DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-26-12
Baltimore, Maryland 21244-1850

March 27, 2026

John Connolly
Assistant Commissioner for Health Care
Administration and Medicaid Director
Minnesota Department of Human Services
540 Cedar Street
St. Paul, MN 55167-0983

Dear Assistant Commissioner Connolly:

The Centers for Medicare & Medicaid Services (CMS) is approving Minnesota's request to extend its Medicaid section 1115(a) demonstration entitled, "Minnesota Substance Use Disorder System Reform" (Project Number 11-W-00320/5), in accordance with section 1115(a) of the Social Security Act (the Act). This approval is effective April 1, 2026, through March 31, 2031, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.

CMS has determined that the Minnesota Substance Use Disorder (SUD) System Reform demonstration is likely to assist in promoting the objectives of the Medicaid statute by increasing access to high-quality, clinically appropriate treatment to beneficiaries with a SUD while they are short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD). This approval is in alignment with State Medicaid Director Letter (SMDL) #17-003 RE: Strategies to Address the Opioid Epidemic.[1] and will continue the authority from the 2019 demonstration approval with two technical updates, which are further described in the next section.

CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as not applicable to expenditures under the demonstration.

CMS acknowledges that chapter 1 of subtitle B of title VII of Public Law 119-21, which CMS refers to as the Working Families Tax Cut (WFTC) legislation, makes additional changes to the Medicaid and CHIP programs. To the extent that any of those changes will affect the authorities within this demonstration, CMS will work with Minnesota to ensure compliance with and

[1] https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

successful implementation of changes within the timelines required under the WFTC legislation during this demonstration period.

Extent and Scope of Demonstration Extension

The demonstration extension aims to continue providing high quality, evidence-based Opioid Use Disorder (OUD) and other SUD treatment services to short-term residents in residential treatment facilities while also improving care coordination for comorbid physical and behavioral health conditions. The state expects to improve health outcomes for Medicaid beneficiaries by increasing access to high quality OUD care; expanding the OUD/SUD provider networks available to serve Medicaid populations; increasing and supporting independence and recovery; increasing community integration; and by making American Society of Addiction Medicine (ASAM) level appropriate levels of care more readily available.

Specifically, the demonstration goals, consistent with the SMDL[2], are to: 1) increase rates of treatment for OUD and SUD, 2) increase adherence to and retention in treatment, 3) improve access to care, 4) reduce the number of opioid-related overdoes and death, and 5) reduce utilization of emergency department and inpatient hospital settings for treatment that is preventable or medically inappropriate through improved access to other continuum of services.

Approval of this demonstration extension will allow Minnesota to continue to provide residential treatment services for individuals who are receiving treatment and withdrawal management for SUD while they are short-term residents in facilities that meet the definition of an IMD to ensure that a broad continuum of care is available to those with SUD. With this approval, the demonstration will extend current features without any programmatic changes.

Per the state's request and as required under the original demonstration approval, the previous certified community behavioral health clinics (CCBHC) expenditure authority successfully transitioned to the Minnesota Medicaid state plan via the June 24, 2021 approval of State Plan Amendment (SPA) 20-16, effective October 1, 2020. As a result, all references to the expired CCBHC authority have been removed from the STCs.

The state also requested a second technical update which is the addition of a Tribal IMD services Medicaid Expenditure Group (MEG) for purposes of budget neutrality. The state requested to report expenditures for Tribal IMD services separately from the fee for service (FFS) IMD services MEG because the state wants to accurately capture the costs of the Tribal-operated IMDs which are associated with the outpatient All-Inclusive Rate established by the Indian Health Service on an annual basis.

Program Integrity

States are responsible for following all applicable federal laws and regulations when they claim and use federal Medicaid funds and must fully comply with all applicable Medicaid laws and regulations under a section 1115 demonstration, except where specific provisions have been

[2] https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

expressly waived or identified as not applicable for that demonstration. This obligation includes all requirements in title XIX of the Act and implementing regulations governing provider screening and enrollment activities, pre- and post-payment review claiming, payment methodologies and rate-setting, utilization controls, and program integrity including processes to identify, investigate, and refer suspected fraud, and methods to receive complaints and identify questionable practices. States must maintain effective systems and safeguards to prevent, detect, and address any fraud, waste, or abuse (FWA) in the delivery of and payment for Medicaid services, including referrals to law enforcement when appropriate.

States should have heightened monitoring and oversight mechanisms in place featuring robust internal controls to identify and remediate all vulnerabilities (including, but not limited to, FWA and beneficiary access issues) inherent in service areas approved as part of a demonstration. Due to program integrity concerns in Minnesota's Medicaid program, CMS is requesting that the state provide a program integrity oversight plan detailing the state's systems and safeguards to prevent, detect, and address any FWA relative to this demonstration. Failure to meet program integrity obligations under federal statutes and regulations or under the terms and conditions of this demonstration approval may result in compliance actions or other enforcement measures that could include requirements to develop and implement corrective action plans, withholdings, deferrals, disallowances, and termination of demonstration authority.

Budget Neutrality

This demonstration project is extended using CMS's current approach to determining budget neutrality as described in CMS SMDL #24-003.[3] However, CMS acknowledges that section 71118 of the WFTC legislation, adds a new subsection (g) to section 1115 of the Act with budget neutrality requirements that will apply beginning January 1, 2027 to CMS approvals of section 1115 Medicaid demonstration project applications, renewals, or amendments.[4] CMS intends to provide additional information prior to January 1, 2027 about the section 1115(g) requirements.

CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs likely would have been in that state absent the demonstration.[5] The demonstration extension is projected to be budget neutral to the federal government. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 demonstration approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" [WOW] costs). The state will be held to the budget neutrality monitoring and reporting requirements as outlined in the STCs.

[3] https://www.medicaid.gov/federal-policy-guidance/downloads/smd24003.pdf
[4] https://www.congress.gov/bill/119th-congress/house-bill/1/text
[5] https://www.medicaid.gov/medicaid/section-1115-demonstrations/budget-neutrality/index.html

Rebasing Without Waiver Baseline

Under this extension, for existing MEGs that were implemented, CMS calculated the WOW baseline by using a weighted average of the state's historical WOW per-member-per-month (PMPM) baseline and its recent actual PMPM costs. The projected demonstration expenditures associated with each MEG in the WOW baseline have been trended forward using the President's Budget all populations trend rate to determine the maximum expenditure authority for the new approval period. Using the President's Budget trend rate aligns the demonstration trend rate with federal budgeting principles and assumptions.

