

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

AUG 16 2019

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

Dear Ms. Zimmerman:

The Centers for Medicare & Medicaid Services (CMS) is issuing technical corrections to the Minnesota section 1115 Medicaid demonstration, entitled, "Minnesota Substance Use Disorder System Reform" (Project No. 11-W-00320/5), which was approved on June 28, 2019, under the authority of section 1115(a) of the Social Security Act (the Act). CMS has issued the following technical corrections, in accordance with Minnesota's request:


- Added clarifying language to Expenditure Authority #1 to state that "This authority is limited to participating residential providers that meet nationally recognized SUD program standards used by the state".
- Updated STC 17, Table 1 (Minnesota SUD/ODU Benefits Coverage with Expenditure Authority) to remove "Partial Hospitalization" as a service provided, to change the status of "Clinically Managed Withdrawal Management" services to state plan amendment (SPA) pending, and by changing the status for Intensive Outpatient (IOP) Services to "not currently included in the state plan". It was also discussed with the state that it would need to address the service gap with IOP services in its Implementation Plan.
- Updated STC 22 by adding the word "Enhanced" to the Description of CCBHC services table; changed the status of Outpatient Withdrawal Management-Level 2 services to being not currently covered under the state plan; and removed "Mental Health Target Case Management for Adults" from the table as a covered service.

To reflect the agreed terms between the state and CMS, CMS has incorporated the technical changes into the latest version of the special terms and conditions (STCs). Please find enclosed the updated STCs.

Your project officer for this demonstration is Mr. Thomas Long. He is available to answer any question concerning your section 1115 demonstration. Mr. Long's contact information is as follows:

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Center for Medicaid and CHIP Services
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Email: thomas.long@cms.hhs.gov

Sincerely,



Andrea J. Casart

Director
Division of Medicaid Expansion Demonstrations

Enclosure

cc: James Scott, Director, Division of Medicaid Field Operations North

**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 disenrolling beneficiaries.

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

	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.
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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

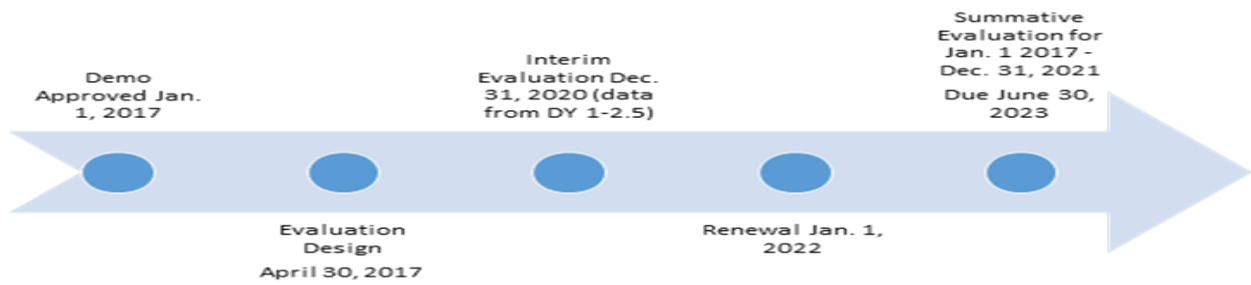
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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

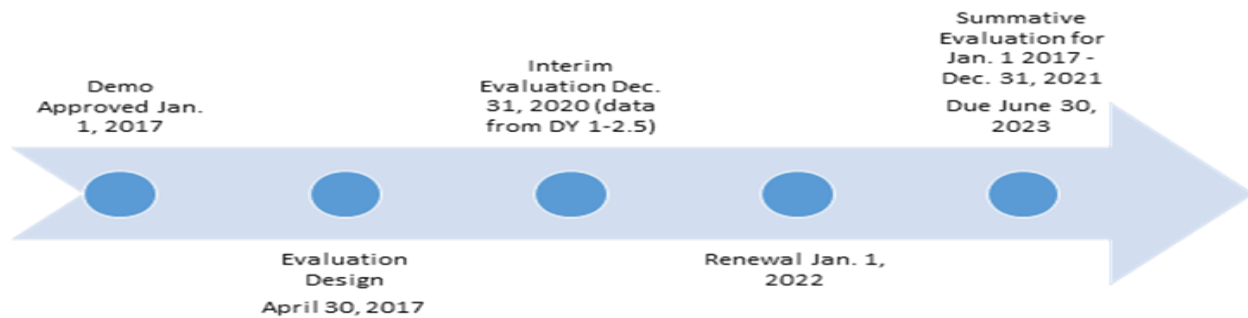
The Act requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design.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

Attachment D

Minnesota Substance Use Disorder Section 1115 Waiver Implementation Plan

Submitted to the Centers for Medicare & Medicaid Services on September 27, 2019



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Introduction

Preliminary statewide data show a decrease in overall drug overdose deaths in Minnesota, with deaths dropping 17% from 733 in 2017 to 607 in 2018. This reduction was primarily driven by a decrease in heroin deaths and deaths that involved prescription opioids.¹ While these reductions are promising, overdose rates remain at historic highs and demonstrate the need for additional work to prevent and treat of substance use disorder².

Despite the progress in reducing opiate overdose deaths overall, deaths related to synthetic opioids, primarily illicitly manufactured fentanyl, continue to increase¹. Opioids and other drugs have been especially harmful in tribal communities and communities of color in Minnesota. In 2017, American Indian Minnesotans were six times more likely to die from a drug overdose than white Minnesotans, and African American Minnesotans were two times more likely to die from a drug overdose than white Minnesotans. These rates of disparity—between American Indians/whites and African Americans/whites—are among the highest in the United States.

To address this crisis, Minnesota is pursuing multiple approaches across its agencies, including this demonstration project, to ensure people who need treatment get high-quality, effective services as quickly as possible across the state. In 2016, Minnesota enacted legislation that directed the Minnesota Department of Human Services (DHS) to seek all necessary federal authority to transform the Medicaid and publicly-funded delivery systems for SUD treatment to one that is more accessible and integrated with the larger health care provider system ([Minn. Stat. § 254B.15](#)).

Under this demonstration, Minnesota plans to test a new way to strengthen the state's behavioral health care system by improving access to the American Society for Addiction Medicine (ASAM) levels of careⁱ. The state will do this through new federal Medicaid funding opportunities for SUD services provided to patients within intensive residential settings (i.e. Institutions for Mental Disease (IMDs)) that have established referral arrangements with other SUD providers to create a continuum of care network. The waiver also seeks to increase the use of evidence-based placement assessment criteria and matching individual risk with the appropriate ASAM level of careⁱ to ensure beneficiaries receive the treatment they need.

This waiver will establish a network of providers interested in providing the comprehensive continuum of ASAM levels of careⁱ to individuals in need of SUD treatment. Providers in Minnesota have expressed interest and commitment in participating in this demonstration and the state plans to implement the demonstration to create statewide access to a comprehensive ASAM-based continuum of care for SUD treatment services. Another important component of

¹ All opioid deaths declined 22% from 422 in 2017 to 331 in 2018. There was a 32% decrease in prescription opioid-involved deaths from 195 in 2017 to 134 in 2018. Heroin overdose deaths decreased 23% from 111 in 2017 to 85 in 2018.

² Minnesota Department of Health. July 9, 2018. *Preliminary 2018 data show decline in opioid deaths*. News Release

this demonstration is the inclusion of the state's six Certified Community Behavioral Health Clinics (CCBHCs) in the SUD provider network.

This Implementation Plan (plan) provides the detail necessary to operationalize Minnesota's vision and goals for improving the outcomes of Minnesota Medicaid enrollees who are suffering from addiction. The plan is organized by the six key milestones identified by CMS. Minnesota has developed cross-agency teams that are responsible for completing the action items in each milestone.

State law enacted by the 2019 Minnesota Legislature provides a framework for the broader implementation of the demonstration statewide over time, including clarifying state law, providing resources for implementation, and creating incentives for participating providers. The legislation codifies required service standards for participating providers that are consistent with ASAM criteria and provides funding necessary to issue provider agreements, conduct a waiver evaluation, provide technical assistance, and develop and implement a utilization review process.ⁱ

Upon waiver approval, Minnesota SUD providers may elect to participate and will enroll as demonstration project 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 levels of care defined by the state. In October 2020, the state plans to publish service standards and staffing requirements for participating providers that are consistent with ASAM criteria in the provider manual.ⁱ 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.¹ Payment rates for participating providers will be increased to support their transition to the ASAM-based standards.

Alignment with CMS Goals and Objectives

Minnesota is committed to providing a full continuum of care for people with opioid use disorder (OUD) and other SUDs, and to implementing evidence-based solutions for expanding access and improving outcomes for beneficiaries in the most cost-effective manner possible. Toward that end, Minnesota's SUD Implementation Plan is designed to achieve the following goals:

1. Increased rates of identification, initiation and engagement in treatment for OUD and other SUDs;
2. Increased adherence to, and retention in, treatment for OUD and other SUDs;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment when the utilization is preventable or medically inappropriate, through improved access to more appropriate services available through the continuum of care;

5. Fewer readmissions to the same or higher level of care for readmissions that are preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries with SUDs.

As such, this implementation plan is organized based on the CMS-required Milestones:

1. Access to critical levels of care for SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care, including medication assisted treatment (MAT);
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

Milestone #1: Access to Critical Levels of Care for OUD and Other SUDs

CMS Specifications:

Coverage of a) outpatient, b) intensive outpatient services, c) medication assisted treatment (MAT) including medications as well as counseling and other services, d) intensive levels of care in residential and inpatient settings, and e) medically supervised withdrawal management.

Minnesota's Response:

Minnesota currently has robust coverage of SUD treatment services under the Medicaid state plan. The state plan includes coverage of outpatient services, counseling, withdrawal management, intensive levels of care in residential and inpatient settings, and MAT. A state plan amendment to cover Screening, Brief Intervention, and Referral to Treatment (SBIRT) is currently pending with CMS. MAT is currently provided in conjunction with outpatient and residential treatment services, but will be expanded under the waiver. 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. As noted above, participating residential and outpatient SUD service providers enrolled in the demonstration will transition with the goal of being fully compliant with the ASAM-based standards by June 30, 2021. Table 1 below identifies each level of care as defined by the ASAM criteria¹, the service and service description, whether the service is currently covered and the authority used to cover it, and any changes that are being proposed under the state plan for this waiver.

Table 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 a 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 Pan 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).	Service not available.	Minnesota will submit a state plan amendment and begin coverage of this service by January 1, 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.
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	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.

ASAM Level of Care	Service	Description	Current Coverage	Future Coverage Under Medicaid State Plan
		cognitive or other impairments.		
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).	Service not available.	The state has no plan to offer this level of care.
4.0	Medically Managed Intensive Inpatient Services	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital.	Service not available.	The state has no plan to offer this level of care.
1-WM	Ambulatory Withdrawal Management without Extended On-Site Monitoring	Mild withdrawal with daily or less than daily outpatient supervision.	. Service not available.	The state has no plan to offer this level of care.
2-WM	Ambulatory Withdrawal Management with Extended On-Site 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 state plan authority or the 223 demonstration after July 1, 2020.

ASAM Level of Care	Service	Description	Current Coverage	Future Coverage Under Medicaid State Plan
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.
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, & antagonist medications) and counseling services provided in either an Opioid Treatment Program (OTP) or Office- based setting (OBOT).	State Plan Attachment 3.1-A, item 13.d. Medication Assisted Therapy	Continuation of current state plan coverage. SUD treatment providers are required to make arrangements for all services indicated in each beneficiary's treatment plan including MAT.

As outlined in Table 1 above, all of the services currently covered under the state plan will continue to be covered while moving towards ASAM-based compliance during the demonstration period. The state will work closely with the provider community to ensure that they are prepared to implement the ASAM-based criteria by June 2021.

The following section summarizes the service coverage changes that will be made under the state plan, as well as changes to the provider manual that will be disseminated through provider training and credentialing and released over the next 12-24 months.

Level of Care 0.5: Early Intervention – Screening, Brief Intervention, and Referral to Treatment (SBIRT)

Current State: The state plan provides coverage for screening and physician services.

Future State: 2019 legislation allows all qualified providers – including primary care clinics, hospitals, and other medical or school settings – to conduct SBIRT screenings. The legislation also authorizes an initial set of treatment services for beneficiaries whose SBIRT result is positive. These initial services include up to four hours of individual or group SUD treatment, two hours of SUD care coordination, and two hours of SUD peer support services provided by qualified individuals. A state plan amendment that includes SBIRT is pending. The state will make changes to the provider manual as necessary.

Level of Care 2.1: Intensive Outpatient

Current State: Current coverage of outpatient services does not meet ASAM standards for intensive outpatient coverage.

Future State: Minnesota will seek legislative authority to add intensive outpatient treatment to the state plan for coverage starting in January 2022. The state will issue provider requirements and service standards consistent with ASAM level 2.1

Actions Needed to Achieve Milestone #1 Across All Service Levels

Action Needed	Timeline
Implement training and technical assistance to align providers with ASAM-based standards	July 2020; ongoing
Publish ASAM-based service standards and staffing requirements in MHCP provider manual	October 2020
Target for providers to reach ASAM-based compliance	June 2021
Begin state plan coverage of Intensive Outpatient treatment	January 2022

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

CMS Specifications:

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

Minnesota's Response:

Minnesota currently uses evidence-based placement criteria that is based on the ASAM six dimensions of multidimensional assessmentⁱ. The state will assess where its current evidence-based assessment policies need to be more closely aligned, with the ASAM placement criteriaⁱ.

