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 24, 2023

Stacie Weeks
Medicaid Administrator
Division of Health Care Financing and Policy
Las Vegas Medicaid District Office
1210 S. Valley View, Suite 104
Las Vegas, NV 89102-1857

Dear Administrator Weeks,

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) Implementation Plan and SUD Health Information Technology Plan (Health IT Plan), which are required by the Special Terms and Conditions (STC), specifically, STC #19, of Nevada's section 1115 demonstration, "Nevada's Treatment of Opioid Use Disorders (OUDs) and SUDs Transformation Project" (Project No: 11-W-00409/9), effective through December 31, 2027. CMS determined that the SUD Implementation Plan and SUD Health IT Plan meet the requirements set forth in the STCs, and thereby approves the state's SUD Implementation Plan and SUD Health IT Plan will enable the state to receive federal financial participation (FFP) for state plan services provided to otherwise-eligible Medicaid beneficiaries who are primarily receiving treatment and withdrawal management services for SUD while residing in institutions for mental diseases (IMD).

The SUD Implementation Plan and SUD Health IT Plan are approved as of the date of this letter through December 31, 2027 and is hereby incorporated into the demonstration STCs as Attachment C (see attached). We appreciate your continued partnership on this 1115 demonstration.

Your project officer for this demonstration is Ms. April Wiley. She is available to answer any question concerning your section 1115 demonstration. Ms. Wiley's contact information is as follows:

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

Sincerely,

5/24/2023

X Andrea J. Casart

Signed by: Andrea J. Casart -S
Andrea J. Casart
Director
Division of Medicaid Expansion Demonstrations

Enclosure

cc: Brian Zolynas, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES EXPENDITURE AUTHORITY

NUMBER: 11-W-00409/9

TITLE: Nevada's Treatment of Opioid Use Disorders (OUDs) and Substance Use

Disorders (SUDs) Transformation Project

AWARDEE: Nevada Department of Health and Human Services

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Nevada for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 1, 2023 through December 31, 2027, 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 Nevada to operate the above-identified section 1115(a) demonstration.

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder** (SUD). Expenditures consistent with the conditions in these STCs for Medicaid state plan services that are furnished to otherwise eligible individuals who are receiving primarily 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).

Title XXI Expenditure Authority:

Residential and Inpatient Treatment for Individuals with Substance Use Disorder.

Expenditures consistent with the conditions in these STCs for otherwise covered services that are furnished to otherwise eligible individuals of the Children's Health Insurance Program (CHIP) who are primarily receiving treatment and withdrawal management services for SUD as short-term residents in facilities that meet the definition of an IMD. All requirements of Title XXI will be applicable to such expenditures for children who are residing in an IMD at the time of application or at the time of renewal and would be ineligible for coverage under CHIP pursuant to 2110(b)(2)(A).

1. Under the authority of section 1115(a)(2) of the Act as incorporated into Title XXI by section 2107(e)(2)(A), state expenditures described below, shall, for the period of this demonstration (January 1, 2023 through December 31, 2027) and based on state's

available allotment under section 2104 of the Act, be regarded as match-able expenditures under the state's Title XXI plan.

CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00409/9

TITLE: Nevada's Treatment of Opioid Use Disorders (OUDs) and Substance Use

Disorders (SUDs) Transformation Project 1115(a) Demonstration

AWARDEE: Nevada Department of Health and Human Services

I. PREFACE

The following are the Special Terms and Conditions (STC) for the "Nevada's Treatment of Opioid Use Disorders (OUDs) and Substance Use Disorders (SUDs) Transformation Project" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Nevada Department of Health and Human Services(hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and 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 January 1, 2023 through December 31, 2027, unless otherwise specified.

The STCs have been arranged into the following subject areas:

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

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: SUD Implementation Plan and Health IT Plan
- Attachment D: Reserved for SUD Monitoring Protocol
- Attachment E: Reserved for SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

This Demonstration will expand statewide access to comprehensive behavioral health services for the most vulnerable Nevadans, including those with opioid use disorders (OUDs) and other substance use disorders (SUDs). This demonstration will provide the state with authority to provide clinically appropriate treatment to individuals diagnosed with a SUD while they are short-term residents in treatment facilities that qualify as IMDs. This demonstration will also address currently unmet needs, support a continuum of treatment options, and provide access to a comprehensive and coordinated system of evidence-based SUD services at varied levels of intensity for Medicaid and Children's Health Insurance Program (CHIP) enrollees. Through coverage for CHIP enrollees, this demonstration will provide access to essential healthcare for children who are diagnosed with a SUD and require treatment in an IMD, and who would otherwise be ineligible for services under Medicaid or for enrollment in CHIP.

This Demonstration will further the objectives of Title XIX and Title XXI of the Social Security Act by improving access to high-quality, person-centered services that produce positive health outcomes for individuals; and advancing innovative delivery system and payment models to strengthen provider network capacity and drive greater value for Medicaid.

The Demonstration will increase access to critical substance use treatment levels of care that are currently not funded within the Nevada Medicaid program. With increased access to a full continuum of substance use treatment, Medicaid beneficiaries will be able to receive the appropriate treatment needed at a time when a beneficiary is determined to need an American Society of Addiction Medicine (ASAM) residential/inpatient level of care within an IMD.

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

- Increase rates of identification, initiation, and engagement in treatment for SUD;
- Increase adherence to and retention in treatment;
- Reduce overdose deaths, particularly those due to opioids;
- 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;
- Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
- Improve access to care for physical health conditions among beneficiaries with SUD;

Additional goals include:

- Increase adherence to treatment for parenting individuals who will have their children with them in the transitional and residential IMD setting;
- Increase access to medical and community-based services in pregnant and parenting individuals in an IMD; and
- Allow for care coordination of services resulting in a better care transition upon discharge

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes. The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and 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. 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 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

- 5. State Plan Amendments. The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process. Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
 - a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
 - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - d. An up-to-date CHIP allotment worksheet, if necessary;

- e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- **8. Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS 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 9.
- **9. Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
 - a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
 - b. <u>Transition and Phase-out Plan Requirements</u>. 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. <u>Transition and Phase-out Plan Approval.</u> 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. <u>Transition and Phase-out Procedures.</u> 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 35.916(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. <u>Federal Financial Participation (FFP)</u>. 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.
- 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.
- 11. Adequacy of Infrastructure. The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
- **12. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply

with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

- **13. Federal Financial Participation (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.
- 14. Administrative Authority. When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 15. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. Eligibility Groups Affected by the Demonstration. All mandatory and optional eligibility groups approved for full benefit coverage under the Nevada Medicaid and CHIP State Plans will be eligible for the Demonstration.

Under the demonstration, an individual eligible for CHIP will continue to be eligible for CHIP. Additionally, individuals who would otherwise be eligible for CHIP, but are residing in an IMD for diagnoses of SUD at the time of application or renewal, will now be eligible for CHIP. All other standards and methodologies for eligibility remain as set forth under the state plan.

17. Applicability of title XXI Maintenance of Effort to Demonstration Populations. The maintenance of effort provision at section 2105(d)(3)(A) of the Act applies to title XXI

eligible children enrolled in this demonstration. This provision requires that, with certain exceptions, as a condition of receiving FFP for Medicaid, states must maintain CHIP "eligibility standards, methodologies, and procedures" for children that are no more restrictive than those in effect on March 23, 2010. See STCs 75, 76 and 77 related to the title XXI funding limits and shortfalls.

V. SUBSTANCE USE DISORDER PROGRAM AND BENEFITS

18. SUD Program Benefits. Effective upon CMS's approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, such as services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. The state will be subject to a statewide average length of stay requirement of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 27, 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.

19. SUD Implementation Plan and Health IT Plan.

- a. The state must submit the SUD Implementation Plan within 90 calendar days after approval of this demonstration. The state must submit the revised SUD Implementation Plan within 60 days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.
- b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 23.
- c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic

content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

- i. Access to Critical Levels of Care for OUD and other SUDs. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval.
- ii. <u>Use of Evidence-based SUD-specific Patient Placement Criteria.</u>
 Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
- iii. <u>Patient Placement</u>. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
- iv. <u>Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities.</u> Currently, residential provider licensure requirements are outlined at Nevada Revised Statutes (NRS) 449.00455 et seq. and Nevada Administrative Code (NAC) 449.019 et seq. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
- v. <u>Standards of Care.</u> Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
- vi. <u>Standards of Care.</u> Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

- vii. <u>Sufficient Provider Capacity at each Level of Care including Medication</u>
 <u>Assisted Treatment for SUD/OUD.</u> An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
- viii. <u>Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD.</u> Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
- ix. <u>Improved Care Coordination and Transitions between levels of care.</u>
 Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.
- x. <u>SUD Health IT Plan.</u> 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 19(d) and Attachment C.
- d. **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 19(a) and 19(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

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 27) 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 in in an addendum to its Annual Report (see STC 28).

