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

June 25, 2025

Bill Hanna
State Medicaid Director
Wisconsin Department of Health Services
1 W. Wilson St.
Madison, WI 53701

Dear Director Hanna:

The Centers for Medicare & Medicaid Services (CMS) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Wisconsin BadgerCare Reform (Project Number 11-W-00293/5) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section

1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The Wisconsin BadgerCare Reform demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on June 29, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 8.6, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Some of the metrics currently required for Substance Use Disorder (SUD) and Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) demonstrations will no longer be required.

CMS is also removing the requirement for a Monitoring Protocol deliverable, which has been required under certain types of section 1115 demonstration, including but not limited to the SUD, SMI/SED, Health-Related Social Needs (HRSN), and reentry demonstrations. Removal of the Monitoring Protocol requirement simplifies and streamlines demonstration monitoring activities for states and CMS.

Demonstration Monitoring Calls

As STC 8.10 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Wisconsin BadgerCare Reform section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Mai Le-Yuen, State Monitoring Lead, Medicaid and CHIP Operations Group

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

State Demonstrations Group

May 12, 2025

Bill Hanna
State Medicaid Director
Wisconsin Department of Health Services
1 W. Wilson St.
Madison, WI 53701

Dear Director Hanna,

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) Monitoring Protocol, which is required by the Special Terms and Conditions (STC), specifically, STC #8.5 "Monitoring Protocol" of Wisconsin's section 1115 demonstration, "Wisconsin BadgerCare Reform" (Project No: 11-W-00293/5), effective October 29, 2024 through December 31, 2029. CMS determined that the Monitoring Protocol, which was submitted on March 27, 2025, meets the requirements set forth in the STCs, and thereby approves the state's SUD Monitoring Protocol.

The Monitoring Protocol is approved for the demonstration period through December 31, 2029 and is hereby incorporated into the demonstration STCs as Attachment B (see attached). In accordance with STC #9.11, the approved SUD Monitoring Protocol may now be posted to your state's Medicaid website.

We look forward to our continued partnership on the Wisconsin BadgerCare Reform section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Mai Le-Yuen, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00293/5**

TITLE: **Wisconsin BadgerCare Reform Section 1115 Demonstration**

AWARDEE: **Wisconsin Department of Health Services**

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Wisconsin for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from October 29, 2024 through December 31, 2029, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable Wisconsin to operate the above-identified section 1115(a) demonstration.

1. **Childless Adults Demonstration Population.** Expenditures for health care-related costs for eligible non-pregnant, uninsured adults ages 19 through 64 years who have family incomes up to 95 percent of the federal poverty level (FPL) (effectively 100 percent of the FPL including the five percent disregard), who are not otherwise eligible under the Medicaid State plan, other than for family planning services or for the treatment of Tuberculosis, and who are not otherwise eligible for Medicare, Medical Assistance, or the State Children's Health Insurance Program (CHIP).

2. **Former Foster Care Youth from Another State.** Expenditures to extend eligibility for full Medicaid state plan benefits to former foster care youth are under age 26, who turned 18 on or before December 31, 2022, who were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected for termination of Federal foster care assistance under title IV-E of the Act), were enrolled in Medicaid on the date of aging out of foster care, and are now applying for Medicaid in Wisconsin.

3. **Residential and Inpatient Treatment Services for Individuals with Substance Use Disorder.** Expenditures for Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment and/or withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable in the list below, shall apply to the Childless Adults Demonstration Population.

Title XIX Requirements Not Applicable to the Demonstration Population:

1. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable the state to require enrollment of the childless adult population in managed care organizations.

2. Comparability **Section 1902(a)(17)/Section 1902(a)(10)(B)**

To the extent necessary to enable the state to establish a non-emergency use of the emergency department copayment of $8 for the childless adult population.

CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00293/5**

TITLE: **Wisconsin BadgerCare Reform**

AWARDEE: **Wisconsin Department of Health Services**

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Wisconsin BadgerCare Reform" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Wisconsin Department of Health Services (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those populations affected by the demonstration are effective from October 29, 2024 through December 31, 2029, unless otherwise specified. The STCs have been arranged into the following subject areas:

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

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

Attachment A. Substance Use Disorder Implementation Plan Protocol (Approved)
Attachment B. Substance Use Disorder Monitoring Protocol (Reserved)
Attachment C. Developing the Evaluation Design
Attachment D Preparing the Interim and Summative Evaluation Reports

Attachment E. Evaluation Design (Reserved)
Attachment F. Monitoring Protocol (Reserved)

2. PROGRAM DESCRIPTION AND OBJECTIVES

With the implementation of the Affordable Care Act provisions that provided federally-funded subsidies to help individuals and families purchase private health insurance, Wisconsin saw the BadgerCare Reform demonstration as an opportunity to reduce the uninsured rate and encourage beneficiaries to access coverage in the private market.

The Wisconsin BadgerCare Reform demonstration provides state plan benefits, other than family planning services and tuberculosis-related services, to childless adults who have effective family incomes up to 100 percent of the Federal Poverty Level (FPL) (effective income is defined to include the five (5) percent disregard). Coverage for this population focuses on improving health outcomes, reducing unnecessary services, and improving the cost- effectiveness of Medicaid services.

In accordance with CMS' November 21, 2016, CMCS Informational Bulletin (CIB), Section 1115 Demonstration Opportunity to Allow Medicaid Coverage to Former Foster Care Youth Who Have Moved to a Different State, the BadgerCare Reform demonstration was amended in December 2017 to add coverage of former foster care youth defined as individuals under age 26 who were in foster care in another state or tribe of such other state when they turned 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Act), were enrolled in Medicaid at that time or at some point while in such foster care, and are now applying for Medicaid in Wisconsin. With the addition of this population, Wisconsin has a new demonstration goal to increase and strengthen overall coverage of former foster care youth and improve health outcomes for this population.

On October 29, 2024, CMS approved a five-year extension of the demonstration to allow the state to continue the existing demonstration authorities, which provide authority for the expansion of eligibility to childless adults, former foster care youth, services for substance use disorders in an institution for mental disease, and the $8 copay for non-emergency use of the emergency department. The extension does not include any changes to the approved demonstration authorities.

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

SUD Goals:

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

6	Improve access to care for physical health conditions among beneficiaries with SUD

3. GENERAL PROGRAM REQUIREMENTS

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

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

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

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

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 3.7 of this section) as a result of the change in FFP.

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

3.5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required,

except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

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

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

a. An explanation of the public process used by the state, consistent with the requirements of STC 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
d. An up-to-date CHIP allotment worksheet, if necessary;
e. The state must identify how it will modify its evaluation design to incorporate the amendment provisions..

3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS at least 12 months in advance from the Governor of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 3.9.

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

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

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.

e. Exemption from Public Notice Procedures, 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the

state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

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

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

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

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

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

3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is

for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

4. ELIGIBILITY AND ENROLLMENT

4.1. **State Plan Eligibility Groups Affected by the Demonstration.** The state plan populations affected by this demonstration are outlined in Table 1, which summarizes each specific group of individuals and specifies the authority under which they are eligible for coverage and the name of the eligibility and expenditure group under which expenditures are reported to CMS and the budget neutrality expenditure agreement is constructed.

4.2. **Demonstration Expansion Eligibility Groups.** Table 1 summarizes the specific groups of individuals, and specifies the authority under which they are eligible for coverage. Demonstration Populations 1 and 2 in Table 1 is made eligible for the demonstration by virtue of the expenditure authorities expressly granted in this demonstration. Coverage of Demonstration Populations 1 and 2 are subject to Medicaid laws and regulations unless otherwise specified in the "Title XIX Requirements Not Applicable to the Demonstration Population" section of the expenditure authorities document for this demonstration.