Hypothetical Budget Neutrality Treatment

Under its current approach to budget neutrality, CMS generally treats expenditures for populations or services which could have otherwise been covered via the Medicaid state plan, or other title XIX authority, such as a section 1915 waiver, as "hypothetical" for the purposes of budget neutrality. In these cases, CMS adjusts budget neutrality to account for the spending which the state could have hypothetically provided through the Medicaid state plan or other title XIX authority. CMS does not, however, currently allow for budget neutrality savings accrual as a result of including hypothetical populations or services in section 1115 demonstration projects. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent budget neutrality "supplemental test" for hypothetical expenditures. These supplemental budget neutrality tests subject the hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's "with waiver" (WW) hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending with savings elsewhere in the demonstration or to refund the FFP to CMS.

The Tribal IMD services MEG will be treated as hypothetical for budget neutrality purposes consistent with other SUD MEGs. For this MEG, CMS calculated the WOW baseline (which refers to the projected expenditures that could have occurred absent the demonstration and which is the basis for the budget neutrality expenditure limit for each approval period). The projected demonstration expenditures associated with this MEG in the WOW baseline have been trended forward using the President's Budget trend rate to determine the maximum expenditure authority for the new approval period. Using the President's Budget trend rate aligns the demonstration trend rate with federal budgeting principles and assumptions.

Mid-Course Correction

CMS has also updated its approach to mid-course corrections to budget neutrality calculations in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (for example, if expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (for example, unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care

(for example, a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

Monitoring and Evaluation

Consistent with the demonstration STCs, the state submitted with the extension application its Interim Evaluation Report[6] for the prior demonstration approval period, which was approved for the period from July 1, 2019 through June 30, 2024. Based on available data in the state's Interim Evaluation Report[7], which includes the time period of January 1, 2020 through December 31, 2022, CMS determined that the state has been able to accomplish goals one and two.

Specifically, the state demonstrated increases in both the percentage of beneficiaries who initiated and engaged in treatment for SUD. These improvements were echoed in the 2023 provider survey, which noted that most respondents were able to effectively assess patient needs and direct patients to appropriate services. The state also demonstrated increases in follow-up care after an IMD stay, and the percentage of beneficiaries who were prescribed medication for OUD.

However, the state has not made progress on other demonstration goals. Specifically, there were significant increases in readmission rates, overdose deaths, and emergency department (ED) visits following residential treatment stays. Additionally, there were substantial decreases in the number of beneficiaries receiving ambulatory or preventive care, as well as in follow-up contact after an ED discharge. The state identified the COVID-19 Public Health Emergency, which was first declared on January 31, 2020 and expired on May 11, 2023, as a primary factor contributing to these challenges and noted that the trends align with national patterns in overdose deaths and ambulatory care utilization.

Based on monitoring data and the state's Mid-Point Assessment Report, the state is not currently reporting an average length of stay (ALOS) that is 30 days or below. However, the state has substantially reduced the ALOS since the start of the demonstration (39.8 days) to the most recent period reported (31.9 days). CMS staff are working with the state to ensure that the state continues to make progress on reducing its ALOS.

Based on the mixed progress made thus far on its goals as well as the opportunities to improve in critical areas such as readmission rates, overdose deaths, and ED visits following residential treatment stays, the state is requesting, and CMS is granting additional time to continue its demonstration. To ensure transparency towards continued progress on more of the demonstration goals and to address the identified areas for improvement, the state is required under this extension to continue conducting systematic monitoring and robust evaluation of the

[6] See the Minnesota SUD Interim Evaluation Report, available at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/mn-sud-reform-appvd-sud-interm-eval-rpt-03112025.pdf

[7] See the Minnesota SUD Interim Evaluation Report, available at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/mn-sud-reform-appvd-sud-interm-eval-rpt-03112025.pdf.

demonstration. In collaboration with CMS, the state must undertake demonstration monitoring, including reporting of relevant metrics data and narrative details describing progress with implementation of all components of the demonstration. In addition, the state is also required to conduct an independent mid-point assessment of the SUD demonstration initiatives, as described in the STCs, to support identifying risks and vulnerabilities and subsequent mitigation strategies.

The state is required to conduct an evaluation of the demonstration which includes the temporary extension approval period that ran from June 30, 2024 through March 31, 2026. The evaluation supports a comprehensive assessment of whether the demonstration components are effective in producing the desired outcomes for its beneficiaries and providers, as well as the state's overall Medicaid program. The demonstration evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components, as described in the STCs.

Consideration of Public Comments

CMS posted the application on Medicaid.gov for a 30-day federal public comment period from February 29, 2024, to April 1, 2024. CMS received three public comments, two of which applied to the application. Both of these comments were supportive of Minnesota's extension application. One of these commenters highlighted the fact that without this demonstration people with Medicaid would be treated differently than people with Medicare or private insurance. The other offered support for the extension.

CMS has concluded that extending the Minnesota SUD System Reform Section 1115(a) demonstration is likely to promote the objectives of Medicaid.

Other Information

CMS's approval of this demonstration extension is conditioned upon compliance with the enclosed set of expenditure authorities and STCs defining the nature, character and extent of anticipated federal involvement in the demonstration. The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer for this demonstration is Jonathan Morancy, who is available to answer any questions concerning your section 1115 demonstration and his contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Jonathan.Morancy@cms.hhs.gov

If you have questions regarding this approval, please contact Sarah Aker, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at Sarah.Aker@cms.hhs.gov.

Sincerely,

[redacted]

Dan Brillman
Deputy Administrator, CMS
Director, Center for Medicaid and CHIP Services

Enclosure

cc: Sandra Porter, State Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 11-W-00320/5

TITLE: Minnesota Substance Use Disorder System Reform

AWARDEE: Minnesota Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Minnesota for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from April 1, 2026 through March 31, 2031, 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 (STCs) and shall enable Minnesota to operate the above-identified section 1115(a) demonstration.

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

Expenditures for Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment and/or withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an Institution for Mental Diseases (IMD).

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00320/5

TITLE: Minnesota Substance Use Disorder System Reform

AWARDEE: Minnesota Department of Human Services

1. PREFACE

The following are the STCs for the Minnesota Substance Use Disorder 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 expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those populations affected by the demonstration are effective from April 1, 2026, through March 31, 2031, unless otherwise specified.