- 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).
 - 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. 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:
 - a. 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/).

¹ Ibid.

- b. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
- c. 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.
- d. 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).
- **20.** 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.

Information Technology's Interoperability Standards Advisory (https://www.healthit.gov/isa/) to locate other industry standards in the interest of efficient implementation of the state plan.

VI. COST SHARING

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

VII. DELIVERY SYSTEM

22. Delivery System. All demonstration beneficiaries will continue to receive services through the same delivery system arrangements as currently authorized in the state.

VIII. MONITORING AND REPORTING REQUIREMENTS

23. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in the amount of \$5,000,000 (federal share) when items required by these STCs (e.g.,

required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount of payments authorized under the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outline in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

24. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones. Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones 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 the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.
- **25. Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- **26.** Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional section 1115 demonstration reporting and analytics functions, the state will work with CMS to:
 - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b. Ensure all section 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
 - c. Submit deliverables to the appropriate system as directed by CMS.
- 27. SUD Monitoring Protocol. The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within 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 within 60 calendar days after receipt of CMS's comments, if any. Once approved, the SUD Monitoring Protocol will be incorporated in the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the Quarterly and Annual Monitoring Reports. Components of the SUD 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 19(a) and 19(c) and reporting relevant information to the state's Health IT plan described in STC 19(d);
 - 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 STC 28 of the demonstration; and
 - c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.
- 28. Quarterly and Annual Monitoring Reports. The state must submit three Quarterly Monitoring Reports and one (1) compiled 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 Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The compiled Annual Monitoring Report (including the fourth quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any.

The reports must 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 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. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these 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. <u>Performance Metrics</u>. 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 will be identified in the approved SUD Monitoring Protocol, and will cover key policies under this demonstration.

Additionally, 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. 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. <u>Budget Neutrality and Financial Reporting Requirements.</u> 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 expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
- d. <u>Evaluation Activities and Interim Findings</u>. 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. <u>SUD Health IT</u>. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 19(d).
- 29. SUD Mid-Point Assessment Report. The state must contract with an independent entity to conduct a Mid-Point Assessment Report by December 31, 2025. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of the demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment report in light of the data from any such prior approval period(s). In the design, planning and conduction of the Mid-Point Assessment Report, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), 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 Report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2025. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 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 modifications to the SUD Implementation Plan and 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 Report include:

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

- e. An assessment of whether the state is on track to meet the budget neutrality requirements.
- 30. Corrective Action Plan Related to Demonstration Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 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.
- **31.** Close-Out Report. Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.
 - a. The Close-Out Report must comply with the most current guidance from CMS.
 - b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 40 and 41, 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's 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's comments.
 - f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 23.
- **32.** Monitoring Calls. CMS will convene periodic conference calls with the state.
 - a. The purpose of these calls is to discuss ongoing demonstration operation, to include (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, 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.
- 33. Post Award Forum. Pursuant to 42 CFR § 431.420(c), within 6 months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual 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 public comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

IX. EVALUATION OF THE DEMONSTRATION

- 34. Cooperation with Federal Evaluators. As required under 42 CFR § 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR § 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 23.
- **35. Independent Evaluator.** The state must use 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.
- 36. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs, CMS's evaluation design guidance for SUD demonstrations, including guidance for approaches to analyzing associated costs, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration

evaluations. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 40 and 41.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

- 37. Evaluation Budget. A budget for the evaluation must 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.
- 38. Evaluation Design Approval and Updates. The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR § 431.424(c), the state will publish the approved Evaluation Design to the state's website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual 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.
- 39. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose

The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of

Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or geography)—to the extent feasible—to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

- **40. 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 extension of the demonstration, 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 or any components within the demonstration that expire 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 extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for the demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.
 - d. The state must submit a revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any.
 - e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
 - f. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.
- 41. Summative Evaluation Report. The state must submit 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. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.
 - a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.

- b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.
- 42. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- **43. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.
- **44. Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close-Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.
- 45. Additional Publications and Presentations. For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given 30 days to review and comment on publications before they are released. CMS may choose to decline to comment on 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.

X. GENERAL FINANCIAL REQUIREMENTS

- **46. 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.
- 47. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this 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 thirty (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.

- 48. 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.
- **49. State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share funding 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.
- **50. Financial Integrity for Managed Care and Other 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/or 438.74.
- **51.** 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.
- **52. 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 23. 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.
- **53.** 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 XI:
 - a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
- **54. 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.
- **55. 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 1: Master MEG Chart								
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description			
Managed Care IMD Services	Нуро 1	X		X	Beneficiaries receiving services through the state's Managed Care Delivery System			
FFS IMD Services	Нуро 2	X		X	Beneficiaries receiving services through the state's Fee for Service Delivery System			

		All additional administrative
		costs that are directly
		attributable to the
ADM	N/A	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

- **56. 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-00209/9). 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. <u>Pharmacy Rebates.</u> Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

- d. <u>Administrative Costs.</u> 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 X, 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 VIII 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. <u>Budget Neutrality Specifications Manual</u>. 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 2: MEG Detail for Expenditure and Member Month Reporting									
MEG (Waiver Name)	Detailed Description	Exclusio ns	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	
IMD Services Managed Care MEG	Beneficiaries receiving IMD Services through the state's Managed Care Delivery System	See STC #20	Follow CMS 64.9 Base Category of Service Definition	Date of service	MAP	Y	01/01/2023	12/31/ 2027	
IMD Services FFS	Beneficiaries receiving IMD	See STC #20	Follow CMS 64.9 Base		MAP	Y	01/01/2023	12/31/ 2027	

MEG	Services	Category	Date of			
	through the	of Service	service			
	state's Fee	Definition				
	for Service					
	Delivery					
	System					
	Report all					
	additional					
	administrativ					
	e costs that					
	are directly	Follow				
	attributable	standard				
	to the	CMS				
ADM	demonstratio	64.10	Date of	ADM	N	
	n and are not	Category	Payment			
	described	of Service				
	elsewhere	Definitions				
	and are not					
	subject to					
	budget					
	neutrality					

 $ADM-administration; DY-demonstration\ year;\ MAP-medical\ assistance\ payments;\ MEG-Medicaid\ expenditure\ group;$

57. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 3: Demonstration Years						
Demonstration Year 1	January 1, 2023 to December 31, 2023	12 months				
Demonstration Year 2	January 1, 2024 to December 31, 2024	12 months				
Demonstration Year 3	January 1, 2025 to December 31, 2025	12 months				
Demonstration Year 4	January 1, 2026 to December 31, 2026	12 months				
Demonstration Year 5	January 1, 2027 to December 31, 2027	12 months				

58. 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 XI. CMS will provide technical assistance, upon request.²

- 59. 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.
- **60. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
 - a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
 - b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
 - c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by

states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

31

² Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget

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.

- 61. Budget Neutrality Mid-Course Correction Adjustment Request. No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
 - a. Contents of Request and Process. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 61.c. 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 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
 - b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:
 - i. Provider rate increases that are anticipated to further strengthen access to care;
 - ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;
 - iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
 - iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
 - v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
 - vi. High cost innovative medical treatments that states are required to cover; or,

- vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.
- c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:
 - 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.

XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- **62. 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, 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.
- 63. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1, Master MEG Chart and Table 2, 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.
- 64. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of

- FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- **65. Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
- **66.** 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.
- 67. Hypothetical Budget Neutrality Test 1: Managed Care IMD Services. 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 4: Hypothetical Budget Neutrality Test 1								
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5

Managed Care IMD	PC	Both	4.3%					
Services				\$1,251	\$1,304	\$1,360	\$1,419	\$1,480

*PC = Per Capita, Agg = Aggregate

Table 5: Hypothetical Budget Neutrality Test 2								
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5
FFS IMD Services	PC	Both	4.3%	\$1,251	\$1,304	\$1,360	\$1,419	\$1,480

68. Hypothetical Budget Neutrality Test 2: FFS IMD Services. 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.

- 69. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
- **70.** Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from January 1, 2023 to December 31, 2027. If at the end of the demonstration approval period the Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

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

XII. MONITORING ALLOTMENT NEUTRALITY

- **72. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement.** The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:
 - a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 and CMS 64 reporting instructions as outlined in section 2115 of the State Medicaid Manual.
 - b. **Use of Waiver Forms.** Title XXI demonstration expenditures will be reported on the following separate forms designated for M-CHIP (i.e., Forms 64.21U Waiver and/or CMS-64.21UP Waiver) and S-CHIP (i.e., Forms CMS-21 Waiver and/or CMS-21P Waiver), identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The state must submit separate CMS-21 and CMS-64.21U waiver forms for each title XXI demonstration population.