Table 1: Eligibility Groups Affected by the Demonstration

Demonstration Expansion Groups	Eligibility Criteria	Funding Stream
Population 1. Childless Adult Demonstration Population	• Ages 19 through 64 • Effective monthly income at or below 100 percent of the FPL • Not pregnant • Do not qualify for any other full-benefit Medicaid or CHIP eligibility group • Are not receiving Medicare • Childless adults may have children, but do not qualify as a parent or caretaker relative (e.g., either the children are not currently living with them or those children living with them are 19 years of age or older)	Title XIX

Population 2. Former Foster Care Youth (FFCY) from Another State	• Under age 26 • Were in foster care under the responsibility of a state other than Wisconsin or a tribe in such other state when they turned 18 or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Act) • Were enrolled in Medicaid at the time of aging out of foster care • Turned 18 on or before December 31, 2022 • Are now applying for Medicaid in Wisconsin, and • Are not otherwise eligible for Medicaid	Title XIX

5. BENEFITS

5.1. **Wisconsin BadgerCare Demonstration.** All enrollees in this demonstration (as described in Section 4) will receive benefits as specified in the Medicaid state plan, to the extent that such benefits apply to those individuals. Beneficiaries in Demonstration Population 1 will not receive family planning services or tuberculosis-related services. In addition, beneficiaries in the Demonstration Population 1 will not receive pregnancy related services, but instead must be administratively transferred to the pregnant women group in the state plan if they are pregnant. Refer to the state plan for additional information on benefits. Out-of-state former foster care youth will receive the same Medicaid State Plan benefits and be subject to the same cost-sharing requirements effectuated by the state for the mandatory title IV-E foster care youth eligibility category enacted by the Adoption Assistance and Child Welfare Act of 1980 (Pub. L. 96-272).

5.2. **Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) Program**. Effective upon CMS's approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include OUD/SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD treatment services, that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. CMS approved the SUD Implementation Plan on October 22, 2019. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 8.5, to ensure short-term residential stays.

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

The coverage of OUD/SUD treatment services and withdrawal management during short term residential and inpatient stays in IMDs will expand Wisconsin's current SUD benefit package

available to all Wisconsin Medicaid recipients as outlined in Table 2. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as impatient facilities under section 1905(a) of the Act.

Table 2: Wisconsin OUD/SUD Benefits Coverage with Expenditure Authority

SUD Benefits	Wisconsin Medicaid Authority	Expenditure Authority
Outpatient Services	State Plan	n/a
Intensive Outpatient Services	State Plan	n/a
Medication Assisted Treatment	State Plan (Individual services covered)	Services provided to individuals in IMDs
Residential Treatment Services	State Plan (Individual services covered)	Services provided to individuals in IMDs
Inpatient Services	State Plan (Individual services covered)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State Plan	Services provided to individuals in IMDs

5.3. **SUD Implementation Plan and Health IT Plan.** The state's SUD Implementation Plan initially approved for the period from June 7, 2019 through December 31, 2023 (and temporarily extended through December 31,2024) remains in effect for the approval period from October 29, 2024, through December 31, 2029, and is affixed to the STCs as Attachment A. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The approved SUD Implementation Plan describes the strategic approach and a detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

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

b. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;

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

d. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. Currently, residential treatment

service providers must be a licensed organization, pursuant to the residential service provider qualifications described in Wisconsin administrative code. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

e. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
f. Standards of Care. Establishment of a requirement that residential treatment providers offer Medication Assisted Treatment (MAT) on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;
g. Sufficient Provider Capacity at each Level of Care, including Medication Assisted Treatment for SUD/OUD. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
h. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
i. Improved Care Coordination and Transitions between Levels of Care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval;
j. SUD Health IT Plan. Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics are detailed in STC 5.4 and Attachment A.
k. SUD Health Information Technology Plan ("Health IT Plan"). The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) (see STC 5.2(j) and STC 5.2), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.
l. The Health IT Plan should describe how technology can support outcomes through care coordination; linkages to public health and prescription drug monitoring programs; establish data and reporting structure to monitor outcomes and support data

driven interventions. Such technology should, per 42 CFR 433.112(b), use open interfaces and exposed application programming interfaces and ensure alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 42 CFR part 170, subpart B.

i. The state must include in its Monitoring Protocol (see STC 10.5) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
ii. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS within its Annual Report (see STC 10.6).
iii. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
iv. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally recognized standards.
v. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally recognized ISA standards.
vi. Components of the Health IT Plan include:
    1. The Health IT Plan must describe the state's alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP)[1].
    2. The Health IT Plan must address how the state's Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.2 States should favor procurement strategies that incorporate qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in RX Check for Interstate data sharing.
    3. The Health IT Plan will describe how technology will support substance use disorder prevention and treatment outcomes described by the demonstration.
    4. In developing the Health IT Plan, states should use the following resources:

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

- States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
- States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-andsystems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
- States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.
- States should review the Office of the National Coordinator's Interoperability Standards Advisory (https://www.healthit.giv/isa/) for information on appropriate standards which may not be required per 45 CFR part 170, subpart B for enhanced funding, but still should be considered industry standards per 42 CFR 433.112(b)(12).

5.4. **SUD Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections 8 (Monitoring and Reporting Requirements) and 9 (Evaluation of the Demonstration) of these STCs.

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

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

6. COST SHARING

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

6.2. **Copayments for Use of the Emergency Department.** Individuals in Demonstration Population 1 are required to pay a copayment for each non-emergent use of the emergency room (ER). This copayment shall be charged consistent with 1916A(e)(1) of the Act and 42 CFR 447.54.

a. Under the provisions of section 1916A(e) of the Act, the state has the authority to impose a copayment for services received at a hospital emergency room if the services are not emergency services.

b. As provided under 42 CFR 447.54, the amount of this co-pay will be $8 for each non-emergent use of the emergency department.
c. The individual must receive an appropriate medical screening examination under section 1867—the Emergency Medical Treatment and Labor Act, or EMTALA provision of the Act.
d. Providers cannot refuse treatment for nonpayment of the co-payment.
e. AI/AN who are currently receiving or who have ever received an item or services furnished by an Indian health care provider or through referral under contract health services are exempt from the copayment requirements outlined above, consistent with section 1916(j) of the Act and 42 CFR 447.56.

7. DELIVERY SYSTEM

7.1. **General**. Demonstration Population 1 will be enrolled in managed care organizations (MCO) that are currently contracted to provide health care services to the state's existing Medicaid and BadgerCare programs. As a condition of eligibility, demonstration enrollees will be required to join a MCO, as long as there is at least two MCOs available in their county of residence unless the rural exception is met in accordance with 42 CFR 438.52.(b). If the county has not been granted a rural exception, the state must offer the option of either MCO enrollment or Medicaid fee-for-service. All demonstration eligible beneficiaries must be provided a Medicaid card, regardless of MCO enrollment. MCOs may elect to provide a MCO specific card to MCO enrollees as well. The state must comply with the managed care regulations published at 42 CFR part 438. Capitation rates shall be developed and certified as actuarially sound, in accordance with 42 CFR 438.4, 438.5 and 438.7. No FFP is available for activities covered under contracts and/or modifications to existing contracts that are subject to 42 CFR part 438 requirements prior to CMS approval of this demonstration authority as well as such contracts and/or contract amendments. The state shall submit any supporting documentation deemed necessary by CMS. The state must provide CMS with a minimum of sixty (60) days to review and approve changes. CMS reserves the right, as a corrective action, to withhold FFP (either partial or full) for the demonstration, until the contract compliance requirement is met.

8. MONITORTING AND REPORTING REQUIREMENTS

8.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. Specifically:
a. The following process will be used: 1) thirty (30) calendar days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (8.1.3) below; or 2) thirty (30) calendar days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information

needed to bring the deliverable into alignment with CMS requirements.

b. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables
c. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a rationale for the cause(s) of the delay and the state's anticipated date of submission. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP). Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
d. If CMS agrees to an interim corrective plan in accordance with subsection 8.1.2, and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, the deferral would be issued against the next Quarterly Statement of Expenditure reported in Medicaid Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state. following the written deferral notification.
e. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
f. As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

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

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

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

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

b. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

8.5. **Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol with 60 calendar days after receipt of CMS's comments, if any. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment F. Progress on the performance measures identified in the Monitoring Protocol must be reported via the Quarterly and Annual Monitoring Reports. Components of the Monitoring Protocol must include:

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 5.2 and reporting relevant information to the state's Health IT plan described in STC 5.2.
b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section 8 (Monitoring and Reporting Requirements) of the demonstration; and
c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and target will be benchmarked against performance in best practice settings.

8.6. **Monitoring Reports.** The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth quarter information) is due no later than90 calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and must not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key operational and other challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics – Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress toward meeting the demonstration's annual goals and overall targets as identified in the approved Monitoring Protocol and will cover key policies under this demonstration. The performance metrics will reflect all components of the state's demonstration, and may include, but are not limited to, measures associated with eligibility and coverage. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration on beneficiaries' outcomes of care, quality and cost of care, and access to care. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals. The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings - Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

e. SUD Health IT - The state will include a summary of progress in regards to SUD Health IT requirements outlined in STC 5.

8.7. **SUD Mid-Point Assessment -** The state must contract with an independent entity to conduct a Mid-Point Assessment by December 31, 2026. This timeline will allow for the Mid-Point Assessment to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. In the design, planning and conduction of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, health care providers (including SUD treatment providers), beneficiaries, community groups, and other key partners.