The STCs have been arranged into the following subject areas:

1	Preface
2	Program Description and Objectives
3	General Program Requirements
4	Eligibility and Enrollment
5	SUD Program and Benefits
6	Cost Sharing
7	Delivery System
8	Monitoring and Reporting Requirements
9	Evaluation of the Demonstration
10	General Financial Requirements
11	Monitoring Budget Neutrality for the Demonstration
12	Schedule of Deliverables for the Demonstration Period

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

Attachment A	SUD Implementation Plan
Attachment B	SUD Evaluation Design (Reserved)

2. PROGRAM DESCRIPTION AND OBJECTIVES

In this demonstration, the state will 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 an IMD. It will also support state efforts to enhance provider capacity, improve the availability of Medication Assisted Treatment (MAT) and improve access to a continuum of SUD evidence-based services at varied levels of intensity, including withdrawal management services.

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

Table 1 – SUD Goals

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

3. GENERAL PROGRAM REQUIREMENTS

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

3.2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3.3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 business days in

advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

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

b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

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

3.6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 3.7 below, except as provided in STC 3.3.

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

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

a. An explanation of the public process used by the state, consistent with the requirements of STC 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;

c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

d. An up-to-date CHIP allotment worksheet, if necessary;

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

3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) section 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 3.9.

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

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

how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(d)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable advance notice requirements and fair hearing rights described at 42 CFR, part 431 subpart E. 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.

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 CRF 431.416(g).

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

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

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

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

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

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

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

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

3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public

benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(d)(5).

3.16. **Program Integrity.** Minnesota must submit, no later than 60 days after demonstration approval, a program integrity oversight plan that addresses oversight in all currently active section 1115 demonstrations in Minnesota. At a minimum, this plan must include:

a. An overview of the state's systems and safeguards to prevent, detect, and address fraud, waste, and abuse (FWA) in each demonstration, including:

i. How the state provides oversight of provider screening and enrollment;
ii. How the state provides oversight of service utilization to ensure beneficiaries were actually eligible to receive demonstration services in each demonstration;
iii. Pre- and post-payment reviews;
iv. Review of payment methodologies and rate-setting;
v. Review of the state's utilization controls;
vi. Audits/investigations and related law enforcement referrals;
vii. Other program integrity measures the state uses, including processes to identify, investigate, and refer suspected fraud, and methods to receive complaints and identify questionable practices; and
viii. An analysis to determine whether there are any significant, state-identified deficiencies in the current processes related to the above described areas in each of the state's demonstrations.

b. A data analytics plan that includes an analysis of provider and beneficiary enrollment growth, service utilization growth, and associated claims growth over the past five years (as applicable) in each demonstration, including in applicable high-risk service areas.

c. Any new processes developed to address state- or CMS-identified program integrity concerns; and,

d. A plan with milestones and an action step timeline subject to CMS approval evidencing how the state will remediate deficiencies identified by the state or CMS in these areas.

This program integrity oversight plan will be subject to CMS approval once submitted post-demonstration approval and the state must adhere to the requirements and milestones outlined in the approved plan as a condition of continued demonstration approval.

4. ELIGIBILITY AND ENROLLMENT

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

5. SUBSTANCE USE DISORDER (SUD) PROGRAM AND BENEFITS

5.1. **SUD Program Benefits**. The demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings.

Under this demonstration beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

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

a. The state's SUD Implementation Plan, initially approved for the period from July 22, 2020 through March 31, 2026, remains in effect for the approval period from April 1, 2026 through March 31, 2031, and is affixed to the STCs as Attachment A. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The approved SUD Implementation Plan describes the strategic approach and a detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

i. *Access to Critical Levels of Care for OUD and other SUDs.* Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval;

ii. *Use of Evidence-based SUD-specific Patient Placement Criteria.* Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect

evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;

iii. *Patient Placement.* Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;

iv. *Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities*. 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 nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

v. *Standards of Care.* Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

vi. *Standards of Care.* Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

vii. *Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD.* An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;

viii. *Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD.* Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. *Improved Care Coordination and Transitions between Levels of Care.* Establishment and implementation of policies to ensure residential and inpatient

facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval;

x. *SUD Health IT Plan.* Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics are detailed in STC 5.2(b) and Attachment A.

b. Health Information Technology Plan ("Health IT Plan"). The SUD Health IT Plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan (see STC 5.2(a)), to develop infrastructure and capabilities consistent with the requirements outlined in the SUD demonstration-type. The state's Health IT Plan, initially approved for the period from July 9, 2019 through March 31, 2026, remains in effect for the approval period from April 1, 2026 through March 31, 2031, and is affixed to the STCs as Attachment A.

The Health IT Plan describes how technology can support outcomes through care coordination; linkages to public health and prescription drug monitoring programs; establish data and reporting structure to monitor outcomes and support data driven interventions. Such technology should, per 42 CFR 433.112(b), use open interfaces and exposed application programming interfaces and ensure alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 42 CFR part 170, subpart B.

i. 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 within its Annual Report (see STC 8.5).

ii. 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.

iii. 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.

iv. 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.

v. Components of the Health IT Plan include:

1. The Health IT Plan must describe the state's alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP).[1]
2. The Health IT Plan must address how the state's Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] States should favor procurement strategies that incorporate qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in RX Check for Interstate data sharing.
3. The Health IT Plan will describe how technology will support substance use disorder prevention and treatment outcomes described by the demonstration.
4. In developing the SUD Health IT Plan, states should use the following resources.
    - States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    - States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.
    - States should review the Office of the National Coordinator's Interoperability Standards Advisory (https://www.healthit.gov/isa) for information on appropriate standards which may not be required per 42 CFR part 170, subpart B for enhanced funding, but still should be considered industry standards per 42 CFR 433.112(b)(12).

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

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

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

6. COST SHARING

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

7. DELIVERY SYSTEM

7.1. 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.

8. MONITORING AND REPORTING REQUIREMENTS

8.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) 30 calendar 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) 30 calendar 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. The extension request must explain the reason why the required deliverable was not submitted, the steps the state has taken to address such issue, and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

c. If CMS agrees to an interim corrective process 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) that meets 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 for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

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.