- c. **Premiums**. Any premium contributions collected under the demonstration shall be reported to CMS on the CMS-21 Waiver and the CMS-64.21U Waiver forms (specifically lines 1A through 1D as applicable) for each title XXI demonstration population that is subject to premiums, in order to assure that the demonstration is properly credited with the premium collections.
- d. Claiming Period. All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the CMS-21 and CMS-64.21U waiver forms, net expenditures related to dates of service during the operation of the demonstration.
- 73. Standard CHIP Funding Process. The standard CHIP funding process will be used during the demonstration. The state will continue to estimate matchable CHIP expenditures on the quarterly Forms CMS-21B for S-CHIP and CMS-37 for M-CHIP. On these forms estimating expenditures for the title XXI funded demonstration populations, the state shall separately identify estimates of expenditures for each applicable title XXI demonstration population.
 - a. CMS will 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 must report demonstration expenditures through Form CMS-21W and/or CMS-21P Waiver for the S-CHIP population and report demonstration expenditures for the M-CHIP population through Form 64.21U Waiver and/or CMS-64.21UP Waiver. Expenditures reported on the waiver forms must be identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). CMS will reconcile expenditures reported on the CMS-21W/CMS-21P Waiver and the CMS 64.21U Waiver/CMS-64.21UP Waiver forms with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.
- 74. Title XXI Administrative Costs. Administrative costs will not be included in the allotment neutrality limit. All administrative costs (i.e., costs associated with the title XXI state plan and the title XXI funded demonstration populations identified in these STCs) are subject to the title XXI 10 percent administrative cap described in section 2105(c)(2)(A) of the Act.
- 75. Limit on Title XXI Funding. The state will be subject to a limit on the amount of federal title XXI funding that the state may receive on eligible CHIP state plan populations and the CHIP demonstration populations described in STC 16 during the demonstration period. Federal title XXI funds for the state's CHIP program (i.e., the approved title XXI state plan and the demonstration populations identified in these STCs) are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.

- **76.** Exhaustion of Title XXI Funds for S-CHIP Population. If the state exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the state must continue to provide coverage to the approved title XXI separate state plan population.
- 77. Exhaustion of Title XXI Funds for M-CHIP Population. If the state has exhausted title XXI funds, expenditures for this population as approved within the CHIP state plan, may be claimed as title XIX expenditures, as approved in the Medicaid state plan. The state must notify CMS in writing at least 90 days prior to an expected change in claiming of expenditures for the M-CHIP population. The state shall report demonstration expenditures for these individuals, identified as "M-CHIP," on the Forms CMS 64.9W and/or CMS 64.9P W.

XIII. 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 19(a)			
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 19(a)			
150 calendar days after demonstration approval	Monitoring Protocol	STC 27			
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STC 27			
180 calendar days after demonstration approval	Draft Evaluation Design	STC 36			
60 days after receipt of CMS comments	Revised Evaluation Design	STC 38			
No later than 60 calendar days after December 31, 2025	Mid-Point Assessment	STC 29			
60 calendar days after receipt of CMS comments	Revised Mid-Point Assessment	STC 29			
December 31, 2026, or with renewal application	Draft Interim Evaluation Report	STC 40(c)			
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 40(d)			
Within 18 months after December 31, 2027	Draft Summative Evaluation Report	STC 41			
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 41(a)			

Monthly Deliverables	Monitoring Calls	STC 32
Quarterly monitoring reports due 60 calendar days after end of each	Quarterly Monitoring Reports, including implementation updates	STC 28
quarter, except 4 th quarter.	Quarterly Expenditure Reports	STC 28(c)
Annual Deliverables - Due 90 calendar days after end of each 4 th quarter	Annual Monitoring Reports	STC 28

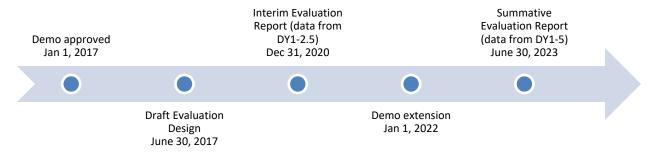
Preparing the Evaluation Design

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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. Evaluations should include findings about 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).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation 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.



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-demonstration-levaluation-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 section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations.

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.

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

- 1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
- 3. A description of the population groups impacted by the demonstration.
- 4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
- 5. 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.

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

- 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
- 2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
- 3. 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 can be measured.
- 4. 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, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health

and health care through specific interventions. 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.

1. **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, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure.

Specifically, this section establishes:

- 1. *Methodological Design* Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
- 2. Target and Comparison Populations Describe the characteristics of the target and comparison populations, incorporating the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally, discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3. Evaluation Period Describe the time periods for which data will be included.
- 4. Evaluation Measures List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

The state also should 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.) 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. 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.
- 5. Data Sources Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
- 6. *Analytic Methods* This section includes the details of the selected quantitative and/or qualitative analysis measures that will adequately assess the effectiveness of the demonstration. This section should:
 - a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-indifferences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.
- 7. *Other Additions* The state may provide any other information pertinent to the Evaluation Design for the demonstration.

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

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

D. Methodological Limitations – This section provides more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these 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.

CMS also 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. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

- 1. When the demonstration is:
 - a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
 - b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).
- 2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
 - a. Operating smoothly without administrative changes;
 - b. No or minimal appeals and grievances;

- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans for the demonstration.

E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated costs, 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, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.
- 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 milestones for the development and submission of the Interim and Summative Evaluation Reports. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation Report is due.

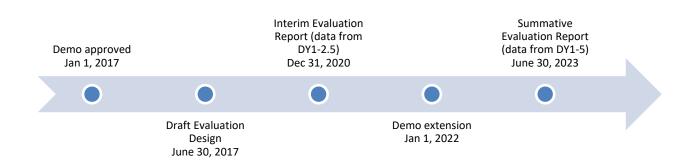
ATTACHMENT B Preparing the Interim and Summative Evaluation Reports

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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. Evaluations should include findings about 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).

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 a deliverable's 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 Interim and Summative Evaluation 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.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are 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). 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. When conducting analyses and developing the evaluation reports, every effort should be made to follow

the methodology outlined in the approved Evaluation Design. 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.

CMS expects Interim and Summative Evaluation Reports 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-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

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 evaluation report submissions must provide comprehensive written presentations 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.

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports 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. The evaluation reports 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.

- A. The format for the Interim and Summative Evaluation reports is as follows: Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results:
- G. Conclusions:
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

- **A.** Executive Summary A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- **B.** General Background Information about the Demonstration In this section, the state should include basic information about the demonstration, such as:
 - 1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
 - 3. A description of the population groups impacted by the demonstration.
 - 4. 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.
 - 5. 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. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).
- **C.** Evaluation Questions and Hypotheses In this section, the state should:
 - 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
 - 2. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.
 - 3. 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.
 - 4. 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.
- **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, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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. The state also should report on, control for, and make 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, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

- 1) *Methodological Design* Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
- 2) *Target and Comparison Populations* Describe the target and comparison populations, describing inclusion and exclusion criteria.
- 3) Evaluation Period Describe the time periods for which data will be collected.
- 4) *Evaluation Measures* List the measures used to evaluate the demonstration and their respective measure stewards.
- 5) *Data Sources* Explain from where the data were obtained, and efforts to validate and clean the data.
- 6) *Analytic Methods* Identify specific statistical testing which was undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
- 7) *Other Additions* The state may provide any other information pertinent to the evaluation of the demonstration.
- **E. Methodological Limitations** This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.
- **F. Results** In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.
- **G. Conclusions** In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:
 - 1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
 - a. If the state did not fully achieve its intended goals, why not?
 - b. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

- **H.** 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 interpretations 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.
- I. Lessons Learned and Recommendations This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
 - 1. What lessons were learned as a result of the demonstration?
 - 2. What would you recommend to other states which may be interested in implementing a similar approach?

a. Attachment(s)

Evaluation Design: Provide the CMS-approved Evaluation Design

Nevada's Treatment of Opioid Use Disorders (OUDs) and Substance Use Disorders (SUDs) Transformation Project Section 1115 Demonstration Waiver – Implementation Plan

May 3, 2023



State of Nevada
Division of Health Care Financing & Policy
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Table of Contents