The state must require that the assessor provide a Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2026. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment with 60 calendar days after receipt of CMS's comments, if any.

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

Elements of the Mid-Point Assessment must include:

1. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol.
2. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date.
3. A determination of factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets.
4. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plans or to other pertinent factors that the state can influence that will support improvement; and
5. An assessment of whether the state is on track to meet the budget neutrality requirements.

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

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

a. The Close-Out Report must comply with the most current guidance from CMS.
b. In consultation with CMS, and per the guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out

or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 9.7 and 9.8, respectively.

c. The state will present to and participate in a discussion with CMS on the Close-Out report.
d. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
e. A revised Close-Out Report is due to CMS no later than 30 days after receipt of CMS' comments.
f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

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

a. The purpose of these calls is to discuss ongoing demonstration operation, including (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The state and CMS will jointly develop the agenda for the calls.

8.11. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

9. EVALUATION OF THE DEMONSTRATION

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

administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.1.

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

9.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than one hundred eighty (180) calendar days after approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

a. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):
b. Attachment C (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a draft Evaluation Design.

9.4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval, the approved Evaluation Design will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the evaluation design in monitoring reports.

9.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments C and D (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS' measure sets for eligibility and coverage, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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

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

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

9.8. **Summative Evaluation Report.** The state must submit to CMS a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs.

a. The Summative Evaluation Report, in alignment with the Evaluation Design, must evaluate the entirety of the demonstration period.
b. Unless otherwise agreed upon in writing by CMS, the state shall submit a revised Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft, if any.
c. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

d. The Summative Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs.

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

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

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

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

10. GENERAL FINANCIAL REQUIREMENTS

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

10.2. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and

CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

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

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

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

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.
b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that

incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

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

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

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

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

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

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

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

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

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

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

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

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

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;
b. Number of providers in each locality of the taxing entities for each locality tax;
c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
d. The assessment rate that the providers will be paying for each locality tax;
e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

10.8. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 11:

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

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

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

Table 3: Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Childless Adult	Hypothetical	X		X	All expenditures for services provided to non-pregnant, uninsured adults ages 19 through 64 years who have family incomes up to 100 percent of the FPL.
SUD	Hypothetical	X		X	All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment.
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

10.11. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00293/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b (in lieu of lines 9 or 10c), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should

be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. **Premiums and Cost Sharing Collected by the State**. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. **Pharmacy Rebates**. Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the MEG Charts and in the STCs in section 11, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section 8, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information

System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 4: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Childless Adult	All expenditures for services provided to non-pregnant, uninsured adults ages 19 through 64 years who have family incomes up to 100 percent of the FPL		Follow standard CMS 64.10 Category of Service Definitions	Date of service	MAP	Y	10/29/24	12/31/29
SUD	All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	N	10/29/14	12/31/29
ADM	All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.		Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	10/29/24	12/31/29

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

g. Demonstration Year Definition. The Demonstration Years (DYs) will be defined as follows:

October 29, 2024 through December 31, 2025	Demonstration Year 12 (DY12)
January 1, 2026 through December 31, 2026	Demonstration Year 13 (DY13)
January 1, 2027 through December 31, 2027	Demonstration Year 14 (DY14)
January 1, 2028 through December 31, 2028	Demonstration Year 15 (DY15)
January 1, 2029 through December 31, 2029	Demonstration Year 16 (DY16)

h. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in section 11. CMS will provide technical assistance, upon request.

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

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

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

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

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

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

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

l. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 10.11(n). If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

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

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

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

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

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

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

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

n. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:
   i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,
   ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

11. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

11.1. **Former Foster Care Youth (FFCY) Budget Neutrality**. CMS has determined that the FFCY demonstration population is budget neutral based on CMS's assessment that the FFCY expenditure authority granted for the demonstration has minimal federal Medicaid expenditures and this population could have been covered through waiver only authority. The state will not be allowed to obtain budget neutrality "savings" from this authority. This population will not include a budget neutrality expenditure limit; however, the state is required to report total expenditures and member months in their demonstration monitoring reports, per STC 8.6. The state must report quarterly claims and report expenditures on the CMS 64.9 WAIVER form. Failure to report FFCY expenditures and member months will result in reinstatement of the budget neutrality requirement. CMS reserves the right to request budget neutrality worksheets, requirements, limits, and analyses from the state at any time, or whenever the state seeks a change to the demonstration, per STC 3.7.

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

11.3. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 3, Master MEG Chart and Table 4, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of

the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

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

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

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

Table 5: Hypothetical Budget Neutrality Test

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 12	DY 13	DY 14	DY 15	DY 16
Childless Adults	PC	Both	5.20%	$611.53	$643.33	$676.78	$711.97	$748.99
SUD	PC	Both	5.10%	$4,274.05	$4,492.12	$4,721.32	$4,962.21	$5,215.39

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

11.8. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the demonstration period, which extends from October 29, 2024 to December 31, 2029. If at the end of the demonstration approval period a Capped Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date. date

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

Table 6: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 12	Cumulative budget neutrality limit plus:	2.0 percent
DY 12 through DY 13	Cumulative budget neutrality limit plus:	1.5 percent
DY 13 through DY 14	Cumulative budget neutrality limit plus:	1.0 percent
DY 14 through DY 15	Cumulative budget neutrality limit plus:	0.5 percent
DY 15 through DY 16	Cumulative budget neutrality limit plus:	0.0 percent

12. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 7: Schedule of Deliverables for the Demonstration Period

Date	Deliverable	STC
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after demonstration approval	SUD Implementation Plan (including Health IT Plan)	STC 5.3
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 5.3
150 calendar days after demonstration approval	Monitoring Protocol	STC 8.5
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STC 8.5
180 calendar days after demonstration approval	Draft Evaluation Design	STC 9.3
60 days after receipt of CMS comments	Revised Evaluation Design	STC 9.4
No later than 60 calendar days after December 31, 2026	Mid-Point Assessment	STC 8.7
60 calendar days after receipt of CMS comments	Revised Mid-Point Assessment	STC 8.7
December 31, 2028, or with renewal application	Draft Interim Evaluation Report	STC 9.7(c)
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 9.7(d)
Within 18 months after December 31, 2029	Draft Summative Evaluation Report	STC 9.8
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC9.8
Monthly Deliverables	Monitoring Calls	STC 8.10
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 8.6
	Quarterly Expenditure Reports	STC 10.11
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 8.6

State of Wisconsin
BadgerCare Reform Demonstration Project

Substance Use Disorder Implementation Protocol

September 24, 2019

Table of Contents

1.0 Introduction

Wisconsin's Section 1115 BadgerCare Reform Demonstration Waiver was approved on October 31, 2018. The approved waiver includes expansion of coverage for the continuum of Substance Use Disorder (SUD) treatment. Although Wisconsin Medicaid currently covers a robust array of treatment for members with SUD, including outpatient counseling, day treatment, psychosocial rehabilitation, medication-assisted treatment (MAT), and inpatient treatment, some gaps remain in the availability of clinically-appropriate, evidence-based treatment.

The waiver authorizes federal funding for treatment provided to Medicaid members in Institutions for Mental Diseases (IMD), allowing Wisconsin Medicaid to establish a residential treatment benefit that provides coverage in all state-certified residential programs, regardless of size. As a result, Wisconsin Medicaid members will have access to high quality, evidence-based opioid use disorder (OUD) and other SUD treatment services.

This document serves as the BadgerCare Reform Demonstration Waiver Implementation Protocol. In accordance with Standard Terms and Conditions (STC) #20 in the waiver, the implementation protocol describes the strategic approach and project plan to meet required milestones for SUD treatment reform in Wisconsin.

Specifically, Wisconsin Medicaid's overall goals for SUD treatment reform include:

1. Increased rates of identification, initiation and engagement in treatment for OUD andother SUDs;
2. Increased adherence to and retention in treatment for OUD and other SUDs;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriatethrough improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where readmissions is preventable or medically inappropriate for OUD and other SUD; and
6. Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs.

Wisconsin Medicaid has identified the following milestones to meet during the project implementation:

1. Access to critical levels of care for OUD and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;

4. Sufficient provider capacity at each level of care, including MAT;
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

2.0 Milestone Completion

Over the course of the demonstration, Wisconsin Medicaid will work with internal and external stakeholders to develop, implement, and monitor SUD treatment initiatives designed to achieve the following milestones:

2.1 Access to Critical Levels of Care for OUD and Other SUDs

Wisconsin Medicaid will establish new coverage policies and enhance existing benefits to provide members access to the full continuum of care for SUD treatment. Currently, Wisconsin Medicaid's largest coverage gap is for the residential level of care. Under this demonstration, Wisconsin will develop coverage policies for residential facilities, including IMD facilities that are not otherwise eligible for matched expenditures under Section 1903 of the Social Security Act.