8.2. **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 Annual Monitoring Report. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar year and each calendar year thereafter until CMS has determined sufficient progress has been made.

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

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

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b. Ensure all 1115, Transformed Medicaid Statistical Information System (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.

8.5. **Monitoring Reports.** The state must submit one Annual Monitoring Report each demonstration year (DY) that is due no later than 180 calendar days following the end of the DY. The state must submit a revised Annual Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. CMS will make on-going determinations about reporting frequency under the demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. See 42 CFR 431.420(d)(1)-(2).

The Annual Monitoring Report 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 Annual Monitoring Report must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve and must be provided in a structured manner that supports federal tracking and analysis.

a. **Operational Updates.** Per 42 CFR 431.428, the Annual Monitoring Report must document any policy or administrative difficulties in operating the demonstration. The Annual Monitoring Report must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and 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 Annual Monitoring Report should also include a summary of all public comments received through post- award public forums regarding the progress of the demonstration.

b. **Performance Metrics.** The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's goals and any applicable milestones. Per 42 CFR 431.428, the Annual Monitoring Report must document the impact of the demonstration on beneficiaries' outcomes of care, quality and overall cost of care, and access to care, as applicable. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals. The Annual Monitoring Report must provide detailed information about deviations from CMS's applicable metrics technical specifications, relevant methodology, plans for phasing in metrics, and data or reporting issues for applicable metrics, in alignment with CMS guidance and technical assistance.

   The state and CMS will work collaboratively to finalize the list of metrics to be reported on in the Annual Monitoring Report. The demonstration's monitoring metrics must cover categories to include, but not be limited to, eligibility, utilization of services, quality of care and health outcomes, and grievances and appeals. The state must report these metrics for all demonstration populations. Demonstration monitoring reporting does not duplicate or replace reporting requirements for other authorities, such as Home and Community Based Services and Managed Care authorities.

   In addition, the state is expected to report monitoring metrics for the following demonstration initiative, as described below and per applicable CMS guidance:

   i. The state's monitoring must cover metrics in alignment with CMS guidance and the demonstration's milestones as outlined in the SUD State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17-003).

The reporting of these monitoring metrics may also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, or geography) and by demonstration component, as appropriate. Subpopulation reporting can support identifying any gaps in quality of care and health outcomes, and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population.

c. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Annual Monitoring Report 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.

8.6. **SUD Mid-Point Assessment**. The state must contract with an independent entity (herein referred to as the Independent Assessor) to conduct an independent Mid-Point Assessment and submit to CMS by May 31, 2029. This timeline will allow for the Mid-Point Assessment to capture approximately the first two and a half years of program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and execution of the Mid-Point Assessment, the state must require that the Independent Assessor consult with key stakeholders such as representatives of MCOs, health care providers, beneficiaries, community groups, and other key partners.

a. The state must require that the assessor provides a Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. If requested, the state must brief CMS on the Mid-Point Assessment. The state must submit a revised Mid-Point Assessment within 60 calendar days after receipt of CMS's comments, if any.

b. Elements of the Mid-Point Assessment include:

1. An examination of progress toward meeting each milestone and timeframe approved in the Implementation Plan;

2. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;

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

4. For milestones or targets identified by the Independent Assessor as at medium to high risk of not being met, recommendations for adjustments in the state's Implementation Plan, or to pertinent factors that the state can influence that will support improvement.

8.7. **Corrective Action Plan Related to Demonstration Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS might withdraw an authority, as described in STC 3.10, if metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals and desired directionality, and the state has not implemented corrective action, and the circumstances described in STC 3.10, are met. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8.8. **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 Close-Out Report must comply with the most current guidance from CMS.

b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 9.7 and 9.8, respectively.

c. The state will present to and participate in a discussion with CMS on the Close-Out Report.

d. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.

e. The revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

8.9. **Monitoring Calls.** CMS will convene no less frequently than quarterly monitoring calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operations and implementation which align with the state's demonstration monitoring reports, including (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in

reported data on metrics and associated mid-course adjustments, eligibility and access, and progress on evaluation activities.

b. These calls will follow the structure of and focus on the topics in the Annual Monitoring Report.

c. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

d. The state and CMS will jointly develop the agenda for the calls.

8.10. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six 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 Monitoring 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 year in which the forum was held.

9. EVALUATION OF THE DEMONSTRATION

9.1. **Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state shall 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 shall 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). This may also include the state's participation — including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable — in a federal learning collaborative aimed at cross state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring, and evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.1.

9.2. **Independent Evaluator.** The state must use an independent entity (herein referred to as the Independent Evaluator) 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 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.

9.3. **Evaluation Design.** The state must submit, for CMS comment and approval, an Evaluation Design no later than 180 calendar 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 Evaluation Design must be developed in accordance with the STCs and any applicable CMS guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

The state is strongly encouraged to use the expertise of the Independent Evaluation in the development of the Evaluation Design. The Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 9.7 and 9.8.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component, unless otherwise agreed upon by the state and CMS. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. The amendment components of the Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

9.4. **Evaluation Design Approval and Updates.** The state must submit a revised Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS approval of the Evaluation Design, the documents will be posted to Medicaid.gov. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each Annual Monitoring Report. Once CMS approves the Evaluation Design, if the state wishes to make changes and the changes are substantial in scope the state must submit a revised Evaluation Design to CMS for approval; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in the Annual Monitoring Report.

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

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as eligibility and various

measures of access, utilization, costs, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance for the demonstration policy components. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of demonstration and other applicable services. Proposed measures should be selected from nationally recognized sources and national measures sets, where possible. Measures sets could include the Consumer Assessment of Health Care Providers and Systems (CAHPS), the Medicaid and CHIP Core Sets of Health Care Quality measures, commonly referred to as the Child and Adult Core Sets, the Behavioral Risk Factor Surveillance System (BRFSS) survey, or measures endorsed by National Quality Forum (NQF).

The state must develop robust evaluation questions and hypotheses related to each demonstration initiative, and per applicable CMS guidance. Specifically:

a. Hypotheses with the SUD component of this section 1115 demonstration must align with the goals of the program, including increasing rates of identification and initiation of and engagement in treatment as well as adherence to and retention in treatment, reducing overdose deaths, reducing utilization of emergency departments and inpatient hospitalizations as well as readmissions to the same or higher levels of care, and improving access to care for physical health conditions.

