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

**State Demonstrations Group**

July 28, 2021

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

Dear Ms. MacDonald:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder System Reform 1115 Demonstration Evaluation Design, which is required by the Special Terms and Conditions (STC), specifically, STC 39, of Minnesota's section 1115 demonstration, "Minnesota Substance Use Disorder System Reform 1115 Demonstration" (Project No: 11-W-00320/5), effective through June 30, 2024. CMS determined that the evaluation design, which was submitted on April 2, 2020 and subsequently revised on February 17, 2021 and May 14, 2021, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore, approves the state's SUD evaluation design.

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

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

We appreciate our continued partnership with Minnesota on the Minnesota SUD System Reform 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S Digitally signed by Danielle Daly -S Date: 2021.07.28 09:42:40 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

Andrea J. Casart -S Digitally signed by Andrea J. Casart -S Date: 2021.07.28 09:39:30 -04'00'

Andrea Casart
Director
Division of Eligibility and Coverage Demonstrations

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

**Evaluation Design Plan**

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

MAY 14, 2021

PRESENTED TO:
CMS

PRESENTED BY:
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# General Background Information

Effective and evidence-based substance use disorder (SUD) treatments exist, but fewer than 1 in 5 individuals in need of treatment in the United States has access to them. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, 21.2 million people age 12 or older needed substance use treatment in 2018, but only 17.5 percent of those who needed treatment received any.[1] In Minnesota, 6.5 percent of residents (about 301,000 individuals) age 12 and older had an SUD between 2015 and 2017.[2] Between 2012 and 2016, Minnesota's total Medicaid spending on SUD treatment increased by 37.8 percent from roughly $160 million to almost $220 million.[3] This increase is partially due to the increase in enrollees utilizing SUD treatment services (about 24,332 in 2012 and 32,015 in 2016); however, per-enrollee spending also increased by 4.7 percent.[4]

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

Of all individuals receiving SUD treatment in Minnesota, 7 out of 10 have their services paid for with public funds, and that proportion—particularly Medicaid's share—is increasing. Medicaid paid for about a quarter of all 2016 SUD treatment admissions, up from 13 percent in 2011.[7] About two-thirds of Medical Assistance enrollees receiving SUD treatment are in the Medicaid expansion group and eligible

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

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

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

[4] Ibid.

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

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

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

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

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

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

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

[9] Ibid.

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

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

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

[13] Ibid.

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

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

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

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

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

## Demonstration Overview

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

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

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

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

- Conducting a provider capacity assessment to create a baseline set of measures to assess the state's capacity to provide each critical level of care and where gaps of care may exist in the state (see Attachment 5 for additional information on the provider capacity assessment).
- Identifying those gaps and developing measures to build capacity at those critical levels of care where the gaps exist.
- Developing measures to ensure sufficient provider capacity at, and beneficiary access to, ASAM critical levels of care.
- Updating provider and service delivery standards to increase the use of evidence-based placement assessment criteria and matching individual risk with the appropriate ASAM level of care to ensure beneficiaries receive the treatment they need. These changes include:
- Residential and outpatient providers participating in the demonstration will transition to ASAM-based standards, with the goal of being fully compliant by June 30, 2021.
- Developing updated SUD treatment service requirements, assessment and placement criteria, and staffing requirements that are consistent with ASAM standards, and publishing them in the provider manual by October 2020.[17]
- Developing a residential treatment provider review process that will be used to ensure compliance with the updated provider requirements.
- Establishing a comprehensive utilization review process to ensure that beneficiaries served in the demonstration have access to appropriate levels of care and necessary interventions.
- Implementing a new provision that MAT must be offered as part of the continuum of care and that providers have at least one medical professional with prescribing authority within their networks.
- Developing proposed future state measures to ensure sufficient provider capacity at, and beneficiary access to, ASAM critical levels of care.
- Developing standards for enhancing and aligning the treatment planning requirements with ASAM criteria and developing further guidance on ASAM-based treatment coordination standards for 1115 Waiver providers.