Following implementation of the new residential benefit by February 2020, Wisconsin Medicaid will reassess coverage for each level of care to identify any additional gaps or barriers to treatment. Initiatives to remove treatment barriers will be prioritized so that Wisconsin Medicaid members can access SUD treatment at the appropriate level of care.

The following table provides an overview of each critical level of care with current Wisconsin Medicaid coverage along with proposed changes.

Level of Care	Current State	Future State	Summary of Actions Needed
Outpatient Services	This is an existing service under the State Plan.	Continue to monitor and evaluate services and expenditures.	No immediate action. Will review coverage policies following implementation of residential benefit and update to State regulations.
Intensive Outpatient Services	This is an existing service under the State Plan.	Continue to monitor and evaluate services and expenditures.	No immediate action. Will review coverage policies following implementation of residential benefit and update to State regulations.
Medication Assisted Treatment	This is an existing service under the State Plan.	Continue to monitor and evaluate services and expenditures.	No immediate action. Will review coverage policies following implementation of residential benefit and update to State regulations.

Residential Treatment Services	The component services of Residential Treatment (e.g. outpatient counseling) are existing services under the State Plan.	Wisconsin Medicaid will develop a new benefit under this demonstration, designed to establish a bundled coverage and reimbursement approach for Residential Treatment. Wisconsin will enroll providers certified as transitional residential programs (Wisc. Admin. Code DHS 75.14) and medically monitored treatment services (Wisc. Admin. Code DHS 75.11). Although the regulations for these programs are not explicitly tied to ASAM guidelines, they align with the ASAM Level of Care 3. Transitional residential programs are most closely aligned with sub-level 3.1 and medically monitored treatment programs are most closely aligned with sub-level 3.7. Wisconsin's new benefit will cover both types of treatment programs.	Wisconsin Medicaid will establish coverage and reimbursement policies aligned with American Society of Addiction Medicine (ASAM) criteria and state regulations, including but not limited to: eligible provider criteria, medical necessity criteria, claims submission and reimbursement guidelines, and utilization management. Benefit design and implementation will be completed by February 2020.

Inpatient Services	This is an existing service under the State Plan.	Coverage for inpatient services will expand to include any previously excluded IMD providers.	Wisconsin Medicaid will provide coverage and reimbursement policy guidance to any facilities previously excluded from providing treatment due to categorization as an IMD. Policy guidance will be distributed to providers by November 2020.
Medically Supervised Withdrawal Management	This is an existing service under the State Plan.	Coverage for medically supervised withdrawal management will expand to include any previously excluded IMD providers.	Wisconsin Medicaid will provide coverage and reimbursement policy guidance to any facilities previously excluded from providing treatment due to categorization as an IMD. Policy guidance will be distributed to providers by November 2020.

2.2 Use of Evidence-based, SUD-specific Patient Placement Criteria

Wisconsin Medicaid establishes standards for the use of patient placement criteria in Administrative Code Chapter DHS 75, "Community Substance Abuse Service Standards." These standards already establish requirements for certified SUD treatment programs to use approved patient placement criteria. Further, the Wisconsin Department of Health Services (DHS) is currently drafting language to revise ch., DHS 75, including updated references to ASAM guidelines.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines	Wis. Admin. Code ch. DHS 75 requires all certified programs to use the Wisconsin-Uniform Placement Criteria (UPC), ASAM patient placement criteria, or other similar patient placement criteria approved by the department. In practice, many certified programs are using the ASAM placement criteria. The WI UPC is a SUD-specific, multidimensional assessment tool first implemented in 1996. This tool established uniform definitions of levels of care, improved patient placement consistency, and established adoption of common standards of program admission, continued stay, and discharge criteria. Admission to a program is based on an intake procedure that includes screening, approved patient placement criteria, and initial assessment.	Wisconsin Medicaid will revise Wis. Admin. Code DHS 75 to update references to ASAM patient placement criteria and clarify whether any additional standards are approved.	The revisions to administrative code were authorized by Wisconsin's governor in July 2018. The new regulations will follow the state's rulemaking process. Listening sessions were held on 5/21/19, 5/23/19, 6/17/19, 6/20/19, 6/27/19, and 7/16/19. The input collected through these sessions is incorporated in rule drafting. A rule draft will then be shared with an Advisory Committee for discussion and comment. This phase of rulemaking will continue through 2019. Following revisions suggested by the Advisory Committee, the draft rule will be published for public comment and analysis of economic impact in 2020. Final rule approval by the Wisconsin legislature is anticipated by early 2021, but may occur sooner if comments on the draft are limited.

Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services at the appropriate level of care (b) interventions are appropriate for the diagnosis and level of care (c) there is an independent process for reviewing placement in residential treatment settings	Wis. Admin. Code ch. DHS 75 requires all certified programs to establish intake procedures so that (a) individuals access services at the appropriate level of care and (b) interventions are appropriate for the diagnosis and level of care. DHS Division of Quality Assurance (DQA) (c) conducts site visits and documentation review to ensure providers comply with these standards. Certification reviews take place for the provider's initial application and renewal applications, including a site visit and license holder and employee background checks. Providers must update their program documentation at least annually and apply for certification renewal at least every 2 years. Wisconsin Medicaid requires prior authorization (PA) of SUD treatment for day treatment programs at the intensive outpatient level of care. PA requests are reviewed by licensed behavioral health clinicians to determine medical necessity, including determining that the	DQA will continue to survey certified SUD treatment programs for compliance with provider credentialing standards, including requirements for use of patient placement criteria. Wisconsin Medicaid will develop utilization management policies (e.g. service authorizations) for Medicaid reimbursement in the design of the residential treatment benefit. The benefit design team will establish policies that balance the need to verify a clinically-appropriate assessment has been performed prior to admitting the individual into residential treatment, including the use patient placement criteria, with the need to rapidly connect individuals with treatment to prevent recurrence of use. The Medicaid team consulted with residential treatment providers in July and August 2019 to solicit their input on the referral, screening, assessment, and admissions process for their programs. Using this information, the benefits team is developing	Wisconsin Medicaid will establish utilization management policies. Wisconsin Medicaid will publish authorization requests forms by December 2019 and provide training to residential treatment programs on request submission. Target date to implement coverage is no later than February 2020.

	requested treatment is at the appropriate level of care. Managed care organizations contracted with Wisconsin Medicaid can make decisions to provide or deny services on the basis of medical necessity and place appropriate limits on a service for the purpose of utilization management, but cannot define medical necessity in a way that is more restrictive than the definition used by Wisconsin Medicaid.	authorization guidelines for initial admittance to residential treatment and authorization guidelines for continued stays in residential treatment.	

2.3 Use of Nationally Recognized SUD-Specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

Wisconsin Medicaid establishes provider qualifications in Administrative Code ch. DHS 75, "Community Substance Abuse Service Standards". DHS is currently drafting language to revise ch. DHS 75, including updated references to evidence-based guidelines.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding, in particular, **the types of services, hours of clinical care, and credentials of staff for residential treatment settings**	Wisconsin establishes residential treatment provider qualifications in Wisconsin Administrative Code. State standards currently describe the types of services, hours of clinical care, and credentials of staff for transitional residential treatment programs and medically monitored treatment programs. Wisconsin Medicaid intends to use these provider qualifications to determine provider eligibility to deliver residential treatment aligned with ASAM Level of Care 3.	The Wisconsin Division of Care and Treatment Services (DCTS) has begun work to update state administrative code to further align provider qualifications with nationally recognized standards.	The revisions to administrative code were authorized by Wisconsin's governor in July 2018. The new regulations will follow the state's rulemaking process. Listening sessions were held on 5/21/19, 5/23/19, 6/17/19, 6/20/19, 6/27/19, and 7/16/19. The input collected through these sessions is incorporated in rule drafting. A rule draft will then be shared with an Advisory Committee for discussion and comment. This phase of rulemaking will continue through 2019. Following revisions suggested by the Advisory Committee, the draft rule will be published for public comment and analysis of economic impact in 2020. Final rule approval by the Wisconsin legislature is anticipated by early 2021, but may occur sooner if comments on the draft are limited.

Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards	All community SUD programs seeking certification under Wisconsin's administrative code are certified by (DQA). DQA conducts site visits and documentation review to ensure providers comply with these standards.	DQA will continue to certify SUD treatment programs and monitor their compliance with state regulations.	No immediate action.
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site.	There are no current requirements that residential treatment facilities offer MAT on-site or facilitate access off site.	The Wisconsin Division of Medicaid Services is working with partners in DCTS and DQA to determine the appropriate regulatory or policy document to establish a requirement for residential treatment facilities to offer MAT on-site or facilitate access off site. Staff will consider available options, including establishing regulatory requirements in state administrative code or reimbursement requirements in Medicaid coverage policies. Staff will assess the impact of the options on current and potential treatment programs and determine which approach will maximize the availability of residential SUD treatment in Wisconsin while ensuring individuals in treatment have access to evidence-based treatment approaches.	DHS staff will implement the requirement by November 2020.

2.4 Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD

Wisconsin Medicaid will use data from the state's Medicaid Management Information System (MMIS) to evaluate provider capacity. Additional information regarding the data collection, reporting, and analytic methodologies will be described in the SUD Monitoring Protocol.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Completion of assessment of the availability of providers enrolled in Wisconsin Medicaid and accepting new patients in the following critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT: • Outpatient services • Intensive outpatient services • MAT (medications as well as counseling and other services) • Intensive care in residential and inpatient settings • Medically supervised withdrawal management	Wisconsin Medicaid currently enrolls healthcare professionals and programs in categories aligned with their state licensure or certification. Wisconsin will use a combination of DEA registration, state program certification, and state licensure information collected during provider enrollment to identify SUD treatment providers, including those that offer MAT.	As Wisconsin Medicaid updates licensure or certification requirements, including revisions to Wis. Admin. Code ch. DHS 75, it will update its methodology to assign the new provider credentials with the appropriate level of care.	Wisconsin will complete baseline measurements for provider capacity at each level of care by November 2019.

2.5 Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse andOUD

Wisconsin Medicaid has and continues to make broad efforts across the state to address the drug abuse epidemic sweeping our communities. Initiatives included Medicaid program coverage revisions as well as broader community initiatives to address opioid addiction. The Wisconsin legislature enacted 30 bills for system improvements directly related to substance use disorders under the Heroin, Opioid Prevention and Education (HOPE) Agenda.

In Wisconsin, controlled substance dispensing initiatives resulted in a 29% decline in opioid prescriptions (1.5 million fewer prescriptions), a 19% decline in benzodiazepines (445,000 fewer prescriptions), and a flat trend in stimulant prescriptions from 2015 to 2018.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	Wisconsin Medicaid established prescribing guidelines in alignment with Centers for Disease Control and Prevention (CDC) guidance. The Wisconsin Medical Examining Board (MEB) published Opioid Prescribing Guidelines in 2016. The MEB published updated guidelines in 2018. Wisconsin Medicaid's Drug Utilization Review (DUR) Board has been focused on opioid related activities. These activities include targeted intervention focused on opioid prescribing when a member's medication use may be outside of published guidance (i.e., CDC Opioid Prescribing Guidelines). Wisconsin Medicaid has drug/drug related criteria that is used to send physicians education letters alerting them to a clinical concern and pharmacies receive a drug/drug alert informing them of a clinical concern before the medication is dispensed. Wisconsin Medicaid has an opioid script limit of five prescription fills a	Continue to monitor and evaluate.	No immediate action.

	month for opioids and some quantity limits for certain opioid products. There is a process in place for the pharmacy to receive an override in case a member needs to exceed the limits for clinically appropriate reasons.		
Expanded coverage of, and access to, naloxone for overdose reversal.	2013 Wisconsin Act 200 established expanded access to naloxone, allowing pharmacies to dispense naloxone via a standing order. In August 2016, DHS issued a statewide standing order allowing any pharmacy to use the order to dispense naloxone. Wisconsin Medicaid covers Naloxone as a preferred drug and does not require prior authorization for coverage. In 2018, Wisconsin Medicaid expanded reimbursement policy to allow Opioid Treatment Programs to be reimbursed for dispensing naloxone.	Continue to monitor and evaluate.	No immediate action.
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	See attachment A for additional detail.	See attachment A for additional detail.	See attachment A for additional detail.

2.6 Improved Care Coordination and Transitions between Levels of Care

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	Current certification requirements for community SUD treatment programs include requirements for assessment, referral, and aftercare services that are designed to ensure all health needs for an individual in treatment are identified and addressed. Wisconsin Medicaid integrates the majority of behavioral health services into its risk-based contracts for managed care. This approach to contracting ensures the managed care entity meets coverage requirements for both physical and behavioral health conditions and coordinates services across these domains.	Wisconsin Medicaid will continue to evaluate the array of services carved into its risk-based managed care contracts to further integrate physical and mental health services. The new residential SUD benefit will be carved into acute managed care plans effective January 2020 to ensure coordination between physical and behavioral health services. Wisconsin Medicaid will also identify opportunities to develop more intensive care coordination models for individuals with SUD, including health homes or other intensive care coordination models. Initial analysis of the health home model for enhanced core coordination for individuals with SUD will be completed in 2020.	Wisconsin Medicaid will revise acute managed care contracts by January 2020 and conduct ongoing monitoring through managed care provider network and quality monitoring.

3.0 Implementation Administration

Please see below for the Wisconsin Medicaid's point of contact for the Implementation Plan.

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Relevant Documents

No additional documents.

Attachment A – SUD Health Information Technology (IT) Plan

Section I.

This section is a continuation of milestone 5 to detail the use of the Prescription Drug Monitoring Program (PDMP) and the State Medicaid Health IT Plan (SMHP). As described in Table 1, Wisconsin Medicaid has developed and implemented an enhanced prescription drug monitoring program (ePDMP).

Wisconsin Medicaid recognizes the value of developing new and innovative tools to connect individuals with timely and appropriate SUD treatment and reduce administrative burden for treatment providers and other healthcare partners. The DHS eHealth Team conducts a Health Information Technology (HIT) landscape assessment each year to evaluate current HIT capabilities and define strategies Wisconsin Medicaid can pursue to advance health IT maturity and objectives.

Initial research identified key priorities to assess and further the adoption and use of HIT among treatment providers, including the need to conduct a behavioral health specific HIT landscape assessment, develop consent management tools to facilitate the flow of clinical information, and improve access to care through telehealth delivery of services. Details on Wisconsin Medicaid's strategic approach to these priorities will be included in an upcoming version of the SMHP.

Wisconsin Medicaid provides assurance that there is existing health IT infrastructure that may be leveraged in conjunction with future HIT initiatives to accomplish the goals of this demonstration.

Table 1. State HIT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program (PDMP) Functionalities			
Enhanced interstate data sharing to better track patient specific prescription data	Wisconsin Medicaid is connected to the National Association of Boards of Pharmacy (NABP) Prescription Monitoring Interconnect (PMPi) and is currently sharing data with 18 other states. Wisconsin Medicaid is in the process of connecting to RxCheck, an additional data sharing hub.	Wisconsin Medicaid will be connected to a second interstate data sharing hub in 2019 and will continue to connect with additional compatible states for interstate data sharing. Work is underway to ensure interstate data can be presented to end users who access PDMP reports from within the workflow of their electronic health record (EHR).	PDMP is awaiting determination from NABP about whether there will be a modified memorandum of understanding to address whether it is allowable for interstate data to be presented to end users who access the PDMP reports from within their EHR workflow. The timeline for connecting to the additional data sharing hub is dependent on interstate coordination. Additional information on progress for interstate data sharing will be provided to CMS as Implementation Updates via quarterly monitoring reporting.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Enhanced "ease of use" for prescribers and other state and federal stakeholders	Wisconsin Medicaid developed and launched a new PDMP application in 2017 with extensive input from stakeholders to improve the PDMP's ease of use. The new web application streamlines registration and reduces the number of clicks for healthcare users to access patient reports. Analytics and visualizations are used in patient reports to bring the most relevant information from a patient's PDMP prescription history to the immediate attention of the user. Wisconsin has also developed a single sign on service offering for prescribers to be able to access patient reports from within their electronic medical record.	PDMP continues to gather feedback from stakeholders about desirable enhancements to continue to improve ease of use. This feedback has been developed as part of a user-led enhancement grant project through the U.S. Department of Justice, Bureau of Justice Assistance.	The user-led enhancement grant project will finalize the selection of any enhancements by October 2019.
Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	The Wisconsin Statewide Health Information Network is one of the entities that offer the single sign on connection to the PDMP from within the community health record.	Continue to monitor and evaluate.	No immediate action.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns [1](see also "Use of PDMP" #2 below)	Long term opioid therapy is currently one of the data-driven alerts that are included in the patient report to help inform prescribers of concerning elements of their patients' prescription history. Alerts figure not only on patient reports but also on prescriber metrics reports that are available to prescribers as a self-assessment tool, to medical coordinators who oversee prescribers, and to the boards that review PDMP data to look for outlying prescribing practices.	PDMP is considering inclusion of an analytics-driven alert to flag patients who are opioid naïve/do not have history of long- term opioid use.	No immediate action.
Current and Future PDMP Query Capabilities			
Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state's master patient index (MPI) strategy with regard to PDMP query)	The PDMP uses data quality software to perform patient matching.	Continue to monitor and evaluate.	No immediate action.
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow	Wisconsin Medicaid has developed a single sign on (SSO) service offering for prescribers to be able to access patient reports from within their electronic medical record. Analytics and visualizations are used in patient reports.	Continue to monitor and evaluate.	No immediate action.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	State law requires prescribers to review the PDMP prior to issuing a prescription order for a controlled substance. When prescribers review their patients' reports, they see alerts and visualizations based on analytics bring the most relevant information from a patient's PDMP prescription history to the immediate attention of the user.	Continue to monitor and evaluate.	No immediate action.
Master Patient Index / Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	The PDMP uses data quality software to perform patient matching	Continue to monitor and evaluate.	No immediate action.
Overall Objective for Enhancing PDMP Functionality & Interoperability			