As part of its evaluation efforts, the state must also conduct an overall demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation and Medicaid health services expenditures. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

CMS underscores the importance of the state undertaking a well-designed beneficiary survey or interviews to assess, for instance, beneficiary understanding of the demonstration policy components and beneficiary experiences with access to and quality of care. To better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—and barriers to—implementation, the state is strongly encouraged to undertake a robust process/implementation evaluation. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

Finally, the state may collect data to support analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, or geography). Such stratified data analyses can provide a fuller understanding of gaps in access to and quality of care and health outcomes, as well as help inform how the demonstration's various policies support improving outcomes.

9.6. **Evaluation Budget.** A budget for the evaluations must be provided with the 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 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.

9.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). The draft Interim Evaluation Report must be developed in alignment with the approved Evaluation Design, and in accordance with the requirements outlined in these STCs and applicable CMS guidance.

a. The Interim Evaluation Reports will discuss evaluation progress and present findings to date as per the approved Evaluation Design.

b. For demonstration authority or any component within the demonstration that expires prior to the overall demonstration's expiration date, and depending on the timeline of the expiration/phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted, or in one year prior to the end of the demonstration, whichever is sooner. When applying for an extension of the demonstration, the Interim Evaluation Report should be posted to the state's website with the application for public comment. If the state does not request an extension for the demonstration, the Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

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

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

9.8. **Summative Evaluation Report**. The state must submit the draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with the approved Evaluation Design, and in accordance with the requirements outlined in these STCs and applicable CMS guidance.

a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft Summative Evaluation Report, if any.

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

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

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

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

9.12. **Additional Publications and Presentations.** For a period of 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 30 calendar 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.

10. GENERAL FINANCIAL REQUIREMENTS

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

10.2. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the MBES/CBES to report total expenditures 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.

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

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

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

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

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

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

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any

necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

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

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

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

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

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

b. For non-risk-based PIHPs and PAHPs, arrangements comply with the upper payment limits specified in 42 CFR 447.362, and if payments exceed the cost of services, the state will recoup the excess and return the federal share of the excess to CMS.

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

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

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

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

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

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

10.7. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 8.1. This report must include:

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

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

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

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

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

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

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

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

10.8. **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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 11.1:

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.

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

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

Table 2: Master MEG Chart

MEG	To Which BN Test Does This Apply?	Without Waiver (WOW) Per Capita	WOW Aggregate	With Waiver (WW)	Brief Description
Fee for Service IMD Services	Hypo 1	X		X	All medical assistance expenditures during an IMD stay month for beneficiaries who receive services via FFS.
Capitated IMD Services	Hypo 1	X		X	All medical assistance expenditures during an IMD stay month for beneficiaries enrolled in capitated managed care.

Tribal IMD Services	Hypo 1	X		X	All medical assistance expenditures during an IMD stay month for beneficiaries who receive services from a Tribal-operated IMD.
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

10.11. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00320/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

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

b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. To ensure 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 MEG Charts and in the STCs in section 11, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** Using the Budget Neutrality Monitoring Tool, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, 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 mut 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 service IMD services	Report all medical assistance expenditures during a SUD IMD month for beneficiaries who receive services via FFS	STC 5.3	Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	7/1/19	3/31/31
Capitated IMD services	Report all medical assistance expenditures during a SUD IMD month for beneficiaries enrolled in capitated managed care	STC 5.3	Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	7/1/19	3/31/31
Tribal IMD services	Report all medical assistance expenditures during a SUD IMD month for beneficiaries who receive services from a Tribal-operated IMD	STC 5.3	Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	4/1/26	3/31/31
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality	n/a	Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	7/1/19	3/31/31

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group

10.12. **Demonstration Years.** DYs for this demonstration are defined in the table below.

Table 4: Demonstration Years

Demonstration Year 8	April 1, 2026 to March 31, 2027	12 months
Demonstration Year 9	April 1, 2027 to March 31, 2028	12 months
Demonstration Year 10	April 1, 2028 to March 31, 2029	12 months
Demonstration Year 11	April 1, 2029 to March 31, 2030	12 months
Demonstration Year 12	April 1, 2030 to March 31, 2031	12 months

10.13. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

10.14. **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 guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

10.15. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 10.15.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. After acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

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

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

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

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

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

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

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

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

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

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

11. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

11.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 2, Master MEG Chart and Table 3, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

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

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

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

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

Table 5: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend Rate	DY 8	DY 9	DY 10	DY 11	DY 12
Fee for service IMD services	PC	Both	5.6%	$4,782	$5,050	$5,333	$5,632	$5,947
Capitated IMD services	PC	Both	5.6%	$1,208	$1,276	$1,347	$1,422	$1,502
Tribal IMD services	PC	Both	5.5%	$26,691	$28,159	$29,708	$31,342	$33,065

*PC = Per Capita, Agg = Aggregate

11.7. **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 Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

11.8. **Budget Neutrality Monitoring Tool.** Per 42 CFR 431.428, the state must document the financial performance of the demonstration. The state must provide quarterly budget neutrality status updates that meet all 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), 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 the demonstration's actual expenditures to the budget neutrality expenditure limits described in the Monitoring Budget Neutrality for the Demonstration section. The quarterly budget neutrality status updates are due no later than 60

calendar days following the end of each demonstration quarter, and are subject to the deferral as described in STC 8.1. CMS will provide technical assistance, upon request.[3]

11.9. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the demonstration period, which extends from April 1, 2026 to March 31, 2031. If at the end of the demonstration approval period the Hypothetical Budget Neutrality test has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

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

Table 6: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 8	Cumulative budget neutrality limit plus:	2.0 percent
DY 8 through DY 9	Cumulative budget neutrality limit plus:	1.5 percent
DY 8 through DY 10	Cumulative budget neutrality limit plus:	1.0 percent
DY 8 through DY 11	Cumulative budget neutrality limit plus:	0.5 percent
DY 8 through DY 12	Cumulative budget neutrality limit plus:	0.0 percent

12. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION

Table 7: Schedule of Deliverables

Deliverable	Timeline	STC
Program Integrity Oversight Plan	No later than 60 days after demonstration approval.	STC 3.16

