteria and matching individual risk with the appropriate ASAM level of care to ensure beneficiaries receive the treatment they need. These changes include:
 - Residential and outpatient providers participating in the demonstration will transition to ASAM-based standards, with the goal of being fully compliant by June 30, 2021.
 - Developing updated SUD treatment service requirements, assessment and placement criteria, and staffing requirements that are consistent with ASAM standards, and publishing them in the provider manual by October 2020.¹⁷
 - Developing a residential treatment provider review process that will be used to ensure compliance with the updated provider requirements.
 - Establishing a comprehensive utilization review process to ensure that beneficiaries served in the demonstration have access to appropriate levels of care and necessary interventions.
 - Implementing a new provision that MAT must be offered as part of the continuum of care and that providers have at least one medical professional with prescribing authority within their networks.
 - Developing proposed future state measures to ensure sufficient provider capacity at, and beneficiary access to, ASAM critical levels of care.
 - Developing standards for enhancing and aligning the treatment planning requirements with ASAM criteria and developing further guidance on ASAM-based treatment coordination standards for 1115 Waiver providers.

Providers electing to participate in the demonstration will be required to establish and maintain formal patient referral arrangements to ensure access to the ASAM critical levels of care defined by the state. Providers must implement at least three of the four evidence-backed practices identified by the Minnesota Management and Budget agency as being cost-effective. These include 12-step facilitation therapy, brief cognitive behavioral therapy, motivational interviewing to enhance treatment engagement, and contingency management. These practices produce a net benefit of between \$4.70 (12-step facilitation therapy) and \$16.10 (motivational interviewing), according to a cost-benefit analysis conducted by Minnesota Management and Budget.¹⁸

¹⁷ Conducted by the DHS Behavioral Health Division and the Division of Licensing.

¹⁸ Minnesota Management and Budget. (2017). Adult and Youth Substance Use Benefit-Cost Analysis.

Participating providers will receive training and technical assistance on the ASAM criteria and the program modifications needed to assure that service delivery models align with these standards. Payment rates for participating providers will be increased to support their transition to the ASAM-based standards.

Minnesota currently had proposed to include its eight CCBHCs in waiver year two of the demonstration to further integrate community mental health and SUD services and to continue federal support of this unique payment model and project. Although the CCBHC model of care follows the concepts of continuity of care that are similar to the goals of the demonstration, CCBHCs are not going to be applying the same ASAM levels of care in a consistent fashion (e.g., many are pretty close to the standards but they have not adopted the criteria in their entirety, and no standard is set forth to shift them over). Thus they are not aligned to the metrics utilized under the ASAM as a framework. For CCBHC’s unique package of services, they must meet distinct requirements for their federal model through SAMHSA, and do not currently report all the evaluation measures defined in the demonstration. For example, the demonstration may require CCBHCs to ensure referral to IMDs that follow ASAM criteria, and this would disrupt the current CCBHC Demonstration project. Given these unique circumstances, CCBHCs will not be participating in the waiver at this time. The state will continue to investigate whether incorporating them into future demonstration years will be feasible.

Exhibit 1. Minnesota Coverage of SUD Treatment Services

ASAM Level of Care	Service	Description	Current Coverage	Future Coverage under Medicaid State Plan
0.5	Early Intervention	Assessment and educational services for individuals who are at risk of developing an SUD. Services may include SBIRT and driving under the influence/while intoxicated programs.	State Plan Attachment 3.1-A/B, Item 13.b. Screening Services; Attachment 4.19-B; Attachment 3.1-A/B, Item 5.a. Physicians’ Services	State law enacted by the 2019 legislature expands SBIRT to allow all qualified providers to deliver the service and establishes minimum treatment services for positive screens. A State Plan amendment is pending.
1.0	Outpatient Services (OP)	Outpatient treatment (usually less than 9 hours a week), including counseling, evaluations, and interventions.	State Plan Attachment 3.1-A/B, Item 13.d. Individual and Group Therapy; Attachment 4.19-B	Continuation of current state plan coverage while moving toward ASAM-based compliance, which is targeted for June 2021.
2.1	Intensive Outpatient Services (IOP)	9-19 hours of structured programming per week (counseling and education about addiction-related and mental health problems).	State Plan Attachment 3.1-A/B, Item 13.d. Individual and Group Therapy; Attachment 4.19-B	Continuation of current state plan coverage while moving toward ASAM-based compliance, which is targeted for January 2022.
3.1	Clinically Managed Low- Intensity Residential Services	24-hour supportive living environment; at least 5 hours of low-intensity treatment per week.	State Plan Attachment 3.1-A/B, Item 13.d. Individual and Group Therapy; Attachment 4.19-B Low intensity for adults only.	Continuation of current state plan coverage while moving toward ASAM-based compliance, which is targeted for June 2021.

ASAM Level of Care	Service	Description	Current Coverage	Future Coverage under Medicaid State Plan
3.3	Clinically Managed Population Specific, High-Intensity Residential Services	24-hour care with trained counselors to stabilize multidimensional imminent danger. Less intense milieu for those with cognitive or other impairments.	State Plan Attachment 3.1-A/B, Item 13.d. Individual and Group Therapy; Attachment 4.19-B	Continuation of current state plan coverage while moving toward ASAM-based compliance, which is targeted for June 2021.
3.5	Clinically Managed Medium- (Youth) & High- (Adult) Intensity Residential Services	24-hour living environment, more high-intensity treatment (level 3.7 without intensive medical and nursing component).	State Plan Attachment 3.1-A/B, Item 13.d. Individual and Group Therapy; Attachment 4.19-B	Continuation of current state plan coverage while moving toward ASAM-based compliance, which is targeted for June 2021.
3.7	Medically Monitored Intensive Inpatient Services	24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting (usually hospital-based).	State Plan Attachment 3.1-A/B, Item 13.d.; Attachment 4.19-B Hospital-Based Residential Services	Continuation of current state plan coverage.
4.0	Medically Managed Intensive Inpatient Services	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital.	State Plan Attachment 3.1-A/B; Attachment 4.19-A Inpatient Hospital Services	Continuation of current state plan coverage.
1-WM	Ambulatory Withdrawal Management without Extended Onsite Monitoring	Mild withdrawal with daily or less than daily outpatient supervision.	State Plan Attachment 3.1-A/B, item 5.a. Physicians' Services Office Visit	Continuation of current state plan coverage.
2-WM	Ambulatory Withdrawal Management with Extended Onsite Monitoring	Moderate withdrawal with all-day withdrawal management support and supervision; at night, has supportive family or supportive living situation.	Currently provided by CCBHCs only.	Continuation of current CCBHC coverage under the CCBHC Demonstration grant.
3.2-WM	Clinically Managed Residential Services Withdrawal Management	Moderate withdrawal but needs 24-hour support to complete withdrawal management and increase likelihood of continuing treatment or recovery.	State Plan Attachment 3.1-A/B. Attachment 4.19-B Withdrawal Management Services	Continuation of current state plan coverage, effective as of July 1, 2019.
3.7-WM	Medically Monitored Inpatient Withdrawal Management	Severe withdrawal and needs 24-hour nursing care and physician visits as necessary; unlikely to complete withdrawal management without medical, nursing monitoring (usually hospital-based).	State Plan Attachment 3.1-A/B. Attachment 4.19-B Withdrawal Management Services	Continuation of current state plan coverage, effective as of July 1, 2019.

ASAM Level of Care	Service	Description	Current Coverage	Future Coverage under Medicaid State Plan
Recovery Support	Recovery Support	Services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovery community, and serve as a personal guide and mentor toward the achievement of goals.	State Plan Attachment 3.1-A/B, Item 13.d; Attachment 4.19-B Peer Recovery Support Services	Continuation of current state plan coverage.
OTS	Opioid Treatment Services (OTS) for Persons Experiencing an OUD	Pharmacological (opioid agonist, partial agonist, and antagonist medications) and counseling services provided in either an Opioid Treatment Program (OTP) or office-based setting (OBOT).	Available for general SUDs, which includes OUDs, and for OUDs in OTP format which are sometimes physician office visits.	State will continue to promote access to OTS through existing mechanisms

Evaluation Design Plan

An overview of the proposed demonstration evaluation plan is presented in Exhibit 1 below. We describe the goals of the waiver and the evaluation hypotheses as well as identify data sources; measures; methodological approaches of the impact of the waiver, including limitations, challenges, and proposed solutions; reporting; timeline and schedule; and communications.

The state of Minnesota has contracted with NORC at the University of Chicago (NORC) to conduct an independent evaluation of the demonstration. NORC is an objective, non-partisan research institution that delivers reliable data and rigorous analysis to guide critical programmatic, business, and policy decisions. NORC will be a DHS partner with expertise in managing mixed-method evaluations for a range of state and federal health care payment and delivery programs, including Medicaid waivers. The evaluation of the demonstration will be informed by NORC's experience developing and implementing rigorous yet pragmatic qualitative and quantitative data collection and analytic approaches to study these programs in close collaboration with our project sponsors and in alignment with federal requirements.

Evaluation Hypotheses and Research Questions

The hypotheses of the 1115 SUD Waiver, as described in the final special terms and conditions (STC), are listed in Exhibit 2, along with research questions to assess the extent to which they are being met and are advancing the objectives of Titles XIX and XXI of the Social Security Act (see Data Sources section below for a description of the data sources). These questions are preliminary and will be refined over time in collaboration with MN DHS. For example, the state may want to add additional research questions or examine impacts under different subgroups, if budget and time allow.

For each research question, we will assess the appropriateness of stratification, for example, by type of health care service, setting (IMDs and residential and inpatient SUD treatment facilities, nonresidential treatment facilities, opioid treatment programs, and MAT providers), geographic unit, and by beneficiary health and socio-demographic characteristics. Where possible, we will also examine impacts for specific vulnerable Title XIX and XXI populations, such as transition-age youth, and pregnant and postpartum women.

Exhibit 2. Waiver Goals and Preliminary Evaluation Questions

Goal 1. Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs

Hypothesis: The demonstration will increase the share of beneficiaries who are identified and treated for OUD/SUD in ways that are consistent with evidence-based care.

1. To what extent did implementation of the 1115 SUD Waiver result in increased screening and identification of members with SUD?
2. Did efforts to improve initiation and engagement facilitated by the 1115 SUD Waiver result in Minnesota Medicaid beneficiaries with SUD, including OUD, receiving more treatment for substance abuse?

Goal 2. Increased adherence to and retention in treatment

Hypothesis: The demonstration will improve adherence to treatment plans, employee retention and the duration of pharmacotherapy.

3. To what extent and how did implementation of the 1115 SUD Waiver result in improvement in:
 - a. adherence to the plan of treatment?
 - b. retention of Minnesota beneficiaries with SUD in addiction recovery management?
 - c. duration of pharmacotherapy, including MAT for OUD, among Minnesota beneficiaries?

Goal 3. Fewer readmissions to the same or higher levels of care where the readmission is preventable or medically inappropriate

Hypothesis: The demonstration will reduce readmissions to the same or higher level of care among beneficiaries with SUD.

4. Did the more comprehensive continuum of covered SUD services and care facilitated by the 1115 SUD Waiver result in fewer readmissions to the same or higher level of care among beneficiaries with SUD?

Goal 4. Improved access to care for physical health conditions among Medicaid beneficiaries

Hypothesis: The demonstration will increase use of preventive health services.

5. Did beneficiaries increase use of preventive health services after implementation of the 1115 Waiver?
6. Do SUD services providers believe that access to care for physical health conditions has improved since the implementation of the 1115 SUD Waiver?

Goal 5. Reduced number of opioid-related overdoses and deaths within the state of Minnesota

Hypothesis: The demonstration will decrease the mortality rate among Minnesota beneficiaries with SUD/OUD.

7. Did the mortality rate among Minnesota beneficiaries with SUD/OUD decrease after implementation of the 1115 Waiver?
8. Did overdose-related mortality rates among Minnesota beneficiaries with SUD/OUD decrease after implementation of the 1115 SUD Waiver?

Goal 6. Patients allowed to receive a wider array of evidence-based services that are focused on a holistic approach to treatment

Hypothesis: The demonstration will increase the share of beneficiaries who are treated for OUD/SUD in ways that are consistent with evidence-based care.

9. What are the challenges to implementing ASAM's critical levels of care?
10. To what extent and how did implementation of the 1115 SUD Waiver result in the incorporation of evidence-based standards into the SUD treatments?
11. To what extent did the 1115 SUD Waiver enable providers to deliver the comprehensive continuum of services and care for SUD and OUD?

Goal 7. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services

Hypothesis: The demonstration will reduce the utilization of the emergency department, avoidable hospitalizations, hospitalizations for ambulatory care sensitive conditions, and intensive inpatient services.