CMS' O	pioi	d and Other SUDs 1115 Demonstration Initiative Goals and Milestones	3
Section	I: N	Nilestone Completion	4
	1.	Access to Critical Levels of Care for OUD and Other SUDs	4
	2.	Use of Evidence-based, SUD-specific Patient Placement Criteria	8
	3.	Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualification	ns
		for Residential Treatment Facilities	12
	4.	Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted	
		Treatment for OUD	15
	5.	Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioi	id
		Abuse and OUD	18
	6.	Improved Care Coordination and Transitions between Levels of Care	21
Section	II: I	mplementation Administration	24
Section	III:	Relevant Documents	24
Attachn	nen	t A – Section I: Template for SUD Health Information Technology (IT) Plan	25
Attachn	nen	t A – Section II: Implementation Administration	29
Attachn	nen	t A – Section III: Relevant Documents	29

SUD Implementation Plan

CMS' Opioid and Other SUDs 1115 Demonstration Initiative:

Goals and Milestones to be Addressed in State Implementation Plan Protocols

Goals:

- 1. Increase rates of identification, initiation and engagement in treatment for OUD and other SUDs.
- 2. Increase adherence to and retention in treatment for OUD and other SUDs.
- 3. Reductions in overdose deaths, particularly those due to opioids.
- 4. Reduce utilization of emergency departments and inpatient hospital settings for OUD and other SUD 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 readmissions is preventable or medically inappropriate for OUD and other SUD.
- 6. Improve access to care for physical health conditions among beneficiaries with OUD or other SUDs.

Milestones:

- 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.
- 6. Improved care coordination and transitions between levels of care.

<u>Section I – Milestone Completion</u>

Milestones

1. Access to Critical Levels of Care for OUD and Other SUDs

Specifications:

To improve Medicaid beneficiaries' access to OUD and SUD treatment services, it is important to offer a range of services at varying levels of intensity across a continuum of care because the type of treatment or level of care needed may be more or less effective depending upon the individual. To meet this milestone, state Medicaid programs must provide coverage of the following services:

- Outpatient Services.
- Intensive Outpatient Services;
- Medication assisted treatment (medications 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 (WM).

Current State:

The State of Nevada has taken deliberate steps in recent years to improve access to behavioral health services for Medicaid beneficiaries. Beginning in 2014, the State adopted an integrated behavioral health clinic model to provide mental health and SUD treatment using American Society of Addiction Medicine (ASAM) criteria as the framework for levels of care and intensity of needs determination for placement (See Table 1 below for a list of benefits covered in a Non - Institution for Mental Disease (IMD) setting also within the 1115 SUD Demonstration application). In support of this effort, the State also leveraged several grants and an intensive technical assistance award through the Medicaid Innovation Accelerator Program to help develop a comprehensive, integrated behavioral health service delivery model.

Table 1: Current Nevada Medicaid and CHIP State Plan SUD Benefits by ASAM Level of Care

ASAM Level of Care	Benefit		
0.5	Early Intervention/Prevention		
1	Outpatient Services		
2.1	Intensive Outpatient Services		
2.5	Partial Hospitalization		
3.1	Individual Services in Clinically Managed Low-		
	Intensity Residential Non-IMD		
3.2 WM	Individual Services in Clinically Managed Residential		
	Withdrawal Management Non-IMD		
3.5	Individual Services in Clinically Managed Residential		
	Non-IMD		
3.7 WM	Individual Services in Medically Monitored Inpatient		
	Withdrawal Management Non-IMD		
4	Medically Managed Intensive Inpatient Services		
	Non-IMD		

4-WM	Medically Managed Intensive Inpatient (Only) Services-Withdrawal Management Non- IMD
Office-Based Opioid Treatment	Medication Assisted Treatment (MAT)
Opioid Treatment Programs	MAT and Methadone Maintenance

Despite the above efforts, gaps in behavioral healthcare services remain for beneficiaries in need of community-based residential treatment and/or withdrawal management. Lack of access to these services has led to excessive use of higher cost services (i.e., emergency room and inpatient hospital services); low rates of initiation and engagement in treatment; failure to stabilize at lower levels of care and unnecessary readmissions to higher levels of care; and incarceration as an alternative to treatment. As such, Nevada is seeking to supplement current Medicaid and CHIP State Plan SUD benefits.

Future State:

Nevada Medicaid offers a full continuum of services consistent with the American Society of Addiction Medicine (ASAM) criteria. To improve quality of care and increase provider capacity, Nevada Medicaid plans to clarify these ASAM levels of care within the State Plan and will continue to encourage and promote availability and access to these services. With the continued evolution of substance use treatment services, Nevada Medicaid is dedicated to ensuring policy maintains consistent with evidenced based standards of care to improve quality and access to services.

To support the growth of providers performing these levels of care, Nevada Medicaid will continue to collaborate across Nevada Department of Health and Human Services' sister division, Division of Public and Behavioral Health (DPBH), to develop reimbursement rates to align with rates funded for gap services through the Substance Abuse Block Grant funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). Nevada Medicaid will utilize DPBH Division Criteria to support the development of a dedicated substance use treatment Medicaid Service Manual to cohesively define Medicaid standards consistent with ASAM outpatient and residential levels of care.

Nevada will continue to recruit and train providers to become eligible to deliver treatment and recovery services to expand access and provider capacity, especially in rural areas. The state will provide ongoing assessment, engagement, and collaboration with the provider community and key stakeholders. Nevada will continue to refine the development of policies, protocols, and strategies to enhance access to services and improve coordination of services. Nevada will include best practices for screening, brief intervention, and referral to treatment (SBIRT) and medication-assisted treatment (MAT) in policy, consider alternative payment methodology (APM) for MAT services, encourage reimbursement optimization, and monitor utilization of telehealth and related technologies.

Table 2 Milestone #1: Access to Critical Levels of Care for OUD and Other SUDs

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of	The Nevada Medicaid State	Nevada will	Review all substance
Outpatient Services	Plan Attachment 3.1A page	continue to provide	use treatment

	6A.1 – 6C provides coverage	services in	service definitions
	for a wide array of outpatient	accordance with	and staff
	services, including:	current State Plan	qualifications to
	 Screening 	and offer a full array	ensure alignment
	 Assessment 	of evidence-based	with ASAM (<i>Timeline</i>
	 Treatment Planning 	outpatient	12-18 months)
	Neuro-	behavioral health	
	cognitive/psychological	services including	Amend State Plan to
	and mental status	substance use	define substance use
	testing	treatment in	treatment services
	 Medication 	accordance with	aligned with ASAM
	management	ASAM, which will be	levels of care.
	 Drug Testing 	available in home	(Timeline 12-18
	 Basic Skills Training 	and community-	months)
	 Psychosocial 	based settings as well as traditional	Nevada Medicaid will
	Rehabilitation	clinical settings as	create a new
	 Crisis Intervention 	appropriate.	Medicaid Service
	 Mental Health 		Manual (MSM)
	Therapies	Nevada will leverage	chapter that is
	 Day Treatment 	strategies and	specific to substance
	 Peer to peer support 	sustainability	use treatment
	services	planning activities	services and remove
	 Case management 	developed with	current policy from
		support of the	MSM 400, which
		SUPPORT Act grants	currently provides a
		awarded to Nevada.	broad array of
			behavioral health
			services. This new
			MSM chapter will
			include policy for the
			provision of
			substance use
			treatment services
			that align with ASAM
			Criteria (Timeline 12-
			18 months)
Coverage of	The Nevada Medicaid State	Nevada will	Over the
Intensive	Plan Attachment 2.1A page 6B	continue to provide	demonstration
Outpatient Services	& 6B 4 (continued) provides	services in accordance with	period, Nevada Medicaid will
	coverage for Intensive	current State Plan to	continue to enroll
	Outpatient Services and Partial Hospitalization Services that	offer access to these	Intensive Outpatient
	include requirements to align	higher levels of	and Partial
	with ASAM criteria and Levels	outpatient care in	Hospitalization
	2.1 and 2.5. These levels are	accordance with	providers to expand
	a.i.a I i i c.c i c v c i a i c	accordance with	PIOVINCID TO CAPULIU
	reimbursable through FFS and	ASAM.	this level of care

	managed care organizations (MCO).		(Timeline: Throughout the course of the Demonstration)
Coverage of medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state)	MAT and the associated counseling and rehabilitative services are currently offered through Section 1905(a)(29) Supplement 2 to Attachment 3.1-A of the Nevada Medicaid State Plan and is reimbursed through FFS and MCO delivery. Currently, MAT can be delivered by a Physician, Advanced Practice Registered Nurse (APRN), Physician's Assistant (PA), and a Nurse Midwife. Many of Nevada's Certified Community Behavioral Health Centers (CCBHC) perform MAT on site and if unable to perform on site coordinate care to a MAT provider. As part of their state certification requirements, a CCBHC must have a medically trained behavioral health care provider, either employed or available through formal arrangement, who can prescribe and manage medications independently under state law, including buprenorphine and other medications used to treat opioid and alcohol use disorders. Nevada has 8 CCBHCs located throughout the State, 4 located in urban counties and 4 located in rural counties. As part of the 9 core service requirements, the associated counseling and	As MAT continues to evolve, Nevada will continue to update the State Plan as well as policy to align with evidenced based practices to support quality treatment of Opioid Use Disorders as well as substance use disorders. Nevada will take advantage of the Consolidated Appropriations Act of 2023 and associated guidance from the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to expand access to MAT.	Nevada Medicaid will remove policy requirements from MSM for providers to have a Data 2000 or X-waiver for prescribing buprenorphine. (Timeframe: 6-12 months) Nevada will further enhance provider capacity by adding pharmacists as an eligible provider to provide MAT and prescribe medication for OUD when budgetary authority can be provided. (Timeline 24-36 months)