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

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

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

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

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

**Exhibit 1.** Minnesota Coverage of SUD Treatment Services

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

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

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

# Evaluation Design Plan

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

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

## Evaluation Hypotheses and Research Questions

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

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

## Exhibit 2. Waiver Goals and Preliminary Evaluation Questions

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

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

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

**Goal 2. Increased adherence to and retention in treatment**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

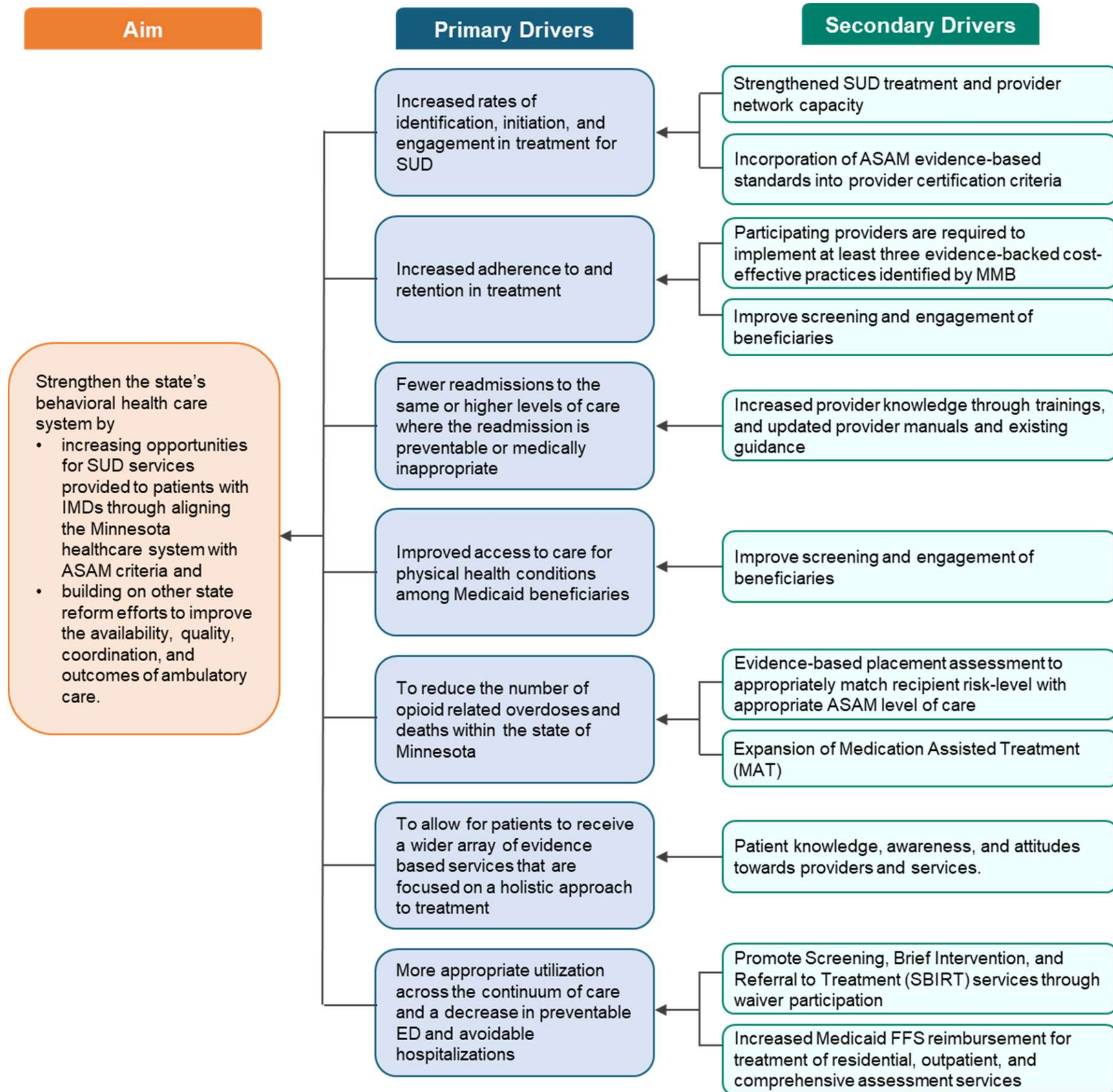
| *Hypothesis: The demonstration will reduce the utilization of the emergency department, avoidable hospitalizations, hospitalizations for ambulatory care sensitive conditions, and intensive inpatient services.* |
|---|
| 12. Did implementation of the 1115 SUD Waiver result in the following, among Medicaid beneficiaries with SUD, following the receipt of treatment services?<br>a. improved use of preventive care<br>b. reduced emergency department utilization<br>c. fewer avoidable hospitalizations<br>d. fewer hospitalizations for ambulatory care sensitive conditions<br>e. fewer avoidable hospitalizations during and after receipt of addiction recovery management services |