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, technical assistance or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Wisconsin Medicaid does not inappropriately pay for opioids	The Wisconsin Department of Safety and Professional Services sends a monthly data extract to DHS for purposes delineated in a Data Use Agreement between the two agencies. The medical coordinator role in PDMP allows those who oversee prescribers to view non- patient-identifiable prescribing practice assessment metrics for the patients they oversee, which allows them to better identify prescribers that may present an opportunity for education about safe opioid prescribing practices. Prescribers can view their own metrics to see how their prescribing compares to their peers of the same specialty, and prescribing boards review similar metrics to help identify critically dangerous prescribing practices for further investigation and possible disciplinary action.	Continue to monitor and evaluate.	No immediate action.

[1] Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1.

Attachment A, Section II – Implementation Administration

Please see below for Wisconsin Medicaid's point of contact for the SUD Health IT Plan.

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Attachment A, Section III – Relevant Documents

No additional documentation.

ATTACHMENT B

Substance Use Disorder Monitoring Protocol (Reserved)

Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) - Planned Metrics (Version 7.0)
State Wisconsin
Demonstration Name BadgerCare Reform

Table: Substance Use Disorder Demonstration Planned Metrics

Standard information on CMS-provided metrics											Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phase-in metrics reporting		
#	Metric name	Metric description	Milestone or reporting topic[a]	Metric type	Reporting category	Data source	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual or other considerations (different data source, definition, codes, target population, etc.)[b]	State plans to phase in reporting (Y/N)	SUD monitoring report in which metric will be phased in (Format DSY(Y) e.g., DY1Q3)	Explanation of any plans to phase in reporting over time
3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries who receive MAT as a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.	Y		1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries who receive MAT as a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 12 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual entries	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for inpatient/residential treatment for SUD in an IMD during the measurement period.	Milestone 2	CMS-constructed	Other annual entries	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.			1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
9	Intensive Outpatient and Partial Hospitalization Services	Number of beneficiaries who used intensive outpatient and/or partial hospitalizations services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.			1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.			1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.			1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
12	Medication-Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.			1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulations categories based on the beneficiary characteristics as of the last day of the data period.
13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Milestone 4	CMS-constructed	Other annual entries	Provider enrollment database; Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Milestone 4	CMS-constructed	Other annual entries	Provider enrollment database; Claims; SAMHSA datasets	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
15	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) [NCQA; NQF 0004e; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following: • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims or EHR	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
17(i)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence: Age 18 and Older (FUA-AD) [NCQA; NQF 0143; Medicaid Adult Core Set; Adjusted HEDIS measure][4]	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a principal diagnosis of alcohol or other drug (AOD) abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported. • Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). • Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
17(j)	Follow-up after Emergency Department Visit for Mental Illness: Age 18 and Older (FUH-MI) [NCQA; NQF 0576; Medicaid Adult Core Set; Adjusted HEDIS measure][4]	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported. • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
18	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) [PQA; NQF 0249]; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative care are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
21	Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA; NQF #2189; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
22	Continuity of Pharmacotherapy for Opioid Use Disorder [USC; NQF 0317*]	Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment	Milestone 1	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Milestone 5	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly entries	Claims	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
25	Readmissions: Among Beneficiaries with SUD	The rate of all-cause readmissions during the measurement period among beneficiaries with SUD	Milestone 6	CMS-constructed	Other annual entries	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual entries	State data on cause of death	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
27	Overdose Deaths (rate)	Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Milestone 5	CMS-constructed	Other annual entries	State data on cause of death	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
32	Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD [Adjusted HEDIS measure]	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Other SUD-related metrics	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y				
36	Average Length of Stay in IMDs	The average length of stay for beneficiaries discharged from IMD inpatient/residential treatment for SUD.	Milestone 2	CMS-constructed	Other annual entries	Claims; State-specific IMD database	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y				
Q1	Number of Prescription Drug Monitoring Program (PDMP) users, number of checks	Total number of active prescribers, dispensers & delegates as of the last day of the month Total number of checks made by all prescribers, dispensers and delegates during the calendar month	Other SUD-related metrics	State-specific	Other quarterly and monthly metrics	PDMP	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase					
Q2	Number of Prior Authorizations.	Number of High-Intensity BSUD PAs end-state approved during the calendar month Number of Low-Intensity BSUD PAs end-state approved during the calendar month	Other SUD-related metrics	State-specific	Other quarterly and monthly metrics	Prior Authorizations	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase					
Q3	*Individuals (18 and older) reported as a percentage of duly members that have experienced Pain Med misuse, Opioid misuse and Heroin Use in the past year.*	% Pain Med Misuse in the past year % Opioid Misuse in the past year % Heroin Use in the past year	Other SUD-related metrics	State-specific	Other annual entries	Department of Public Health	Year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease				DY12Q3	This metric will be updated in October/November of the calendar year and report on the previous Calendar Year. So DY12Q3 will report on FY 2024.

Medicaid Section 1115 SUD Demonstrations Protocol (Part A) – Planned Subpopulations (Version 7.0)

State: Wisconsin

Demonstration Name: BadgerCare Reform

Table: Substance Use Disorder Demonstration Planned Subpopulations

Planned subpopulation reporting						Alignment with CMS-provided technical specifications manual			
						Subpopulations		Relevant metrics	
Subpopulation category	Subpopulations	Reporting priority	Relevant metrics	Subpopulation type	State will report (Y/N)	Attest that planned subpopulation reporting within each category matches the description in the CMS-provided technical specifications manual (Y/N)	If the planned reporting of subpopulations does not match (i.e., column G = "N"), list the subpopulations state plans to report (Format comma separated)[a,b,c]	Attest that metrics reporting for subpopulation category matches CMS-provided technical specifications manual (Y/N)	If the planned reporting of relevant metrics does not match (i.e., column I = "N"), list the metrics for which state plans to report for each subpopulation category (Format metric number, comma separated)
EXAMPLE: *Age group* ***(Do not delete or edit this row)***	*EXAMPLE:* *Children <18, adults 18–64, and older adults 65+*	*EXAMPLE:* *Required*	*EXAMPLE:* *Metrics #1-3, 6-12, 23, 24, 26, 27*	*EXAMPLE:* *CMS-provided*	*EXAMPLE:* *Y*	*EXAMPLE:* *N*	*EXAMPLE:* *Children/Young adults 12-21, Adults 21-65*	*EXAMPLE:* *N*	*EXAMPLE:* *1, 2, 3*
Age group	Children <18, adults 18–64, and older adults 65+	Required	Metrics #1-3, 6-12, 23, 24, 26, 27	CMS-provided	Y	Y		Y	
Dual–eligible status	Dual-eligible (Medicare-Medicaid eligible), Medicaid only	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y		Y	
Pregnancy status	Pregnant, Not pregnant	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y		Y	
					N	N	1 - WI Medicaid does not have access and cannot provide subpopulation breakouts by criminal justice status. WI will research the feasibility of obtaining criminal justice status data and report on the feasibility in a future report to CMS. 2 - WI will report data for remaining subpopulation categories and determine subpopulation categories based on the beneficiary characteristics as of the last day of the data period.	N	
Criminal justice status	Criminally involved, Not criminally involved	Required	Metrics #1-3, 6-12	CMS-provided					
OUD population	Opioid diagnosis	Recommended	Metrics #2-12, 23, 24, 26, 27, 36	CMS-provided	Y	Y		Y	
[Insert row(s) for any state-specific subpopulation(s)]									

[a] If the state is not reporting a required subpopulation category (i.e., column F = "N"), enter explanation in corresponding row in column H.