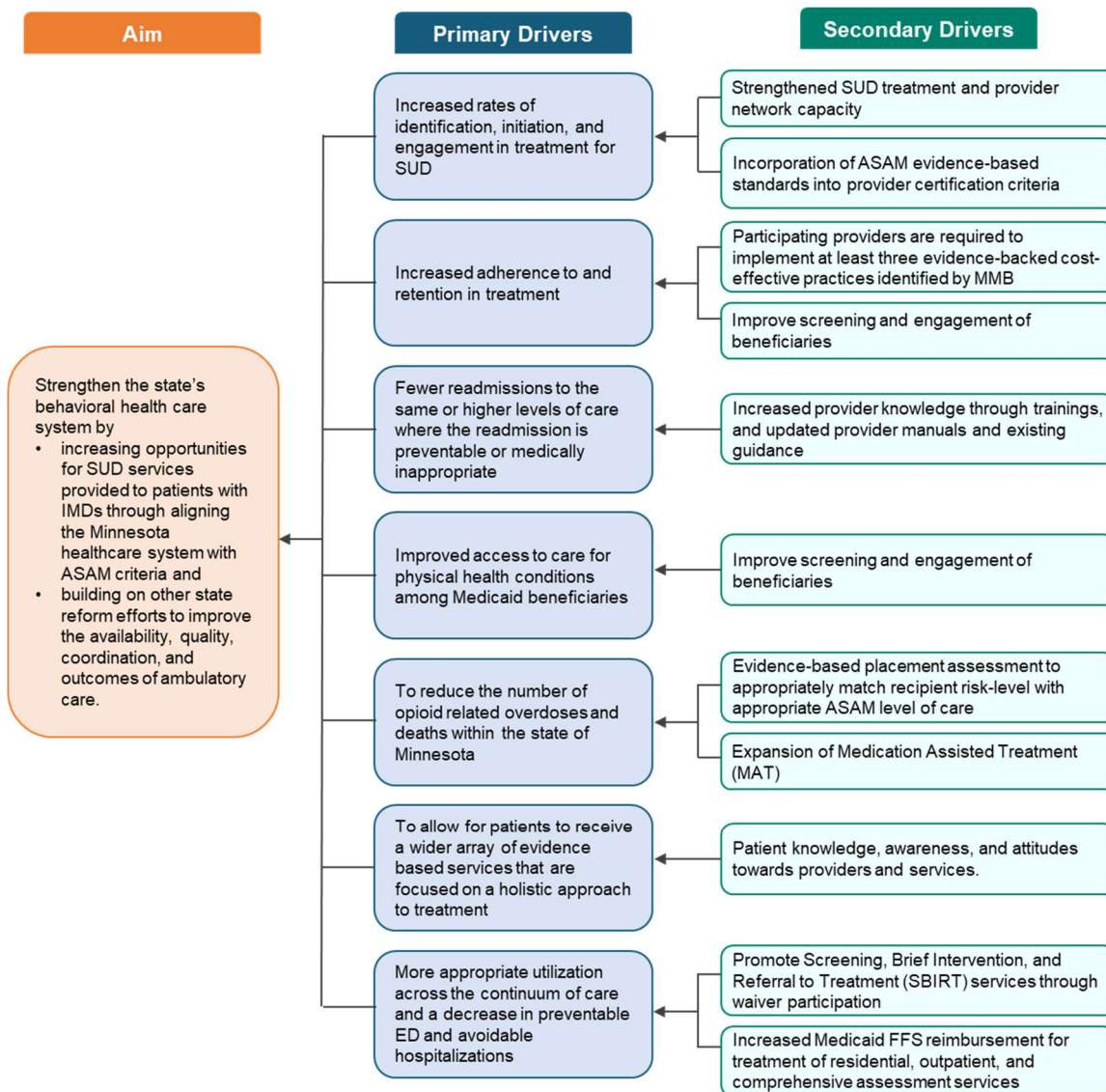
12. Did implementation of the 1115 SUD Waiver result in the following, among Medicaid beneficiaries with SUD, following the receipt of treatment services?
 - a. improved use of preventive care
 - b. reduced emergency department utilization
 - c. fewer avoidable hospitalizations
 - d. fewer hospitalizations for ambulatory care sensitive conditions
 - e. fewer avoidable hospitalizations during and after receipt of addiction recovery management services
-

Demonstration Driver Diagram

Exhibit 3 below illustrates the primary and secondary drivers for the demonstration aim of strengthening the state’s behavioral health system by increasing opportunities for SUD services provided to patients at IMDs through aligning the Minnesota health care systems with ASAM criteria and building on other state reform efforts to improve the availability, quality, coordination, and outcomes of ambulatory care.¹⁹

¹⁹ This evaluation design plan reflects an evaluation of the CMS-approved Minnesota Substance Use Disorder System Reform Section 1115(a) Demonstration. This demonstration included seven goals and the preliminary evaluation questions presented above reflect specific hypothesis as they relate to the demonstration goals. Therefore, we do not include cost as a driver in the driver diagram below. While cost reduction for SUD services is not a goal of the demonstration, NORC plans to conduct exploratory analysis on cost reduction. See Exhibit 7 below for details on that analysis.

Exhibit 3. Demonstration Driver Diagram



Methodology

The evaluation approach is guided by the goals of the waiver. Exhibit 4 presents our overall evaluation approach to addressing the research questions, including data sources and analytic methods.

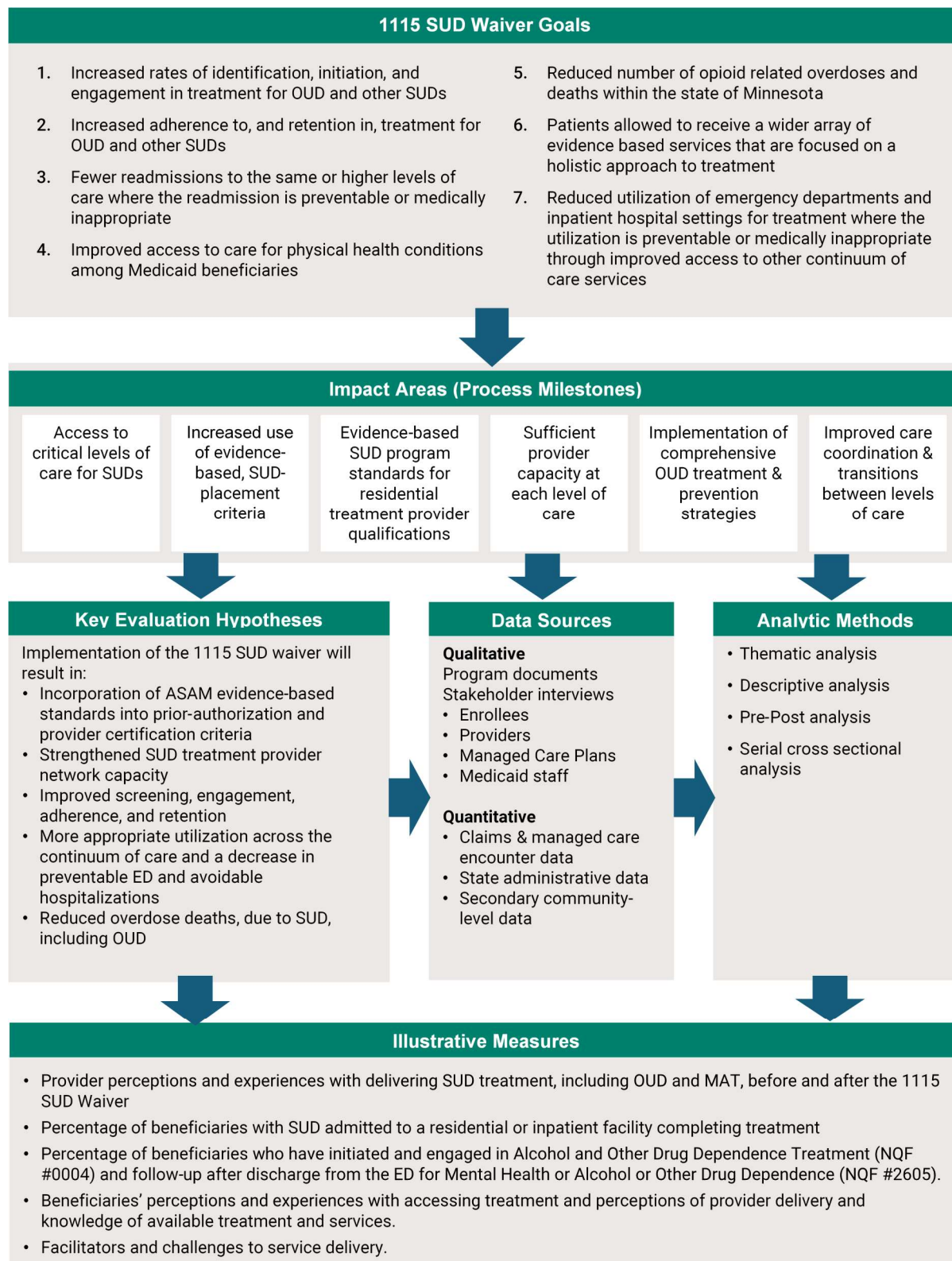
The different outcomes and target populations included in the demonstration necessitate a combination of evaluation design approaches. Following CMS guidance, our analyses will include descriptive statistics, pre-post, interrupted time series, qualitative data collection, and mixed-methods analyses to integrate data from both quantitative and qualitative analyses. This approach ensures a robust and appropriate design to assess the effectiveness of the MN DHS 1115 Waiver. Data sources include administrative data such as Medicaid claims and encounter data, and other administrative data. Additionally, we will incorporate data from national datasets such as the American Community Survey on community characteristics. Qualitative data will also be collected and analyzed, including document review of waiver-related materials and interviews conducted with providers, administrators, and other stakeholders, such as tribal organizations.

For most analyses, a serial cross-sectional model or pre-post design will be used to characterize differences over time for participants. Where possible, a two-year pre-demonstration period will serve as a baseline (historical benchmark), and where there are no equivalent pre-demonstration data available (due to new provider billing codes and other changes to service delivery allowed under the waiver), the first year of the demonstration will serve as a baseline (benchmark) for those outcomes.

We use baseline data as a benchmark and compare trends within the state over time. There are no standard benchmarks or pre-determined targets for most measures, and comparisons to other states are complicated by the complex evolution and timeline of services covered under different state plans and eligibility thresholds. Comparisons with national levels are complicated by long lag times in national data (often two years) that make timely assessment less meaningful, as compared to data before and after the demonstration in Minnesota. However, we do make comparisons with national data for inpatient admissions for persons with an SUD, and all-cause and opioid overdose mortality. More details on this approach are described in the Analytic Approach section of this document.

The timing of the data acquisition will vary depending on the data source, the reporting requirements and needs, and information that emerges during the course of the evaluation.

Exhibit 4. Overview of Proposed Minnesota SUD System Reform Section 1115(a) Demonstration Project Evaluation Plan



Target and Comparison Group

Target Group and Attribution. The target population of the demonstration is all individuals enrolled in Medicaid who receive any services for SUD.²⁰ This approach is an “intent-to-treat” (ITT) design, evaluating the impact of the demonstration for all beneficiaries receiving SUD/OD treatment services from all providers. This ITT design avoids the “volunteer bias” from limiting the evaluation to only beneficiaries who received care from participating providers. In a sensitivity analysis, we may examine impacts from care received by participating providers, using attribution rules based on the plurality care received. We discuss this further in the Methodological Limitations section.

We will conduct analyses at the beneficiary level. Depending on the measure, analyses will be conducted for all adults, children, for adults who receive treatment for OUD/SUD in short-term residential and inpatient settings that qualify as an IMD, which are not otherwise matchable expenditures under Section 1903 of the Social Security Act. Subgroups may also include beneficiaries receiving services from tribal providers, and subgroups defined by race/ethnicity, and urban rural status.

The baseline period is 2017-2018 and performance years 2020-2023. For each group, we will examine the distribution of months of Medicaid coverage in the pre-demonstration or baseline period and during the demonstration. For most analyses, 12 months of coverage is desirable. Based on the examination of months of coverage, we would balance months of coverage in our propensity score models to “match” beneficiaries in the baseline and demonstration phases, and controlling for differences in duration of coverage for beneficiaries in our regression analyses (described further in the document). Additional matching criteria includes Medicaid enrollment groups (FFS or managed care organization (MCO) plans), beneficiary demographics, and community socio-demographic measures. This would help ensure both adequate study sample and similarity of the groups.

Comparison Group. All providers are eligible for participation in the demonstration, and all Medicaid beneficiaries are eligible for services. Both of these factors limit the construction of a comparison group. Providers who do not participate may be different in unobserved ways from those who do participate on factors that are not captured in claims data (such as case-mix at facilities, geographic distances, staff mix and credentials across the referral network, and telemedicine capabilities). At the same time, the state anticipates a “spillover” effect of establishing ASAM criteria statewide: providers in the state are expected to engage with ASAM guidelines, though non-participating providers will not be required to demonstrate adherence to ASAM criteria. Non-participating providers may adopt the ASAM framework, as this approach becomes part of the culture of care in the state, and the evaluation would have no way of knowing if this is occurring. Further, beneficiary placement is expected to be made on the basis of ASAM levels of care guidelines. It may be the case that more severe cases are assigned to providers with a greater treatment capacity. For example, patients’ SUD severity may influence which IMD they are referred to, and the capacity to manage severe patients may be associated with participation in the demonstration. Comparisons to patients with private coverage are not appropriate due to differences in social risk factors and other unmeasurable barriers to health that Medicaid patients may have that are not typically present in

²⁰ The evaluation will not use sampling, but rather will include all beneficiaries who received services during the study period. For MAT services, we estimate at least 18,000-20,000 unique beneficiaries annually, and for outpatient, residential, and inpatient, we estimate at least 148,000-150,000 annually, based off of one year of baseline data (July 1, 2018, to June 30, 2019).

a commercially insured population. Thus, the use of an ITT design and the lack of available out of state or within state comparison group precludes a comparison group. We compare outcomes for beneficiaries in the pre- and post-demonstration periods. We will use data from national sources (described in the Analytic methods) as comparison points of references, but note these are not risk-adjusted and are not true comparisons groups.