Additionally, Minnesota will develop an independent utilization review process over the next two years to ensure that beneficiaries have access to the necessary levels of care, that interventions are appropriate for the level of care needed, and that there is an independent process for reviewing appropriate placement in residential treatment settings. In addition, the state will ensure that the continuum of care extends beyond the intensive inpatient and outpatient treatment settings in order to promote sustained and long-term recovery and minimize readmissions.

A. Patient Placement Assessment

Current State: All 87 Minnesota counties, 11 American Indian Tribes, and eight managed care organizations (MCOs) are required to conduct an assessment that incorporates the six dimensions of the ASAM placement criteriaⁱ to assess the SUD treatment needs of beneficiaries. Findings from the assessment must be documented in an assessment and placement summary that includes a risk rating for each of the six dimensions, a narrative summary supporting the risk descriptions, a determination of whether the client has a SUD, and information relevant to treatment services planning that is recorded using the following six dimensions:

- Dimension 1: Acute intoxication/withdrawal potential; the client's ability to cope with withdrawal symptoms and current state of intoxication;
- Dimension 2: Biomedical conditions and complications; the degree to which any physical disorder of the client would interfere with treatment for substance use, and the client's ability to tolerate any related discomfort. The license holder must determine the impact of continued chemical use on the unborn child, if the client is pregnant;
- Dimension 3: Emotional, behavioral, and cognitive conditions and complications; the degree to which any condition or complication is likely to interfere with treatment for substance use or with functioning in significant life areas; and the likelihood of harm to self or others;

- Dimension 4: Readiness for change; the support necessary to keep the client involved in treatment service;
- Dimension 5: Relapse, continued use, and continued problem potential; the degree to which the client recognizes relapse issues and has the skills to prevent relapse of either substance use or mental health problems; and
- Dimension 6: Recovery environment; whether the areas of the client's life are supportive of or antagonistic to treatment participation and recovery.

These dimensions are further defined in [Minnesota Rules, part 9530.6622](#).

Although Minnesota's SUD assessment requirements utilize risk ratings according to the six ASAM dimensionsⁱ the resulting placement recommendations do not currently align with the ASAM levels of careⁱ. A client's placement falls into two categories: outpatient care (with any necessary MAT) or inpatient care. The inpatient levels of care are described in more detail under Milestone 3.

Comprehensive Assessment: SUD treatment providers may also conduct a comprehensive assessment of the client's SUD to determine the appropriate level of treatment using the criteria described above. All assessments be completed within three calendar days after service initiation for a residential program or during the initial session for all other programs. If the comprehensive assessment is not completed during the initial session, the client-centered reason for the delay and planned completion date must be documented in the client's file. If available, the alcohol and drug counselor may use current information provided by a referring agency or other source as a supplement. ([Minnesota Statutes, section 245G.05](#))

Assessment Summary: Alcohol and drug counselors must complete an assessment summary within three calendar days after service initiation. If the comprehensive assessment is used to authorize the treatment service, the alcohol and drug counselor must prepare an assessment summary on the same date the comprehensive assessment is completed. If the comprehensive assessment and assessment summary are to authorize treatment services, the assessor must determine appropriate service options for the client using the six ASAM dimensionsⁱ and document the recommendations. ([Minnesota Statutes, section 245G.05](#))

Initial Services Plan: Providers must complete an initial services plan on the day of service initiation. The plan must address the client's immediate health and safety concerns, identify the needs to be addressed in the first treatment session, and make treatment suggestions for the client during the time between intake and completion of the individual treatment plan. The initial services plan must include a determination of whether a client is a vulnerable adult, as defined in regulation. Adult clients of a residential program are defined as vulnerable adults. An individual abuse prevention plan is required for clients who meet the definition of a vulnerable adult. ([Minnesota Statutes, section 245G.04](#))

Minnesota's Certified Community Behavioral Health Clinics (CCBHCs) provide integrated care in an outpatient setting and will become part of the ASAM continuum of careⁱ established within this waiver demonstration. Not only are CCBHCs required to provide integrated mental health

and SUD treatment, they must complete primary care screenings and utilize care coordination to ensure clients are receiving coordinated medical care. The [CCBHC federal criteria](#) require both an initial evaluation and comprehensive evaluation as well as an integrated treatment plan. In Minnesota, the state-specific standards for CCBHCs require the use of the ASAM six dimensionsⁱ as an architecture for assessment, treatment planning and documentation of progress. The initial and comprehensive evaluations include risk ratings for all six dimensions and utilize the current SUD placement criteria as described above. Once a CCBHC client enters SUD treatment at a CCBHC clinic, the CCBHC follows the same requirements in state law as all other SUD treatment providers.

Future State: SUD assessments will continue to be based on the ASAM six dimensions of multidimensional assessment.ⁱ Minnesota will update patient placement criteria to align with the ASAM levels of care by June 2021. Minnesota plans to work with the provider community to more closely align with ASAM patient placement criteria by matching patients' risk ratings directly with the ASAM levels of care instead of to the current Minnesota levels of care, which are more general (outpatient services or inpatient care).ⁱ This will be helpful in completing placement assessments and ensuring that clients have access to the most appropriate services at the right time.

All providers who conduct assessments must be a qualified provider and trained in the ASAM dimensions and levels of care.ⁱ Minnesota will expand training and technical assistance opportunities for providers over the next 12 to 24 months. To enhance and strengthen the use of ASAM criteria, new provider manuals will be released, refresher training will be developed for, and technical assistance will be provided to, staff that are conducting assessments and to SUD treatment providers within the 12 to 24 months following the waiver approval.ⁱ The state will align its multi-dimensional assessment tool with ASAM's placement criteria and require participating providers to make treatment recommendations accordingly.

B. Utilization Management

Current State: Current utilization management practices consist of licensing review audits. Every two years, or more frequently as needed, licensing site visits are conducted and a random sample of client files are reviewed to ensure that documentation meets the statutory requirements as defined in state law. Determination of medical necessity, completion of the ASAM Six Dimensions of multidimensional assessment, and the placement recommendations must be made by an alcohol and drug counselor. Licensing audits include a review of the comprehensive assessment, assessment summary, treatment plan and weekly treatment plan reviews to ensure that clients are receiving treatment as identified in the treatment plan.ⁱ While licensing reviews account for some of the utilization management practices, Minnesota does not currently have a standardized utilization management review process for clients who receive SUD services through the fee-for-service (FFS) delivery system.

Approximately 60 percent of Medicaid enrollees receiving SUD treatment are enrolled in a managed care organization (MCO). MCO contracts include language that MCOs cannot require prior authorization before beginning treatment – so once an assessment has been conducted,

treatment can begin. However, each MCO has different utilization review policies and procedures. For residential treatment stays, MCOs authorize a set number of initial days covered and then request concurrent or continued stay information for approval of continued placement. MCOs conduct post-payment review of outpatient SUD services to verify medical necessity, appropriateness of care, over and under-utilization of services, and evaluation of service delivery and outcomes.

The certification for CCBHCs is contingent on each clinic maintaining a license under Minnesota Statutes, section 245G for their outpatient SUD treatment services. Licensing staff review client files to ensure documentation is complete and that services are being delivered according to the treatment plan. Additionally, the certification process and ongoing monitoring for CCBHCs includes utilization management to ensure the proper integration of SUD treatment with mental health and social services.

Future State: Minnesota intends to develop a comprehensive, independent utilization review process over the next two years to ensure that beneficiaries served in FFS MA have access to the necessary levels of care, that interventions are appropriate for the diagnosis, and that there is an independent process for reviewing placement in residential treatment settings. The state issued a Request for Information (RFI) in September 2019 to solicit feedback from organizations that conduct utilization management for SUD services. DHS is using this feedback to develop a Request for Proposal (RFP) to contract with an independent utilization review agent to conduct concurrent and post payment review of SUD treatment services. The vendor chosen for this project will review whether the level of treatment meets medical necessity standards including whether the service is appropriate for the beneficiary’s condition, the service intensity is supported by clinical data or rationale, and that the treatment duration is appropriate. DHS has a goal of executing this contract by January, 2021 and implementing the utilization review process by July 2021. To the extent possible, DHS will ensure that the standards for utilization management in FFS align with the practices of MCOs.

Actions Needed to Achieve Milestone #2

Action Needed	Timeline
Begin process of updating MCO contracts to define participating providers	December 2019
Implement training and technical assistance to align providers with ASAM-based standards	July 2020; ongoing
Update MCO contracts to align utilization management practices with ASAM-based placement criteria	September 2020 (for January 2021 contract initiation)
Begin utilization management process that includes an independent utilization review process for residential placements	July 2021
Communicate changes to providers	Ongoing

Milestone #3: Use of Nationally-Recognized SUD-Specific Program Standards to

CMS Specifications:

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

Minnesota's Response:

Minnesota Statutes, sections [245G](#) and [254B.05](#) outline the current state requirements for licensed treatment facilities and provider eligibility requirements. DHS analysis of ASAM requirements indicates that Minnesota's SUD treatment providers meet a majority of ASAM standards, but the state will be working with providers over the next 12 to 18 months to ensure full alignment with the ASAM-based standards developed by the state.

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

Current State: The DHS Division of Licensing enforces standards to protect the health, safety, rights, and well-being of children and adults in residential substance use disorder treatment facilities. The division provides oversight, processes variances to licensing rules, provides technical assistance, conducts investigations of reported licensing violations, issues corrections orders and, if appropriate, recommends fines and conditional licenses or other licensing actions. Regulatory methods are defined in Minnesota Statutes, Chapter 245A. 09, Subdivision 7, paragraph (e) unless otherwise specified in statute, and the commissioner may conduct routine inspections every two years. Minnesota Statutes, chapter 245G details licensing standards for SUD treatment providers that are residential and non-residential including opioid treatment programs.

Licensors and/or investigators inspections may range from a full inspection (physical plant inspection, policy and procedure review, resident files, and personnel files) to a targeted reviewer investigation. Licensing inspections are conducted utilizing a checklist depicting regulations and documenting if license holder is in compliance. Depending on the inspection, if a license holder has failed to comply with an applicable law or rule, the commissioner may issue a correction order, conditional license, or sanction. When issuing a conditional license or sanction, the nature, chronicity, or severity of the violation of law or rule and the effect of the violation on the health, safety, or rights of persons served by the program is considered.

License holders are subject to statutory requirements under Minnesota Statutes, chapter 245G.

The Licensing Division verifies compliance with statutory requirements that detail the following:

- Treatment service requirements;
- Service initiation and termination policies;
- Client documentation and record keeping requirements including client assessment, treatment and discharge planning, medication orders, and personnel records;
- Staff requirements and qualifications;
- Operational and personnel policies;
- Client rights, including the process for filing grievances;
- Emergency procedures, including definitions of circumstances, processes, and contact information; and
- Evaluation, including the requirement that providers must participate in data reporting to the state.

Future State: DHS is comparing current residential treatment facility requirements with the ASAM residential levels of careⁱ and defining the enhanced expectations for residential treatment facilities. The areas for which initial differences have been identified involve medical policies for specific levels of service and the involvement of credentialed medical staff. Staff with the DHS Behavioral Health Division and the Division of Licensing will develop updated SUD treatment service requirements, assessment and placement criteria, and staffing requirements that are consistent with ASAM standardsⁱ and publish them in the provider manual by October 2020.

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

Current State: Minnesota outlines its provider requirements in Minnesota Statutes, chapter 245G, which details SUD licensure requirements. The DHS Licensing Division is responsible for reviewing provider applications and attestations of both provider qualifications and meeting service requirements. Licensing visits include, but are not limited to review of client files, documentation, staff files, client interviews and staff interviews. The interval for these reviews is every two years, and more frequently if reviewing a complaint.

DHS has taken steps to ensure provider compliance with standards, primarily through billing validation and provider audits, but the state also conducts licensing program monitoring visits. Medicaid managed care health plans also conduct provider audits. Any time there is a question or concern about licensing, the DHS Managed Care Division investigates and/or conducts an audit.

Future State: The DHS Behavioral Health Division has drafted standards in alignment with the ASAM criteria for each of the critical levels of care that will be implemented during this demonstration. To enroll in the demonstration, providers will be required to submit an enrollment checklist. The enrollment checklist will require providers to identify which standards that their programs do not currently meet and explain how they will implement the additional standards required for each level of care and the date in which they will have these additional requirements implemented; to be no later than June 30, 2021. The Division of

Licensing provide oversight of SUD providers in accordance with current state standards. DHS will pursue legislation in 2021 clarifying the agency authority to provide oversight and administer sanctions based on the updated standards beginning in July of 2021.

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

As discussed in Milestones 4 and 5, Minnesota has engaged in efforts to promote and expand MAT services across the state. Currently there are 17 opioid treatment programs (OTP) operating in the state and in recent years there has been an increase in the number of tribally licensed programs that offer MAT services. Current SUD placement guidelines outlined in Minnesota Rules, part [9530.6622](#), and structured similarly to ASAM’s six dimensionsⁱ, require placing authorities to refer a client with an OUD and a risk rating of two (2) or more in dimension 5 to an OTP. Minnesota has also expanded the availability of MAT by authorizing mid-level nurse practitioners and physician assistants to dispense medications used to treat OUD. This allowance, in addition to information the state has regarding practitioners utilizing the Drug Addiction Treatment Act of 2000’s waiver to increase patient prescribing capacity to 275, has increased the capacity for MAT across the state. Minnesota is also supporting expansion of MAT access through grant funded initiatives (outlined in Milestone 5), which include use of Project ECHO to engage a range of provider environments and professionals – from the prescribers, to social service staff, to licensed alcohol and drug abuse counselors, to clinic administrators and beyond. Through this process, Minnesota is working to expand access to MAT and improve quality of services across the state.

There is currently no general requirement in Minnesota that residential treatment facilities offer MAT on site or facilitate access off site. However, 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. State law requires participating residential providers to offer MAT services or facilitate MAT access offsite where clinically appropriate.