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

Evaluation Design	No later than 180 calendar days after approval of the demonstration. Revised no later than 60 days after receipt of CMS comments.	STC 9.3 and 9.4
SUD Mid-Point Assessment	May 31, 2029 Revised no later than 60 days after receipt of CMS comments.	STC 8.6 and 8.6(a)
Interim Evaluation Report	One year prior to the end of the demonstration period, or when the extension application is submitted, whichever is sooner. Revised no later than 60 days after receipt of CMS comments.	STC 9.7 and 9.7(d)
Summative Evaluation Report	No later than 18 months after the end of the demonstration period. Revised no later than 60 days after receipt of CMS comments.	STC 9.8 and 9.8(a)
Annual Monitoring Report	No later than 180 calendar days after the end of each demonstration year.	STC 8.5
Quarterly Budget Neutrality Status Updates	No later than 60 calendar days following the end of each demonstration quarter.	STC 11.8

Attachment A
SUD Implementation Plan
Approved July 22, 2020

Minnesota Substance Use Disorder Section 1115 Waiver Implementation Plan

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

DEPARTMENT OF HUMAN SERVICES

Table of Contents

DEPARTMENT OF HUMAN SERVICES

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 disorder[2].

Despite the progress in reducing opiate overdose deaths overall, deaths related to synthetic opioids, primarily illicitly manufactured fentanyl, continue to increase[1]. 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 care[i]. 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 care[i] 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 care[i] 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.[i] 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 criteria[i], 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 criteria[i] 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 assessment[i]. The state will assess where its current evidence-based assessment policies need to be more closely aligned, with the ASAM placement criteria[i].

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 criteria[i] 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 dimensions[i] the resulting placement recommendations do not currently align with the ASAM levels of care[i]. 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 dimensions[i] 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 care[i] 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 dimensions[i] 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 Criteria[i] 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 reviewor 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 care[i] 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 standards[i] 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 dimensions[i], 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

Communicate changes to providers	Ongoing

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.

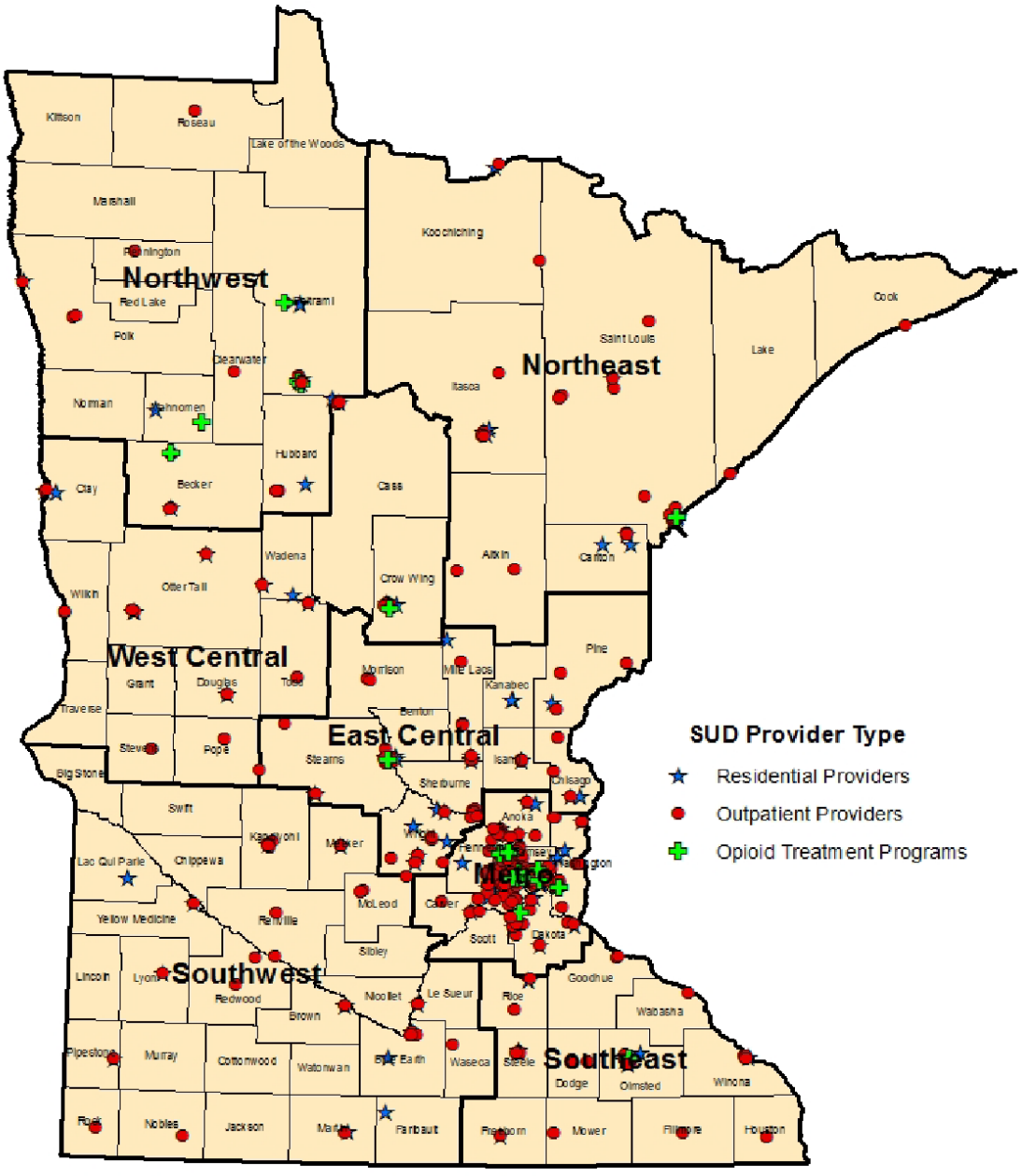
Minnesota's Response:
The state has approximately 415 licensed programs providing SUD treatment services in Minnesota – 145 of which are located in rural areas. Treatment settings include free-standing for-profit and not-for-profit organizations, hospitals, tribal governments and state-operated treatment 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.