[b] If the state is reporting on the Dual-eligible status, Pregnancy status, Criminal justice status, and OUD population subpopulation categories, the state should use column H to outline its subpopulation identification approach as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions.

[c] If the state is planning to phase in the reporting of any of the subpopulation categories, the state should (1) select N in column G and (2) provide an explanation and the

Medicaid Section 1115 SUD Demonstrations: Monitoring Protocol (Part A) – Reporting Schedule (Version 7.0)
State: Wisconsin
Demonstration Name: BadgerCare Reform

Instructions:

(1) In the reporting periods input table (Table 1), use the prompt in column A to enter the requested information in the corresponding row of column B. All monitoring report assess and reporting periods should use the format DYWQ# or CYM and all dates should use the format MM/DD/YYYY with no spaces in the cell. The information entered in these cells will auto-populate the SUD demonstration reporting schedule in Table 2. All cells in the input table must be completed in entirety and in the correct format for the standard reporting schedule to be accurately auto-populated.

(2) Review the state's reporting schedule in the SUD demonstration reporting schedule table (Table 2). For each of the reporting categories listed in column F, select 'Y' or 'N' in column H, "Deviation from standard reporting schedule (YN)" to indicate whether the state plans to report according to the standard reporting schedule. If a state's planned reporting does not match the standard reporting schedule for any quarter and/or reporting category (i.e., cell(s) H=“Y”), the state should describe these deviations in column I, "Explanation for deviations (if column H='Y')" and set column J, "Proposed deviations from standard reporting schedule," to indicate the SUD demonstration periods with which it wishes to overwrite the standard schedule (columns K). All other columns are locked for editing and should not be altered by the state.

Table 1. Substance Use Disorder Demonstration Reporting Periods Input Table

	Demonstration reporting periods/dates
Dates of first SUD demonstration year (DSUD-1/Y1):	
Start:	01/01/1970
End:	12/31/1970
Dates of first quarter of the baseline period for CMS-constructed metrics:	
First reporting quarter:	DYWQ1
Start:	01/01/2024
End:	03/31/2024
Broader section 1135 demonstration reporting period corresponding with the first SUD reporting quarter, if applicable. If there is no broader demonstration, fill in the first SUD reporting period. (Format DD/DM; e.g., DD/DM):	
First SUD monitoring report due date (per 42 CFR 438.66(d)(5)(ii)(A)):	09/30/2024
First SUD monitoring report in which the state plans to report annual metrics that are established quality measures: (SUD-1/Y1 and SUD-2/Y2 and SUD-3/Y3 and SUD-4/Y4 and SUD-5/Y5):	DY1Q1 DY1Q2 04/01/2025 06/30/2025
Dates of last SUD reporting quarter:	
Start:	10/01/2029
End:	12/31/2029

Table 2. Substance Use Disorder Demonstration Reporting Schedule

SUD reporting quarter start date (MM/DD/YYYY)	SUD reporting quarter end date (MM/DD/YYYY)	Monitoring report due (per 42 CFR 438.66(d)(5)(ii)(A)) (MM/DD/YYYY)	Broader section 1135 reporting period, if applicable; else SUD reporting period (Format DD/DM; e.g., DD/DM)	SUD reporting period (Format DYWQ#; e.g., DY1Q1)	Reporting category	For each reporting category, assessment period for which information is captured in monitoring report per standard reporting schedule (Format DYWQ#; e.g., DY1Q1)[a]	Deviation from standard reporting schedule (Y/N; n.a.)	Explanation for deviations (if column H='Y')	Proposed deviations to measurement period from standard reporting schedule in column G (Format DYWQ#; e.g., DY1Q1)
01/01/2024	03/31/2024	09/30/2024		DYWQ1	Narrative information	DYWQ1			
					Electronics and accruals	DYWQ1			
					Other monthly and quarterly metrics				
					Annual metrics that are established quality measures				
					Other annual metrics				
04/01/2024	06/30/2024	03/31/2025		DYWQ2	Narrative information	DYWQ2			
					Electronics and accruals	DYWQ2			
					Other monthly and quarterly metrics	DYWQ2	Y	4 month claims lag for all claimed	
					Annual metrics that are established quality measures				
					Other annual metrics				
07/01/2024	09/30/2024	12/31/2025		DYWQ3	Narrative information	DYWQ3			
					Electronics and accruals	DYWQ3			
					Other monthly and quarterly metrics	DYWQ3	Y	4 month claims lag for all claimed	DY1Q3
					Annual metrics that are established quality measures				
					Other annual metrics				
10/01/2024	12/31/2024	03/31/2025		DYWQ4	Narrative information	DYWQ4			
					Electronics and accruals	DYWQ4			
					Other monthly and quarterly metrics	DYWQ4	Y	4 month claims lag for all claimed	DY1Q3
					Annual metrics that are established quality measures				
					Other annual metrics				
01/01/2025	03/31/2025	09/30/2025		DY1Q1	Narrative information	DY1Q1			
					Electronics and accruals	DY1Q1			
					Other monthly and quarterly metrics	DY1Q1	Y	4 month claims lag for all claimed	DY1Q4
					Annual metrics that are established quality measures				
					Other annual metrics	DY1	Y	4 month claims lag for all claimed	N/A
04/01/2025	06/30/2025	03/31/2026		DY1Q2	Narrative information	DY1Q2			
					Electronics and accruals	DY1Q2			
					Other monthly and quarterly metrics	DY1Q2	Y	4 month claims lag for all claimed	DY1Q1
					Annual metrics that are established quality measures				
					Other annual metrics	DY2	Y	4 month claims lag for all claimed	DY1
07/01/2025	09/30/2025	12/31/2026		DY1Q3	Narrative information	DY1Q3			
					Electronics and accruals	DY1Q3			
					Other monthly and quarterly metrics	DY1Q3	Y	4 month claims lag for all claimed	DY1Q2
					Annual metrics that are established quality measures				
					Other annual metrics				
10/01/2025	12/31/2025	03/31/2026		DY1Q4	Narrative information	DY1Q4			
					Electronics and accruals	DY1Q4			
					Other monthly and quarterly metrics	DY1Q4	Y	4 month claims lag for all claimed	DY1Q3
					Annual metrics that are established quality measures				
					Other annual metrics				
01/01/2026	03/31/2026	09/30/2026		DY2Q1	Narrative information	DY2Q1			
					Electronics and accruals	DY2Q1			
					Other monthly and quarterly metrics	DY1Q4	Y	4 month claims lag for all claimed	DY1Q4
					Annual metrics that are established quality measures				
					Other annual metrics	DY3	Y	4 month claims lag for all claimed	N/A
04/01/2026	06/30/2026	03/31/2027		DY2Q2	Narrative information	DY2Q2			
					Electronics and accruals	DY2Q2			
					Other monthly and quarterly metrics	DY2Q2	Y	4 month claims lag for all claimed	DY1Q1
					Annual metrics that are established quality measures				
					Other annual metrics	DY4	Y	4 month claims lag for all claimed	N/A
07/01/2026	09/30/2026	12/31/2027		DY2Q3	Narrative information	DY2Q3			
					Electronics and accruals	DY2Q3			
					Other monthly and quarterly metrics	DY2Q3	Y	4 month claims lag for all claimed	DY2Q1
					Annual metrics that are established quality measures				
					Other annual metrics				
10/01/2026	12/31/2026	03/31/2027		DY2Q4	Narrative information	DY2Q4			
					Electronics and accruals	DY2Q4			
					Other monthly and quarterly metrics	DY2Q3	Y	4 month claims lag for all claimed	DY2Q2
					Annual metrics that are established quality measures				
					Other annual metrics				
01/01/2027	03/31/2027	09/30/2027		DY3Q1	Narrative information	DY3Q1			
					Electronics and accruals	DY3Q1			
					Other monthly and quarterly metrics	DY2Q4	Y	4 month claims lag for all claimed	DY2Q3
					Annual metrics that are established quality measures				
					Other annual metrics	DY5	Y	4 month claims lag for all claimed	N/A
04/01/2027	06/30/2027	03/31/2028		DY3Q2	Narrative information	DY3Q2			
					Electronics and accruals	DY3Q2			
					Other monthly and quarterly metrics	DY3Q1	Y	4 month claims lag for all claimed	DY2Q4
					Annual metrics that are established quality measures				
					Other annual metrics	DY6	Y	4 month claims lag for all claimed	DY3
07/01/2027	09/30/2027	12/31/2028		DY3Q3	Narrative information	DY3Q3			
					Electronics and accruals	DY3Q3			
					Other monthly and quarterly metrics	DY3Q2	Y	4 month claims lag for all claimed	DY3Q1
					Annual metrics that are established quality measures				
					Other annual metrics				
10/01/2027	12/31/2027	03/31/2028		DY3Q4	Narrative information	DY3Q4			
					Electronics and accruals	DY3Q4			
					Other monthly and quarterly metrics	DY3Q3	Y	4 month claims lag for all claimed	DY3Q2
					Annual metrics that are established quality measures				
					Other annual metrics				
01/01/2028	03/31/2028	09/30/2028		DY4Q1	Narrative information	DY4Q1			
					Electronics and accruals	DY4Q1			
					Other monthly and quarterly metrics	DY3Q4	Y	4 month claims lag for all claimed	DY3Q3
					Annual metrics that are established quality measures				
					Other annual metrics	DY7	Y	4 month claims lag for all claimed	N/A
04/01/2028	06/30/2028	03/31/2029		DY4Q2	Narrative information	DY4Q2			
					Electronics and accruals	DY4Q2			
					Other monthly and quarterly metrics	DY4Q1	Y	4 month claims lag for all claimed	DY3Q4
					Annual metrics that are established quality measures				
					Other annual metrics	DY8	Y	4 month claims lag for all claimed	DY4
07/01/2028	09/30/2028	12/31/2029		DY4Q3	Narrative information	DY4Q3			
					Electronics and accruals	DY4Q3			
					Other monthly and quarterly metrics	DY4Q2	Y	4 month claims lag for all claimed	DY4Q1
					Annual metrics that are established quality measures				
					Other annual metrics				
10/01/2028	12/31/2028	03/31/2029		DY4Q4	Narrative information	DY4Q4			
					Electronics and accruals	DY4Q4			
					Other monthly and quarterly metrics	DY4Q3	Y	4 month claims lag for all claimed	DY4Q2
					Annual metrics that are established quality measures				
					Other annual metrics				
Add rows for any additional information you plan to report									