Actions Needed to Achieve Milestone #3

Action Needed	Timeline
Providers electing to participate provide verification of formal referral arrangements to ensure access to each of the ASAM levels of care ⁱ	January 2020 ongoing
Implement training and technical assistance to align providers with ASAM-based standards	July 2020; ongoing
Update MCO contracts to reflect residential provider requirement changes	September 2020 (for January 2021 contract initiation)
Publish ASAM-based service standards and staffing requirements in MHCP provider manual	October 2020
Develop residential treatment provider review process and initiate ongoing monitoring process	June 2021

Milestone #4: Sufficient Provider Capacity at Critical Levels of Care Including for Medication-Assisted Treatment for Opioid Use Disorder

CMS Specifications:

Completion of assessment of the availability of Medicaid enrolled providers accepting new patients at the critical levels of care throughout the state including those that offer MAT.

Minnesota's Response:

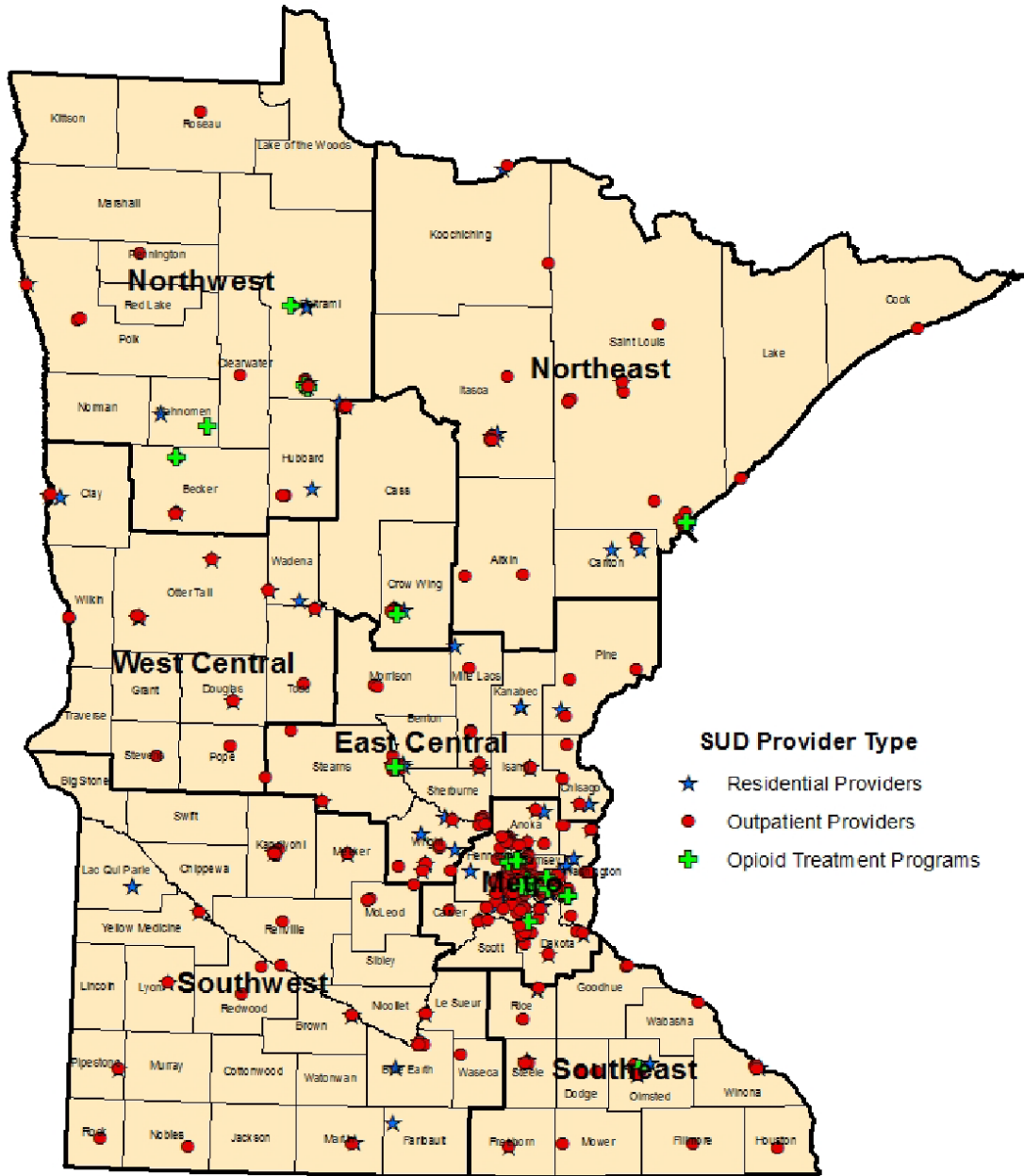
The state has approximately 415 licensed programs providing SUD treatment services in Minnesota – 145 of which are located in rural areas. Treatment settings include free-standing for-profit and not-for-profit organizations, hospitals, tribal governments and state-operated treatment services. Approximately 175 of these programs provide integrated, co-occurring services, and others coordinate mental health services via partnerships with community resources. There are currently 23 Minnesota counties with no state licensed SUD providers.

The state is aware that there is a demand for broader access to MAT. The state has found that there are several providers not yet prescribing buprenorphine in office based settings. DHS administers grants funding technical assistance to physicians, nurse practitioners, and physician assistants who wish to apply for a waiver to prescribe buprenorphine. These activities include immersive mentoring with clinics prescribing in office settings.

Current state: In order to link people to services with real time availability, Minnesota funds an online tool called Fast Tracker. Fast Tracker's platform allows providers to consistently update whether they are accepting new clients, enabling users to search for available mental health and SUD services. Minnesota will be utilizing data from this platform in the Monitoring Protocol and demonstration evaluation as a means to monitor for provider capacity. DHS is working with Managed Care Organizations to promote the use of the Fast Tracker system to assist MCOs in making SUD placements.

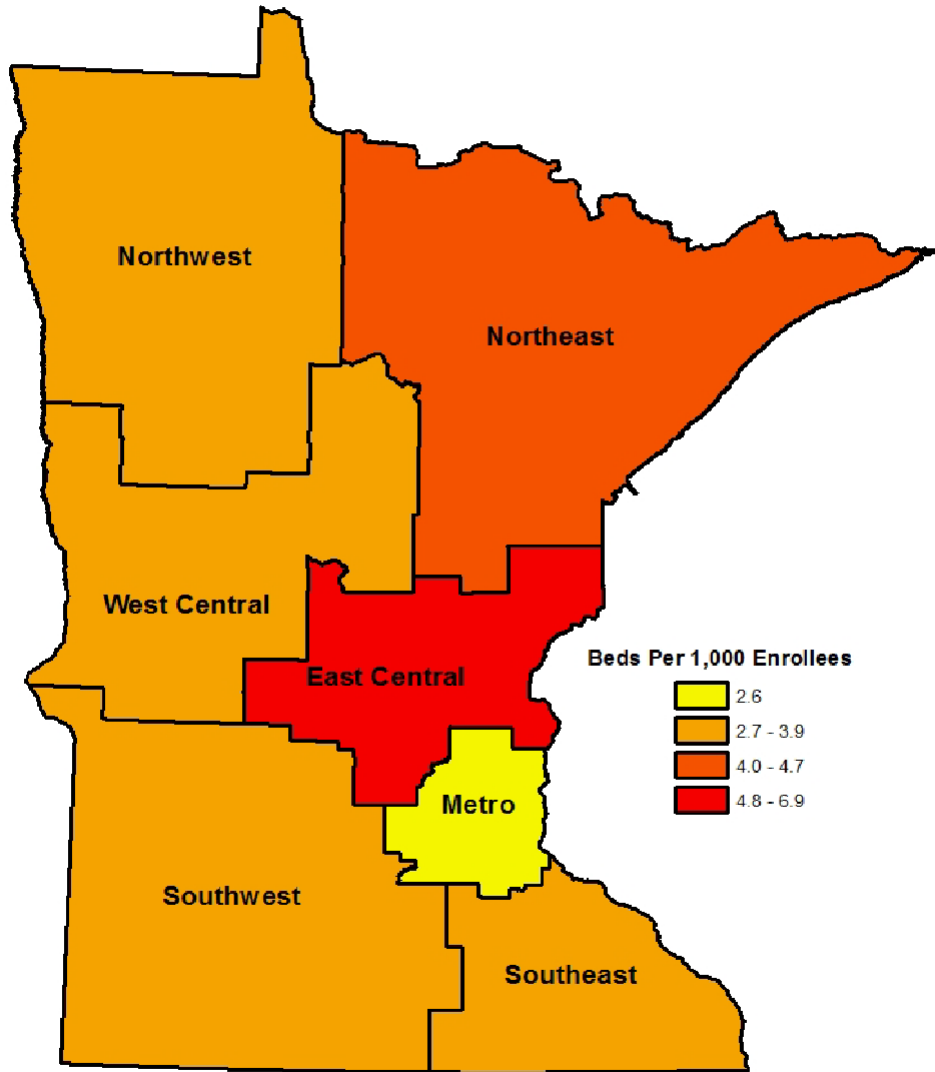
Below is a series of maps showing SUD treatment capacity in Minnesota for three different levels of care in seven regions of the state. The first map shows the location of "active" SUD treatment providers in Minnesota. To be included as an active provider, a SUD treatment provider must have provided at least one SUD treatment service to people eligible for publicly-funded treatment between July 2017 and June 2018. Three additional maps merge provider data with Medicaid enrollment data to create a provider-to-enrollee ratio. Minnesota will use these ratios to monitor trends in SUD treatment provider availability at the enrollee level.

SUD Treatment Providers Serving Medicaid Enrollees in FY2018



Source: Minnesota Department of Human Services, BHD (5/8/2018)

**Residential SUD Treatment Beds per 1,000
Medicaid Enrollees: SFY2018**

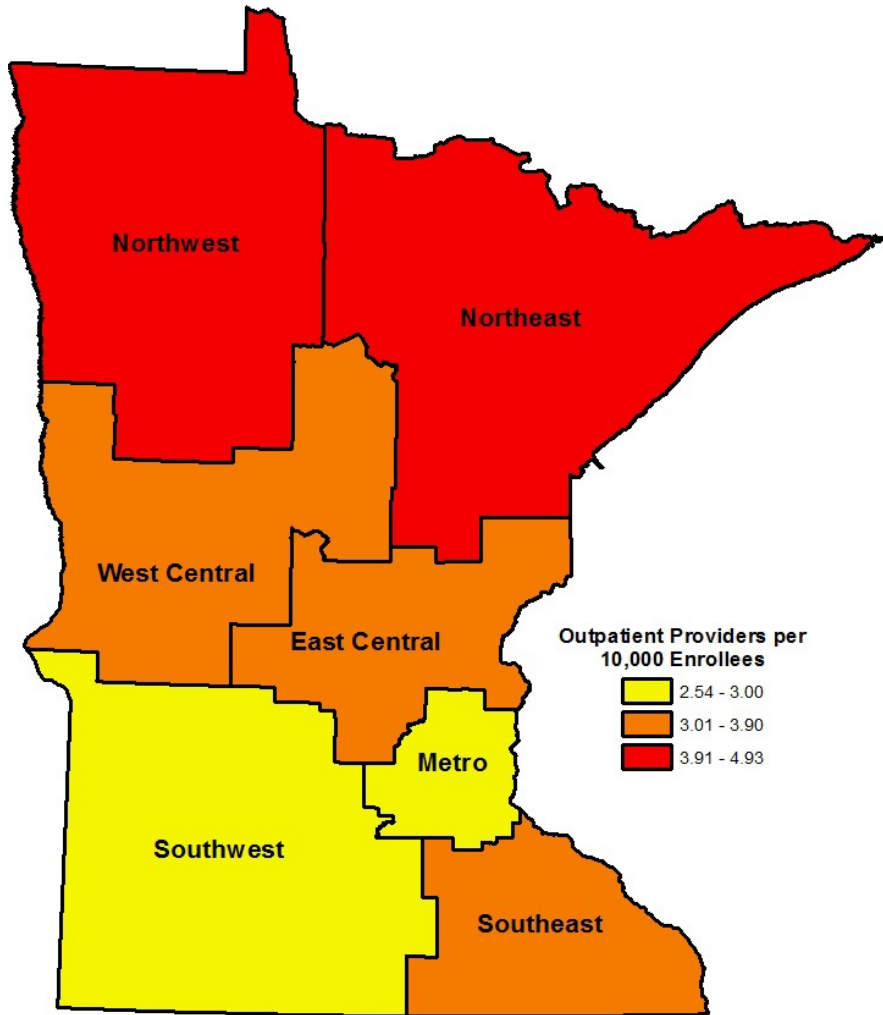


Source: Minnesota Department of Human Services, BHD (5/8/2019)

Regions	# of MA Enrollees	# of residential beds	Ratio of residential beds per 1000 MA enrollees	# of MA enrollees that received this level of care
Northwest	51,619	198	3.8	1103 (2.1%)
Northeast	70,955	332	4.7	1546 (2.2%)
West Central	73,076	284	3.9	1156 (1.6%)
East Central	115,314	796	6.9	1343 (1.2%)
Southwest	105,680	376	3.6	1197 (1.1%)
Southeast	90,428	309	3.4	1242 (1.4%)
Metro	586,142	1498	2.6	6481 (1.1%)

Source: Minnesota Department of Human Services, BHD (5/8/2019)