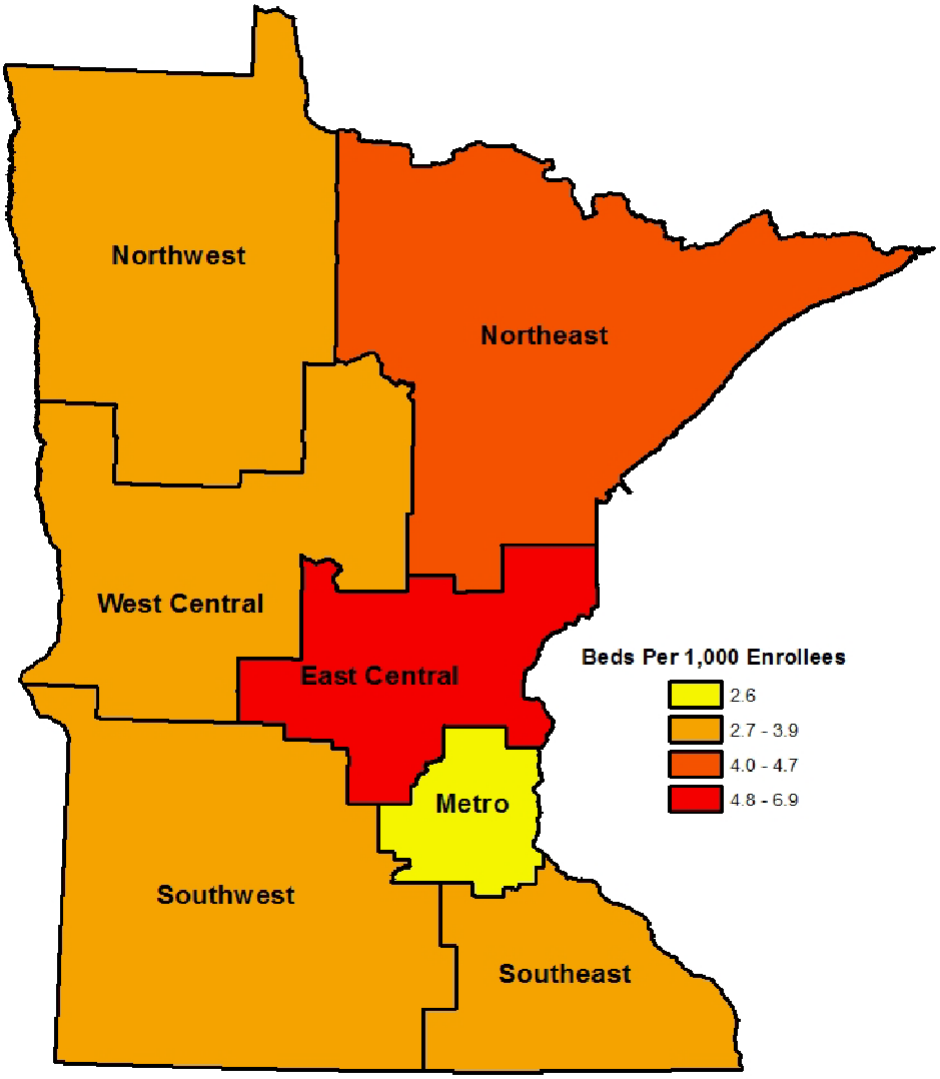
Below is a series of maps showing SUD treatment capacity in Minnesota for three different levels of care in seven regions of the state. The first map shows the location of "active" SUD treatment providers in Minnesota. To be included as an active provider, a SUD treatment provider must have provided 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 (5/8/2019)

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

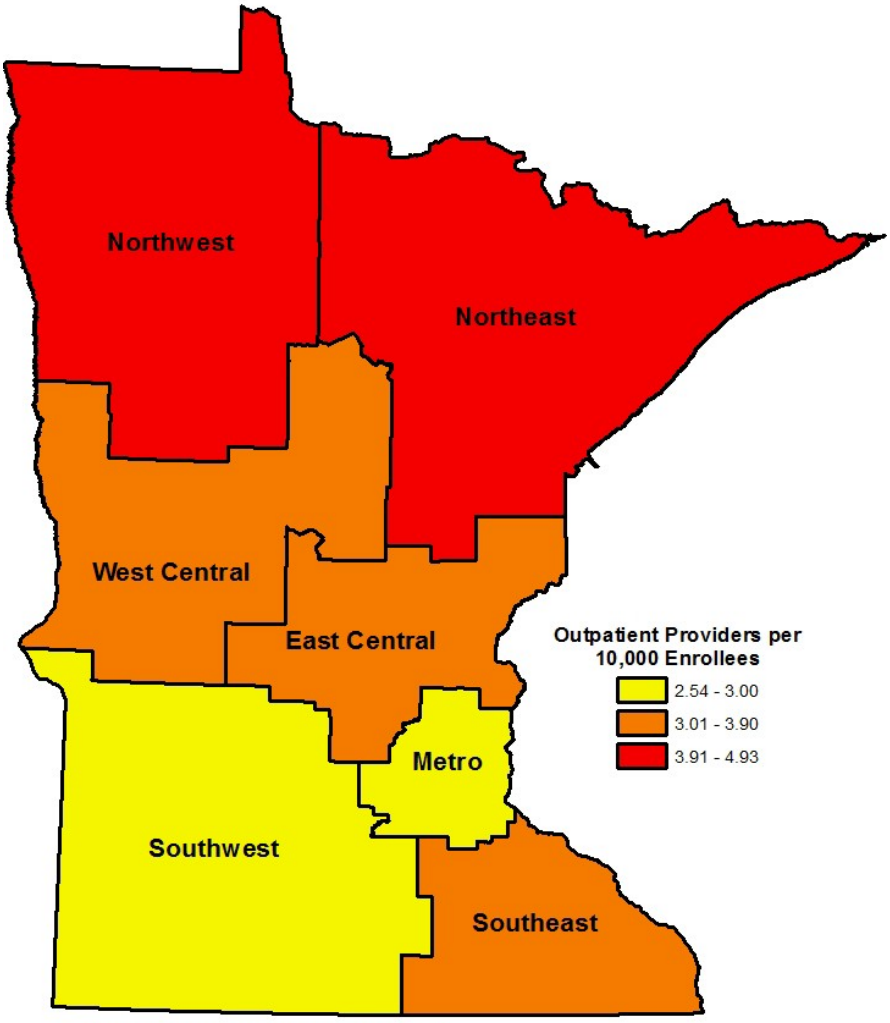


Source: Minnesota Department of Human Services, BHD (5/8/2019)