The evaluation will match beneficiaries in the (baseline) pre-demonstration phase to those in the demonstration phase, separately for FFS and managed care, using a three-step process (Exhibit 5).

Exhibit 5. Strategy to Construct the Baseline and Demonstration Groups

Step	Approach
1. Identify Medicaid providers and markets in the baseline	<ul style="list-style-type: none"> ■ Identify providers in each type of treatment setting. ■ Define comparable health care market characteristics for providers from which to select beneficiaries.
2. Match beneficiaries	<ul style="list-style-type: none"> ■ Match beneficiaries using a beneficiary-level entropy balancing approach. ■ The entropy model will be based on factors such as demographic characteristics, health status and conditions, type and severity of SUD, health service use, Medicaid program eligibility status, and health care access information (distant to and density of providers) and market characteristics.
3. Assess differences	<ul style="list-style-type: none"> ■ Assess differences between the baseline and demonstration groups.

Evaluation Period

The 1115 Waiver period covers July 1, 2019, through June 30, 2024. Data to be used for the evaluation will: 1) include a two-year, pre-demonstration, baseline period before the waiver, 2) exclude a 12-month ramp-up period that extends 12 months from the formal launch date (July 1, 2019), during which changes to the provider manual regarding ASAM levels of care were disseminated, provider trainings initiated, service coverage changes newly implemented, and 3) include a demonstration period from July 1, 2020, through June 30, 2024. At this point, apart from the ramp-up period, we do not plan to make further restrictions on the time-period assessed for the demonstration phase due to the COVID-19 pandemic. We have competing hypothesis about the impact of COVID-19 on care-seeking. On the one-hand, a reduction in the availability of some services due to health system resource constraints may reduce the availability of providers and also reduce treatment seeking on the part of Medicaid beneficiaries. At the same time, the stress of COVID-19 has driven up the prevalence of OUD, leading to a larger percentage of the population needing and potentially seeking care. Because our measures focus on process and outcomes for persons who seek care pre and post-demonstration, we may still observe improvements in the care received.

The provider capacity assessment will be conducted in mid-2020. In addition, a SUD midpoint assessment report is scheduled for November 30, 2021 (but given delays in implementation, this may be postponed). This report includes an independent assessment to examine progress and assess the risk of not achieving milestones in the SUD Implementation Plan or meeting performance targets in the SUD Monitoring Protocol. An interim evaluation report is due December 30, 2022, and will provide updates on implementation experience and evaluation findings to date associated with as many of the research

questions in the approved evaluation design as data permits. The final evaluation report is due on June 30, 2024. After the demonstration ends, NORC will work with MN DHS to consider a summative report of evaluation findings, to be produced by the end of 2024. In addition, monthly progress reports on tasks and deliverables and key milestones performed under the contract will be submitted to MN DHS. Quarterly and annual information for federal reporting will also be submitted to MN DHS and will include progress on evaluation activities, key milestones accomplished, interim findings available, challenges encountered, and how they were addressed.

Evaluation Measures

The development of measures is an iterative process that was refined in consideration of:

- Overlap with monitoring measures, to reduce redundancy in reporting
- Specificity with MN DHS goals, as to where the program may have the most impact

Changes to the outcome measures will be recorded in the annual update to the Evaluation Design Plan.

To test hypotheses around the core research questions for each domain of focus, NORC's evaluation will build on the proposed outcome measures listed in Exhibit 5. The proposed outcome measures are drawn from CMS' core set of health care quality measures for Medicaid, measures listed in Minnesota's demonstration request, measures used in the literature, and from recognized sources such as the Agency for Healthcare Research and Quality's quality measures and those endorsed by the National Quality Forum (NQF).

Claims-Based Measures

Using Minnesota Medicaid claims, we will construct a number of measures to assess the waiver's impact on utilization and quality of care outcomes for the program populations and, as possible, for key subpopulations (Exhibit 6). Additional subpopulations (defined by geographic region, for example) may be added.

The successful construction of these measures will be dependent on data quality and availability; we will work with MN DHS to create a final list of outcome measures after conducting a data quality assessment. The list of proposed measures will be refined periodically, with guidance from MN DHS and informed by the evaluation work underway. Measures will be analyzed by facility type or treatment setting, where relevant (such as nonresidential SUD treatment centers, inpatient or residential addiction SUD treatment facilities).

Non-Claims-Based Measures

In addition to the claims-based outcome measures, we will examine the feasibility of using data from the Drug and Alcohol Abuse Normative Evaluation System (DAANES). It contains a rich set of data on beneficiaries' substance use history (e.g., frequency, age of onset, and route of administration), diagnoses, chemical health severity ratings, conditions surrounding admission, legal status, referral sources,

demographics, living arrangements, and education. We can examine how SUD treatment and outcomes change before and after the demonstration (for beneficiaries receiving care from providers) to assess improvements in services across the continuum of care for beneficiaries receiving services from providers, on dimensions such as severity on admission (whether the patient has relapsed), attendance at self-help, and reason for discharge (i.e., completed the program or left early), and social outcomes such as the number of arrests. Comparisons over time (serial cross-sectional analyses) would be made within specific SUD ICD-10 diagnostic categories.

Exhibit 6. Evaluation Measures and Analytic Approach

Hypothesis	Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach
Goal 1: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs						
The demonstration will increase the share of beneficiaries who are identified and treated for OUD/SUD in ways that are consistent with evidence-based care.	Percentage of beneficiaries with an initiation and engagement of alcohol and other drug dependence treatment	NQF #0004	Number of beneficiaries who initiated treatment within 14 days of a new SUD diagnosis	Total number of beneficiaries diagnosed with a new episode of SUD	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults
	Percentage of beneficiaries with an initiation and engagement of alcohol and other drug dependence treatment	Medicaid Adult Core Set	Number of beneficiaries with two or more claims for SUD treatment within 34 days	Total number of beneficiaries with a new diagnosis of SUD	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults
	Providers offering screening services with SBIRT for SUD and/or OUD and/or referral to treatment	National Behavioral Health Quality Framework (NBHQF) Goal 3A	Number of providers offering screening, services, and/or referral to treatment	Total number of eligible providers	MN MMIS	Descriptive and post-only analysis
Goal 2: Increased adherence to, and retention in, treatment treatment for OUD and other SUDs						
The demonstration will improve adherence to treatment plans.	Follow-up after IMD stay	MN DHS constructed	Number of patients with an SUD diagnosis and IMD discharge with an outpatient (follow-up) visit within 30 days of discharge	Number of patients with an SUD and IMD discharge	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults
	Continuity of pharmacotherapy for opioid use disorder	NQF #3175	Number of beneficiaries pharmacotherapy for OUD who have at least 180 days of continuous treatment	Total number of beneficiaries receiving MAT for OUD (excluding those deliberately phased out)	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults

Hypothesis	Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach
	Follow-up after ED visit for alcohol and other drug abuse or dependence	NCQA; NQF #2605; CMS Medicaid Adult Core Measure	Number of patients with an SUD and ED discharge with an outpatient visit within 30 days of discharge	Number of patients with an SUD and ED discharge	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults
	Time to treatment	Aligns with NBHQF Goal 1; CMS SUD Evaluation measure set	Sum of (date of clinical assessment to date of first treatment)	Number of days between first clinical assessment and date of Initiation into treatment	MN MMIS	Descriptive and serial cross-sectional analysis; subgroups of children and adults
	Percent of beneficiaries with SUD admitted to a residential or inpatient facility completing treatment	MN DHS constructed	Number of beneficiaries completing an episode of treatment services (reason for discharge = completion)	Number of beneficiaries admitted to a residential or inpatient facility for treatment services	DAANES	Descriptive and pre-post (annual); subgroups of adults and children, by reason for admission
Goal 3: Fewer readmissions to the same or higher levels of care where the readmission is preventable or medically inappropriate						
The demonstration will reduce readmissions to the same or higher level of care among enrollees with SUD.	All-cause hospitalization within 30 days of discharge from an inpatient or residential treatment facility among patients with an SUD	NQF #1768, CMS MIPS QM #458	Number of beneficiaries with an SUD hospitalized for any diagnosis within 30 days of discharge from the index stay at an inpatient or residential treatment facility	Number of beneficiaries with an SUD discharged from an inpatient or residential treatment facility	MN MMIS	Descriptive and serial cross-sectional analyses; adults age 18 and over
	All-cause hospitalization among patients with an SUD	Included for comparison to national data	Number of beneficiaries with an SUD hospitalized for any diagnosis	Number of beneficiaries with an SUD	MN MMIS	Descriptive and serial cross-sectional analyses; adults age 18 and over; comparison to TEDS-A data
Goal 4: Improve access to care for physical health conditions among Medicaid beneficiaries						
The demonstration will increase use of preventive health services.	Percentage of beneficiaries with an SUD receiving ambulatory or preventive care	HEDIS measure/ NCQA	Number of Medicaid beneficiaries with SUD who had an ambulatory preventive care visit	Number of beneficiaries with SUD	MN MMIS	Descriptive and serial cross-sectional analyses; subgroups of children and adults
	Qualitative data from providers, by provider type, including IMDs	Independent evaluator	NA	NA	Interviews with providers	Qualitative analysis
	Qualitative data from beneficiaries	Independent evaluator	NA	NA	Interviews with beneficiaries	Qualitative analysis

Hypothesis	Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach
Goal 5: Reduce the number of opioid-related overdoses and deaths within the state of Minnesota						
The demonstration will decrease the mortality rate among Minnesota enrollees with SUD/OD.	All-cause drug overdose mortality rate	MN DHS	Number of beneficiaries with OUD/SUD who died due to any drug overdose	Number of beneficiaries with an OUD/SUD	MH DHS (death certificates)	Descriptive and serial cross-sectional analyses (annual); comparison to national data
	Opioid overdose mortality rate	MN DHS	Number of beneficiaries with OUD/SUD who died due to an opioid overdose	Number of beneficiaries with an OUD/SUD	MH DHS linked with MDH opioid death data	Descriptive and serial cross-sectional analyses (annual); comparison to national data
Goal 6: Allow for patients to receive a wider array of evidence-based services that are focused on a holistic approach to treatment						
The demonstration will increase the share of beneficiaries who are treated for OUD/SUD in ways that are consistent with evidence-based care.	Percentage of OUD patients initiated with MAT	MN DHS constructed	Number of beneficiaries with an OUD who were prescribed MAT	Total number of beneficiaries with an OUD	MN MMIS	Descriptive and serial cross-sectional analyses;
	Percentage of beneficiaries with an SUD accessing support services following discharge from an inpatient facility or residential treatment center ²¹	MN DHS constructed	Number of beneficiaries receiving support services within 30 days of discharge from an inpatient facility or residential treatment center	Number of beneficiaries discharged from an inpatient facility or residential treatment center	DAANES	Descriptive and pre-post (annual);, by reason for admission
	Use of peer supportive services among beneficiaries admitted to treatment	MN DHS constructed	Number of beneficiaries admitted for treatment and electing peer support services	Number of beneficiaries admitted for treatment	DAANES	Descriptive and pre-post (annual);
	Continuity of use peer-support services among beneficiaries admitted to treatment	MN DHS constructed	Number of peer support services provided during treatment followup	Number of beneficiaries admitted for treatment and electing peer supportive services	DAANES	Descriptive and pre-post (annual); by reason for admission
	Percent of beneficiaries admitted for SUD treatment who were satisfied with services	MN DHS constructed	Number of beneficiaries admitted for SUD treatment reporting they were helped "a lot" by services	Number of beneficiaries admitted for SUD treatment	DAANES	Pre-post demonstration (annual) by provider type and beneficiary demographics

²¹ Types of services may include: supportive housing, living skills development, individual or group counseling, relationship/family counseling, coordination of services, spiritual support, therapeutic recreation, employment or educational services, childcare, transportation services.

Hypothesis	Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach
	Provider perceptions and experiences with delivering SUD treatment, including OUD and MAT, before and after the 1115 SUD Waiver	Independent evaluator	NA	NA	Interviews with providers	Qualitative analysis examining the different experiences by provider type
	Beneficiaries' perceptions and experiences with accessing treatment and perceptions of provider delivery and knowledge of available treatment and services	Independent evaluator	NA	NA	Interviews with beneficiaries	Qualitative analysis of the varying experiences of beneficiaries for different demographic and geographic groups
Goal 7: Reduced utilization of ED and inpatient hospital settings for treatment where the utilization is preventable						
Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	ED utilization per 1,000 beneficiaries for SUD	MN DHS constructed	Number of ED visits per 1,000 beneficiaries with an SUD	Number of beneficiaries with an SUD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults; comparison to national data
	ED visits following discharge from treatment	Aligns with NBHQF Goal 3; MN DHS constructed	Number of ED visits within 30 days of discharge from an inpatient residential treatment facility among beneficiaries with an SUD		MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults
	Hospitalizations for ambulatory care sensitive conditions (ACSC)	NQF 9999/HEDIS measure	Number of Medicaid beneficiaries with SUD who were hospitalized for an ACSC	Total number of Medicaid beneficiaries with SUD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults

This evaluation design plan reflects an evaluation of the CMS-approved Minnesota Substance Use Disorder System Reform Section 1115(a) Demonstration. This demonstration included seven goals and the preliminary evaluation questions presented above reflect specific hypothesis as they relate to the demonstration goals. Cost reduction for SUD services is not a goal of the demonstration, as an outcome of treating patients in the most appropriate setting with the most appropriate services and improving follow-

up may increase, as patients obtain necessary care.²² Costs for other services, such as emergency department (ED) visits, hospitalizations, or cost for treating co-morbidities may decline as patients are stabilized and better able to manage their physical and mental health. We we will conduct analyses (Exhibit 7) to examine whether the total cost of care for beneficiaries reduced, and what are the sources of spending for beneficiaries with SUD. Cost measures will be disaggregated by SUD and non-SUD services, and by service setting (e.g., inpatient, ED visits, non-ED outpatient, office-based, and pharmacy).