**Outpatient SUD Treatment Providers per 10,000
Medicaid Enrollees: FY2018**

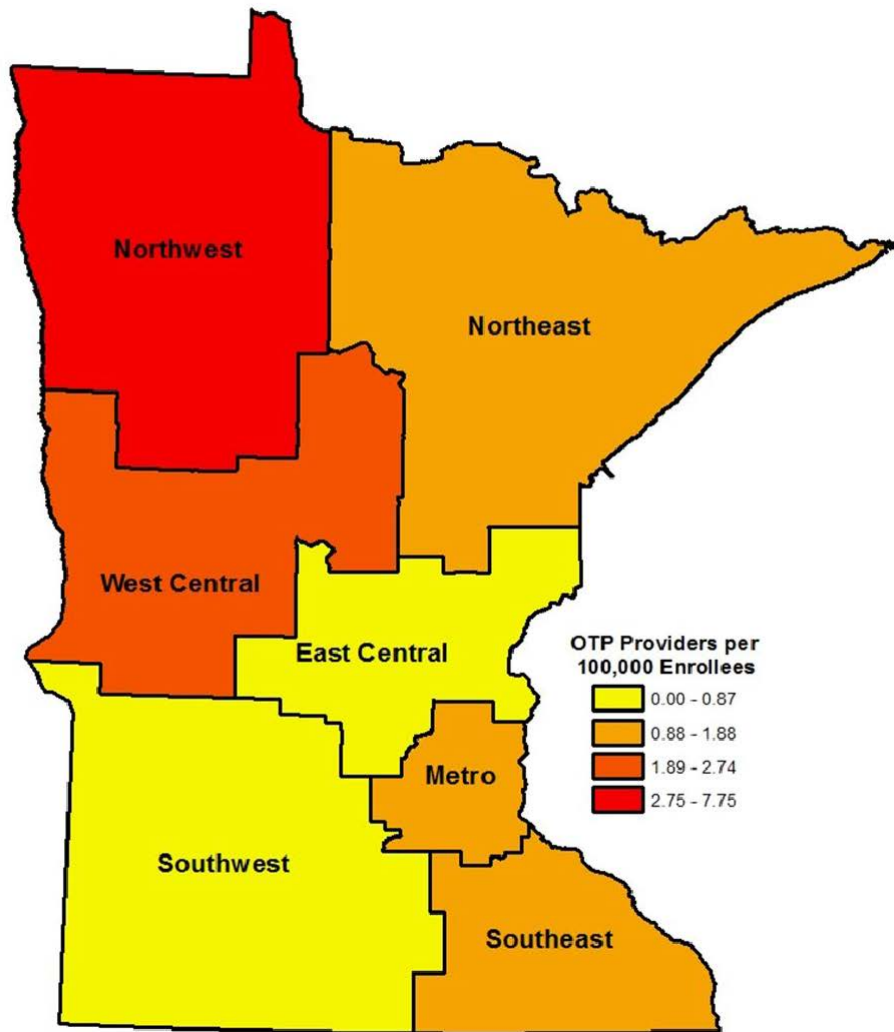


Source: Minnesota Department of Human Services, BHD (5/8/2019)

Regions	# of MA Enrollees	# of active providers of outpatient SUD services	Ratio of active providers per 10,000 MA enrollees	# of MA enrollees that received this level of care
Northwest	51,619	21	4.07	1138 (2.2%)
Northeast	70,955	35	4.93	1808 (2.5%)
West Central	73,076	24	3.28	1074 (1.5%)
East Central	115,314	43	3.73	2287 (2.0%)
Southwest	105,680	30	2.84	1334 (1.3%)
Southeast	90,428	28	3.1	1257 (1.4%)
Metro	586,142	149	2.54	9861 (1.7%)

Source: Minnesota Department of Human Services, BHD (5/8/2019)

Opioid Treatment Programs per 100,000
Medicaid Enrollees: FY2018



Source: Minnesota Department of Human Services, BHD (5/8/2019)

Regions	# of MA Enrollees	# of active providers of OTP clinics	Ratio of active providers per 100,000 MA enrollees	# of MA enrollees that received this level of care
Northwest	51,619	4	7.75	471 (0.9%)
Northeast	70,955	1	1.41	744 (1.0%)
West Central	73,076	2	2.74	247 (0.3%)
East Central	115,314	1	0.87	520 (0.5%)
Southwest	105,680	0	0	83 (0.1%)
Southeast	90,428	1	1.11	259 (0.3%)
Metro	586,142	11	1.88	4532 (0.8%)

Source: Minnesota Department of Human Services, BHD (5/8/2019)

Future State: Minnesota is currently implementing statutory changes required through the Substance Use Disorder Reform Act enacted in July 2017. There is an expectation that these reforms and the implementation of this waiver will expand access to the full SUD continuum of care for Medicaid beneficiaries. Minnesota is committed to the ongoing monitoring of SUD treatment services by furthering the state's data and analytics studies as they relate to statewide interactions between provider capacity and beneficiary access so that the state may respond to the complex SUD needs of its Medicaid population.

A critical step in this process is expanding access to intensive outpatient SUD treatment. Minnesota's state plan includes coverage of outpatient services, and providers already offer the 9-19 hours of outpatient treatment specified under ASAM level 2.1. DHS will add intensive outpatient treatment to the state plan effective January 1, 2022 and include provider and service standards consistent with ASAM level 2.1. The Department is confident that this service will be available to beneficiaries in many areas across the state.

To support this commitment, and as part of the waiver implementation, Minnesota will develop proposed future state measures to ensure sufficient provider capacity at, and beneficiary access to, ASAM critical levels of careⁱ in partnership with the state's contracted vendor for the independent evaluation of the overall demonstration. The state is currently in the contracting process with a vendor to develop and implement the provider capacity assessment and 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. Upon identifying those gaps, the state can begin to develop measures to build capacity at those levels of care where the gaps exist.

Workforce Development Efforts

The state is currently undertaking several efforts to expand the SUD provider workforce across the state. The 2017 legislation included additional provider types to include recovery community organizations (RCO), counties, and licensed individuals in private practice. Within this legislation, RCOs may become eligible vendors to provide peer support services. Counties may become eligible vendors to provide comprehensive assessments and treatment coordination. Qualified licensed professionals in private practice may become eligible vendors to provide SUD treatment services.

The Minnesota Department of Health (MDH) Office of Rural Health and Primary Care supports the SUD workforce in multiple ways. The office:

- Collects health professional licensing data and publishes [reports](#) with analysis of the workforce.
- Funds [loan forgiveness awards](#) to mental health professionals, which includes professionals providing SUD services in rural and underserved urban areas.
- Funds [grants](#) to expand clinical training for Mental Health Professional educational programs, particularly those who send students to rural and underserved areas.
- Funds grants to FQHCs.

- Funds [grants](#) to safety net clinics that provide care to underserved populations throughout the state, including SUD services.
- Funds [grants](#) to clinics that serve American Indian communities not living on a Reservation. Projects often include SUD services.
- Funds [grants](#) to mental health safety net clinics, many of which provide SUD services.
- Develops policy recommendations through the Governor-appointed [Rural Health Advisory Committee](#), which has added behavioral health to this year's work plan.
- Participates formally in consortia for multiple HRSA-funded grant projects to address the opioid epidemic, known as the Rural Communities Opioid Response Program (RCORP).
- Provides technical assistance to National Health Service Corps (NHSC) participants and sites, which includes mental health professionals, and new funding earmarked for SUD providers.
- Provides technical assistance to safety net clinics and hospitals looking to maximize reimbursement, sustain workforce, and build partnerships to integrate care across sectors.
- Promotes promising models and best practices from communities that are integrating care.

In addition, recent contract amendments with two RCOs funded through state grant dollars required the RCOs to partner with underrepresented communities in two parts of the state – Rochester and the Twin Cities Metro area – to train and coach up to 20 members from within those underrepresented communities to become culturally-responsive Peer Recovery Specialists.

MAT-Specific Efforts: Minnesota has engaged in efforts to promote and expand MAT services across the state. Currently there are 17 Opioid Treatment Programs operating in the state and in recent years there has been an increase in the number of tribally licensed programs that offer MAT services. Current SUD placement guidelines outlined in Minnesota Rules, part 9530.6622, and structured similarly to ASAM's six dimensions¹, require placing authorities to refer a client with an OUD and a risk rating of two or more in dimension 5 to an OTP. Minnesota has also expanded the availability of MAT by authorizing mid-level nurse practitioners and physician assistants to dispense medications used to treat OUD. This allowance, in addition to information the state has regarding practitioners utilizing the Drug Addiction Treatment Act of 2000's waiver to increase patient prescribing capacity to 275, has increased the capacity for MAT across the state. Further grant funded MAT-expansion activities, including the use of Project ECHO, are described in detail in Milestone 5.

The expansion of telemedicine for mental health services is a priority for DHS. There are efforts across the state to increase broadband access, which will facilitate further telemedicine services the state will be undertaking additional efforts to provide technical assistance to providers on the use of and billing for telemedicine services as they expand.

Summary of Actions Needed to Achieve Milestone #4

Action Needed	Timeline
Providers electing to participate provide verification of agreement to submit pertinent data for assessment measures	January 2020, ongoing
Assess provider capacity at critical levels of care and plan a response to address gaps where identified, including for MAT	Within 12 months of approval
Baseline measurements collected for provider capacity assessment	July 2020

Milestone #5: Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD

CMS Specifications:

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

Minnesota's Response:

Minnesota has numerous efforts underway to address opioid abuse and OUDs. In 2018, Governor Dayton released the [Minnesota Opioid Action Plan](#), which provides a comprehensive summary of the state's current and planned actions related to:

- Prevention;
- Emergency Response;
- Treatment and Recovery; and
- Law Enforcement.

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

A. [Implementation of Opioid Prescribing Guidelines Along with other Interventions to Prevent Opioid Abuse](#)

Opioid Prescribing Guidelines

The 2015 Minnesota Legislature established an opioid prescribing improvement program at DHS. The program includes three components: 1) statewide opioid prescribing guidelines for acute, post-acute and chronic pain; 2) a state prescriber education campaign; and 3) a quality improvement program within the state's Medicaid and MinnesotaCare programs.

The program includes an opioid prescribing workgroup, an advisory group composed of consumers, health care and mental health professionals, law enforcement, and MCO representatives. In 2018, the workgroup released Minnesota’s opioid prescribing guidelines for acute pain, post-acute pain, and chronic pain to be used by all providers and payers. The guidelines provide a framework for safe and thoughtful opioid prescribing for pain management. Three following key principles guided the creation of the Minnesota opioid prescribing guidelines:

- Prescribe the lowest effective dose and duration of opioids for acute pain.
- The post-acute pain period is the critical timeframe to prevent chronic opioid use.
- Providers should avoid initiating chronic opioid therapy for new chronic pain patients, and carefully manage those who remain on opioid medications.

Pharmacy Management

Sound opioid prescribing in Medicaid is supported in the following ways:

- Prior authorization is required for opioid prescription exceeding 90 morphine milligram equivalents (MME) per day. This is a reduction from the threshold previously set at 120 MME per day.
- The initial fill of an opiate prescription is limited to no more than a seven-day supply. The new limit applies to all claims where the member does not have a paid claim for the same drug, or a similar drug containing the same active ingredient(s), in the previous 90 days.
- Minimum early refill threshold for opioids is set at 85 percent for FFS plans. Managed care plans have the option of setting the threshold at a higher level (e.g., 90percent).
- Policies and procedures are established to address opioid policy exceptions for members with specific conditions (e.g., cancer diagnosis, palliative care etc.).
- Universal Pharmacy Policy Workgroup (UPPW) is a group composed of pharmacy policy experts from managed care plans and the state that will develop a universal pharmacy policy for high risk and controlled substance medications including opiates. Members of the UPPW must be pharmacists or physicians licensed by the state or individuals with significant pharmacy policy expertise. The workgroup is chaired by state staff. Policies regarding utilization of opioids (maximum daily limits, early refill threshold, etc.) are consistent across all managed care and FFS plans.
- Opiate utilization, alone or in combination with other high-risk medications, is reviewed periodically by the Drug Utilization Review Board.

Provider Education

DHS uses a number of vehicles to educate providers on prescribing guidelines, including:

- DHS recently released [‘Flip the script,’](#) a provider education campaign aimed to improve opioid prescribing practices. ‘Flip the script’ provides opioid prescribers with videos, fact sheets, and podcasts that cover the opioid prescribing guidelines, pain

assessment guidelines, and tips to engage in difficult conversations with patients about opioids. These guidelines contain extensive content on tapering and the importance of identifying OUD and referral for OUD treatment as well as non-pharmacologic treatment as discussed here: <https://mn.gov/dhs/opip/opioid-guidelines/factors-in-treatment/non-opioid-non-pharmacologic-treatment.jsp>

- DHS funds three Project ECHO videoconference knowledge-sharing networks focused on opioid prescribing and treatment of opioid use disorder across Minnesota (CHI St. Gabriel's Health, Hennepin Healthcare System, and Wayside Recovery Center). DHS anticipates expanding Project ECHO in the coming months with federal State Opioid Response funding (see description below).

Quality Improvement Program

Minnesota is developing a quality improvement program, which will include thresholds for terminating providers from the program. As part of this program, beginning in 2019, DHS will provide opioid prescribing reports to all health care providers who prescribe opioids for pain management and treat people enrolled in Medicaid and MinnesotaCare. These reports will compare a prescriber's opioid prescribing rates to the average rates of their specialty group. The data within the reports will come from DHS administrative claims and encounter data, eligibility data, and provider enrollment data.