## Demonstration Driver Diagram

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

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

## Exhibit 3. Demonstration Driver Diagram



# Methodology

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

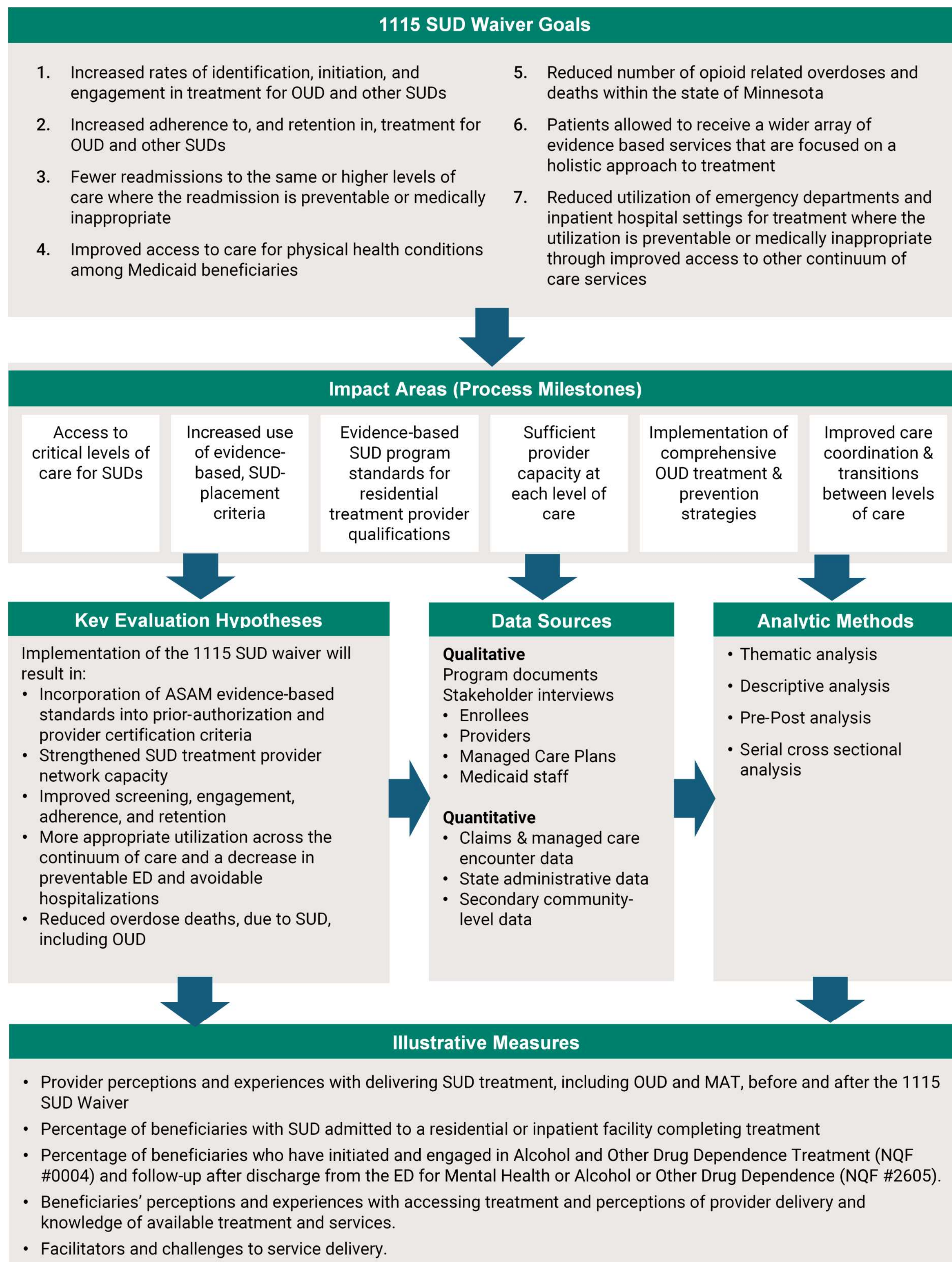
The different outcomes and target populations included in the demonstration necessitate a combination of evaluation design approaches. Following CMS guidance, our analyses will include descriptive statistics, pre-post, interrupted time series, qualitative data collection, and mixed-methods analyses to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