We will also calculate waiver-related administrative costs using MN DHS staff member number of hours spent on administering the SUD waiver and the waiver evaluation efforts, times the hourly wage rate. MN DHS will provide NORC with the total aggregate staff cost per year, which will be allocated over the number of beneficiaries with an SUD (only for the total cost calculation, and not the cost categories) to estimate the PBPM cost, including the demonstration costs. We will also calculate the total federal costs, calculated as the total cost excluding the administrative costs times the federal match rate.

Note that in Minnesota, (unlike some state Medicaid Management Information Systems, which do not include amounts that MCOs pay to providers), MCOs report the actual amounts paid to providers for encounters. The audit and quality control process for encounter data is described below. We can therefore use these MCO payments, adhering to our DUA, and ensuring the data will only be reported in aggregate, at the program level (FFS or MCO). Because encounter data have paid amounts, data will not be dissaregatged by FFS or MCO at the county level (in any sensitivity analyses). This is because some counties may have only one health plan.

²² The state is expected to maintain or reduce spending in comparison to what would have been spent absent the demonstration. The Monitoring Reports will document the financial performance of the demonstration, including budget neutrality, and quarterly and annual expenditures associated with the populations affected by this demonstration.

Exhibit 7. Exploratory Analysis Measures and Analytic Approach

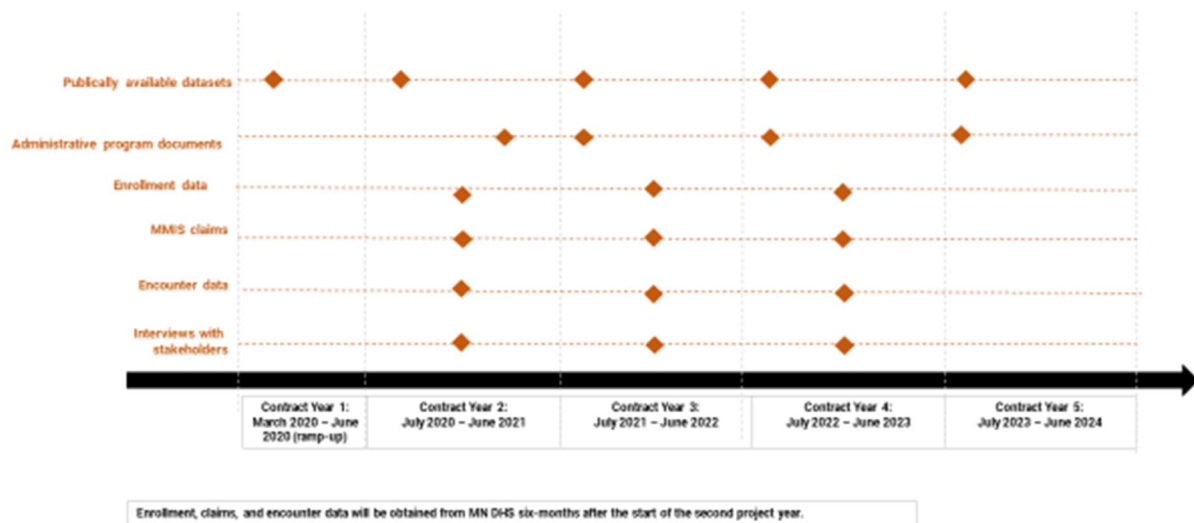
Hypothesis	Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach
The demonstration will facilitate cost-effective health care delivery by reducing avoidable costs for beneficiaries with an SUD by providing coordinate care across settings and enabling management of physical health care.	Total PMPM spending for beneficiaries with an SUD	MN DHS	Total Medicaid spending for beneficiaries who received any SUD service, including administrative costs	Total member months in the demonstration for beneficiaries with an SUD	MN MMIS and administrative data on staff hours and wages	Descriptive analysis and serial cross-sectional; subgroups of children and adults
	Total Federal cost	MN DHS	Total cost of demonstration times the federal match rate	NA	MN MMIS	Descriptive analysis and serial cross-sectional
	Spending on SUD services for beneficiaries with an SUD, by setting	MN DHS	Spending on SUD services for beneficiaries with an SUD	Total member months in the demonstration for beneficiaries with an SUD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults, by inpatient, non-ED outpatient, ED, RX, and office-based settings
	Spending on non-SUD services for beneficiaries with an SUD:	MN DHS	Spending on non-SUD services for beneficiaries with an SUD	Total member months in the demonstration for beneficiaries with an SUD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults, by inpatient, non-ED outpatient, ED, RX, and office-based settings
	Total PMPM spending for beneficiaries with SUD who received services in an IMD	MN DHS	Total Medicaid spending for beneficiaries who received SUD services in an IMD	Total member months in the demonstration among beneficiaries who received services in an IMD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults
	Spending on SUD services for beneficiaries with an SUD who received	MN DHS	Spending on SUD services for beneficiaries with an SUD who received services in an IMD	Total member months in the demonstration for beneficiaries with an SUD who received	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults, by

	services in an IMD			services in an IMD		inpatient, non-ED outpatient, ED, RX, and office-based settings
	Spending on non-SUD services for beneficiaries with an SUD who received services in an IMD	MN DHS	Spending on non-SUD services for beneficiaries with an SUD who received services in an IMD	Total member months in the demonstration for beneficiaries with an SUD who received services in an IMD	MN MMIS	Descriptive analysis and serial cross-sectional; subgroups of children and adults, disaggregated by inpatient, non-ED outpatient, ED, RX and office-based settings

Data Sources

The following section provides an overview of the various data sources that will inform this evaluation. The data will be collected and incorporated into the evaluation deliverables according to the timeline in Exhibit 8.

Exhibit 8. Data Source Timeline



1. Quantitative Data Sources. The proposed quantitative approach for the Minnesota SUD System Reform Section 1115(a) demonstration Project evaluation will utilize a variety of secondary data sources as described below.

MN DHS administrative and enrollment data. NORC will draw upon MN DHS administrative data for both the quantitative and qualitative analysis. Administrative data in the form of program documents and any available provider documentation for 1115 Waiver beneficiary data will be critical to NORC’s assessment of the availability of evidence-based SUD treatment services in the state. Additionally, NORC will use enrollment data on beneficiary program enrollment (FFS or managed care), demographic and geographic (ZIP code) measures for the quantitative analysis to stratify the population by various subgroups. NORC will perform quality checks on all enrollment data to assess reliability and completeness of enrollment data. NORC will also obtain opioid death data from the state on a regular basis. The state obtains Minnesota death certificate data from the Minnesota Department of Health Medical Examiner’s Office. The information is updated in its data warehouse on a weekly basis.

Minnesota Medicaid Management Information System (MMIS) claims and encounter data. To quantify the impact of the 1115 Waiver on measures (as specified in Exhibit 5) of health care utilization and quality, and examine total spending, the NORC team will use claims and encounter data (for FFS and managed care beneficiaries, respectively) from the MN DHS. Our evaluation plan includes for a nine-month run-off period to allow for completeness of submission and adjudication. MN DHS will provide the NORC team with claims and encounter data for all beneficiaries with an SUD diagnosis.

To ensure a high degree of validity and quality of claims and encounter data, MN DHS utilizes its federally certified Medicaid Management Information System (MMIS) to receive and process encounter claims data. The processing of receiving and processing encounters parallels that of fee-for-service claims, except includes additional validation checks. A modified set of instructions for encounter submissions are explained in the NCPDP Companion Guides, found on DHS’s public website.²³

To ensure high quality submissions, MMIS receives ongoing batch submissions from MCOs at least twice a month. By contractual obligation, the MCOs submit data directly to the state each month in a uniform manner. The contracts have encounter data reporting requirements for the MCOs to submit complete and accurate encounter data. Incentives and withhold measures are included in the contracts to help ensure complete and accurate encounter data. The MCOs are also penalized for uncorrected errors. MCOs submit each transaction file biweekly, and they are required to submit claims within 30 days of adjudication.

MN DHS Data Warehouse staff monitor loads to ensure that each one finishes without error. After each cycle, they compare the record count to the number of unique claim identifiers added to the Claim Header Table to ensure that a row is added for each claim. Staff checks various counts from one reporting period to another, looking for unusual increases or decreases. MCOs are given feedback reporting that tells them what was received and loaded and any discrepancies resolved.

²³ Please see: <https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/mcos/encounter-data/>

The Encounter Data Quality Unit (EDQU) within DHS has built extensive web based reporting for the MCOs regarding the quality, completeness and timeliness of managed care encounter claims data submitted to DHS. The EDQ continually works with the MCOs on quality improvement projects. Since 2013, the EDQ has met with the MCOs quarterly to discuss and address any problems and issues with encounter data reporting. DHS is also documenting encounter data processes and has developed quality assurance protocols for the MCOs and for DHS to follow to ensure completeness and accuracy of encounter data.

Additionally, DHS uses a control reporting process as an interactive activity with the MCOs whereby DHS compares aggregated claim counts and paid amounts derived from the raw encounter data, and compares to what the MCOs expect the aggregates to be, based on their financial reporting. Discrepancies are very closely scrutinized by way of feedback data (raw data) given to the MCOs of what resides in DHS databases. Where there exist discrepancies in the aggregated data, line by line comparisons are done of the raw data to see where there are deficiencies on either side.

A formal audit was conducted in 2020 that confirmed that data are being properly decrypted and loaded to MMIS, and accurately/completely loaded to the Teradata data warehouse.

NORC analysts will also use well-established quality control checks to assess state claims data for accuracy and perform necessary cleaning and data management. These include performing checks completeness and outliers of the data (and for the exploratory analysis on cost, the payment amount for services). NORC will also perform validation checks on the individual components of any outcome measures and analytic datasets constructed from claims data.

Non-Claims-Based Data

The NORC team will examine the utility of other publically available data that can provide characteristics on the markets and contexts of providers.²⁴ These data will help control for changes in the communities of providers over time, be used for matching cross-sections of beneficiaries over time, and will also characterize the communities' socio-demographic and health resource availability. We will use data from the American Community Survey to examine socio-demographic data (e.g., age, race/ethnicity, poverty, education, median income). The Area Health Resource Files from the Health Resources and Services Administration contain measures of the number of health care professions, health facilities, hospital utilization, hospital expenditures, and environment at the county and state levels. For example, data can be used to characterize the markets of providers at different levels of care.

2. Qualitative Data Sources. To strengthen the team's understanding of stakeholders' perspectives on implementation of the 1115 SUD Waiver and its outcomes, NORC proposes to conduct primary data

²⁴ The evaluation does not plan to include national survey data, such as SAMSHA's National Survey of Drug Use and Health, to examine population-level changes. Use of most national data is precluded because they do not allow readily available state-level results for desired indicators, such as unmet need for SUD treatment. State-level results are not accessible unless the team applies for and receives access to the data through a Restricted Data Center. This approach is not within the budget and is not critical to the evaluation.

collection through a series of in-depth interviews with beneficiaries and other key stakeholders, including consumer advocates, providers, managed care plans, and state Medicaid staff.

NORC will begin its qualitative research with a document review to inform its primary data collection. A document review will catalogue, enumerate, and synthesize descriptive details of the waiver program and its implementation by the state. NORC analysts will conduct a thorough review of waiver-related documents, such as Minnesota’s SUD System Reform Section 1115(a) Demonstration Project Waiver Request, CMS-approved Monitoring Protocols, and provider training materials, which provide comprehensive background material on the demonstration. NORC will conduct its systematic review using a standardized instrument developed in Excel and organized by domain and subdomain or category where appropriate, such as provider, treatment type, and ASAM levels of care. NORC will provide reviewers with data definitions and inclusion criteria, and the team will use this instrument to catalog abstracted information from the program documents in an Excel spreadsheet. The extracted data will be reviewed by a second analyst to ensure quality and identify potential gaps.

NORC will use the results of the document review to refine and tailor the core protocols for beneficiary, provider, managed care plan, and DHS informant interviews. The resulting protocols will include questions for each of the relevant domains and subdomains for the different groups of key informants, including waiver program details and relevant context for responses, such as SUD services provided. The interview protocols will be reviewed and revised in collaboration with MN DHS.

Qualitative data collection efforts are informed by the initial document review and will produce information on:

- Whether and how the 1115 SUD Waiver was implemented as intended, including challenges and how they were overcome
- Perceptions of gaps in provider capacity at ASAM critical levels of care and their impact on waiver implementation
- The extent to which evidence-based standards have been incorporated into patient placement criteria and whether they have affected rates of patient engagement and treatment initiation, and service utilization
- The extent to which certification requirements improve adherence to ASAM criteria among providers

Exhibit 9 summarizes the objectives of this component of the evaluation by respondent type.