The opioid prescribing workgroup developed the following seven measures of opioid prescribing to be applied at the individual provider level:

1. Rate of prescribing an index opioid prescription (index opioid prescription is the first opioid prescription after a period of 90 days of opioid naiveté).
2. Rate of prescribing an index opioid prescription over the recommended dose (100 cumulative MME for non-surgical provider specialties; 200 cumulative MME for surgical specialties).
3. Rate of prescribing more than 700 cumulative MME during the acute and post-acute pain period.
4. Rate of prescribing chronic opioid analgesic therapy.
5. Rate of prescribing high-dose (≥ 90 MME/day) chronic opioid analgesic therapy.
6. Rate of prescribing concomitant opioid and benzodiazepine therapy.
7. Percent of patients on chronic opioid analgesic therapy who receive opioids from three or more providers.

Additionally, Minnesota has an [opioid dashboard](#), which is a one-stop shop for all statewide data related to opioid use, misuse, and overdose death prevention. It includes indicators about opioid overdose death, nonfatal overdose, use, misuse, substance use disorder, prescribing practices, supply, diversion, harm reduction, co-occurring conditions, and social determinants of health. The Opioid Dashboard integrates numerous sources of data and makes it more transparent and available to the entire state. It allows for data-driven decision-making and shares information about upstream actions and promising practices.

Other Interventions

Fatality Review, Data and Analysis

This component provides funding for overdose fatality reviews, a systematic process that enables the state and local communities to understand the circumstances of these preventable deaths and identify strategies to prevent future overdoses. Nine states have recently authorized the fatality review process to examine and understand drug overdose fatalities. Overdose fatalities are not unpredictable and random. An in-depth, multi-disciplinary review of each fatality can identify failures or oversights in medical care, gaps in community services (e.g. access to mental health or medical treatment, coordination between service providers, including emergency medical services), the need for changes to state laws or government practices, or emerging causes of death (i.e. new synthetic opioids or drugs in the community). Minnesota Department of Health (MDH) staff will support and develop overdose fatality reviews across Minnesota. MDH will partner with tribal governments, counties, local public health, law enforcement, health care providers, other state agencies, and other community groups. MDH staff will lead some reviews; however, part of their responsibility will be to train partners across the state to lead fatality reviews at the local level. Most of the requested funding will support the work of the fatality reviews through grants awarded at the community level (\$1.3 million in FY20 and \$1.4 million in FY21).

Federal/State Opioid Response (SOR) Grant

In September 2018, the U.S. Department of Health and Human Services awarded more than \$17 million to Minnesota to expand services and supports and use population-specific approaches to reach isolated and vulnerable communities. Services will be implemented to expand access to prevention, treatment and recovery support for hard-to-serve populations such as pregnant and parenting women, culturally-specific populations (such as Native American, African American, Chicano/Latino, or Asian), and individuals re-entering communities from the criminal justice system. Collectively, SOR grantees will expand the availability of MAT by increasing the number of OBOT providers serving targeted hard-to-serve individuals with OUD and high acuity levels in terms of mental health and medical comorbidities, and increase the number of waived prescribers in primary care so individuals with OUD who enter any of our 400+ state licensed SUD treatment programs have access to MAT with behavioral therapies.

Activities are expected to include:

- Expand MAT and improve recovery resources;
- Grow opioid-specific services for people leaving incarceration;
- Offer more opioid use disorder training; and
- Build the opioid use disorder workforce.

DHS is currently in contract negotiations with potential grantees for awarding these grants.

Federal/State Targeted Response (STR) Grants for Collaborative Treatment Efforts

Minnesota received more than \$10 million in federal grants over two years to help establish more collaborative treatment efforts statewide. The goal of this grant is to encourage collaborative care between opioid treatment programs, health care clinics, care coordinators, and county and tribal entities. Grants focus on increasing provider capacity to identify and treat opioid addiction (including neonatal cases) and improving access to Naloxone to treat opioid overdoses. STR grants were implemented with a focus on reaching Minnesota communities experiencing significant disparities, including American Indian and African American Minnesotans. Minnesota has long recognized the importance and effectiveness of MAT for pregnant women and new mothers, therefore STR funds were also used to increase capacity reaching pregnant women. Minnesota's STR has been granted a one-year, no-cost extension for grantees with remaining funds, which were less than half of the original STR grantees. Below are more detailed descriptions of two Minnesota STR funded activities. Overall, Minnesota granted funds to more than 43 initiatives through the STR grants.

Integrated Care for High Risk Pregnancies (ICHRP) Initiative

STR funds were directed to existing Integrated Care for High Risk Pregnancies (ICHRP) Initiative grantees (see description below) to adopt an advocacy/case management model of supportive recovery-based intervention for women with opiate use disorder. The model is based on core aspects of the Parent Child Assistance Program (PCAP), an evidence-based approach cited by the Association of Maternal and Child Health Programs as a Best Practice. PCAP's primary aims are to assist mothers in obtaining drug treatment, staying in recovery, and resolving myriad complex problems related to their substance abuse; to assure that the children are in safe, stable home environments; and to prevent the births of future alcohol- and drug-exposed children. Mothers are enrolled during pregnancy or up to six months postpartum. Culturally specific intervention activities are undertaken by paraprofessional case managers who have successfully overcome difficult personal, family, or community life circumstances similar to those experienced by their clients. The case managers conduct regular home visits, connect families with services, and coordinate services among a multidisciplinary network of community providers.

Minnesota's Opioid-focused Project ECHO

STR funds were used to launch a Minnesota Project ECHO focused on building knowledge, capacity and quality of services among prescribers, social services, behavioral health treatment providers and administrators in clinic and other provider settings. Three organizations are contracted to serve as ECHO hubs: (1) The Division of Addiction Medicine at Hennepin County Medical Center (HCMC), also known as Hennepin Healthcare; (2) CHI St. Gabriel's Health; and (3) Wayside Recovery Center. The hubs engage Minnesota's medical and substance use recovery communities in a series of learning collaboratives via videoconference "clinics" focusing on evidence-based assessment and management of patients with opioid use disorders and associated comorbidities. The teaching faculty and audience are multidisciplinary and work together to discuss patient needs within the context of effective, patient-centric models of health care delivery. Hub professionals assist community providers in the stabilization of their patients through education, consultation, and direct care with the ultimate goal of empowering

general medical and substance use treatment practices to bring quality evidence-based care to their patients.

Thus far, the Minnesota Project ECHO project has successfully broadcast over 100 ECHO sessions. Hennepin Healthcare ECHO staff partnered with Minnesota Hospital Association to create a 2-day Buprenorphine Boot Camp, supported by Wayside Recovery Center and CHI St Gabriel's Health, to kick start their clinical teams' efforts to prescribe buprenorphine for opioid use disorder. One hundred eighty participants from 32 clinics, including 50 providers registered to get DATA-2000 waivers and another 33 who are already waived attended the event. As part of STR funding, Hennepin Health is also providing technical assistance and buprenorphine waiver training as necessary to primary care providers to become certified to provide MAT. The Hennepin Medical Center Opioid ECHO lead physician currently mentors 14 providers (nine physicians, three nurse practitioners, and two physician assistants) related to buprenorphine prescribing. All of them are actively prescribing buprenorphine for opioid use disorder. Through the STR funding this same physician co-facilitated a Half & Half buprenorphine waiver training for 69 providers (April 2018 and Feb 2019). In addition, Minnesota's Opioid ECHO hubs are contributing to national research by participating in an ECHO Institute study of the impact of Opioid ECHO on health and healthcare based on Medicaid claims data to evaluate the impact of Opioid ECHO on provider processes, patient outcomes and costs.

Opioid Overdose Prevention Pilot Projects

In 2017, MDH received a one-time appropriation of \$1 million to replicate the overdose prevention efforts of St. Gabriel's Hospital in Little Falls, MN. MDH awarded funding to eight communities and tribal nations. The Governor's 2019 budget proposal expanded the work occurring in the first eight communities for an additional year to allow them to assess the effectiveness and sustainability of their work. The funds also support similar drug overdose prevention grants to eight new communities for two years. Each year, the program would allow eight communities to "graduate" and eight new intervention communities would initiate prevention work (\$1.3 million in FY 20 and \$2.3 million each year thereafter).

Each community implements six major activities to reduce opioid use or abuse and reduce rates of opioid addiction:

1. Establishing multidisciplinary controlled substance care teams that may consist of physicians, pharmacists, social workers, nurse care coordinators, and mental health professionals;
2. Delivering health care services and care coordination, through controlled substance care teams, to reduce the inappropriate use of opioids by patients and rates of opioid addiction;
3. Addressing any unmet social service needs that create barriers to managing pain effectively and obtaining optimal health outcomes;
4. Providing prescriber and dispenser education and assistance to reduce the inappropriate prescribing and dispensing of opioids;

5. Promoting the adoption of best practices related to opioid disposal and reducing opportunities for illegal access to opioids; and
6. Engaging partners outside of the health care system, including schools, law enforcement, and social services to address root causes of opioid abuse and addiction at the community level.

Legislation to Move to Client-Centered Model

The 2017 Minnesota Legislature enacted new reforms to Minnesota's SUD treatment system to move from an acute, episodic-based system to a client-centered model of care, with an emphasis on managing SUD as a chronic disease. These changes remove barriers that have prevented Minnesotans on Medicaid from accessing substance abuse treatment. The reform package allows patients to more quickly access services, and adds important services like withdrawal management, treatment coordination and peer support.

Medication-Assisted Treatment (MAT) for Opioids

As discussed in Milestones 3, 4, and throughout this section, Minnesota has engaged in efforts to promote and expand MAT services across the state. Currently there are 17 Opioid Treatment Programs (OTP) operating in the state and in recent years there has been an increase in the number of tribally licensed programs that offer MAT services. Current SUD placement guidelines outlined in Minnesota Rules 9530.6622, and structured similarly to ASAM's six dimensionsⁱ, require placing authorities to refer a client with an OUD and a risk rating of two or more to an OTP. Minnesota has also expanded the availability of MAT by authorizing mid-level nurse practitioners and physician assistants to dispense medications used to treat OUD. This allowance, in addition to information the state has regarding practitioners utilizing the Drug Addiction Treatment Act of 2000's waiver to increase patient prescribing capacity to 275, has increased the capacity for MAT across the state.

Many of the activities discussed in this section are supporting expansion of MAT access through federally funded STR, SOR and MAT Expansion grants and additional state funding. Launched through Minnesota's STR grants in 2017, Minnesota is using Project ECHO to educate and engage a range of provider environments and professionals about MAT--from the prescribers, to social service staff, to licensed alcohol and drug abuse counselors, to clinic administrators and beyond (see STR summary language above). Through this process, Minnesota is working to expand access to MAT and improve quality of services across the state.

The 2017 Minnesota Legislature provided \$825,000 for health care providers to purchase direct injectable drugs to treat opioid addiction. The Minnesota Department of Corrections is also developing a strategic plan to expand access to MAT for the criminal justice-system. DHS has also received a \$6 million SAMHSA MAT expansion grant. The project is a partnership with the Red Lake Nation, the White Earth Tribal Government, and Fairview Medical Center. The first two organizations are targeting Native American communities, while the latter is targeting African American communities.

Federal Strategic Prevention Framework for Prescription Drugs

In 2016, Minnesota received a \$1.5 million federal grant over five years to prevent and reduce opioid abuse and reduce opioid overdoses. The grant requires that state agencies: 1) design, implement, enhance, and evaluate primary prevention efforts using evidence-based methods; 2) work with pharmaceutical and medical communities on risks of overprescribing; and 3) raise community awareness and bring opioid abuse prevention activities and education to schools, communities, parents, prescribers, and their patients.

Integrated Care for High-Risk Pregnancies

In 2015, the Legislature directed DHS to implement a state-funded pilot grant program—called the Integrated Care for High Risk Pregnancies (ICHRP) Initiative—to improve birth outcomes for high-risk women by addressing opioid use and low birth rate (Minnesota Statute § 256B.79). ICHRP targets pregnant women who are Medicaid enrollees and who are at significantly elevated risk for adverse outcomes of pregnancy. Adverse outcomes include low birth weight, prematurity, maternal opiate addiction, and other reportable prenatal substance abuse. Half of the funds were awarded to five tribes to address opioid-exposed pregnancies. The grant supports planning, system development and integration of medical, chemical dependency and social services, incorporates screening, collaborative care planning, referral, and follow up for behavioral and social risks, and encourages use of community-based paraprofessionals such as peer recovery support workers, doulas and community health workers. In 2019 the Legislature continued the ICHRP grant program. It is anticipated that the pilot may inform future policy development to sustain these efforts in Medicaid.

Minnesota Residential Treatment for Pregnant and Postpartum Women (PPW)

The PPW program is designed to expand and enhance women’s pregnant and postpartum SUD services across the continuum of care (prevention, treatment and recovery) for women, children and families who receive treatment for SUDs. The PPW focuses on low-income women, age 18 and over, who are pregnant or postpartum, and their minor children, age 17 and under, who have limited access to quality health services including traditionally underserved populations, especially racial and ethnic minority women.

In Minnesota, these underserved populations with the largest disparities include American Indian women, African American women and women receiving treatment services in rural areas. The MN PPW supports evidence-based parenting and treatment models, including trauma-specific services in a trauma-informed context. New and existing grants, through curricula and treatment program services, collaborations, and a required PPW evaluation will measure outcomes specific to the identified target populations with the highest disparities in our state.

Limiting Opioid Prescriptions and Improving Warning Efforts

In 2017, Governor Dayton and the Legislature passed a law requiring opiate prescriptions to contain a label that says “Caution: Opioid: Risk of overdose and addiction.” The bill also limits

opiates to a four-day supply for certain situations of dental or ophthalmic pain but provides health care providers discretion if he/she determines that a larger quantity is needed.

Pharmacy Drop-Off Sites

In 2016, the Legislature passed and the Governor signed legislation allowing any Minnesota pharmacy to be a drop-off site for unused prescriptions, including opioids.