[a] **SUD demonstration start date**. For monitoring purposes, CMS defines the start date of the demonstration as the effective date listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval state that the demonstration is effective January 1, 2026 – December 31, 2035, the state should consider January 1, 2026 to be the start date of the demonstration. Note that that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration, that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2028, with an effective date of January 1, 2029 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration. To generate an accurate reporting schedule, the start date as listed in Table 1 of the "SUD reporting schedule tab" should align with the first day of a month. If a state's SUD demonstration begins on any day other than the first day of the month, the state should list its start date as the first day of the month in which the effective date occurs. For example, if a state's effective date is listed as January 15, 2026, the state should indicate "01/01/2026" as the start date in Table 1 of the "SUD reporting schedule" tab. Please see Appendix A for more information on determining demonstration quarter timing.

[b] The auto-populated reporting schedule in Table 2 outlines the date the state is expected to report for each demonstration year and quarter. However, states are not expected to begin reporting any metrics data until after monitoring protocol approval. The state should see Section B of the Monitoring Report Instructions for more information on retrospective reporting of data following protocol approval.

ATTACHMENT C:

DEVELOPING THE EVALUATION DESIGN

Introduction

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

Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115- demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation- resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

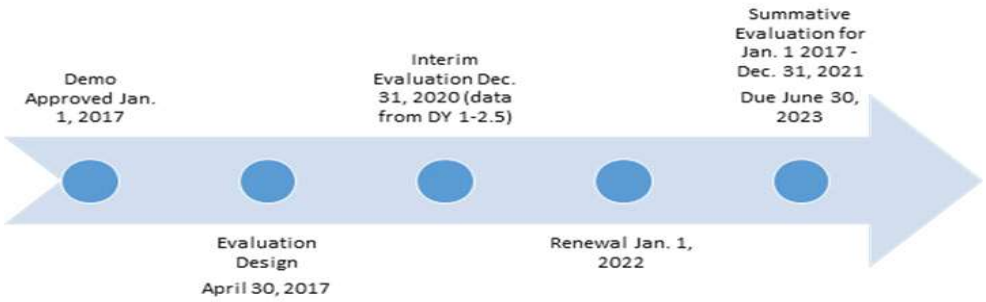
The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline for a 5-year demonstration). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) calendar days

of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs

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

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

    a. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

    b. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

    c. A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

    d. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

    e. Describe the population groups impacted by the demonstration.

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

a. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

b. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

c. Identify the state's hypotheses about the outcomes of the demonstration:

i. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

ii. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

2.2. **Methodology –** In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

i. *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

ii. *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

iii. *Evaluation Period* – Describe the time periods for which data will be included.

iv. *Measures* – List all measures that will be calculated to *Evaluation* evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

1. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
2. Qualitative analysis methods may be used, and must be described in detail.
3. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
4. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
5. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
6. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

v. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

vi. *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

1. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

2. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
3. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
4. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

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

2.4. **Special Methodological Considerations** – CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

a. When the state demonstration is:

   i. Long-standing, non-complex, unchanged, or

   ii. Has previously been rigorously evaluated and found to be successful, or

   iii. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

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

   i. Operating smoothly without administrative changes; and

   ii. No or minimal appeals and grievances; and

   iii. No state issues with CMS-64 reporting or budget neutrality; and

   iv. No Corrective Action Plans (CAP) for the demonstration.

3. Attachments

3.1. **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The Evaluation Design should include "No Conflict of Interest" signed by the independent evaluator.

3.2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3.3. **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT D:

PREPARING THE INTERIM AND SUMMATIVE EVALUATION REPORTS

Introduction

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

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.

Intent of this Attachment

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

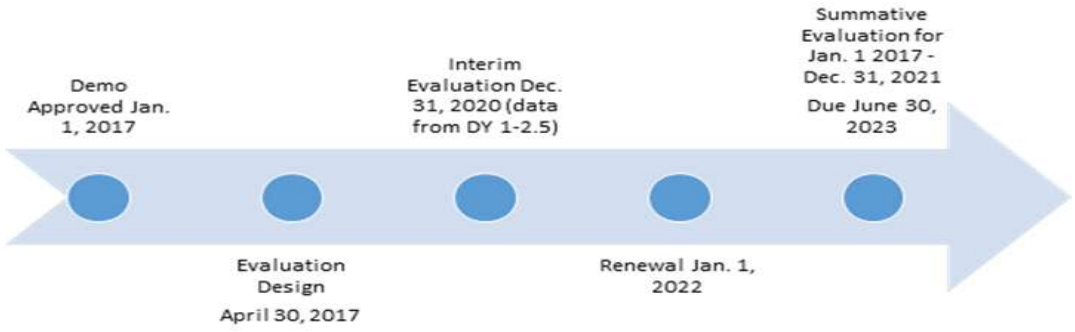
The format for the Interim and Summative Evaluation reports are as follows:

13. Executive Summary;
14. General Background Information;

15. Evaluation Questions and Hypotheses;
16. Methodology;
17. Methodological Limitations;
18. Results;
19. Conclusions;
20. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
21. Lessons Learned and Recommendations; and
22. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline for a 5-year demonstration). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Evaluation Design and reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

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

a. **Executive Summary –** A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

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

   i. The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

   ii. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.

   iii. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration.

   iv. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

   v. Describe the population groups impacted by the demonstration.

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

   i. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

   ii. Identify the state's hypotheses about the outcomes of the demonstration;

      a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
      b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
      c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

d. **Methodology –** In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The Evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

   Specifically, this section establishes that the approved Evaluation Design was followed by describing:

   i. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc?

   ii. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.

   iii. *Evaluation Period* – Describe the time periods for which data will be collected

   iv. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?

   v. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.

   vi. *Analytic Methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

   vii. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

f. **Methodological Limitations** – This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

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

h. **Conclusions** – In this section, the state will present the conclusions about the evaluation results.

   i. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

ii. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

1. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

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

i. What lessons were learned as a result of the demonstration?

ii. What would you recommend to other states which may be interested in implementing a similar approach?

Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT E
EVALUATION DESIGN (Reserved)

ATTACHMENT F
SUD MONITORING PROTOCOL