		T	
	rehabilitative services can be done at the location of a CCBHC.		
	Additionally, Nevada Medicaid's telehealth policies allow for payment parity between face to face and telehealth delivery of services. Many associated behavioral health services to MAT can be done through telehealth delivery, such as counseling.		
	Nevada Medicaid has an open formulary for all drugs that are medically necessary, FDA approved, and are provided by a manufacturer participating in the Medicaid Drug Rebate Program and therefore does not have a formulary listing		
	covered drugs.		
Coverage of	Nevada Medicaid State Plan	With 1115 waiver	Provide enrollment
Intensive levels of	Attachment 3.1-A page 1 and	demonstration	opportunity for IMDs
care in residential	page 1a currently covers	authority, Nevada	under the 1115
and inpatient	inpatient stays consistent with	Medicaid will	waiver authority and
settings	ASAM level of care 4.0 in a	expand coverage	training support for
300000	non-IMD setting through FFS	through FFS and	residential treatment
	and MCO delivery.	MCO delivery of	providers <i>(Timeline</i>
	and McO delivery.	ASAM level 3.1, 3.2	6-12 months)
	Nevada Medicaid MCO are	Withdrawal	0-12 months)
	contractually permitted to	Management, 3.5,	The State Plan
	authorize coverage for stays of	and 3.7 Withdrawal	already covers
	up to 15 days in an IMD for	Management in	individual services
	inpatient services related to	both an IMD and	that can be provided
	SUD in lieu of other settings;	non-IMD setting.	in a non-IMD,
	however, this option is limited	Holl livid setting.	substance use
	to managed care enrollees and	Nevada will evaluate	disorder residential
	the allowance is not always	the reimbursement	setting. To provide
	sufficient to meet	rates as well as	greater clarity that
	beneficiaries' clinical needs.	consider bundled	the State covers
	20	payment for	these services for the
		residential levels of	treatment of
	1	1	l . .
į		care for substance	substance use
		care for substance use treatment.	substance use disorders, amending

necessary to define substance use treatment services aligned with intensive levels of care in residential and inpatient settings that meet ASAM criteria. (Timeline 12-24 months) Nevada Medicaid will create a new Medicaid Service Manual (MSM) chapter that is specific to substance use treatment services and remove current policy from MSM 400, which currently provides a broad array of behavioral health services. This new MSM chapter will include policy for the provision of substance use treatment services that align with ASAM Criteria for outpatient levels of care, ASAM Level 1, 2.1, and 2.5 and residential levels of care ASAM Levels 3.1, 3.2 WM, 3.5, and 3.7 WM (Timeline 12-24 months) Nevada Medicaid will define reimbursement for residential levels of care as well as evaluate and

			collaborate with the DPBH to align reimbursement rates based on gap services funded through the Substance Abuse Block Grant for residential levels of care. (Timeline: 24-36 months)
Coverage of medically supervised withdrawal management	Nevada Medicaid covers withdrawal management for medically complex SUD patients in a hospital setting via the covered inpatient level of care benefit located on state plan Attachment 3.1-A page 1 and page 1a.	Nevada Medicaid will add medically supervised ASAM level 3.7 withdrawal management services to the Medicaid state plan and make these services available in non-IMD residential and inpatient settings.	The State Plan already covers individual services that can be provided in a non-IMD, substance use disorder residential setting. To provide greater clarity that the State covers these services for the treatment of substance use disorders, amending the State Plan is necessary to define substance use treatment services aligned with clinically managed residential withdrawal management and medically supervised withdrawal management that meet ASAM criteria. (Timeline 12-24 months) Nevada Medicaid will create a new Medicaid Service Manual (MSM) chapter that is

	specific to substance use treatment services and remove current policy from MSM 400, which currently provides a broad array of behavioral health services. This new MSM chapter will include policy for the provision of substance use treatment services that align with ASAM Criteria for outpatient levels of care, ASAM Level 1, 2.1, and 2.5 and residential levels of care ASAM Levels 3.1, 3.2 WM, 3.5, 3.7 WM, and 4.0 WM (Timeline 12-24 months)
	WM, and 4.0 WM

2. Use of Evidence-based, SUD-specific Patient Placement Criteria

Specifications:

Implementation of evidence-based, SUD-specific patient placement criteria is identified as a critical milestone that states are to address as part of the demonstration. To meet this milestone, states must ensure that the following criteria are met:

- Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g., the ASAM Criteria, or other patient placement assessment tools that reflect evidencebased clinical treatment guidelines; and
- Utilization management approaches are implemented to ensure that (a) beneficiaries have access to SUD services at the appropriate level of care, (b) interventions are appropriate for the diagnosis and level of care, and (c) there is an independent process for reviewing placement in residential treatment settings.

Current State:

With the adoption of the American Society of Addiction Medicine (ASAM) criteria and the development of a community behavioral health safety net in recent years, Nevada has made considerable progress in meeting the milestones utilizing an SUD-specific patient placement criteria. Nevada Medicaid currently requires ASAM criteria to be utilized within the State Plan, Medicaid Service Manual policy, and DPBH Division criteria for substance use treatment provides.

Future State:

Allowing flexibilities around prior authorization gives providers room to take action to effectively and expediently handle patient needs. Bringing balance to both effectiveness and expedience is important to a growing focus on SUD treatment. Prior authorizations are used to manage quality, utilization, and cost; however, they can present a significant barrier to treatment. Administrative burden is consistently reported as a leading cause of provider burnout as it affects providers' perceptions of their ability to provide quality care. In order to support individuals returning to a healthy state of being, administrative barriers that interfere with recovery must be addressed.

Table 3. Milestone #2: Use of Evidence-based, SUD-specific Patient Placement Criteria

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	Nevada Medicaid State Plan requires ASAM criteria for IOP & PHP (3.1-A pg. 6b.4 - 6b.4 continued page 1), and MAT (Supplement 2 to attachment 3.1-A) Nevada Medicaid Services Manual requires ASAM patient placement criteria to establish guidelines for level of care placements within the substance abuse continuum.	Nevada Medicaid and DPBH will continue to collaborate in ensuring SUD-specific, multidimensional evidenced based assessment tools aligned with ASAM are used universally throughout the Nevada substance use treatment system of care. This can be further enforced with clearer definition of ASAM Criteria with State Plan for all levels of substance use treatment services.	Nevada Medicaid will amend State Plan to require inclusion of a full psychosocial assessment covering the six dimensions in accordance with The ASAM Criteria for all substance use treatment services. (Timeline: 12-18 months)
Implementation of a utilization management approach such that: (a) beneficiaries have access to SUD services	Nevada Medicaid requires the use of ASAM criteria to guide service delivery and level of care placement for outpatient SUD	The state will continue utilization review processes currently in place that require the use of ASAM criteria for the appropriate	The state meets the milestone but plans actions to ensure beneficiary access to the appropriate level of care. Leverage the
	services. These	level of care.	SUPPORT Act post

at the appropriate level of care.

services are currently available within non-IMD settings.

Through a contracted vendor, the Center for the Application of Substance Abuse Technologies (CASAT), **DPBH** monitors access to SUD services through certification on-site visits to ensure proper documentation is in place to support the appropriate level of care. DPBH also utilizes the peer review process to continuously improve treatment services to alcohol and drug users within the treatment agencies across the State.

Nevada Medicaid does not currently reimburse for residential levels of care in an IMD setting or if a provider is receiving funding through DPBH. DPBH utilizes substance abuse block grant funding to reimburse for residential services.