Opioid Stewardship Fund and Advisory Council

In 2019, the Legislature created an opioid stewardship fund, funded by fees collected by the Board of Pharmacy, to address rising rates of opioid use through grant programs. The new law establishes an opioid stewardship advisory council to develop and oversee a comprehensive and effective statewide effort to address the impacts of the opioid crisis. The council will be tasked with reviewing local, state, and federal initiatives and funding related to prevention and education, treatment, and services for individuals and families experiencing and affected by opioid abuse and promote innovation and capacity building to address the opioid addiction and overdose epidemic. It will help ensure that opioid stewardship funding aligns with existing state and federal funding in order to achieve the greatest impact and support a coordinate state effort to address the opioid addiction and overdose epidemic.

Culturally Specific Prevention Grants

This grant program addresses the overdose disparities in Minnesota and strives to identify and interrupt the root causes of the overdose epidemic. MDH will distribute grants to organizations working directly with urban American Indians and Minnesota's 11 tribal nations. The community organizations and tribal nations will implement components of the Menomonie Project, a whole health initiative designed by the Menomonie Nation (Wisconsin) that has resulted in clear reductions in overdose death and hospitalizations. The Menomonie Project emphasizes high school graduation rates, employment, reclaiming language, prescribing practices, social services, and family supports (\$2.4 million in FY20 and \$4.5 million each year thereafter).

Know the Dangers Website

Minnesota launched a website – www.knowthedangers.com – to educate the public about opioid facts and how to get help for yourself or someone you know.

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

Minnesota has numerous efforts under way to improve access to Naloxone, including:

- The Minnesota opioid prescribing guidelines recommend that providers of opioids consider co-prescribing naloxone to individuals vulnerable for opioid overdose or to their loved ones.

- The Minnesota Board of Pharmacy (BOP) developed the Opioid Antagonist (Naloxone) Protocol which allows participating pharmacies to issue a legally valid prescription for naloxone and then to dispense it.
- MDH provides funding to regions to purchase Naloxone and to provide training to first responders – including state troopers, sheriffs, local law enforcement, tribal police, fire, and EMS – across the entire state. Often, our first responders have opportunities to save lives and can do so when equipped with training (so ensure proper administration of either the injectable or inhalation Naloxone) and are provided with at least two doses of Naloxone per first responder (\$1 million each year).
- Through the federal STR grants, organizations are expanding distribution efforts in Greater Minnesota and in tribal communities. DHS issued grants that support organizations and communities with the greatest need, including Brainerd, the Iron Range, White Earth, Duluth and St. Louis County, and St. Cloud. (The grants also support expanded access in the Twin Cities metropolitan area.)
- DHS funded three community-based organizations to provide naloxone distribution and training across Minnesota to syringe services programs, businesses, and individuals under the STR funding. DHS is currently working on negotiating contracts with existing and new grantees for naloxone distribution and training.
- MDH recently hired a Statewide Naloxone Coordinator to increase pharmacy participation in the Opioid Antagonist Protocol and ensure a thorough, coordinated response among various naloxone training and distribution initiatives across Minnesota.

Additionally, in 2014, the Minnesota Legislature enacted a law allowing for more widespread distribution and administration of Naloxone to reduce or prevent opioid overdoses. The law protects first responders and certain licensed health care professionals from civil liability or criminal prosecution for administering opioid antagonists to a person experiencing an opioid overdose.

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

By law, all controlled substance prescribers and pharmacists in Minnesota must enroll in the Minnesota Prescription Monitoring Program (MNPMP) and maintain a user account. However, at this time, prescribers are not required to use the MNPMP. Under [245G.22 Subdivision 16](#), upon admission to a methadone clinic outpatient treatment program, the medical director (or a delegate) must check the MNPMP and continue to do so at least quarterly. If MNPMP data shows there are multiple prescribers or multiple prescriptions for controlled substances, the MNPMP must be checked monthly. Additionally, the Board of Pharmacy sends alerts to

prescribers and pharmacies about individuals who, based on PMP data, may be “doctor shopping”.

In October 2018, the MNPMP was queried 695,715 times compared to 89,893 queries in October 2017, an increase of 673.9 percent year-over-year.³ Minnesota, including all of the state’s health licensing boards, is working to increase the number of providers and pharmacies who use the MNPMP. Additionally, the MNPMP allows for interstate data sharing with 38 states utilizing PMP InterConnect.

The state uses a NarxCare and PMP AWARe software solution to aggregate and analyze prescription information from MNPMP and present visual, graphical and advanced analytic insights, and machine learning risk scores to help physicians, pharmacists and care teams provide better patient safety and outcomes. NarxCare also provides clinical tools and resources that support patients’ needs, including connectivity to treatment options, when appropriate.

Minnesota is planning to enhance MNPMP functionality and interoperability, including by linking it to systems in which prescribers will be able to view electronic health records and easily link them with the MNPMP (currently, staff have to leave the electronic health record, go to the MNPMP, and then go back to the electronic health record). MDH is applying for CDC Overdose Data to Action funding, a key strategy of which is to support the improvement of MNPMP functionality, interoperability, and provider utilization.

Summary of Actions Needed to Achieve Milestone #5

Action Needed	Timeline
Continue to support the use of the MNPMP when prescribing, and the use of the Prescribing Guidelines	Ongoing By December 2020, opioid prescribers over predetermined prescribing thresholds will be required to use and document use of the PDMP as part of the prescribing improvement program.
Identify opportunities for expanding MNPMP functionality and use	Ongoing
Increase the use of MNPMP by providers and pharmacists	Ongoing

³Total queries include prescribers, pharmacists, delegates, and administrative users granted access according to Minnesota Statutes 152.126. In September 2018 one statewide pharmacy chain and one health system integrated a one-click feature to view a MNPMP report from within their pharmacy dispensing system and electronic health record system via Appriss Health’s PMP Gateway managed service. Previous months reflect system direct queries only.

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

CMS Specifications:

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

Minnesota's Response:

Minnesota is working to ensure that there is a full continuum of care in place in order to effectively serve beneficiaries with SUDs. The state is in the process of implementing new services provider requirements to ensure residential and inpatient providers link beneficiaries, especially those with OUDs, to community-based services and supports at each point in the care continuum. Virtually all of the activities described as the "current state" below will also carry forward to the future state.

Current State: Minnesota has enacted updated state laws defining treatment coordination provider qualifications ([245G.11, Subdivision 7](#)), a new care coordination service called "SUD treatment coordination" ([245G.07, Subdivision. 1\(6\)](#)), and outlined requirements for treatment planning services and reviews ([245G.06, Subdivision. 3](#)). Together these three elements have established the foundation for a successful continuum of care. When a beneficiary enters treatment, an individual treatment plan is required, and as a part of that plan, the provider must include resources to refer the client when the client's needs are to be addressed concurrently by another provider (245G.06). In addition, the provider must document treatment coordination activities in the weekly treatment plan review. The review includes the date, the type and amount of each treatment service, including treatment coordination activities, and the client's response. Treatment coordination activities occur throughout the client's treatment, when the decision is made to transition to a new level of care and when a discharge summary is completed. The discharge summary includes "continuing care recommendations, including transitions between more or less intense services, or more frequent to less frequent services, and referrals made with specific attention to continuity of care for mental health, as needed" (245G.06 subd. 4). The DHS Licensing Division monitors the requirements for licensed treatment providers.

Adults or adolescents eligible for Medicaid who have a SUD diagnosis and need treatment services are also eligible for SUD treatment coordination. Treatment coordination may be provided by a SUD-licensed treatment facility, a county/tribe, or a licensed individual who has specific knowledge in SUD and who meets the qualifications identified in 245G.11 subdivision 4. An individual is qualified to provide SUD treatment coordination if they meet the staff qualifications as a treatment coordination provider under 245G.11, Subdivision 7; and:

1. Is skilled in the process of identifying and assessing a wide range of client needs;

2. Is knowledgeable about local community resources and how to use those resources for the benefit of the client;
3. Has successfully completed 30 hours of training on care coordination for an individual with substance use disorder; and
4. Has either a bachelor's degree in one of the behavioral sciences or related fields; or current certification as an alcohol and drug counselor, level I, by the Upper Midwest Indian Council on Addictive Disorders; and has at least 2,000 hours of supervised experience working with individuals with substance use disorder.

SUD treatment coordinators must receive at least one hour of supervision regarding individual service delivery from an alcohol and drug counselor or a mental health professional who has substance use treatment and assessments within the scope of their practice, on a monthly basis.

SUD treatment coordinators must also:

1. Provide assistance in coordination with significant others to help in the treatment planning process whenever possible;
2. Provide assistance in coordination with, and follow up for, medical services as identified in the treatment plan;
3. Facilitate referrals to SUD services as indicated by a client's medical provider, comprehensive assessment, or treatment plan;
4. Facilitate referrals to economic assistance, social services, housing resources, and prenatal care according to the client's needs;
5. Provide life skills advocacy and support accessing treatment follow-up, disease management, and education services, including referral and linkages to long-term services and supports as needed; and
6. Document the provision of treatment coordination services in the client's file.

SUD treatment coordinators are required to assist people in making appointments, getting to appointments, and following through on recommended treatment (e.g. filling prescriptions, etc.). SUD treatment coordinators are also required to assist people in obtaining public benefits such as cash benefits, food support, and subsidized housing. Lastly, SUD treatment coordinators are expected to assist people with navigating between SUD levels of care based on their medical necessity and choice.

SUD treatment coordination is available to any person deemed eligible through a comprehensive assessment. Some people will receive treatment coordination while receiving residential or outpatient SUD treatment. Licensed treatment facilities all are required to provide treatment coordination per 245G.07. Residential treatment providers are expected to provide this service as a part of the per diem payment. A person receiving SUD treatment coordination services can receive other Medicaid care coordination or case management services as appropriate. The expectation is that the SUD treatment coordinator will

communicate with other care coordinators or case managers to ensure duplication and errors regarding care coordination responsibilities are avoided.

Certified Community Behavioral Health Clinics

Care coordination is the linchpin of the CCBHC model of care. CCBHCs are required to coordinate care across settings and providers to ensure seamless transitions for people across the full spectrum of health and social services, including acute and chronic medical needs and behavioral health needs. As providers of outpatient SUD services within the continuums of care described in this waiver, the CCBHCs can provide SUD treatment coordination or CCBHC care coordination as people's level of care needs increase and decrease throughout care.

Future State: Minnesota is in the process of establishing provider requirements for participating SUD providers and anticipates publishing final guidance by October 2020. These requirements will emphasize the importance of treatment coordination to support the transitions between appropriate levels of care during treatment, and at the end of the treatment process. The preliminary requirement for providers seeking to participate will be referral agreements attesting to the residential providers' ability to coordinate treatment within all of the ASAM levels of careⁱ thereby supporting the providers' ability to conduct treatment coordination and promote long-term recovery. [To help ensure seamless transitions for people across a full spectrum of health and social services, participating providers will be required to provide peer recovery support services to assist beneficiaries and facilitate access to the additional services they need. In addition to requiring that providers offer peer recovery support services, the state will establish within its utilization management practices, a requirement that utilization reviews include oversight of treatment coordination and peer recover support services and the provider's follow through on client referrals.](#)

Minnesota's SUD providers must provide discharge planning including documentation of continuing care recommendations including any ongoing behavioral health treatment (245G.06 subd. 4). Minnesota's 1115 Policy Team (mentioned in Milestone 3), which includes individuals from the licensing division who currently monitor for this requirement, will develop standards for enhancing and aligning the discharge plan requirements with ASAM criteriaⁱ and publish these standards in the provider manual by October 2020. Minnesota's policy leads for SUD treatment coordination are also developing further guidance on ASAM- based treatment coordination standards for 1115 waiver providers.

Development of these standards is part of the broader growth of Minnesota's SUD treatment efforts and its support of the 1115 waiver implementation for residential and non-residential providers by June, 2021. Current and future work includes engagement with relevant business areas to facilitate updates to Minnesota's provider manual and necessary system changes, stakeholder engagement, identifying roles and responsibilities of providers of treatment coordination above and beyond what is identified in statute to avoid duplication of services, other development of training necessary for providers, ongoing communication and training with designated pilot participants and coordination with managed care organizations.

The state is also exploring utilization of a cloud based service such as the Omnibus Care Plan (OCP), which is a care coordination platform created by SAMHSA that facilitates the service coordination for recipients who are being served by multiple disparate providers and provider networks. Service coordination between disparate providers and provider networks is going to be one of the most critical components of the Integrated Behavioral Health project, Continuum of Care/SUD reform project, 1115 SUD Waiver project, and the Housing Stabilization Services project. Omnibus Care Plan would provide a cloud-based service coordination tool for any provider to use with other providers, the state, counties, and service recipients. Finally, the state has been undertaking an extensive redesign of case management and care coordination services in Medicaid writ large, and the SUD-related needs will be considered in the design.

Summary of Actions Needed to Achieve Milestone #6

Action Needed	Timeline
Providers electing to participate provide verification of formal referral arrangements to ensure access to each of the ASAM levels of care ⁱ	January 2020; ongoing
Implement training and technical assistance to align providers with ASAM-based standards.	July 2020; ongoing
Update MCO contracts to reflect any necessary residential provider requirement changes	September 2020 (for January 2021 contract initiation)
Publish ASAM-based service standards and staffing requirements in MHCP provider manual	October 2020
Develop residential treatment provider review process and initiate ongoing monitoring process	June 2021
Communicate changes to providers	Ongoing

ⁱ Mee-Lee D, Shulman GD, Fishman MJ, Gastfriend DR, Miller, eds. The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions. 3rd ed. Carson City, NV: The Change Companies; 2013. Copyright 2013 by the American Society of Addiction Medicine.