Exhibit 9. Qualitative Analysis: Respondent Type and Knowledge Objectives

Respondent Type	Knowledge Objectives
Beneficiaries and consumer advocates	<ul style="list-style-type: none"> ■ Community-level resources for SUD treatment ■ Experience accessing SUD treatment services ■ Perceptions about care experience and satisfaction ■ Identify unmet service needs ■ Key barriers to accessing SUD services, including differences by demographics and geography ■ Key barriers to staying in treatment
Providers	<ul style="list-style-type: none"> ■ Knowledge of new 1115 SUD Waiver-related benefits ■ Perceptions about the extent to which SUD treatment coverage standards align with the ASAM criteria ■ Perceptions about appropriate staffing at different ASAM critical levels of care ■ Observations regarding patient’s unmet service needs ■ Perceptions of gaps in provider capacity and ways to address those gaps ■ Perceptions about patient placement criteria for clinically managed residential services and medically managed inpatient services ■ Adequacy of reimbursement rates for new SUD treatment services ■ Key challenges and facilitators of implementation, including differences for urban and rural providers ■ Perceptions of the impact of other state/federal interventions on the demonstration implementation
Managed care plans	<ul style="list-style-type: none"> ■ Perceptions about the extent to which prior authorization guidelines adhere to ASAM criteria ■ Perceptions about the extent to which SUD treatment coverage standards align with the ASAM criteria ■ Perceptions about the size/adequacy of the provider network for SUD services and variations by urban and rural geography ■ Observations regarding beneficiaries unmet service needs ■ Views about the operational challenges inherent in the implementation of the waiver ■ Key challenges and facilitators of implementation ■ Operational challenges faced and how they were overcome
DHS staff	<ul style="list-style-type: none"> ■ Key policy or administrative challenges in implementing the waiver, underlying causes, and mitigation strategies ■ Key achievements and the underlying drivers of success ■ Perceptions about support and technical assistance from CMS

Semi-structured interviews rely on common questions across interviewees, which facilitates comparisons across domains of inquiry, and also allow for flexibility as the researcher can follow up with tailored probing questions to further explore a theme or clarify a given response. NORC interviewers and analysts will use the results of the document review to refine and tailor the core protocols for key informants in the demonstration evaluation. The resulting protocols will include questions for each of the relevant domains and subdomains for the different groups of key informants, including waiver program details and relevant context for responses, such as SUD services provided. Protocols for beneficiary, provider, managed care plan, and DHS informant interviews will each contain several common and related questions that track implementation progress and document stakeholder perceptions of the demonstration’s goals and milestones. The interview protocols will be reviewed and revised in collaboration with MN DHS.

NORC will conduct 25 interviews with beneficiaries who received SUD treatment and an additional 10 key informant interviews with providers, managed care plans, and DHS staff in both the second and third contract years. Beneficiary and provider interviews will include representatives from urban and rural communities. NORC will work with DHS on a strategy to select the individuals for interviews. With regard to the selection and recruitment of beneficiaries who received SUD treatment, recruitment materials and consent information will acknowledge that this is a highly personal issue and that we are asking about a sensitive topic. All materials will emphasize that the information is confidential and that no personally identifiable information (PII) will be collected. NORC will work closely with the participating providers to ensure that the recruitment materials and interview protocols are also suitable and clearly written for beneficiaries.

NORC's Internal Review Board (IRB) has a Federalwide Assurance and is registered with the Office for Human Research Protections. It has corporate responsibility for monitoring research procedures to ensure the confidentiality of persons and establishments participating in a study. In most cases, NORC's own IRB policies are equivalent to or more rigorous than the strictest federal requirements. As part of the IRB application process, NORC will develop a procedure for de-identifying all PII from the interview information and creating a unique identifier during data collection. Additionally, NORC will consult with its IRB about any additional precautions the project team should consider given the vulnerability of the target population. For example, NORC will explore the possibility of developing an at-risk protocol that will connect individuals with supportive resources in the event someone becomes distressed during an interview.

A senior NORC team member will lead each interview, and interviews will be conducted by telephone. NORC will record, transcribe, and review each interview in order to ensure data quality prior to analysis.

Analytic Methods

The proposed data analytic approaches (Exhibit 10) are designed to provide a robust quantitative impact assessment while enabling us to examine if there are patterns across outcomes, by service setting, or by beneficiary subpopulation and to gain insights from contextual data from secondary sources. We will also incorporate data from our Provider Capacity Assessment into our mixed-methods analysis and use qualitative data from interviews with beneficiaries, providers, and other stakeholders to answer the evaluation research questions.

Exhibit 10. Evaluation Measures and Analytic Approach

Measure Type	Analytic Approach		
	Descriptive Statistics	Content Analysis	Time-Series Analysis
1. Evidence-based standards		X	
2. SUD treatment infrastructure		X	
3. Medicaid beneficiaries identified as having SUD or OUD	X		X
4. SUD and OUD services	X		X
5. Comprehensive continuum of covered SUD services and care		X	
6. Adherence to treatment plan and treatment retention	X	X	X
7. Duration of pharmacotherapy for OUD	X		X
8. Overdose mortality rate, SUD, and OUD	X		X
9. ED visits, avoidable hospitalizations, readmissions	X		X
10. Access and use of ambulatory and preventive care	X	X	X
11. Unmet need for substance use treatment		X	

Quantitative Analytic Methods

To answer research questions on the impact of the demonstration, the NORC team will conduct a quantitative analysis of Medicaid claims and administrative data. The analysis of the quantitative data sources will supplement the rich information produced by the qualitative analysis. First, we will undertake descriptive analyses overall and for each subgroup of the demonstration population. We will then use serial cross-sectional analysis (with or without baseline data where appropriate) to test hypotheses around the research questions related to program reach and impact. Where appropriate (i.e., we have baseline data) we will use propensity-scoring to ensure beneficiaries are similar on observed characteristics over time.

Descriptive Analysis

Descriptive Summary Statistics. Summary statistics, including frequencies and percentages of unadjusted beneficiary covariates and outcomes, will be reported to characterize the beneficiary characteristics. Descriptive analyses will be focused on settings of care, provider types, and beneficiary populations. Results of our descriptive analyses will be presented in tables and visuals, in the interim and final evaluation reports.

Serial Cross-Sectional Analysis. This approach uses repeated observations of outcomes over time on different cross-sections of beneficiaries. It will allow us to monitor the progress of utilization and quality measures. Serial cross-sectional (SCS) analysis can be used both where baseline data exist, and for newly expanded services, such as the number of beneficiaries receiving services in IMDs, and withdrawal management for certain provider types. Where sufficient baseline data exist, we track outcomes observed during a two-year baseline period before the demonstration implementation date, and over the period from July 1, 2020, to June 30, 2024 (excluding a ramp-up period). Average outcomes in each time period will be estimated with a multivariate model; this will allow our team to track changes in performance over the evaluation period, and will provide valuable insight when compared to the baseline period data. Results can be presented graphically and in tables in the interim and final evaluation reports. We will

estimate models using the following generalized regression equation, with the appropriate distribution model (such as linear, count, or gamma distributions):

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

Where Y_t is the outcome at time t , T represents the time elapsed since the start of the program β_0 represents the baseline (where $T=0$), X_t is a dummy variable indicating the pre-intervention period, β_2 is the level change following the intervention, and β_3 indicates the slope change following the program.²⁵

Comparisons with National Data

As mentioned above, national data, as points of comparison, often have a significant time lag or lack disaggregation by payer type. For example, the National Survey on Drug Use and Health (NSDUH) does not allow for calculation of data by payer type, and is lagged three years (the latest available are from 2018). Nonetheless, we will explore the following measures (Exhibit 11) and data sets to compare changes over time between Minnesota and national estimates.

²⁵ Bernal JL, Cummins S, Gasparrini A. (2017). Interrupted time series regression for the evaluation of public health interventions: a tutorial. *International Journal of Epidemiology*, 46(1):348-355. <https://doi.org/10.1093/ije/dyw098>

Exhibit 11. National Benchmark Data Sources and Measures

MN DHS Measure	National benchmark source and variable or measure
Time to treatment (<i>Subset to beneficiaries admitted to treatment facilities available in TEDS-A</i>)	Treatment Episode Data Set (TEDS) Admissions: <i>DAYWAIT</i> : Days waiting to enter substance use treatment
Use of peer supportive services among beneficiaries admitted to treatment (<i>Subset to beneficiaries admitted to treatment facilities available in TEDS-D</i>)	TEDS-Discharges: <i>FREQ_ATND_SELF_HELP_D</i> : Attendance at substance use self-help groups in past 30 days prior to discharge
Number of beneficiaries with OUD/SUD who died due to any drug overdose (all-drug overdose death rate)	CDC National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) Multiple Cause of Death File, as updated on the NORC Opioid misuse tool, all-drug overdose death rate.
Number of beneficiaries with OUD/SUD who died due to an opioid overdose	CDC National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) Multiple Cause of Death File, as updated on the NORC Opioid misuse tool, opioid related overdose death rate

Beneficiary-Level Entropy Balancing

In order to ensure that beneficiaries we examine in the baseline and demonstration period are not systematically different, we will use entropy balancing (EB), an optimization technique that balances the pre-demonstration and Demonstration periods based on a given set of covariates.²⁶ Similar to more traditional propensity score methods, in EB the observations in the demonstration period all have weights equal to one, and the baseline observations are weighted relative to the treatment observations on a set of identified covariates. This ensures that, when weights are applied in an analysis, both groups will be similar in regards to the identified covariates. However, EB has a number of advantages over traditional propensity methods, including:

- The ability to balance covariates not only on mean, but also on variance and skewness, which leads to better balance across the entire distribution than is typically achieved by propensity methods
- The optimization algorithm renders obsolete the time-consuming system of iteratively selecting balance covariates and manually checking balance for variables of interest
- Flexibility of the EB weights to be operationalized like any other weight in a regression model or other analysis

²⁶ Hainmueller J. (2012). Entropy balancing for causal effects: a multivariate reweighting method to produce balanced samples in observational studies. *Political Analysis*, 20:25-46.

- No observations will be discarded in the estimation of EB weights, so the entire analytic population can be retained for the weighted analysis

While EB is a relatively novel method, it has previously been used in at least one other CMS evaluation in the context of an observational cohort.^{27,28} We compute beneficiary-level EB weights using the ebalance package in Stata.²⁹ In order to account for year-level trends and/or exogenous factors within the analytic population, we will run the EB model separately in each year. The EB model includes the demographic (e.g., age, sex, race/ethnicity), enrollment (e.g., months of eligibility), health status (e.g., behavioral health condition and other chronic conditions), and community characteristics (e.g., median income). We would then assess the *balance*, or test for significant differences between the groups before and after applying EB weights, on sociodemographic and health status covariates. Standardized differences between -0.1, 0.1 are considered to indicate an acceptable balance between the two groups. We would then incorporate the final EB weights into regression models.

Subgroup Analyses

Individual responses to the demonstration may differ from the average treatment effect for a variety of reasons; therefore, it is important to examine whether or not the effect of a program varies across beneficiary subgroups.³⁰ Sample size permitting, we will work with MN DHS to identify the potential subpopulations of interest, based on the results of our descriptive analyses. These may include variation in impacts by geographic region, (e.g., rural, urban), demographics (e.g., race/ethnicity), and health status (e.g., specific SUD, OUD, and persons with co-morbid mental and behavioral health illness).

Sensitivity Analysis

To test the impact of the demonstration, we will implement the SCS approach using quarterly data (with exceptions for mortality and DAANES measures), and we hypothesize that effects should become larger in the latter half of the demonstration, as implementation is fully actualized. However, to gain more certainty on impact and variation in impact, we propose three additional sensitivity analyses:

- 1) Variation in the attribution to providers: we can look for “dose” effect and examine how impacts may vary by the proportion of care, as measured by spending on mental health and substance use treatment, received from participating providers. Beneficiaries who receive more care from participating providers would be expected to have better outcomes. Similarly, we can examine how care outcomes vary by the proportion of care received from non-participating providers.
- 2) Where possible, we will examine how the average trend varies by the number of quarters included in the baseline.

²⁷ Parish WJ, Keyes V, Beadles C, Kandilov A. (2018). Using entropy balancing to strengthen an observational cohort study design: lessons learned from an evaluation of a complex multi-state federal demonstration. *Health Services and Outcomes Research Methodology*, 18:17-46.

²⁸ Centers for Medicare & Medicaid Services. (2017). *Evaluation of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration: Final Report*. <https://downloads.cms.gov/files/cmmt/mapcp-finalevalrpt.pdf>

²⁹ Hainmueller J, Yiqing X. (2013). *Ebalance: a stata package for entropy balancing*. *Journal of Statistical Software*, 54(7).

³⁰ Kravitz RL, Duan N, Braslow J. (2004). Evidence-based medicine, heterogeneity of treatment effects, and the trouble with averages. *Milbank Quarterly*, 82(4):661-687. Erratum in: *Milbank Quarterly*, 2006, 84(4):759-760.

- 3) The evaluation team will also work with the state to examine geographic regions where the implementation of training on ASAM criteria and provider participation was staggered. We can examine how impacts vary in relation to the time of adoption of ASAM criteria and IMD provider participation. We hypothesize impacts will be found where ASAM training was first conducted and among the early entrants of providers into the demonstration.

Sample Size and Power Calculations

NORC will assess the effect size or minimum detectable effect (MDE) as part of the power analysis for each outcome variable. MDE is the smallest true effect in the average outcome between baseline and demonstration groups that we will be able to detect in our proposed study designs. For claims-based analyses of performance outcomes, sample size and power considerations depend on our evaluation study designs.

Effect Size for SCS Analysis. For m members clustered within k groups (baseline and demonstration groups), the total sample size for the serial cross-sectional design for a continuous outcome variable of interest, n^* , is given by:

$$n^* = m^*k^* = \left(t_{\frac{\alpha}{2}} + t_{\beta}\right)^2 2 \frac{\sigma^2}{\delta^2} (1 + (m - 1)\rho)$$

Where, α is the probability of committing a type 1 error, and $1 - \beta$ is the power, σ^2 is the variance of the outcome, δ is the MDE, $(1 + (m - 1)\rho)$ is the variance inflation factor, and ρ is the intraclass correlation.