As part of DPBH
Division Criteria
requirements, ASAM
Criteria is used for all
substance use
treatment levels of
care even if not funded
through Nevada
Medicaid.

State staff will leverage its enhanced Medicaid Management Information System (MMIS), to ensure the state is able to capture data needed to calculate any required quality measures.

planning demonstration grant activities to support growth in increased provider capacity at every ASAM level of care (Timeline: 6 – 18 months)

State staff will continue to consider and evaluate policies that will enhance access to this service array, including review of prior authorization requirements to ensure these are not barriers to access to care. Reviewing data based on the number of prior authorization approvals, denials, or partial approvals may indicate if adjustment to prior authorization criteria and policies are needed to support increased access to care and to minimize the administrative burden on providers. (Timeline: Throughout the Demonstration period)

Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care.

Nevada Medicaid utilizes a Quality Improvement Organization (QIO-like) vendor, currently Gainwell Technologies, for utilization management and prior authorization requests for medical necessity determinations. Nevada's QIO-like vendor utilizes ASAM criteria and MSM policy to support medical necessity and approval of services.

DPBH utilizes certification reviews to ensure medical necessity and proper levels are care are aligned with ASAM criteria.

The Managed Care Entities are responsible for their own utilization management criteria that aligns with FFS criteria. All inpatient and residential placements will require prior authorization to support the utilization management process and will be determined through the QIO-like vendor to determine the interventions approved support the diagnosis and level of care.

Quality measures to be collected will be explored with treatment providers to identify ways to support appropriate utilization management. With support of state collected data, like plan all cause readmissions, identification of follow up care, initiation of substance use diagnosis and engagement in treatment, this will be a valuable resource to support utilization management of SUD services.

Define prior authorization requirements for each reimbursable ASAM level of care and add additional policy to new MSM SUD chapter that describes each ASAM level of service available, including but not limited to duration of time services are typically delivered within each level of care setting, admission criteria consistent with ASAM Criteria, noncovered services, etc.. This will be developed to educate treatment providers and support utilization management to validate interventions are appropriate for the diagnosis and level of care determined.

(Timeline: 6 – 12 months)

Develop process to collect quality measures from providers (*Timeline:* 24-36 months)

Implementation of a utilization management approach such that (c) there is an independent process for reviewing placement in residential treatment settings.

For Nevada Medicaid reimbursable services within a residential setting, the QIO-like contracted vendor utilizes ASAM criteria and Medicaid Services Manual policy to determine medical necessity for services. The QIO monitors

Collaboration between
Nevada Medicaid,
DPBH and CASAT to
establish consistent
provider standards
within Medicaid
Services Manual as well
as DPBH division
criteria. When on site
reviews occur for
residential treatment
providers, there will be

With the addition of services in residential settings that are considered an IMD under waiver authority, Nevada Medicaid will use the QIO-like contracted vendor that currently uses ASAM criteria and MSM policy to determine

oversight of the lengths	one standard that	medical necessity for
of stay.	meets requirements	placement in
	across Medicaid	residential treatment
For residential	reimbursable and state	IMD settings.
treatment settings not	funded programs.	(Timeframe: 6-12
reimbursed through		months)
Nevada Medicaid,		
DPBH utilizes the		
Center for the		
Application of		
Substance Abuse		
Technologies (CASAT)		
to provide certification		
of residential		
treatment providers		
through on site reviews		
and ongoing		
educational support.		
These reviews include		
clinical documentation		
reviews to ensure		
appropriate placement		
for SUD levels of care.		

3. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

Specifications:

Through the new Section 1115 initiative, states will have an opportunity to receive federal financial participation (FFP) for a continuum of SUD services, including services provided to Medicaid enrollees residing in residential treatment facilities that qualify as institutions for mental diseases. To meet this milestone, states must ensure that the following criteria are met:

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

Current State:

The Division of Public and Behavioral Health (DPBH), Bureau of Health Care Quality and Compliance (BHCQC) has licensure authority over various health care facilities in the State of Nevada. For substance

use treatment facilities, the role of BHCQC is to license and regulate these facilities for compliance with safety and structure requirements. They serve as the regulatory authority for compliance with NRS and NAC Chapter 449.

In conjunction with the licensing component, the Bureau of Behavioral Health Wellness and Prevention (BBHWP) within DPBH certifies agencies for substance use prevention, treatment, and recovery efforts per NRS and NAC Chapter 458. This certification is conducted by the Center for the Application of Substance Abuse Technologies (CASAT). BBHWP alongside BHCQC work together to ensure the quality of services are held to a high standard. Certification allows for review of clinical records for appropriate level of care placement.

Future State:

All Nevada Medicaid enrolled substance use treatment providers are required to submit their SAPTA certification upon enrollment verifying their compliance with the Bureau of Health Care Quality and Compliance (BHCQC) licensure as well as certification requirements based on ASAM level of care and DPBH Division Criteria. MMIS enhancements are in process to allow Nevada Medicaid to enroll residential and clinic provider groups as well as individual substance use treatment providers to inform value and enhance quality to delivery of SUD treatment.

Table 4. Milestone #3: Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

Milestone Criteria	Current State	Future State	Summary of Actions
willestone Criteria	Current State	ruture State	Summary of Actions
			Needed
Implementation of	Nevada Medicaid does	Nevada Medicaid will	MMIS will incorporate
residential treatment	not currently	continue to ensure all	system enhancements
provider qualifications	reimburse for	residential treatment	to enroll substance use
in licensure	residential treatment	providers are qualified	treatment providers
requirements, policy	level of care for SUD	to provide services in	that are licensed or
manuals, managed	treatment in an IMD	accordance with ASAM	certified as individual
care contracts, or	for 22-64.	criteria with the	Medicaid providers and
other guidance.		established DPBH	will be able to link to a
Qualification should	Residential provider	Division criteria. When	substance use
meet program	licensure requirements	a substance use	treatment provider
standards in the ASAM	are outlined at NRS	treatment professional	agency (Timeline: 6 -12
Criteria or other	449.00455 et seq. and	becomes licensed or	months).
nationally recognized,	NAC 449.019 et seq.	certified, they will have	
SUD-specific program	and align with ASAM	opportunity to enroll as	
standards regarding, in	criteria.	an individual specialty	
particular, the types of		linked to a substance	
services, hours of	The BHCQC licenses	use treatment facility	
clinical.	health facilities in	performing services to	
	Nevada, including but	Nevada Medicaid	
	not limited to, facilities	eligible individuals.	
	for the treatment of		
	abuse of alcohol or		

	T		
	drugs. This regulatory		
	body provides		
	oversight for health		
	care inspections and		
	complaints. BBHWP		
	provides certification		
	to all entities in Nevada		
	that provide substance		
	use prevention or		
	treatment services that		
	receive state or federal		
	dollars. Both entities		
	collaborate with		
	requirements for each		
	when conducting on-		
	site visits of all		
	substance use		
	treatment facilities.		
Implementation of a	Nevada's process for	Already implemented.	No action required.
state process for	licensure and	, ,	'
reviewing residential	certification of		
treatment providers to	residential treatment		
ensure compliance	providers is established		
with these standards	through DPBH. The		
	Bureau of Health Care		
	Quality and		
	Compliance (BHCQC)		
	licenses health facilities		
	in Nevada, including		
	but not limited to,		
	facilities for the		
	treatment of abuse of		
	alcohol or drugs. This		
	regulatory body		
	provides oversight for		
	health care inspections		
	and complaints. The		
	Bureau of Behavioral		
	Health Wellness and		
	Prevention (BBHWP)		
	provides certification		
	to all entities in Nevada		
	that provide substance		
	use prevention or		
	treatment services that		
	receive state or federal		
	dollars. Both entities		
	collaborate with		
	Collaborate With		

Implementation of requirement that residential treatment facilities offer MAT onsite or facilitate access	requirements for each when conducting onsite visits of all substance use treatment facilities. Per DPBH Division Criteria, certified treatment programs, private, public, or funded cannot deny	Enforce requirements of facilities offering MAT on-site through use of Medicaid Service Manual policy.	Update Medicaid Service Manual policy to include requirement of offering all FDA- approved MAT on-site
off site.	treatment services to clients that are on stable medication maintenance for the treatment of an opioid use disorder, including FDA approved medications.		or facilitate access to off-site MAT. (Timeline: 12-18 months)

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

Specifications:

To meet this milestone, states must complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care listed in Milestone 1. This assessment must determine availability of treatment for Medicaid beneficiaries in each of these levels of care, as well as availability of MAT and medically supervised withdrawal management, throughout the state. This assessment should help to identify gaps in availability of services for beneficiaries in the critical levels of care.