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

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

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

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



## Target and Comparison Group

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

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

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

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

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

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

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

**Exhibit 5.** Strategy to Construct the Baseline and Demonstration Groups

| Step | Approach |
|---|---|
| **1. Identify Medicaid providers and markets in the baseline** | ■ Identify providers in each type of treatment setting.<br>■ Define comparable health care market characteristics for providers from which to select beneficiaries. |
| **2. Match beneficiaries** | ■ Match beneficiaries using a beneficiary-level entropy balancing approach.<br>■ The entropy model will be based on factors such as demographic characteristics, health status and conditions, type and severity of SUD, health service use, Medicaid program eligibility status, and health care access information (distant to and density of providers) and market characteristics. |
| **3. Assess differences** | ■ Assess differences between the baseline and demonstration groups. |

## Evaluation Period

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

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

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

## Evaluation Measures

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

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

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

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

## Claims-Based Measures

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

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

## Non-Claims-Based Measures

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

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

**Exhibit 6.** Evaluation Measures and Analytic Approach

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

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

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

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

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

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

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

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

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

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

## Exhibit 7. Exploratory Analysis Measures and Analytic Approach

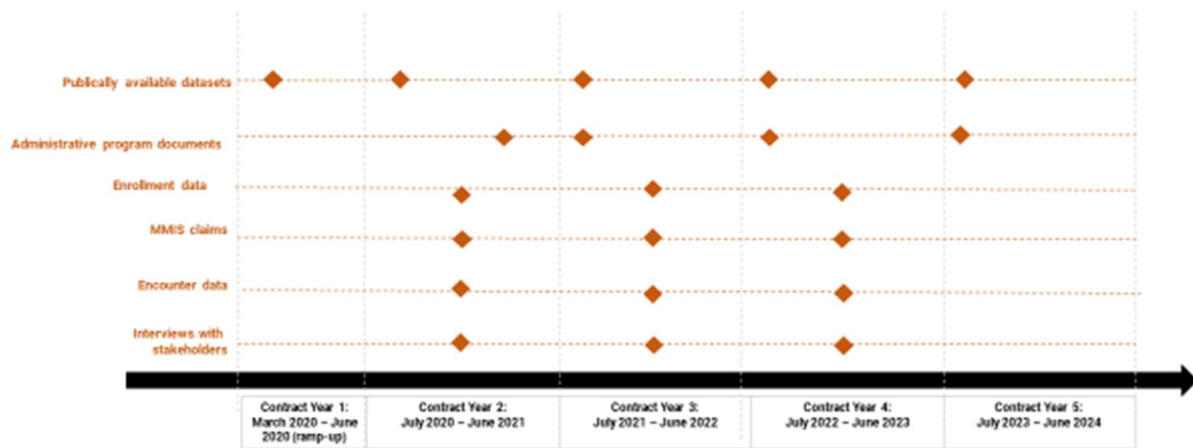
| Hypothesis | Measure Description | Measure Steward | Numerator | Denominator | Data Source | Analytic Approach |
|---|---|---|---|---|---|---|
| The demonstration will facilitate cost-effective health care delivery by reducing avoidable costs for beneficiaries with an SUD by providing coordinate care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