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

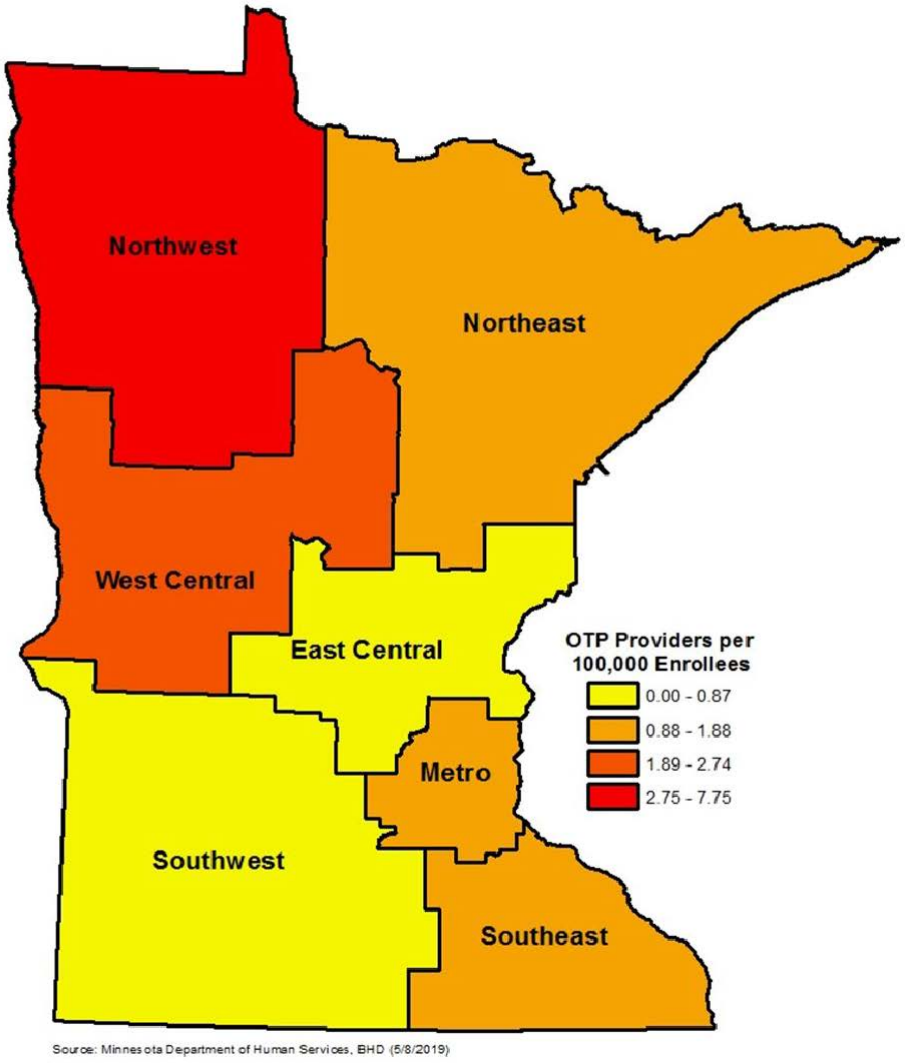


Source: Minnesota Department of Human Services, BHD (5/8/2019)

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



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 care[i] 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 dimensions[i], 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., 90 percent).
- 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-treatement.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 waivered 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 negations 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 waivered 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 dimensions[i], 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 AWARxE 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

[3] Total 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 polices 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 care[i] 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 criteria[i] 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 AWARxE, 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
Criterion 1: Enhanced interstate data sharing in order to better track patient specific prescription data	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.	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.	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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 2: Enhanced "ease of use" for prescribers and other state and federal stakeholders	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. Currently we have 46 healthcare entities and pharmacies that have signed up with Appriss Health to use PMP Gateway Services (the software program that integrates access to the PMP database into the clinical workflow), and another 10 are awaiting approval.	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. 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.	MN BOP, Controlled Substances Reporting Section, Director; MN Management and Budget, Impact Evaluation Unit Manager; Researchers as assigned by funding partner (J-Pal). 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. 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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 3: Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	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. 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: 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	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.	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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	prescribers and dispensers. The task force is governed under MN Statutes Chapter 152.126, Subd. 3		
Criterion 4: Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns	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 patters 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	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	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. Legislative approval would be required to allow DHS staff access to prescriber audit trail information from the PMP.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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. 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. In 2019, Governor Tim Walz signed the Opiate Epidemic Response into law.	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.	

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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. 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. 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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—		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	treatment coordination, peer recovery support, and withdrawal management—will be added.		
Criterion 5: Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP	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.	Any systems integration or data sharing will hinge on legislative approval, as noted previously. 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	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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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	correct data inaccuracies or duplicate records without jeopardizing program efficiencies or historical records for members, while also preserving confidentiality for the member. 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.).	
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	46 healthcare entities and pharmacies within Minnesota have contracted with Appriss Health to use PMP Gateway Services, a software solution that integrates the PMP into the clinical workflow. Another 10 are awaiting approval.	The BOP will consider the feasibility of conducting a randomized controlled trial to determining 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.	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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
			continue to promote integration to access the PMP within the clinical workflow.
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	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.	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. 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.	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. Both fiscal and policy barriers will be addressed in a collaborative manner by BOP and identified stakeholders.
Criterion 8: Enhance the master patient index (MPI) or master data management service (MDMS) in support of	There is currently a DHS Unique Person Identifier (UPI) project underway, which is an	While Minnesota currently does not have the statutory authority to create a universal master	In addition to the creation of the UPI by DHS, the BOP (in collaboration with other stakeholders) would

Milestone Criteria	Current State	Future State	Summary of Actions Needed
SUD care delivery.	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. 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.	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. 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	need to utilize predictive analytics to forecast increased risk of long-term opioid use based on initial prescribing characteristics. Any systems integration or data sharing will hinge on legislative approval, and fiscal collaboration, as noted previously.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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.	comprehensive record of a member's healthcare and eligibility.	
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	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	All implemented programs will benefit from increased utilization of and integration with the MN PDMP. 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. 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	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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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. 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	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.	

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) ***(web front-end to PRISM)***	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)	• 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)***	Enables MHCP-enrolled providers to: • 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	Manages Minnesota Sex Offender Program business operations, including: • 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)	• 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.

Name and Title: Michael Landgren, Human Services Redesign and Transformation Lead
Telephone Number: (651) 431-2251
Email Address: michael.landgren@state.mn.us

ATTACHMENT B
Evaluation Design (Reserved)