Current State:

In September 2019, the U.S. Department of Health and Human Services (HHS) and CMS awarded Nevada DHCFP the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act Planning Grant in the amount of \$1,684,013 over 18 months, October 2019 through March 2021.

The purpose of the planning grant was to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services through:

- An ongoing assessment of the substance use disorder treatment needs of the state;
- Recruitment, training, and technical assistance for Medicaid providers offering substance use disorder treatment or recovery services; and
- Improved reimbursement for and expansion of the number or treatment capacity of Medicaid providers.

Nevada is committed to providing Nevadans with a broad service delivery system to increase access to behavioral health services with an emphasis on SUD or OUD by providing a coordinated, comprehensive, and whole-person approach. At the start of the SUPPORT Act planning grant, the lead agency, the DHCFP, established the Nevada SUPPORT Act Core Team (Core Team) as an active governance body, spearheaded by leadership from Nevada Medicaid and the DPBH's Substance Abuse Prevention and Treatment Agency (SAPTA). The Core Team's work engaged a diverse representation from other state agencies and divisions, as well as community partners and providers. Two major milestones accomplished during this phase of the SUPPORT Act grant that supported provider expansion of substance use treatment including MAT services were the implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) codes and creation of a comprehensive MAT policy. SBIRT codes were activated on March 2, 2020, for various providers including physicians, Advanced Practice Registered Nurses (APRNs), physician assistants (PAs), and nurse midwives. An SBIRT Toolkit was also developed, and training was provided to Nevada's largest female reproductive health practice. The comprehensive MAT policy documents the process of treatment to outline expectations, the use of buprenorphine medication, and qualification of providers. A MAT billing guide was also created to further clarify billing expectations when performing MAT services. In December of 2020, through the work of the SUPPORT Act planning grant, Nevada was able to publish the Substance Use Disorder & Opioid Use Disorder in Nevada: Policy Analysis and Infrastructure Assessment Report please find link to report under Section III: Relevant Documents. The purpose of the assessment report is to present the current policy and infrastructure landscape regarding SUD service system in Nevada, including provider capacity, benefit design and coverage, prior authorization management, integrated care delivery, and reimbursement. The report also illustrates areas of opportunity, and includes emerging and best practices, as well as recommendations to enhance and expand SUD treatment and recovery services statewide.

The assessment report covers the following main areas:

- Current Opioid Use and Provider and Treatment and Recovery Services Capacity in Nevada.
- Nevada Substance Abuse Healthcare System Landscape, Challenges, and Opportunities.
- Benefits Utilization Management Landscape and Opportunities.
- Technology-Enabled Approaches to Expand Capacity and Services.
- Application and Expansion of the Hub-and-Spoke Model.
- Fiscal Projections.

The report was developed between March 2020 and June 2020, and utilized information from various sources, including specific DHHS stakeholder discussions and communications, as well as statewide and county-level assessments, epidemiology and surveillance briefs, provider surveys, data reports, document review, and other research.

In September 2021, Nevada was among five states awarded the CMS SUPPORT Act Post-Planning Demonstration Grant Award. The Demonstration project further aims to increase the treatment capacity of providers participating under the Medicaid state plan (or a waiver of such plan) to provide SUD treatment and recovery services. This phase of the grant is awarded through September 2024.

Additionally, SAPTA funded providers are required to participate in a referral-based platform called OpenBeds. The primary functions of the platform are real-time cloud-based bidirectional referrals, bed

registry, and storing Comprehensive Addiction and Recovery Act (CARA) Plans of Safe Care. Data indicators that can be captured within this platform are the number of referrals, length of time to acknowledge a referral, bed capacity over 90%, average bed availability per day, gender, age, difficult to place clients, the reason for declined referral, payment method, special population, and substances. The providers can also track the referrals. There is an analytics section that can help the providers with staffing leaves and referral turnaround time. In addition, the platform can be used to link to social determinants of health by sending a request to Nevada 211.

Future State:

Nevada will continue to leverage the work developed through both phases of the SUPPORT Act Planning and Post Planning grants. With the construction of focused data reporting requirements, Nevada will leverage quarterly data reports identifying Nevada's current provider capacity for substance use treatment services, including MAT services, and monitor trends to evaluate provider capacity. Nevada will continue to evaluate and refine the SUD Data Book developed through the DHHS's Office of Analytics.

Nevada has increased focus in the delivery of crisis services across the state. During the 2021 Nevada Legislative session, Senate Bill 156 and Senate Bill 390 were passed to further Nevada's development of a comprehensive crisis response system. Senate Bill 156 required Nevada Medicaid to reimburse for crisis stabilization services performed in a Crisis Stabilization Center endorsed under a hospital licensure. To further expand crisis stabilization services, Nevada plans to reimburse for intensive crisis stabilization services within a CSC but also to providers meeting certification standards within a community setting to address crisis needs across the state. Senate Bill 390 enacted the 988 surcharge on telecommunication and established the Crisis Response account to support the infrastructure of the 988 call-center, interoperability technology, GPS deployment of mobile crisis teams, the implementation of mobile crisis teams, and provide sustainable funding for uncompensated care for services within the crisis continuum. Along with the legislation of Senate Bill 390, Nevada Medicaid was awarded the Section 9813 Mobile Crisis Planning Grant through the CMS to support the state in be preparing to elect and implement the new American Rescue Plan "State Option to Provide Qualifying Community-Based Mobile Crisis Intervention Services," that coincided with the national requirement of 988 behavioral health crisis line in July of 2022. States with a SPA, 1915(b) waiver, 1915(c) waiver, or 1115 waiver program with corresponding authority for Community-Based Mobile Crisis Intervention Services may receive an 85% FMAP for expenditures on qualifying Community-Based Mobile Crisis Intervention Services for the first 12 quarters (3 years) within the five-year period beginning April 1, 2022, during which the state meets the conditions for the 85% FMAP. With development of both intensive crisis stabilization services and community based mobile crisis teams, Nevada strives to increase high quality access to individuals struggling with a mental health or substance use crisis.

As Nevada moves forward with the implementation of the Crisis Response System, the Division of Public and Behavioral Health (DPBH) has released a Request For Information (RFI) for feedback on what Nevada is calling the Nevada Behavioral Health Crisis Care Hub (NBHCCH) serving as the software and call center to organize and deploy crisis response services, including a Suicide Lifeline, Designated Mobile Crisis Teams, and a bed registry. Once responses have been received, DPBH will release a Request For Proposal (RFP) targeted for Fall of 2023 for interested vendors of the NBHCCH. With the support of a NBHCCH, there will be increased interoperability and access to critical levels of care for individuals struggling with a mental health or substance use issue.

Table 5. Milestone #4: Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD

Milestone Criteria	Current State	Future State	Summary of Actions
			Needed
Completion of	Through Section 1003	Increase quality access	Nevada Medicaid will
assessment of the	of the SUPPORT Act	to individuals	integrate intensive
availability of	planning and post	experiencing a mental	crisis stabilization
providers enrolled in	planning grants,	health or substance	services within the
Medicaid and	Nevada has collected	use crisis.	State Plan and MSM to
accepting new patients	significant data for		support individuals
in the following critical	identifying the amount		experiencing a
levels of care	of enrolled Medicaid	Evaluate and refine the	substance use disorder
throughout the state	providers performing	SUD Data Book	crisis in need of
(or at least in	substance use	developed through the	stabilization. With this
participating regions of	treatment services,	DHHS's Office of	new provider type and
the state) including	including MAT. On a	Analytics.	specialty, the Medicaid
those that offer MAT:	quarterly basis, Nevada		enrollment checklists
 Outpatient 	reviews data evaluating		will include language to
 Intensive 	the amount of enrolled		participate in statewide
Outpatient	Nevada Medicaid		crisis response system.
Services	providers and the		Once NBHCCH is
 MAT (including 	amount of individuals		effective, these
counseling and	with a diagnosis of SUD		providers can be
medication)	receiving care in an		integrated into the
Intensive	outpatient setting,		response system for
levels of care	inpatient setting and		individuals
in residential	by provider type.		experiencing a mental
and inpatient			health or substance
settings	SAPTA funded		use crisis. (<i>Timeframe:</i>
Medically	providers are		6-12 months)
supervised	participating in a		
withdrawal	referral-based platform		
management	called OpenBeds. The		Nevada Medicaid will
	primary functions of		update MCO vendor
	the platform are real-		contracts to include
	time cloud-based		time and distance
	bidirectional referrals,		standard ratios for
	bed registry, and		providers delivering
	storing Comprehensive		services under this
	Addiction and Recovery		waiver (<i>Timeline: 6-12</i>
	Act (CARA) Plans of Safe		months)
	Care. Data indicators		
	that can be captured		
	within this platform are		
	the number of referrals,		Nevada Medicaid will
	length of time to		utilize data gathered
	acknowledge a referral,		

bed capacity over 90%, average bed availability per day, gender, age, difficult to place clients, the reason for declined referral, payment method, special population, and substances. The providers can also track the referrals. There is an analytics section that can help the providers with staffing leaves and referral turnaround time. addition, the platform can be used to link to social determinants of health by sending a request to Nevada 211.

through the SUPPORT **Act Post Planning** Demonstration as well as Medicaid enrollment information to identify specific counts of current providers performing and accepting new patients at all critical levels of care through state collected information and also provider surveys to achieve a comprehensive updated outlook for provider capacity at critical levels of care.