Qualitative Analytic Methods

The qualitative analysis will characterize the implementation experiences and perspectives of beneficiaries receiving SUD treatment services, the providers delivering care, and administrators of covered services at managed care plans and MN DHS. The evaluation will employ a theme-based approach to analyzing qualitative data, guided by the document review and core research questions around access, capacity, implementation experience, challenges, and effectiveness. As indicated in the analytic objectives in Exhibit 6, these data will be used to explore and confirm the results of the quantitative analysis, providing insight into changes in provider practice, access to treatment, including in IMDs, and the impact of the focus on the ASAM criteria.

To organize program documents and interview transcripts, NORC will utilize NVivo software (QSR International Pty Ltd., Melbourne, Australia). The approach to coding will include the following steps:

- Develop and define analytic categories based on research questions and the domains of focus
- Operationalize the research questions into a codebook, which provides clear and concise guidelines for categorizing all qualitative data collected
- Refine the codebook as needed to ensure strong inter-coder reliability and accuracy of applying codes

Senior analysts will create an initial list of analytic categories based on the research questions and document review and then draft a codebook to guide the coding of interview data. The codebook will

specify definitions and inclusion/exclusion criteria for each code where appropriate, an example of how the code is applied, and source. Coding is an iterative process, and we anticipate additional categories and codes will arise out of the initial key informant interviews, and we will update the codebook in real-time.

Following best practices in qualitative research data analysis, the qualitative team will meet frequently to review codes and definitions. Evaluation team members will regularly review and code data to enhance the analysis and concordance of the results.

Methodological Limitations

We are aware and attentive to factors that may impact the evaluability of the demonstration, and will take a number of steps (Exhibit 12) to identify and mitigate these concerns. As described above, concerns around data validity and consistency across managed care plans are mitigated through allowing for a nine-month run-off period and extensive quality control process within MN DHS. We exclude a nine-month “ramp-up” period to be able to better detect impacts from the demonstration. We also acknowledge the difficulty in capturing independent effects of the demonstration, given the many other ongoing initiatives to improve the quality of SUD treatment, including OUD, across the care continuum.³¹ For example, Minnesota is supporting the expansion of MAT access through grant-funded initiatives, which include the use of Project ECHO to engage a range of provider environments and professionals. Through this process, Minnesota is working to expand access to MAT and improve the quality of services across the state. Disentangling the effects of the waiver on SUD and OUD outcomes in the context of other policy initiatives will be a challenge. We will document and describe other state policy changes that may affect care for Medicaid beneficiaries and occur during the demonstration period. In addition, not all services may be observed in claims: beneficiaries may pay out of pocket for services, which would be unobserved in our analyses.

We will also address how other secular changes affect evaluation outcomes through a mix of qualitative and quantitative strategies, including tailoring our open-ended interview questions to focus on program-specific activities and initiatives; for example, we use measures and assess outcomes where the demonstration may have the most impact, such as on the well-being of persons receiving SUD treatment in an IMD.

It may be possible to identify specific groups (e.g., geographic areas, groups of providers) that are targeted or involved in other initiatives and incorporate that information into adjusted regression models as a covariate, where possible. It may also be possible to identify and adjust regression models to account for beneficiaries who have a higher likelihood of receiving services under other programs. This would allow us to examine how beneficiary outcomes vary in catchment areas where there are other MN DHS SUD programs or grants being implemented. For example, we would work with MN DHS to define ZIP codes where other programs exist and test for any moderating effects. Exhibit 12 notes several additional challenges and proposed solutions that are specific to this evaluation.

³¹ A synthesis of these initiatives is provided in the *Minnesota Substance Use Disorder Section 1115 Waiver Implementation Plan* submitted to the Centers for Medicare & Medicaid Services on September 27, 2019.

Exhibit 12. Key Challenges and Proposed Solutions

Challenges	Proposed Solutions
In the ITT design, beneficiaries may get care from providers not in the demonstration	For sensitivity analyses descriptively assess the “spillover” of care from the providers in the demonstration, and examine outcomes at the highest and lowest quartiles of spillover
Heterogeneity in impacts across subgroups not captured in focus on overall impacts	Perform subgroup analysis to compare impacts on outcomes Include fixed effects and/or interaction terms in regression models Draw insights from qualitative and mixed-methods findings to contextualize findings and determine appropriate subgroups where relevant
May be difficult to isolate the effects of the demonstration in the context of other reform initiatives	Assess the impact of the demonstration within the context of other state/federal interventions through qualitative data collection and possibly how impacts vary in different geographic areas affected by other MN DHS SUD program efforts
Sample size concerns for subgroup analyses	Investigate subgroup sample sizes prior to conducting the statistical analysis, and conduct power analyses as needed. Multivariate statistical analysis might be unable to perform on inadequately sized subgroups; in these cases, we will try to integrate qualitative data on the effect of the demonstration on different subgroups.
Qualitative data collection through semi-structured interviews may experience selection bias such as when conducting outreach to patients suffering severe disease	Identify diverse representatives across the populations of interest, beneficiaries, providers, as well as managed care plans and DHS staff. A participant screening tool to help us understand potential bias during recruitment. We will use this information to conduct targeted participant recruitment during data collection.
Semi-structured interview participants from managed care plans or providers may experience barriers to participation	NORC will work to create flexible scheduling options and limit the length of interviews to be conducive to greatest participation.

Attachment 1. Independent Evaluator

Independent Evaluator Selection Process

Procurement for an evaluation contractor to assist the State in executing its demonstration evaluation plan was pursuant to the State of Minnesota procurement guidelines. Minnesota Department of Human Services (MN DHS) Behavioral Health Division has contracted with NORC at the University of Chicago (NORC) to evaluate their demonstration for the next four years. NORC was selected based on a proposal submission in response to a request for proposal. The State retains responsibility for monitoring the SUD delivery system, mid-point assessment of the program's effectiveness and overall demonstration performance. To mitigate any potential conflict of interest, NORC is responsible for:

- Secondary analysis of data collected for monitoring purposes;
- Benchmarking performance to national standards;
- Evaluating changes over time;
- Interpreting results; and
- Producing evaluation reports.

As part of this evaluation, NORC is responsible for final measure selection, conducting all data analysis, measuring change overtime and developing sensitivity models as necessary to address study questions.

Since its founding in 1941, NORC has become a pivotal organization for national and global exploration and reflection. Working closely with our partners and clients, NORC has shaped the questions, gathered and analyzed the data, and derived the insights that have allowed governments, nonprofit organizations, businesses, and citizens around the world to make more informed public and personal decisions about issues ranging from health care and education to economic development and the workforce. In the process, NORC has also been one of the leading innovators in research methodology and the adoption of new technologies that have helped shape the field of modern research and set the standard for rigorous, culturally sensitive, transparent, and unbiased inquiry into the most pressing issues facing society.

Team Member Experience

The NORC team evaluating the demonstration includes individuals with subject matter expertise in program evaluation, SUD programs, statewide health care programs, and Medicaid programs, along with extensive experience in program evaluation and project management. Scott Leitz, senior fellow at NORC, leads the NORC team. Leitz has first-hand knowledge of state-level Medicaid operations and strategy, including as the former assistant commissioner of MN DHS with oversight of the Medicaid program; he understands the context in which MN DHS operates and will be an informed partner in creating a feasible

evaluation strategy for MN DHS. At NORC, Leitz co-leads an evaluation of Rhode Island’s 1115 Waiver Demonstration and directs NORC’s technical assistance teams supporting the Medicaid Innovation Accelerator Program and State Innovation Model Initiative.

Kathleen Rowan, PhD, MPH, leads the quantitative analyses. Dr. Rowan has extensive experience performing mixed-methods evaluations, overseeing analytic tasks involving claims and survey data, and preparing reports for various audiences. Susan Cahn, DrPH, MA, MHS, who has led numerous large qualitative studies for Centers for Medicare & Medicaid Services (CMS) and other agencies, will lead qualitative data collection and analysis.

Exhibit 10 profiles each of the team members, their expertise, and their roles on the project.

Exhibit 10. NORC Team Member Experience and Anticipated Contributions

Key Personnel
Scott Leitz, MA, Senior Fellow, Project Director (Estimated time: 475 hours*)
<ul style="list-style-type: none"> ■ Provides expert leadership for the NORC health care department, with emphasis on state health care policy ■ Serves as project director for NORC contracts to support the CMS State Innovation Model initiative and Medicaid Innovation Accelerator Program, Value-Based Payment and Financial Simulation ■ Previous roles include assistant commissioner at the MN DHS responsible for overseeing and managing the state's Medicaid program; director of public policy for Children's Hospitals and Clinics of Minnesota, and several positions at the Minnesota Department of Health. One portfolio responsibility was Minnesota's Office of Rural Health and Primary Care, focused on ensuring access to care and services in rural and underserved areas of the state
Mollie Hertel, MPP, AM, Senior Research Scientist, Project Manager (Estimated time: 1140 hours*)
<ul style="list-style-type: none"> ■ Has extensive experience in project management, including designing and executing large qualitative and quantitative research studies ■ Currently manages a multistate qualitative research project for the Medicare Payment Advisory Commission (MedPAC), involving focus groups and interviews ■ Previously worked at the U.S. Government Accountability Office, managing several projects specific to Medicaid payments and beneficiary access ■ Led a mixed-methods evaluation of Mercy Maricopa Integrated Care for Aetna, an integrated physical and behavioral health Medicaid managed care plan, which included developing multiple respondent protocols, conducting interviews with plan officials and social service organizations, and analyzing results into a final report
Kathleen Rowan, PhD, MPH, Senior Research Scientist, Quantitative Lead (Estimated time: 900 hours*)
<ul style="list-style-type: none"> ■ Serves as project director for the Health Resources and Services Administration’s Behavioral Health Workforce Substance Use Disorder Evaluation, including implementation of five surveys across 18,000 health centers, 300 grantees, and 15,000 participants ■ Serves as quantitative team lead for the CMS evaluation of the Next Generation Accountable Care Organization (NGACO) Model, including the development of analytic strategies, analysis of claims and survey data, mixed-methods analysis; prepares findings for various audiences ■ Provides technical assistance to CMS for review of state evaluation plans for Section 1115 Waiver Demonstrations ■ Conducted quantitative analyses the CMS Innovation Centers’ Health Care Innovation Awards, the Beacon Community Cooperative Agreement Program Evaluation for the Office of the National Coordinator for Health Information Technology, and numerous survey projects
Jennifer Smith, PhD, MPH, Senior Data Scientist, Quantitative Data Support (Estimated time: 92 hours*)
<ul style="list-style-type: none"> ■ Develops quality assurance protocols to ensure accurate programming and reporting of data ■ Past roles include using Medicare, Medicaid, hospital discharge data, Maryland All-Payer Claims Database, and social determinant datasets to assess quality, cost, and utilization patterns within a Medicaid/Exchange churn population ■ Holds experience in developing programming to evaluate mental health, substance abuse, continuous care, shadow pricing encounter data, and dual-eligible populations within claims data
Susan Cahn, DrPH, MA, MHS, Senior Research Scientist, Qualitative Lead (Estimated time: 780 hours*)

Key Personnel

- Designed and conducted qualitative primary data collection and convened a community of practice with 31 hospitals and 10 public health and community organizations
- As a senior member of the NGACO qualitative evaluation team, leads efforts in designing questionnaires, conducting interviews, and analyzing interview data, and provides technical assistance to states through the Medicaid Innovation Accelerator Program
- Leads several activities for CMS’s Office of Minority Health, including claims analyses and the analysis of quantitative and qualitative data on Medicare Advantage health plans for the development of an engagement strategy

Lauren Isaacs, MPH, MSW, Principal Research Analyst, Qualitative Analyst (Estimated time: 720 hours*)

- Roles include the delivery of health equity technical assistance to external stakeholders; developing interview guides, recruiting participants, and conducting key informant interviews about diabetes with providers and other health care professionals; conducting an environmental scan and literature reviews
- Works on two ongoing multistate qualitative research projects for MedPAC, involving key informant interviews and focus groups with providers, beneficiaries, health plans, state Medicaid agencies, beneficiary advocates, and other health care organizations

*Over 55-month contract period

Attachment 2. Evaluation Budget

Outlined below in Exhibit A.1 is the independent evaluation budget, broken down by evaluation activity.