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

## Data Sources

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

**Exhibit 8.** Data Source Timeline



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

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

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

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

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

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

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

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

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

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

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

## Non-Claims-Based Data

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

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

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

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

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

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

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

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

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

## Exhibit 9. Qualitative Analysis: Respondent Type and Knowledge Objectives

| Respondent Type | Knowledge Objectives |
|---|---|
| **Beneficiaries and consumer advocates** | ■ Community-level resources for SUD treatment<br>■ Experience accessing SUD treatment services<br>■ Perceptions about care experience and satisfaction<br>■ Identify unmet service needs<br>■ Key barriers to accessing SUD services, including differences by demographics and geography<br>■ Key barriers to staying in treatment |
| **Providers** | ■ Knowledge of new 1115 SUD Waiver-related benefits<br>■ Perceptions about the extent to which SUD treatment coverage standards align with the ASAM criteria<br>■ Perceptions about appropriate staffing at different ASAM critical levels of care<br>■ Observations regarding patient's unmet service needs<br>■ Perceptions of gaps in provider capacity and ways to address those gaps<br>■ Perceptions about patient placement criteria for clinically managed residential services and medically managed inpatient services<br>■ Adequacy of reimbursement rates for new SUD treatment services<br>■ Key challenges and facilitators of implementation, including differences for urban and rural providers<br>■ Perceptions of the impact of other state/federal interventions on the demonstration implementation |
| **Managed care plans** | ■ Perceptions about the extent to which prior authorization guidelines adhere to ASAM criteria<br>■ Perceptions about the extent to which SUD treatment coverage standards align with the ASAM criteria<br>■ Perceptions about the size/adequacy of the provider network for SUD services and variations by urban and rural geography<br>■ Observations regarding beneficiaries unmet service needs<br>■ Views about the operational challenges inherent in the implementation of the waiver<br>■ Key challenges and facilitators of implementation<br>■ Operational challenges faced and how they were overcome |
| **DHS staff** | ■ Key policy or administrative challenges in implementing the waiver, underlying causes, and mitigation strategies<br>■ Key achievements and the underlying drivers of success<br>■ Perceptions about support and technical assistance from CMS |

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

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

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

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

## Analytic Methods

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

**Exhibit 10.** Evaluation Measures and Analytic Approach

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

## Quantitative Analytic Methods

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

## Descriptive Analysis

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

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

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

$$Yt = \beta 0 + \beta 1T + \beta 2Xt + \beta 3TXt$$

Where Yt is the outcome at time t, T represents the time elapsed since the start of the program $\beta 0$ represents the baseline (where T=0), Xt is a dummy variable indicating the pre-intervention period, $\beta_2$ is the level change following the intervention, and $\beta_3$ indicates the slope change following the program.[25]

## Comparisons with National Data

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

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

**Exhibit 11.** National Benchmark Data Sources and Measures

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

### Beneficiary-Level Entropy Balancing

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

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

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

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

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

### *Subgroup Analyses*

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

### *Sensitivity Analysis*

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

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

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

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

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

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

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

### *Sample Size and Power Calculations*

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

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

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

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

## Qualitative Analytic Methods

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

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

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

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

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

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

## Methodological Limitations

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

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

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

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

## Exhibit 12. Key Challenges and Proposed Solutions

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

# Attachment 1. Independent Evaluator

## Independent Evaluator Selection Process

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

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

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

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

## Team Member Experience

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

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

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

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

## Exhibit 10. NORC Team Member Experience and Anticipated Contributions

| Key Personnel |
| --- |
| **Scott Leitz, MA, Senior Fellow, Project Director *(Estimated time: 475 hours*)*** |
| ■ Provides expert leadership for the NORC health care department, with emphasis on state health care policy<br>■ Serves as project director for NORC contracts to support the CMS State Innovation Model initiative and Medicaid Innovation Accelerator Program, Value-Based Payment and Financial Simulation<br>■ Previous roles include assistant commissioner at the MN DHS responsible for overseeing and managing the state's Medicaid program; director of public policy for Children's Hospitals and Clinics of Minnesota, and several positions at the Minnesota Department of Health. One portfolio responsibility was Minnesota's Office of Rural Health and Primary Care, focused on ensuring access to care and services in rural and underserved areas of the state |
| **Mollie Hertel, MPP, AM, Senior Research Scientist, Project Manager *(Estimated time: 1140 hours*)*** |
| ■ Has extensive experience in project management, including designing and executing large qualitative and quantitative research studies<br>■ Currently manages a multistate qualitative research project for the Medicare Payment Advisory Commission (MedPAC), involving focus groups and interviews<br>■ Previously worked at the U.S. Government Accountability Office, managing several projects specific to Medicaid payments and beneficiary access<br>■ Led a mixed-methods evaluation of Mercy Maricopa Integrated Care for Aetna, an integrated physical and behavioral health Medicaid managed care plan, which included developing multiple respondent protocols, conducting interviews with plan officials and social service organizations, and analyzing results into a final report |
| **Kathleen Rowan, PhD, MPH, Senior Research Scientist, Quantitative Lead *(Estimated time: 900 hours*)*** |
| ■ Serves as project director for the Health Resources and Services Administration's Behavioral Health Workforce Substance Use Disorder Evaluation, including implementation of five surveys across 18,000 health centers, 300 grantees, and 15,000 participants<br>■ Serves as quantitative team lead for the CMS evaluation of the Next Generation Accountable Care Organization (NGACO) Model, including the development of analytic strategies, analysis of claims and survey data, mixed-methods analysis; prepares findings for various audiences<br>■ Provides technical assistance to CMS for review of state evaluation plans for Section 1115 Waiver Demonstrations<br>■ Conducted quantitative analyses the CMS Innovation Centers' Health Care Innovation Awards, the Beacon Community Cooperative Agreement Program Evaluation for the Office of the National Coordinator for Health Information Technology, and numerous survey projects |
| **Jennifer Smith, PhD, MPH, Senior Data Scientist, Quantitative Data Support *(Estimated time: 92 hours*)*** |
| ■ Develops quality assurance protocols to ensure accurate programming and reporting of data<br>■ Past roles include using Medicare, Medicaid, hospital discharge data, Maryland All-Payer Claims Database, and social determinant datasets to assess quality, cost, and utilization patterns within a Medicaid/Exchange churn population<br>■ Holds experience in developing programming to evaluate mental health, substance abuse, continuous care, shadow pricing encounter data, and dual-eligible populations within claims data |
| **Susan Cahn, DrPH, MA, MHS, Senior Research Scientist, Qualitative Lead *(Estimated time: 780 hours*)*** |