Minnesota Substance Use Disorder System Reform Section 1115 Demonstration

Health Information Technology (IT) Plan

Section I

Part 1: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

Minnesota Prescription Monitoring Program

The Minnesota Prescription Monitoring Program (PMP) was established in 2009 to promote public health and welfare by detecting abuse, misuse and diversion of controlled substance prescriptions.

The Minnesota Board of Pharmacy administers and oversees the operation of the PMP program and has selected Appriss Health to develop a data base that collects and stores prescribing and dispensing data.

Appriss Health's prescription drug monitoring program, PMP AWARe, is a web-based program that facilitates the collection, analysis and reporting of information on the dispensing of controlled substances.

Minnesota law requires that pharmacies and prescribers who dispense from their offices submit prescription data to the PMP system for all Scheduled II, III, IV and V controlled substances, butalbital and gabapentin dispensed in or into Minnesota. Minnesota licensed prescribers and pharmacists, and their delegated staff may be authorized to access information from the PMP database. This protected health information is collected and stored securely.

Additionally, Minnesota law mandated the Board of Pharmacy to appoint an advisory task force, made up of representatives from health related licensing boards, other state agencies, professional associations and members of the public. The Task Force advises the Board on the development and operation of the PMP including, but not limited to:

- (1) technical standards for electronic prescription drug reporting;
- (2) proper analysis and interpretation of prescription monitoring data;
- (3) an evaluation process for the program; and
- (4) criteria for the unsolicited provision of prescription monitoring data by the board to prescribers and dispensers.

As noted, the PMP is administered and overseen by the Minnesota Board of Pharmacy. As such, the Minnesota Department of Human Services (DHS) has limited influence over the PMP. DHS will continue to work with the Minnesota Board of Pharmacy and its advisory task force to identify opportunities to align the capabilities of the PMP with the SUD Health IT Plan requirements.

Interstate Data Sharing

Minnesota participates in an interstate PMP data exchange system, which allows permissible users in other states access to Minnesota PMP data. Conversely, other states allow Minnesota permissible users access to their data. This is accomplished using a secure method called the PMP InterConnect. There are

currently 42 states or jurisdictions exchanging data with the Minnesota PMP.

Table 1: Strategies to Increase Utilization and Improve Functionality of Minnesota’s PDMP

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Criterion 1: Enhanced interstate data sharing in order to better track patient specific prescription data</p>	<p>Minnesota is currently connected to the interstate sharing hub PMP Inter-Connect and is presently sharing access with the Military Health System, the District of Columbia and 40 states, who wish to share access or who have authority to share access according to their laws.</p>	<p>The Minnesota Board of Pharmacy (BOP) will pursue ongoing efforts at interconnecting with Oregon, Utah, Georgia, New Hampshire, Vermont, Puerto Rico, Guam, California, Nebraska and Missouri. Additional interstate data sharing opportunities will be investigated as they are recognized, with the intent that Minnesota is connected with all states in efforts to track patient-specific prescribing data. The Minnesota Department of Human Services’ Behavioral Health Division will actively collaborate with and support the efforts of the BOP in expanding interstate data sharing agreements.</p>	<p>This is dependent on the laws of each of the partner states and their technical capabilities. Currently, California and Oregon have no authority to share, Missouri is county based, thus some barriers with authority on their side, and Nebraska permits all licensed medical providers to access their data, which is an outlier in the PDMP community, making it challenging to allow two-way sharing. As statutory changes take place, the states and territories will be added as partners. Monitoring Progress: MN BOP, Controlled Substances Reporting, Director. In addition, MN BOP will explore the potential use of additional funding through CMS or SAMHSA in 2020, in order to potentially expand interstate data sharing possibilities, as other states have done.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Criterion 2: Enhanced “ease of use” for prescribers and other state and federal stakeholders</p>	<p>At present, Minnesota health care providers and prescribers have the opportunity to leverage electronic health records that are integrated with access to the PMP database to make safer prescribing decisions easier.</p> <p>Currently we have 46 healthcare entities and pharmacies that have signed up with Appriss Health to use PMP</p> <p>Gateway Services (the software program that integrates access to the PMP database into the clinical workflow), and another 10 are awaiting approval.</p>	<p>The MN BOP will explore the potential of conducting randomized controlled trials to determine the return on investment for statewide integration of access to the PMP report via the electronic health record systems. This study will be conducted beginning in 2020 with estimated completion by 2021.</p> <p>Minnesota will continue to promote integration to access the PMP database within the clinical workflow to bring up the number of clinics offering this service.</p>	<p>MN BOP, Controlled Substances Reporting Section, Director; MN Management and Budget, Impact Evaluation Unit Manager; Researchers as assigned by funding partner (J-Pal).</p> <p>Milestones: Planning phase to be completed by 7/31/2020. Start of integration activities no later than 8/1/2020, RCT to begin between no later than 8/1/2020 and continue through 9/30/2021. Monitoring Progress: MN BOP, Controlled Substances Reporting Section, Director.</p> <p>Responsible: MN BOP, Controlled Substances Reporting Section, Director. Seeking sustainable funding to offer statewide services. Initial funding has been established and will last until 9/30/2021. Progress Monitoring: MN Board of Pharmacy, Controlled Substances Reporting Section, Director.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Criterion 3: Enhanced connectivity between the state’s PDMP and any statewide, regional or local health information exchange</p>	<p>There is no current connectivity between the PMP and any state or local health information exchange (HIE). Connectivity between the PMP and state or local HIEs is not allowed under state law.</p> <p>In the meantime, the PMP is governed by the MN PMP Advisory Task Force, whose purpose is to advise the MN Board of Pharmacy , as they will continue to do, on the development and operation of the prescription monitoring program, including, but not limited to:</p> <ul style="list-style-type: none"> Technical standards for electronic prescription drug reporting; Proper analysis and interpretation of prescription monitoring data. Evaluation process for the program; Criteria for the unsolicited provision of prescription monitoring data by the board to 	<p>In order to increase the efficiency and effectiveness of use of the PMP, Minnesota Board of Pharmacy (BOP) has embarked on a path to improve interoperability of PMP information and content. The end goal is to provide all MN authorized healthcare entities – ambulatory care units, acute care facilities, emergency care units, pharmacies, and others – the ability to integrate access to MN PMP information into their Health IT systems, be they Electronic Medical Records (EMRs), Electronic Health Records (EHRs), Health Information Exchanges or Pharmacy Management Systems. The integrated solution will allow users to access the same information that is available in the MN PMP within their clinical workflows, including patient prescription history, summary information, and clinical risk indicators.</p>	<p>The Minnesota Legislature would need to pass legislation to allow this. The current legislative makeup has a strong data-privacy concern and has not expressed interest in passing legislation to allow for connectivity between the PMP and state or local HIEs. Regardless, collaboration between BOP, DHS, MDH, and other SUD treatment entities will focus on increasing the potential connectivity between the existing PMP and other HIE’s, and submitting legislative language that would allow for such exchanges of information.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>prescribers and dispensers.</p> <p>The task force is governed under MN Statutes Chapter 152.126, Subd. 3</p>		
<p>Criterion 4:Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns</p>	<p>Minnesota law requires DHS to provide individualized opioid prescribing reports to all health care providers who prescribe opioids for pain management and treat MinnesotaCare or Medicaid enrollees. The reports provide data to prescribers on their prescribing patterns and those of their anonymized peers. The data provided in the reports is from Medicaid and MinnesotaCare administrative claims data. The reports do not use data from the PMP. The goal of sharing this data with providers is to support quality improvement. The first reports went out to prescribers in July 2019. Minnesota is</p>	<p>Minnesota will continue to refine the reports to meet the needs of the state-mandated Opioid Prescribing Improvement Program (OPIP). There are quality improvement thresholds for five of the seven opioid prescribing sentinel measures. Providers whose prescribing rate is above the threshold for any of the five measures will be required to participate in the quality improvement program if they also prescribed above a certain volume of opioid analgesic prescriptions to Minnesota Medicaid and MinnesotaCare enrollees in the measurement year. The reports present the comparative rates in bar graphs, and the quality improvement threshold is clearly</p>	<p>MN BOP is in the process of securing a contract with APPRISS Health for their PMP Gateway product using grant funds from the Department of Justice, Bureau of Justice Assistance which will pay for roughly 1 year of PMP Gateway Service. In addition, the BOP holds an interagency agreement with the MN Department of Health, using funds from their Center for Disease Control (CDC), Opioid Data to Action (OD2A) grant, to off-set a quarter of the cost of the annual service agreement.</p> <p>Legislative approval would be required to allow DHS staff access to prescriber audit trail information from the PMP.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>utilizing the MN- ITS mailbox to send the reports to prescribers that have registered to receive the communication through the web-based HIPPA compliant system. Providers who have not signed up for the MN-ITS mailbox will receive the notice through the U.S. Postal Service for the first year.</p> <p>Governor Dayton and the Minnesota Legislature established the Opioid Prescribing Improvement Program in 2015 to reduce opioid dependency and misuse in Minnesota related to opioid prescriptions. The Opioid Prescribing Work Group will convene through 2021 to advance the program, which includes the goal of working collaboratively with the Minnesota medical community.</p> <p>In 2019, Governor Tim Walz signed the Opiate Epidemic Response into law.</p>	<p>marked in each graph. Prescribers will receive additional information about participating in the quality improvement review. Participation in the quality improvement program is based on the follow-up set of reports, which will be released in 2020. The follow-up set of reports will provide updated data and prescribing rates reflecting the time after receipt of this first report. DHS will work to expand prescriber enrollment and will continue to refine reporting and quality improvement processes.</p>	