Exhibit A.1. Independent Evaluation Budget

Activity	Total Estimated Cost					Total
	Year 1	Year 2	Year 3	Year 4	Year 5	
Project Management¹						
Staff	\$10,424.99	\$7,851.32	\$4,074.64	\$3,945.58	\$3,872.25	\$30,168.77
Administrative and Other Costs	\$9,575.01	\$8,148.68	\$6,925.36	\$7,054.42	\$7,127.75	\$38,831.23
Subtotal	\$20,000.00	\$16,000.00	\$11,000.00	\$11,000.00	\$11,000.00	\$69,000.00
Evaluation Design Plan						
Staff	\$47,693.52					\$47,693.52
Administrative and Other Costs	\$47,306.48					\$47,306.48
Subtotal	\$95,000.00					\$95,000.00
Provider Assessment						
Staff	\$27,440.46	\$1,813.10	\$1,901.19	\$1,977.24	\$1,961.93	\$35,093.92
Administrative and Other Costs	\$27,559.54	\$2,186.90	\$2,098.81	\$2,022.76	\$2,038.07	\$35,906.08
Subtotal	\$55,000.00	\$4,000.00	\$4,000.00	\$4,000.00	\$4,000.00	\$71,000.00
Qualitative Data Collection and Analysis						
Staff	\$5,026.49	\$36,964.43	\$23,946.17	\$17,776.42	\$13,222.89	\$96,936.41
Administrative and Other Costs	\$4,973.51	\$38,035.57	\$26,053.83	\$17,223.58	\$11,777.11	\$98,063.59
Subtotal	\$10,000.00	\$75,000.00	\$50,000.00	\$35,000.00	\$25,000.00	\$195,000.00
Quantitative Data Collection and Analysis						

Activity	Total Estimated Cost					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Staff	\$5,019.96	\$48,189.85	\$38,045.91	\$31,336.86	\$25,862.54	\$148,455.13
Administrative and Other Costs	\$4,980.04	\$46,810.15	\$36,954.09	\$28,663.14	\$24,137.46	\$141,544.87
Subtotal	\$10,000.00	\$95,000.00	\$75,000.00	\$60,000.00	\$50,000.00	\$290,000.00
Reporting²						
Staff	\$30,486.70	\$30,724.44	\$30,839.45	\$45,597.41	\$55,454.77	\$193,102.77
Administrative and Other Costs	\$29,513.30	\$29,275.56	\$29,160.55	\$44,402.59	\$54,545.23	\$186,897.23
Subtotal	\$60,000.00	\$60,000.00	\$60,000.00	\$90,000.00	\$110,000.00	\$380,000.00
Total	\$250,000.00	\$250,000.00	\$200,000.00	\$200,000.00	\$200,000.00	\$1,100,000.00

¹Includes regular meetings, status updates, and any ad hoc meetings.

²Includes required CMS quarterly, annual, interim, and final evaluation report.

Attachment 3. Timeline and Major Milestones

The demonstration evaluation requires several deliverables to CMS to comply with the special terms and conditions (STC) associated with the expenditure authorities. These include an evaluation design plan, midpoint assessment, quarterly and annual updates, and interim and final evaluation reports. The MN DHS seeks support in generating these deliverables. In addition, MN DHS requires an assessment of provider capacity to achieve Milestone 4 and monthly reports on evaluation progress. Exhibit A.2 presents an overview of each of these reports, including key dates and proposed content and format for each.

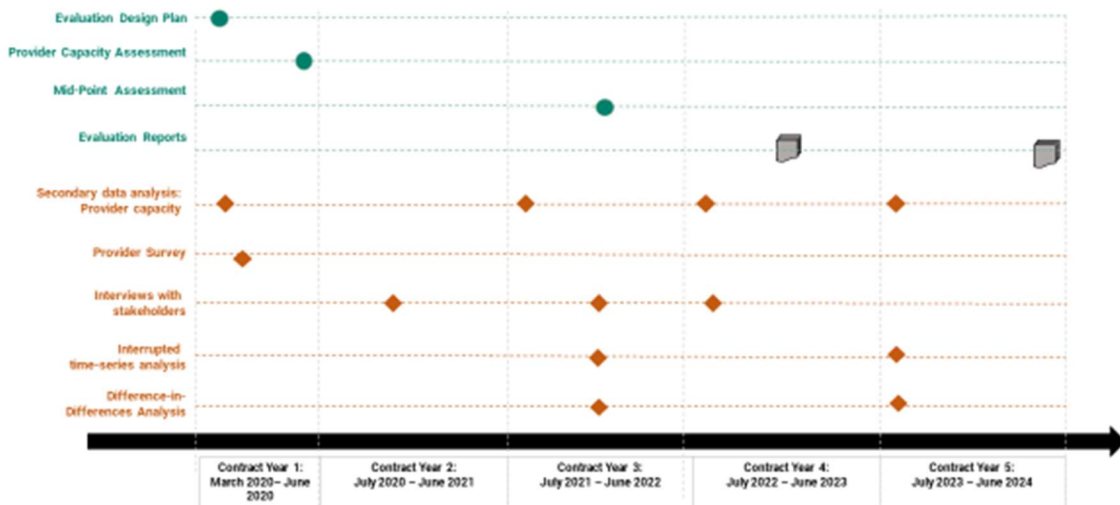
Exhibit A.2. Overview of Reports: Schedule and Overview

Key Dates	Proposed Content and Format
Evaluation Design Plan	
Draft to CMS: April 1, 2020 Revised draft: < 45 days of CMS response	<ul style="list-style-type: none"> ■ A roadmap for the methodological approaches and analytical steps to address each research question driving the demonstration evaluation ■ Informed by CMS' Design Plan Template ■ Planned approaches to address each evaluation question and hypothesis ■ Qualitative and quantitative methodologies ■ Measures, including measure specifications and data sources ■ Baseline and comparison groups ■ Operational details for secondary data acquisition and primary data collection
Provider Capacity Assessment (Milestone 4)	
Initial assessment: July 1, 2020 Update throughout demonstration period	<ul style="list-style-type: none"> ■ Supports state in completing Milestone 4 ■ Determines availability of treatment for Medicaid beneficiaries in each level of care, including MAT and medically supervised withdrawal ■ Identifies gaps in the availability of services
SUD Midpoint Assessment	
MN to submit to CMS: December 31, 2021	<ul style="list-style-type: none"> ■ Independent assessment to examine progress and assess risk in not achieving milestones in SUD Implementation Plan or meeting performance targets in SUD Monitoring Protocol

Key Dates	Proposed Content and Format
Interim Evaluation Report	
MN to submit to CMS: June 30, 2023	<ul style="list-style-type: none">■ Updates on implementation experience and evaluation findings to date associated with as many of the research questions in approved Evaluation Design as data permits■ Most comply with Attachment B of STC

Key Dates	Proposed Content and Format
Final Evaluation Report	
MN to submit to CMS: December 30, 2025	<ul style="list-style-type: none"> ■ Summative report of evaluation findings as described in the approved Evaluation Design ■ Qualitative and quantitative findings on: <ul style="list-style-type: none"> ● Rates of identification, initiation, and engagement in treatment ● Adherence to and retention in treatment ● Overdose deaths, particularly those due to opioids ● Utilization of emergency department and inpatient hospital setting for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services ● Readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate ● Access to care for physical health conditions among members ● Must comply with Attachment B of STC
Information for Federal Reporting	
Quarterly and annually	<ul style="list-style-type: none"> ■ Updates for MN DHS to include in reports to CMS ■ Progress on evaluation activities ■ Key milestones accomplished ■ Interim findings, as available ■ Challenges encountered and how they were addressed

Exhibit A.3. Timeline of Analytic Activities and Deliverables



Attachment 4. American Society for Addiction Medicine Continuum of Care

The adoption of the American Society for Addiction Medicine (ASAM) model will provide a framework for Minnesota’s SUD continuum of care. Beginning in the early 1990s, the ASAM developed, validated, and refined a six-dimension model to assess the level and intensity of treatment needed for a given individual at a specific moment in time.³² These dimensions include: 1) acute intoxication and potential for withdrawal, 2) biomedical conditions, complications, and past history, 3) emotional, behavioral, and cognitive conditions, 4) readiness to change, 5) relapse, continued use, or continued problems, and 6) recovery and living environment.

Based on measures within each of these dimensions and in combination, applying the ASAM criteria results in a clinical recommendation for treatment services ranging from early intervention (at the low end of the scale) to medically managed intensive inpatient services (at the high end). ASAM has scored this continuum of care based on the relative level of resource intensity of the services ranging from 0 for no services, 0.5 for early intervention, 2.0 for intensive outpatient service, 3.0 for residential/inpatient services, and 4.0 for medically managed intensive inpatient services.^{33, 34, 35} Exhibit A.4 presents the ASAM Continuum of Care.

In practice, clinicians may not be able to make referrals to all levels, if some are not locally available or not covered by insurance. For example, in private insurance, residential treatment services are not always covered and generally require prior authorization.³⁶ Research shows that patients who are routed to levels of care not suited to their needs, or patients who are denied services because of shortages in providers or lack of reimbursement, are likely to suffer poor outcomes and may consume more resources in the form of repeated emergency admissions for detoxification and patient stabilization. Improper, ineffective, or lack of adequate services contributes to the so-called “revolving door” of detox admissions.

³² American Society of Addiction Medicine. (2017). The ASAM Criteria. http://asamcontinuum.org/wp-content/uploads/2017/05/The-ASAM-Criteria_2017_pg1n2_PRINT_FINAL_v9_small.pdf

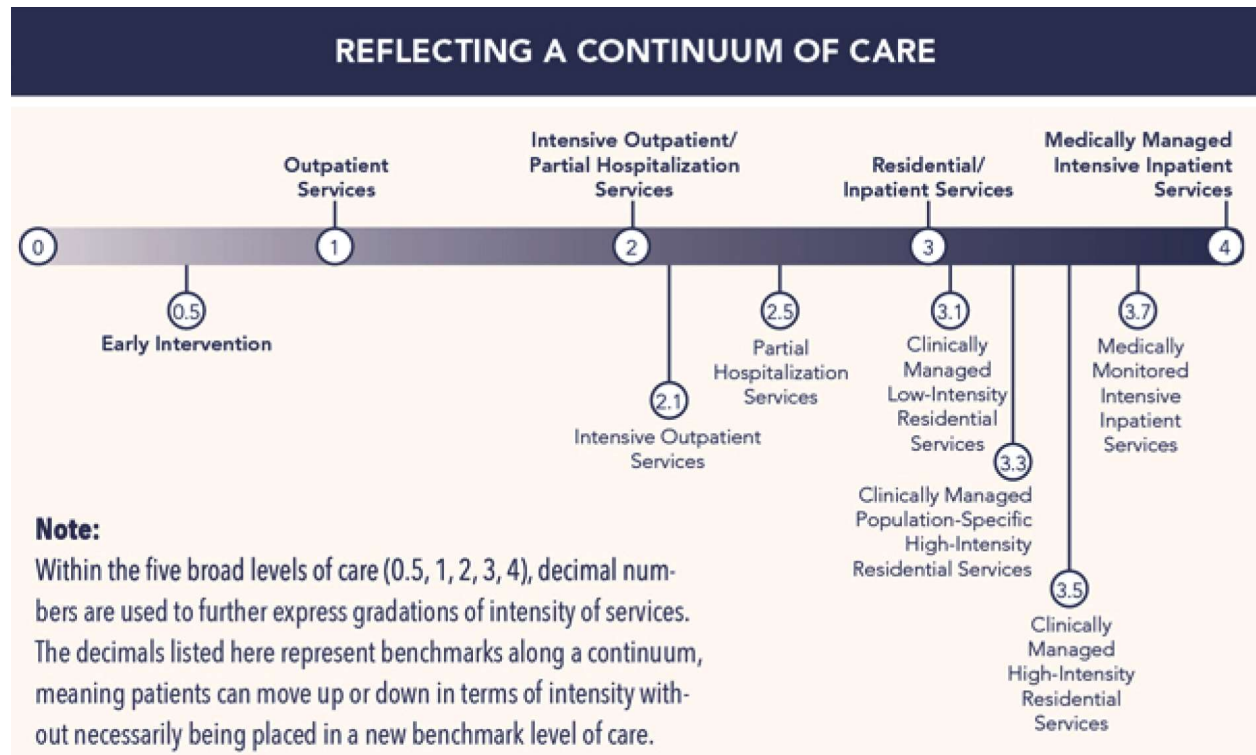
³³ Ibid.

³⁴ Ibid.

³⁵ Ibid.

³⁶ Horgan CM, Stewart MT, Reif S, Garnick DW, Hodgkin D, Merrick EL, et al. (2016). Behavioral health services in the changing landscape of private health plans. *Psychiatric Services*, 67(6):622-629; Quinn AE, Reif S, Merrick EL, Horgan CM, Garnick DW, Stewart MT. (2017). How do private health plans manage specialty behavioral health treatment entry and continuing care? *Psychiatric Services*, 68(9):931-937. <https://doi.org/10.1176/appi.ps.201600081>

Exhibit A.4. ASAM Continuum of Care



Source: <https://www.asam.org/resources/the-asam-criteria/about>

Attachment 5. Provider Capacity Assessment

As specified in the STC agreement with CMS, MN DHS will implement a plan to ensure sufficient provider capacity at each level of care, including MAT for OUD. The baseline of this assessment will provide data on the availability of health care professionals across the state and the ratio of providers per Medicaid beneficiary. This would include not only providers currently serving Medicaid beneficiaries but all providers.

Then, immediately after the effective date of the contract with MN DHS, NORC and MN DHS will work with the Health Workforce Planning and Analysis Unit, housed within the Minnesota Office of Rural Health and Primary Care at the Minnesota Department of Health. These divisions collect and analyze Minnesota-specific data on nearly 20 different licensed health care professions. They provide data and analyses to legislators, reporters, workforce planners, researchers, and others, for a variety of purposes, including data about health care professions by county. The Health Workforce Planning and Analysis Unit develops reports and presentations on individual professions and a wide range of health care specialties, including mental health.

In coordination with these units, NORC will update the baseline by assessing the availability of providers in the key levels of care throughout the state, including those that offer MAT.

An effective provider capacity assessment (PCA) will help MN DHS understand the gaps in SUD treatment capacity and allocate resources effectively. We will work with MN DHS to assess the availability of providers enrolled in Medicaid and accepting new patients, and to assess the overall health workforce capacity to provide each of the ASAM critical levels of care. We will use a mixed-methods approach, using primary and secondary data, to ensure MN DHS has in-depth information on SUD health workforce availability and skill-mix across settings, as well as community resources to support treatment.