| Key Personnel |
| --- |
| ■ Designed and conducted qualitative primary data collection and convened a community of practice with 31 hospitals and 10 public health and community organizations<br>■ As a senior member of the NGACO qualitative evaluation team, leads efforts in designing questionnaires, conducting interviews, and analyzing interview data, and provides technical assistance to states through the Medicaid Innovation Accelerator Program<br>■ Leads several activities for CMS's Office of Minority Health, including claims analyses and the analysis of quantitative and qualitative data on Medicare Advantage health plans for the development of an engagement strategy |
| **Lauren Isaacs, MPH, MSW, Principal Research Analyst, Qualitative Analyst *(Estimated time: 720 hours*)*** |
| ■ Roles include the delivery of health equity technical assistance to external stakeholders; developing interview guides, recruiting participants, and conducting key informant interviews about diabetes with providers and other health care professionals; conducting an environmental scan and literature reviews<br>■ Works on two ongoing multistate qualitative research projects for MedPAC, involving key informant interviews and focus groups with providers, beneficiaries, health plans, state Medicaid agencies, beneficiary advocates, and other health care organizations |

*Over 55-month contract period

# Attachment 2. Evaluation Budget

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

**Exhibit A.1.** Independent Evaluation Budget

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

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

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

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

# Attachment 3. Timeline and Major Milestones

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

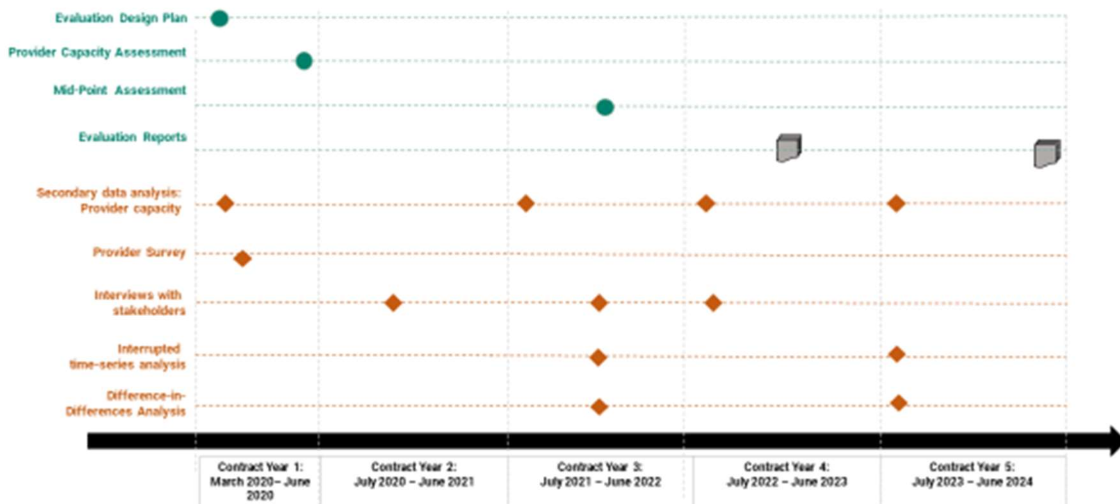
**Exhibit A.2.** Overview of Reports: Schedule and Overview