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>The bill secures sustainable funding to fight the opioid crisis. The Opiate Epidemic Response bill establishes the Opioid Epidemic Response Advisory Council to develop and implement a comprehensive and effective statewide effort to address the opioid addiction and overdose epidemic in Minnesota.</p> <p>The State Government Opioid Oversight Project (SOOP) is several MN state agencies working together at every level — from prevention, to emergency response, to treatment — in order to eliminate duplication of efforts, align work and leverage resources.</p> <p>The Opioid Prescribing Workgroup published prescribing guidelines for acute, post-acute and chronic pain prescribing protocols for our Medicaid recipients. Efforts include: The Minnesota Department of Health’s (MDH) Data</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>driven prevention initiative has created an online data dashboard, and will next focus on a statewide strategic plan. The Department of Public Safety (DPS) collaborated with the MDH to share law enforcement and public health data in order to identify new trends. The Department of Human Services (DHS) is creating a campaign directed to health care providers on how to educate patients about the safe use of opioids. The DHS received a federal grant to raise awareness and bring prescription drug abuse prevention education to schools, communities, parents, prescribers and their patients. Substance use disorder reforms passed in 2017 (as proposed by DHS) mean that individuals will soon be able to go directly to providers to receive an assessment, providers will be reimbursed for services off-site, and three new services—</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>treatment coordination, peer recovery support, and withdrawal management—will be added.</p>		
<p>Criterion 5: Facilitate the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP</p>	<p>Minnesota’s PMP vendor provides the Minnesota Board of Pharmacy patient matching within the system. There is no interaction with a master patient index. However, The Prescription Monitoring Program (PMP) offers prescribers and dispensers the ability to view controlled substance prescription history for individual patients. As of July 2017, prescribers and pharmacist are required to have a PMP account. The BOP sends out controlled substance insight alerts to prescribers and pharmacies concerning individuals who, based on PMP data, may be doctor shopping.</p>	<p>Any systems integration or data sharing will hinge on legislative approval, as noted previously.</p> <p>While Minnesota currently does not have the statutory authority to create a universal master patient index (MPI) that can be used across all systems, payers, program, and benefits, Minnesota DHS is working to develop a Universal Person Identifier (UPI). Ideally, this UPI could be used across all business departments and programs that would leverage efficiency and coordination for citizens, workers, and systems. The MPI would have well defined rules to identify and</p>	<p>In addition to the creation of a universal MPI, the BOP (in collaboration with other stakeholders) would need to utilize predictive analytics to forecast increased risk of long-term opioid use based on initial prescribing characteristics.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>State law provides DHS with limited authority to access the PMP: (1) for purposes of placing a recipient into the Restricted Recipient Program and monitoring their care; and (2) for purposes of monitoring care of people receiving care from an opioid treatment program</p>	<p>correct data inaccuracies or duplicate records without jeopardizing program efficiencies or historical records for members, while also preserving confidentiality for the member.</p> <p>Specific to healthcare, the ideal MPI could be used across multiple payers and follow a member from plan to plan regardless of who is providing coverage (public programs, private insurance, Medicare, etc.).</p>	
<p>Criterion 6: Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow</p>	<p>46 healthcare entities and pharmacies within Minnesota have contracted with Apriss Health to use PMP Gateway Services, a software solution that integrates the PMP into the clinical workflow. Another 10 are awaiting approval.</p>	<p>The BOP will consider the feasibility of conducting a randomized controlled trial to determine the return on investment for statewide integration of access to the PMP report via the electronic health record systems. The study will be conducted beginning in 2020 with estimated completion by 2021.</p>	<p>Responsible: MN Board of Pharmacy, Controlled Substances Reporting Section, Director. Seeking sustainable funding to offer statewide services. Initial funding has been established and will last until 9/30/2021. Progress Monitoring: MN Board of Pharmacy, Controlled Substances Reporting Section, Director. Minnesota DHS will</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
			continue to promote integration to access the PMP within the clinical workflow.
<p>Criterion 7: Develop enhanced supports for clinician review of the patients’ history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription</p>	<p>In December 2018 Minnesota launched NarxCare, a robust analytics tool and care management platform that helps prescribers and dispensers analyze real-time controlled substance data from PMPs and provides clinical resources for risk assessment and patient support, including interactive graphical representation of the PMP data, with risk scores and morphine milligram equivalents.</p>	<p>Minnesota will continue to work with its PMP vendor to include additional data which would be provided from outside (of the PMP), such as overdose event data, etc.</p> <p>Once the new system is fully implemented, additional analytic capabilities will be explored and implemented, as feasible, in order to enhance provider workflow / business processes, to support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance, and to promptly address the issues related to over-prescription of opioids.</p>	<p>MN Board of Pharmacy, Controlled Substances Reporting Section, Director. Seeking sustainable funding to offer statewide services. Initial funding has been established and will last until 9/30/2021. Progress Monitoring: MN Board of Pharmacy, Controlled Substances Reporting Section, Director.</p> <p>Both fiscal and policy barriers will be addressed in a collaborative manner by BOP and identified stakeholders.</p>
<p>Criterion 8: Enhance the master patient index (MPI) or master data management service (MDMS) in support of</p>	<p>There is currently a DHS Unique Person Identifier (UPI) project underway, which is an</p>	<p>While Minnesota currently does not have the statutory authority to create a universal master</p>	<p>In addition to the creation of the UPI by DHS, the BOP (in collaboration with other stakeholders) would</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
SUD care delivery.	<p>enterprise wide solution to (1) merge duplicate client records and (2) prevent duplicate records in the future. Gaps have been identified between current and future state requirements and specific, objective and relevant factors identified for each gap. Systems impacted include legacy systems and Minnesota Electronic Technology Systems (METS). One outcome is improved oversight of Program Eligibility which will reduce fraud, waste and abuse.</p> <p>The 2019 Minnesota legislative session passed requirements for the Unique ID project to design and implement a corrective plan to address the issue of Medical Assistance enrollees being assigned more than one personal identification number.</p>	<p>patient index (UPI) that can be used across all systems, payers, program, and benefits, ideally, Minnesota is developing a UPI that will ultimately be used across all business departments and programs, that would leverage efficiency and coordination for citizens, workers, and systems. The MPI would have well defined rules to identify and correct data inaccuracies or duplicate records without jeopardizing program efficiencies or historical records for members, while also preserving confidentiality for the member.</p> <p>Specific to healthcare, the UPI could be used across multiple payers and follow a member from plan to plan regardless of who is providing coverage (public programs, private insurance, Medicare, etc.). This could create a uniform and</p>	<p>need to utilize predictive analytics to forecast increased risk of long-term opioid use based on initial prescribing characteristics.</p> <p>Any systems integration or data sharing will hinge on legislative approval, and fiscal collaboration, as noted previously.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>This must be completed by June 30, 2021. A report to the legislature is due February 15, 2020 detailing the progress and plan to meet the deadline.</p>	<p>comprehensive record of a member’s healthcare and eligibility.</p>	
<p>Criterion 9: Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids</p>	<p>MN has several programs in place to implement effective controls and minimize risk of inappropriate opioid overprescribing. As a result, prescriptions for opioid analgesics in Minnesota declined over the last few years, but the state still seeks to impose penalties against certain physicians who overprescribe them. New opioid prescriptions for residents benefitting from state programs fell 33% since 2016. Opioid dosages exceeding new state guidelines have also declined, falling by more than one-half. There is a new state law under which DHS sends private reports to providers each year regarding personal prescription rates. DHS also manages a</p>	<p>All implemented programs will benefit from increased utilization of and integration with the MN PDMP.</p> <p>In addition, thresholds that will trigger quality improvement (and ultimately termination from the Minnesota Health Care Program enrollment) will be refined on an ongoing basis.</p> <p>The Opioid Prescribing Work Group (OPWG) is an advisory body of experts convened to forward DHS’ Opioid Prescribing Improvement Program (OPIP). The program plays a crucial role in Minnesota’s response to the crisis of prescription opioid misuse and abuse, namely addressing inappropriate</p>	<p>MN BOP, DHS, MDH, and other stakeholders will, on an ongoing basis, explore streamlining of collaboration and communication between all existing SUD monitoring programs and the MN PDMP.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>quality improvement program for providers who prescribe beyond community standards. Physicians with high prescribing rates could potentially be removed from such programs as MinnesotaCare and Medical Assistance.</p> <p>The application, Drug and Alcohol Abuse Normative Evaluation System (DAANES) is a web-based application which tracks chemical dependency treatment episodes in Minnesota. Fulfills federally mandated reporting requirements necessary to receive federal funds. Primary functions of DAANES includes: (1) tracking detoxification services (2) tracking chemical dependency treatment services; and (3) tracking and reporting the State's Methadone Treatment Program</p>	<p>prescribing behavior among Minnesota health care providers. The OPWG, stakeholders, and collaborative agencies will work with BOP to develop data collection mechanisms and sharing agreements that will address those providers that exhibit persistently concerning prescribing practices.</p>	

Acronyms:

DHS – Department of Human Services

MDH – Minnesota Department of Health

DCT – Direct Care and Treatment

Part 2: Attestation

Statement 1: Indicate whether the state has 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

The state has sufficient Health IT infrastructure within state Medicaid and pharmacy systems, contracted managed care organizations, and provider electronic health records. The state has a high level of electronic health record adoption and health information exchange to achieve the goals of the demonstration. There are more than 385 active computer systems within the DHS environment. The applications listed here are considered major because of size, scope, and/or impact.

DHS System	Primary Function(s)
Avatar	Certified health care case management system focused on behavioral health, individuals with intellectual and developmental disabilities, addiction treatment and public health. Avatar provides: care coordination between providers and staff that regularly interact with the individuals that we serve, electronic submission of bills for the services provided and expected reimbursement, electronic submission of mandated measures for CMS, and other items. Functions include an electronic record of mental and physical treatment, a record of medications prescribed, taken and refused, a vital record, health care directives, and assessments for the likelihood of suicide, fall risk, drug usage, and willingness to participate in treatment.
MAARC	The 24/7 state centralized common entry point operated by DHS under Minnesota Statutes 626.557.9 . This is for the public and mandated reporters to report suspected maltreatment of a vulnerable adult. Reports are accepted over the phone at 844-880-1574 by the public and online by mandated reporters at mn.gov/dhs/reportadultabuse/ .
MAXIS	Public assistance eligibility and payments
Minnesota Child Support Online (MCSO) <i>(web front-end to PRISM)</i>	Parent and employer access to view case and payment information, track progress, get contact information, check appointments, make payments and view financial status of their case. Child support participants can update financial statements and Pro Se documents. Employers can access payment information, report employee terminations, and make payments.

MEC²	Helps determine client eligibility, pays providers, supports program integrity and tracks child care expenses
METS (Minnesota Eligibility Technology System)	Health care eligibility determination and plan enrollment (Minnesota Health Care Programs as well as assisted and private health coverage)
MMIS (Medicaid Management Information System)	<ul style="list-style-type: none"> • Provider enrollment • Claims processing • Provider payments • Third-party liability programs • Service authorizations Managed care capitation payments
MnChoices	Assessment and support planning for Minnesotans who need long-term services and supports
MN-ITS (provider “front-end” to MMIS)	<p>Enables MHCP-enrolled providers to:</p> <ul style="list-style-type: none"> • Verify client eligibility • Submit authorization and service agreement requests • Submit claims • Copy, replace or void a previously-submitted claim • Check claim status Retrieve remittance advices, authorization and service agreement letters and other provider communications
Phoenix	<p>Manages Minnesota Sex Offender Program business operations, including:</p> <ul style="list-style-type: none"> • Housing location of clients • Scheduling of vocational, educational, health appointments, clinical sessions, and therapeutic recreation programming • Client and facility tracking • Staff routing and ticketing Clinical and health services information
PRISM (parents, employers use MSCO)	Child support collection and enforcement
SMI (Shared Master Index)	<ul style="list-style-type: none"> • Cross-reference of the person identifying numbers in the major DHS systems, MNsure and many county systems. • Provides a reusable person search function to remove duplicate client records across program areas and DHS/county systems. • Unifies information from multiple systems onto a single client/case profile view. Streamlines the interchange of information among state and county systems.
SSIS (Social Services Information System)	Case management system for county social workers supporting child protection, foster care, adoption, children’s mental health and other child welfare programs. Also supports adult maltreatment reporting, waiver claiming and other adult services.

Statement 2: Indicate whether the state’s SUD Health IT Plan is “aligned with the state’s broader State Medicaid Health IT Plan (SMHP) and if applicable, the state’s Behavioral Health (BH) Health IT Plan

Minnesota received approval from CMS on November 3, 2011 and the most recent SMHP addendum was approved by CMS on February 9, 2017.

The State’s SUD Health IT Plan and the Behavioral Health IT Plan are aligned with the SMHP.

Although significant progress has been made towards many of the goals originally established in Minnesota’s SMHP, the results of Minnesota’s HIT survey¹ reveal that gaps remain in providers’ ability to consistently exchange clinical information. Minnesota has implemented value-based purchasing strategies, which increase the accountability of providers to engage in well-coordinated, patient-centered health care. Payment reform and expanded integrated care models such as the Integrated Health Partnership initiative, Behavioral Health Homes, Certified Community Behavioral Health Clinics (CCBHC), and others, have brought increased focus on the need to address gaps in providers’ ability to send and receive admission, discharge, and transitions of care information including with providers outside their own clinic systems, on a different EHR platform, and across a full complement of care settings including long-term services and supports and behavioral health.

Over the past several years, Minnesota has been able to advance much of its HIT activity under the State Innovation Model (SIM) grant, and is using lessons from SIM to shape planning and identification of future needs. In continued support for ongoing activities related to established goals, the state has identified some new activity and objectives required to advance the meaningful use of health information technologies and promote electronic health information exchange. Ongoing activities include: DHS continues to maintain the MEIP website with current technical assistance, program information, and links to federal resources; DHS distributes program updates through the MEIP e-List on an as-needed basis; DHS staff provide presentations to professionals and organizations representing EPs and EHS; DHS collaborates with other HITECH programs through the e-Health Advisory Committee and Workgroups and presents at HITECH program educational events; DHS continues to work in cooperation with the State Office of Rural Health and Primary Care to provide updates and information to rural and safety net stakeholders; DHS provides a quarterly update to the e-Health Advisory Committee on program activities.

The Minnesota e-health Roadmap for Behavioral Health, Health, Local Public health, Long-Term and Post-Acute Care, and Social Services documented recommendations and actions that can accelerate adoption and use of e-health in these priority settings is now completed. Planned activities include: (1) Testing of the use of a personal health record that contains both their acute health care and long-term services and supports information for people enrolled in community-based services and supports. (2) Include behavioral health, long-term care, and DHS DCT in onboarding to MN Encounter Alerting Service so that applicable care coordinators from these settings can access timely care transition information about Medicaid enrollees. Implementation is expected to continue to include other provider types who serve Medicaid beneficiaries.

Part 3: Advancing Interoperability using Health IT Standards

Statement 3: Indicate that the state will include appropriate standards referenced in the ONC Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B in subsequent MCO contract amendments or Medicaid funded MCO/Health Care Plan re-procurements

The Minnesota e-Health Initiative (the Initiative) is a private/public collaboration focused on accelerating the adoption and use of e-health. The Advisory Committee is a 25-member legislatively authorized committee appointed by the Commissioner of Health to lead the Initiative. It represents the spectrum of Minnesota's health community, including providers, payers, public health, researchers, vendors, consumer, and more. The Advisory Committee has the responsibility to

1. Make recommendations to the Commissioner of Health on policies and strategies, and
2. Provide guidance to the community that support its mission to.

These responsibilities support the goals of the Initiative to

- Empower consumers with information to make informed health and medical decisions.
- Inform and connect health care providers by promoting the adoption and use of interoperable EHRs and health information exchange.
Protect communities and improve public health by advancing efforts to make public health systems interoperable and modernized.
- Modernize the infrastructure through:
 - a) Adoption of standards for health information exchange;
 - b) Policies for strong privacy and security protection of health information;
 - c) Funding and other resources for implementation;
 - d) Training and informatics education; and
 - e) Assessing and monitoring progress on adoption, use and interoperability.

The Initiative will continue to encourage and support efforts to implement e-prescribing of controlled substances (EPCS) to help address the opioid misuse epidemic. They will provide input on e-Health Strategies for Preventing and Responding to Drug Overdose and Substance Misuse, and address ongoing priority topics such as:

- Full implementation of SCRIPT standards
- Promote use of Diagnosis code on prescriptions
- Advance medication management therapy
- How to improve medication reconciliation process.

Additional ancillary and ongoing activities advancing interoperability include:

- Minnesota Electronic Health Records Incentive Program (MEIP), implements and maintains an incentive payment system for Medicaid providers to implement an Electronic Health Record

- The Minnesota Promoting Interoperability Program (MPIP) was created in response to the passage of the HITECH Act as part of the American Recovery and Reinvestment Act of 2009, which mandated the creation of a state-run program to supervise the distribution of incentive funds for meeting the requirements for promoting the interoperability of electronic health records as defined by CMS. Project accomplishments: continued operation of MPIP attestation portal, continued payments processing, collection of meaningful use criteria and clinical quality measures, data analysis and coordination with quality improvement team at DHS.
- Health Information Exchange (HIE) activities, such as a new MMIS Enterprise Service bus (ESB), which once operationalized, will allow greater sharing of data with less work and development needed directly on the mainframe systems. The ESB will integrate across systems and the enterprise and is foundational to any project that needs to access data from another system. Business value includes: provides real time information for DHS agency systems that need MMIS information, reduce need for MMIS staff to answer or provide MMIS data questions by providing well-documented services.

Section II – Implementation Administration

Please provide the contact information for the state’s point of contact for the SUD Health IT Plan.

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