This assessment will determine the availability of treatment for Medicaid beneficiaries in each of these levels of care, as well as the availability of MAT and medically supervised withdrawal management, throughout the state, including tribal organizations and Indian Health Service facilities. We will draw on the methodologies and findings recently documented in ASPE's *Needs Assessment Methodologies in Determining Treatment Capacity for Substance Use Disorders*,³⁷ and use both primary and secondary sources. Four key components of the best practices articulated in ASPE's guidelines are shown in the left column of **Exhibit A.5**, with NORC's approach in the right column.

The baseline needs assessment will use secondary data—state provider data and Medicaid enrollment data—to create a provider-to-beneficiary ratio. The midpoint assessment may include a provider survey, along with Options 2 and 3.

³⁷ Assistant Secretary for Planning and Evaluation. (2019). *Needs Assessment Methodologies in Determining Treatment Capacity for Substance Use Disorders: Final Report*. <https://aspe.hhs.gov/system/files/pdf/262436/SUDNetCap.pdf>

Exhibit A.5. Proposed Approach to Provider Capacity Assessment

Component	Approach
1. Baseline measurement of the current condition	<ul style="list-style-type: none"> ■ NORC will collect data on personnel and facility-level “inputs” available across the state and across the range of personnel skills, from peer recovery specialists (as billing codes for peer specialists become available) to providers with DATA 2000 waivers for MAT. ■ Assessment will specifically capture the minimum required by CMS for Milestone #4 on the availability of providers enrolled in Medicaid and accepting new patients at the critical levels of care throughout the state (or at least in participating regions of the state), including those that offer MAT.
2. Specification of optimal mix of resources required for each level of care, according to the ASAM criteria	<ul style="list-style-type: none"> ■ NORC will help the MN DHS define optimal staffing in a collaborative manner to ensure stakeholders have input.
3. Recommendations for actions	<ul style="list-style-type: none"> ■ NORC will develop recommendations for the MN DHS to address gaps, prioritized collaboratively through stakeholder input.

For the baseline assessment, we will use existing administrative and claims data to develop a comprehensive understanding of the Minnesota SUD workforce capacity, particularly the current and near-term ability to serve Medicaid patients. The midpoint assessment may include a survey of providers.

The secondary data available from MN DHS includes data on active outpatient SUD treatment providers serving publically funded SUD clients, residential beds, and opioid treatment centers, and Medicaid enrollment data. Using these data, we will create a provider-to-beneficiary ratio. We may also use Medicaid claims data to assess the volume of services for each provider. However, these data will be lagged, and reflect services used, rather than the service capacity for potential Medicaid beneficiaries, or the population that could experience a need for care. These data will also not indicate if the provider is accepting new patients.

We will also assess the feasibility of using data from the Drug Enforcement Administration registration database to obtain data on practitioners with DATA 2000 Waivers (who can provide MAT) and data from the National Survey of Substance Abuse Treatment Services (N-SSATS). The N-SSATS contain data on facilities’ types of treatment available, facility operation and type, special groups served, payment options, counts of clients served, and licensure, as well as counts of facilities that provide MAT and the number of MAT clients. While this survey will be helpful about facility inputs, N-SSATS does not cover private practices, care that occurs within primary care, and it does not capture staff-mix at facilities or health workforce personnel, nor does it capture unmet treatment needs.

Finally, in discussion with MN DHS, we can build on the initial assessment to understand the socioeconomic characteristics of communities and how these characteristics vary according to provider capacity and beneficiary need, as well as the overall prevalence of SUD and SUD treatment. Data sources for this may include the American Community Survey and other county-level data. We will also discuss with MN DHS the utility of GIS mapping analysis to understand geographic distribution of clinicians by facility type, community socioeconomic characteristics, urban/rural locations, and SUD prevalence as well as distances between beneficiaries and providers, in terms of driving time or public transportation time. We will link these secondary data using ZIP code information on providers and SUD service users.

After the initial baseline, we will discuss with MN DHS the utility and feasibility of primary data collection at the midpoint in the demonstration, via a web-based survey emailed to providers, to improve the accuracy of the secondary data and understand gaps in service delivery. This would update, complement, and strengthen the baseline data by providing the most specific and timely information on the behavioral health workforce. We would work with MN DHS to construct the survey questionnaire, which would include a comprehensive list of the types of personnel necessary to deliver the specific types of services, and ask each provider to report the health care workforce personnel, hours worked each week, and average wait times to see different types of providers at their practice or facility. We anticipate the questionnaire would take no more than 10 minutes to complete. Details of the outreach strategy and follow-up plan will be subject to resources, and developed in collaboration with MN DHS. For example, in addition to email outreach and follow-up, we could use text message reminders and work with MN DHS to develop materials about the survey for posting on the MN DHS website (such as a fact sheet and frequently asked questions).

Provider Capacity Assessment Research Questions and Measures

The goals of the PCA are to determine the availability of providers throughout the state who are enrolled in Medicaid, their capacity to deliver each level of ASAM services, and their ability to accept new patients. **Exhibit A.6** shows the goals, research questions, measures, and data sources used in the PCA. The PCA will help support informed decisions around the implementation of activities to meet each of the eight waiver goals (described in Part 2). It will also ensure MN DHS meets the Milestone 1 requirement of the waiver.

Exhibit A.6. Preliminary Research Questions Measures and Sources for the Provider Capacity Assessment

Assessment Question	Measures	Sources
Goal 1: Determine availability of Medicaid-enrolled providers who have delivered treatment for Medicaid beneficiaries in each of ASAM critical levels of care, as well as the availability of MAT and medically supervised withdrawal management, throughout the state		
Hypotheses: The PCA will help ensure sufficient provider capacity at each level of ASAM care for SUD, including OUD		
<p>1. For each level of ASAM care, what are the number of providers in the state accepting new Medicaid patients?</p> <p>2. What proportion of beneficiaries are more than 30 miles from services, for each level of ASAM care?</p> <p>3. What are the average wait times for beneficiaries, for each subgroup, and for each level of ASAM care?</p>	<ul style="list-style-type: none"> ■ Number of providers with active enrollment who have provided behavioral health care in the last 12 months, per beneficiary by ASAM level of care, by county and subgroup ■ Number of providers with active enrollment who have provided SUD services per SUD beneficiary, by ASAM level of care, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup ■ Number of providers with a DATA-2000 waiver (certified to prescribe or dispense buprenorphine) who have dispensed BUP in the last 12 months, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup ■ Number of beneficiaries at each level of ASAM care who are more than 30 miles from the nearest available provider, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup ■ Average wait times for each service at each level of ASAM care, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup 	TBD

The assessment will estimate provider-to-beneficiary ratios, including ratios for specific subgroups of interest. First, we analyze available claims and provider data to develop provider-focused measures that considered how frequently providers were delivering care to Medicaid beneficiaries and the number of beneficiaries they saw. After the baseline, we can then explore beneficiary-focused measures that examine *the number of providers* a beneficiary saw and the volume of care they received from those types of providers. In examining both sets of measures, we looked for evidence of gaps in provider network adequacy.

Other statistics on provider capacity can be targeted for the midpoint assessment and indefinitely forward. For example, MN DHS may want to examine the average number of encounters per provider to understand range, and examine providers that are either high or low outliers in the number of beneficiaries served, or encounter volume. Studying high-volume providers can help MN DHS understand how many beneficiaries can be served by provider types and the threat to overall provider capacity posed by the withdrawal of high-volume providers. Analyses could also examine population groups based on eligibility groupings and for selected diagnoses. Population groups receiving care from a large numbers of providers, such as beneficiaries with an SUD and chronic condition may have significant needs or preferences for providers.

Other data that may inform adequacy could include:

- Provider language other than English
- Taking new patients
- Reasonable accommodation for disabilities
- Triage services
- Appointment scheduling (time to an appointment)
- Office wait times
- Telehealth services

Specification of the Optimal Mix of Resources

We propose to work with the MN DHS and other stakeholder agencies, such as the MN DHS’s Office of Rural Health and Primary Care, to identify the optimal set of providers to deliver each level of care.

There are a number of decision points to be made about what are optimal staffing requirements for each level of care, and while the ASAM criteria provide guidance, the MN DHS and its stakeholders may have specific insights and experiences that inform care delivery. This optimal mix of staff may vary by geographic area and by subpopulation (such as youth, pregnant women, and elderly populations), urban/rural considerations, and health personnel who can provide services to incarcerated individuals. For example, some populations and geographic areas may require more or fewer resources to ensure adherence to treatment, such as assistance with transportation or housing.

Subject to resource availability, we will work with the MN DHS and relevant stakeholders to help the MN DHS determine the sufficient staff and staffing ratio at each level of care (such as certified

counselors, licensed psychologists, peer recovery specialists, and trainees, mental health professionals, licensed psychiatrists, licensed practitioners), as well as the community resources available to support wraparound services and other social determinants of treatment. Network adequacy standards used by CMS for Medicaid MCOs offer another approach; however, these standards have not been validated for impact on health and may vary by beneficiary levels of co-morbid conditions and other subpopulations. In addition to optimal network standards for each level of care and subpopulation considerations, other community assets should be inventoried and assessed for availability to meet treatment needs.

Identify Gaps and Recommendations for Strategies to Address Gaps

Following the analysis of survey and secondary data, we will identify areas of the state that lack access and provide visualizations of counties and regions within the state, with respect to accessibility. We will then work with the MN DHS to conduct key informant interviews to collect data on stakeholder perspectives on strategies to address gaps in the network access (see proposal section Evaluation Design, Qualitative Data Collection, and Analysis). These include interviews with providers, beneficiaries receiving SUD services, and community leaders, which will provide a holistic picture of the experiences of communities with SUD treatment and facilities. They will enable the MN DHS to understand how provider groups are addressing short-term and long-term gaps in existing providers, and how community leaders are providing social and other support services.

We will also discuss with the MN DHS the feasibility and desire for NORC to facilitate stakeholder meetings to develop strategies to improve provider capacity to deliver SUD services. For example, we can help the MN DHS use frameworks, such as the Mobilizing for Action through Planning and Partnerships (MAPP)³⁸ model to gather stakeholder input and discuss options to expand provider networks, such as:

- MCO contracting strategies
- Provider contracting strategies
- Budget/legislative requests
- Purchasing strategies across agencies
- Adding benefits

³⁸ National Association of County and City Health Officials. (2015). *Mobilizing for Action through Planning and Partnerships (MAPP) Handbook*.

Attachment 6. Promoting Objectives of Titles XIX and XXI

Minnesota's SUD System Reform Section 1115(a) Demonstration Project is expected to improve health outcomes for Medicaid enrollees by expanding the OUD/SUD provider networks and supporting ASAM criteria-based prevention, treatment, and recovery services, and enhancing community integration. CMS has identified six goals in addressing SUD, and OUD specifically. Progress toward these goals in states implementing SUD Section 1115(a) Waivers will be measured against six CMS-defined milestones, as cross-walked below.

Goal 1. Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs. As providers in demonstration states move to align with ASAM level-of-care criteria to assess patient placement needs (Milestone 2), provider capacity to screen and identify patients in need of varying levels of SUD treatment will be enhanced, and patient initiation and engagement in OUD and other SUDs treatment will improve.

Goal 2. Increased adherence to, and retention in, treatment for OUD and other SUDs. As patients requiring treatment for OUD and other SUDs are screened using evidence-based criteria such as ASAM and receive treatment in the appropriate setting (Milestone 2), states will see increased adherence to and retention in SUD treatment. This will be supported through access to critical levels of care including outpatient, intensive outpatient, MAT, intensive residential and inpatient care, and medically supervised withdrawal management (Milestone 1); sufficient provider capacity at each level of care (Milestone 4); and use of ASAM criteria to establish standards for residential treatment provider qualifications to promote quality of residential SUD treatment, including MAT (Milestone 3).

Goal 3. Reductions in overdose deaths, particularly those due to opioids. Through effective implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD (Milestone 5), including expanded coverage of and access to naloxone for overdose reversal, 1115 SUD Waiver states will see a reduction in overdose deaths.

Goal 4. Reduced utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment when the utilization is preventable or medically inappropriate, through improved access to more appropriate services available through the continuum of care. By ensuring access to care for OUD and other SUDs at each level of care (Milestone 1) and sufficient provider capacity across all levels (Milestone 4), SUD 1115(a) Waiver Demonstration states will reduce preventable or medically inappropriate utilization of emergency departments for OUD and SUD treatment. The state will conduct a provider capacity assessment of the availability of providers enrolled in Medicaid and accepting new patients at the critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT. Treatment in inpatient hospital settings will be limited to patients for whom placement is clinically appropriate as determined through ASAM criteria (Milestone 2).

Goal 5. Fewer readmissions to the same or higher level of care for readmissions that are preventable or medically inappropriate. Preventable or medically inappropriate readmissions will be reduced in SUD 1115(a) Waiver Demonstration states through improved care coordination and transitions

between levels of care (Milestone 6). This includes linking enrollees with OUD and SUDs with community-based services and supports following treatment in residential and inpatient facilities.

Goal 6. Improved access to care for physical health conditions among enrollees with SUDs.

Access to care for physical health conditions among enrollees with SUDs, including enrollees with co-morbid medical conditions, will be supported through improved care coordination (Milestone 6) and efforts to link enrollees with other needed care and services beyond SUD treatment.