| Key Dates | Proposed Content and Format |
|---|---|
| **Evaluation Design Plan** | |
| Draft to CMS:<br>April 1, 2020<br>**Revised draft:**<br>**< 45 days of CMS response** | ■ A roadmap for the methodological approaches and analytical steps to address each research question driving the demonstration evaluation<br>■ Informed by CMS' Design Plan Template<br>■ Planned approaches to address each evaluation question and hypothesis<br>■ Qualitative and quantitative methodologies<br>■ Measures, including measure specifications and data sources<br>■ Baseline and comparison groups<br>■ Operational details for secondary data acquisition and primary data collection |
| **Provider Capacity Assessment (Milestone 4)** | |
| Initial assessment:<br>July 1, 2020<br>Update throughout demonstration period | ■ Supports state in completing Milestone 4<br>■ Determines availability of treatment for Medicaid beneficiaries in each level of care, including MAT and medically supervised withdrawal<br>■ Identifies gaps in the availability of services |
| **SUD Midpoint Assessment** | |
| MN to submit to CMS:<br>December 31, 2021 | ■ Independent assessment to examine progress and assess risk in not achieving milestones in SUD Implementation Plan or meeting performance targets in SUD Monitoring Protocol |

| Key Dates | Proposed Content and Format |
|---|---|
| **Interim Evaluation Report** | |
| MN to submit to CMS: June 30, 2023 | ■ Updates on implementation experience and evaluation findings to date associated with as many of the research questions in approved Evaluation Design as data permits<br>■ Most comply with Attachment B of STC |

| Key Dates | Proposed Content and Format |
|---|---|
| **Final Evaluation Report** | |
| MN to submit to CMS: December 30, 2025 | ■ Summative report of evaluation findings as described in the approved Evaluation Design<br>■ Qualitative and quantitative findings on:<br>• Rates of identification, initiation, and engagement in treatment<br>• Adherence to and retention in treatment<br>• Overdose deaths, particularly those due to opioids<br>• Utilization of emergency department and inpatient hospital setting for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services<br>• Readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate<br>• Access to care for physical health conditions among members<br>• Must comply with Attachment B of STC |
| **Information for Federal Reporting** | |
| Quarterly and annually | ■ Updates for MN DHS to include in reports to CMS<br>■ Progress on evaluation activities<br>■ Key milestones accomplished<br>■ Interim findings, as available<br>■ Challenges encountered and how they were addressed |

## Exhibit A.3. Timeline of Analytic Activities and Deliverables



# Attachment 4. American Society for Addiction Medicine Continuum of Care

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

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

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

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

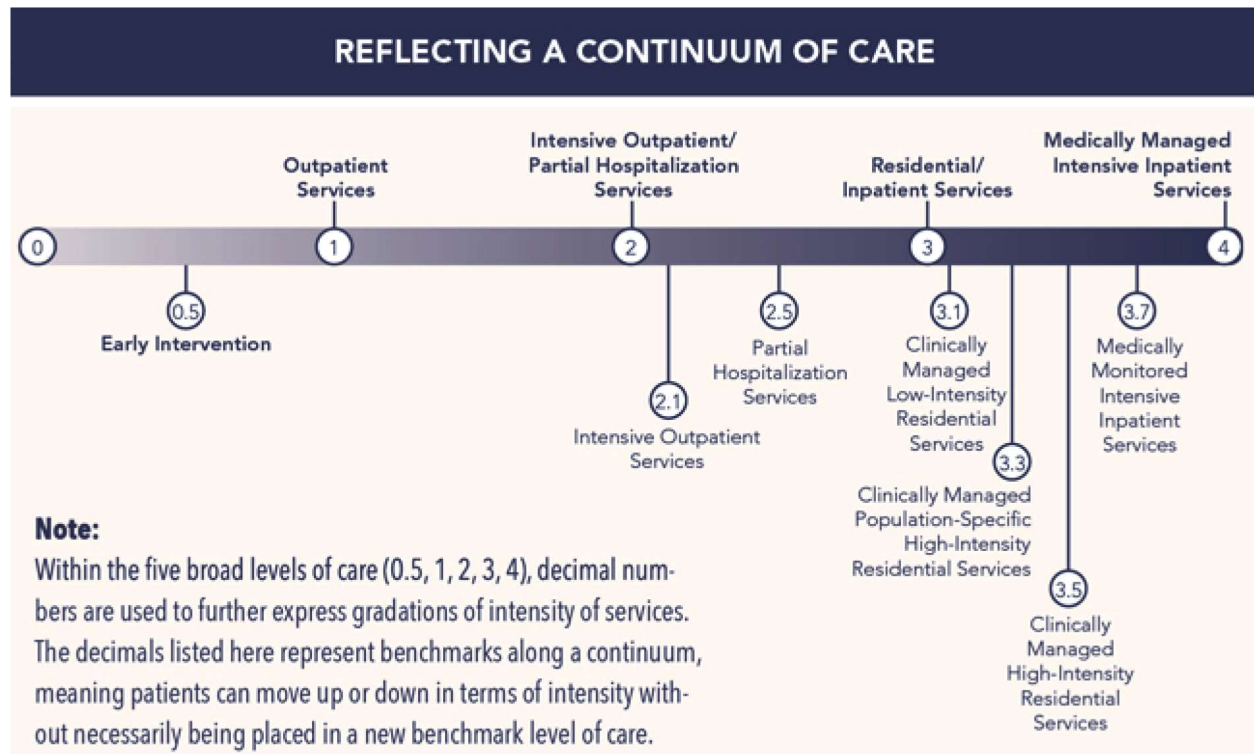
[33] Ibid.

[34] Ibid.

[35] Ibid.

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

**Exhibit A.4.** ASAM Continuum of Care




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

# Attachment 5. Provider Capacity Assessment

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

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

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

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

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

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

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

## Exhibit A.5. Proposed Approach to Provider Capacity Assessment

| Component | Approach |
|---|---|
| **1. Baseline measurement of the current condition** | ■ NORC will collect data on personnel and facility-level “inputs” available across the state and across the range of personnel skills, from peer recovery specialists (as billing codes for peer specialists become available) to providers with DATA 2000 waivers for MAT.<br>■ Assessment will specifically capture the minimum required by CMS for Milestone #4 on the availability of providers enrolled in Medicaid and accepting new patients at the critical levels of care throughout the state (or at least in participating regions of the state), including those that offer MAT. |
| **2. Specification of optimal mix of resources required for each level of care, according to the ASAM criteria** | ■ NORC will help the MN DHS define optimal staffing in a collaborative manner to ensure stakeholders have input. |
| **3. Recommendations for actions** | ■ NORC will develop recommendations for the MN DHS to address gaps, prioritized collaboratively through stakeholder input. |

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

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

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

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

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

## Provider Capacity Assessment Research Questions and Measures

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

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

| Assessment Question | Measures | Sources |
|---|---|---|
| **Goal 1: Determine availability of Medicaid-enrolled providers who have delivered treatment for Medicaid beneficiaries in each of ASAM critical levels of care, as well as the availability of MAT and medically supervised withdrawal management, throughout the state** | | |
| **Hypotheses: The PCA will help ensure sufficient provider capacity at each level of ASAM care for SUD, including OUD** | | |
| **1. For each level of ASAM care, what are the number of providers in the state accepting new Medicaid patients?**<br>**2. What proportion of beneficiaries are more than 30 miles from services, for each level of ASAM care?**<br>**3. What are the average wait times for beneficiaries, for each subgroup, and for each level of ASAM care?** | ■ Number of providers with active enrollment who have provided behavioral health care in the last 12 months, per beneficiary by ASAM level of care, by county and subgroup<br>■ Number of providers with active enrollment who have provided SUD services per SUD beneficiary, by ASAM level of care, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup<br>■ Number of providers with a DATA-2000 waiver (certified to prescribe or dispense buprenorphine) who have dispensed BUP in the last 12 months, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup<br>■ Number of beneficiaries at each level of ASAM care who are more than 30 miles from the nearest available provider, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup<br>■ Average wait times for each service at each level of ASAM care, by geographic strata (e.g., county and urban/rural) and beneficiary subgroup | TBD |

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

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

Other data that may inform adequacy could include:

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

## Specification of the Optimal Mix of Resources

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

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

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

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

### Identify Gaps and Recommendations for Strategies to Address Gaps

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

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

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

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

# Attachment 6. Promoting Objectives of Titles XIX and XXI

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

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

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

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

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

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

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

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