(Timeline: 12 months)

Refine data collection to collect specifics on individually enrolled substance use treatment providers available in Nevada once new Substance **Use Treatment** Provider Type and individual enrollment specialties are created and providers are enrolled. (Timeline: 24 months -duration of waiver)

Further develop and refine the SUD Data Book developed through the DHHS's Office of Analytics.

(Timeline: 12-24 months)

5. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid **Abuse and OUD**

Specifications:

To meet his milestone, states must ensure that the following criteria are met:

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

Current State:

Nevada has recently made great strides to improve the behavioral health related outcomes described above. For example, the Good Samaritan Drug Overdose Act of 2015 was signed into law on May 5, 2015, and codified as Chapter 453C in Nevada Revised Statutes. The law provides immunity for personal use and possession of controlled substances for those seeking medical attention during a drug overdose. It also requires that prescribing physicians obtain a patient utilization report from the state's Prescription Monitoring Program (PMP) before initiation of a schedule II, III, or IV prescription drug for a new patient, or for a course of treatment lasting longer than seven days that is part of a new course of treatment for an existing patient. Further, the Act expands access to the opioid antagonist Naloxone by allowing providers to prescribe and/or dispense the product to persons positioned to assist another person at risk for overdose and by allowing a pharmacist with standing orders to store and dispense the product without a prescription.

The Nevada legislature passed the Prescription Drug Abuse Prevention Act unanimously and it was signed into law on June 16, 2017. The law, which went into effect on January 1, 2018, expands and updates state laws requiring doctors and hospitals to report any drug overdoses to the State; permits licensing boards to access Prescription Monitoring Program data to investigate inappropriate prescribing, dispensing, ouse of a controlled substance; and requires that prescribers perform a risk assessment before prescribing a controlled substance. A prescription medical agreement with the patient must be created for prescriptions over 30 days. In addition, the prescriber must complete a risk of abuse assessment and obtain a patient utilization report every 90 days for the duration of the prescription.3 Lastly, the law created the "Prescribe 365" initiative, which states that no patient should receive more than 365 days' worth of medication in any consecutive 365-day period. This impacts all prescriptions for controlled substances; however, most provisions apply specifically to only those controlled substances prescribed to treat pain. In 2019, the Legislature passed AB239, which further refined the law. Under the law, prescribers must review a patient's PMP report and perform a risk assessment before prescribing a controlled substance. The law includes guidelines for the treatment of acute pain and exemptions are made for hospice, palliative, cancer, and sickle cell prescriptions. This and other requirements are expected to reduce the number of people who develop SUD and OUD, while maintaining access to appropriate pain management medications and enhancing alternative pain management strategies.

Comprehensive knowledge of pain management strategies and training about pain management competencies that cross disciplines are known barriers to implementation of the law. Other challenges include communication between pharmacists and prescribers, confusion over interpretation of new provisions, misinformation to patients and prescribers, and knowledge of resources for SUD treatment.

However, despite these challenges, data from the Nevada Prescription Monitoring Program indicates

there has been an overall reduction in opioid prescriptions for pain. From January of 2017 to January of 2021, the rate of opioid prescriptions per 100 Nevada residents decreased by approximately 40%. Opioid prescriptions with a less than a 15-day supply decreased by 76% during this same time period.

In April 2018, *Prescription Nation 2018: Fighting America's Opioid Epidemic* acknowledged Nevada as one of two states recognized in 2018 by the National Safety Council for addressing six key indicators to address the crisis: 1) mandating prescriber education; 2) implementing opioid prescribing guidelines; 3) integrating prescription monitoring program into clinical setting; 4) improving data collection/sharing; 5) treating opioid overdose; and 6)increasing availability of opioid use disorder treatment.

Future State:

Nevada will work to expand the roles of pharmacists to include Opioid Maintenance Therapy (OMT) and explore reimbursable services regarding opioid management for pharmacists. An expansion to allow pharmacists would increase access to OMT to address opioid abuse and OUD. If a model could be established to partner pharmacies with established Opioid Treatment Programs (OTP) and create a fair level of reimbursement for a pharmacist's clinical services, this would serve as a win-win because it would expand the program as well as the pharmacist's clinical role in MAT.

Table 6. Milestone #5: Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	Prescription monitoring thru the PBM and RX Team - new system in place Buprenorphine/Naloxone and Buprenorphine are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the Nevada Drug Utilization Review Board.	Already completed.	No action required.
	The Pharmacy Lock-In Program is intended to prevent recipients from obtaining excessive quantities of controlled substances through multiple visits to		

	physicians, clinics, and		
	pharmacies. When a		
	recipient has shown		
	patterns of abuse/misuse		
	of Nevada Medicaid		
	benefits, or the DHCFP		
	has determined that the		
	recipient requires close		
	medical management,		
	the recipient may be		
	"locked-in" to a specific		
	pharmacy. This means		
	that Medicaid will only		
	pay for controlled		
	substance prescriptions		
	at a single pharmacy.		
Expanded coverage	Nevada Medicaid does	Over the course of the	This milestone is met,
of, and access to,	not require any prior	demonstration,	as statewide access to
naloxone for overdose	authorization for	Nevada will continue	naloxone is already in
reversal	naloxone, which ensures	to support the	place. Nevada will
reversar	that eligible Medicaid	statewide distribution	continue work across
	beneficiaries can receive	of naloxone through	DHHS to support
	the medication easily.	increased provider	
	_		access, training, and
	Additionally, naloxone is	communication	awareness of coverage
	available without a	through web	through increased
	prescription throughout	announcements and	provider
	the state of Nevada as	monthly SUD	communication
	part of an ongoing effort	treatment provider	through web
	to prevent drug overdose	engagement meetings	announcements and
	deaths in Nevada.	and provide consistent	monthly SUD
	There is training	and integrated	treatment provider
	supported by CASAT and	trainings conducted	engagement meetings.
	other community	across stakeholder	(Timeline: 6 months -
	partners for overdose	types.	Demonstration
	reversal, funded through		Period)
	the State Opioid	As supported through	
	Response Grant.	CMS' bulletin issued	If given budgetary
		January 2017, Nevada	authority, Nevada will
		will expand timely	further increase access
		access to certain drugs	to naloxone by adding
		in the interest of	pharmacists as an
		public health,	approved prescriber
		specifically including	under a collaborative
		naloxone. These	practice agreement
		options included	(CPA) with other
		expanding the scope	licensed prescribing
		of practices and range	healthcare providers
		of services that	like physicians,
	l		> p/2.2.2/

		pharmacists can provide, "including dispensing drugs based on their own independently initiated prescriptions, collaborative practice agreements (CPA) with other licensed prescribing healthcare providers like physicians, 'standing orders' issued by the state [health authority], or other predetermined protocols".	'standing orders' issued by the state. (Timeline: 24-36 months)
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	Nevada State Board of Pharmacy oversees the vendor contract for the prescription drug monitoring program. Two Nevada Medicaid staff members have the ability to query the database. Query of the prescription drug monitoring program has been incorporated in the operations of the Pharmacy Lock-In Program	Nevada Medicaid is exploring additional data the program will need to provide regarding provider checking drug history and calculation for averages of morphine milligram equivalent prescribed for different groups.	Evaluate dashboard capabilities (Timeframe: Throughout Demonstration Period)

6. Improved Care Coordination and Transitions between Levels of Care

Specifications:

To meet this milestone, states must implement policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

Current State:

In 2016, Nevada was selected to participate in the federal Section 223 of the Protecting Access to Medicare Act demonstration program to develop a network of Certified Community Behavioral Health Centers (CCBCHs). These entities, a provider type in Nevada Medicaid, are designed to provide a comprehensive range of mental health and SUD services to vulnerable individuals, including members of the armed services and veterans. CCBHCs are responsible for providing nine specific service types, with

an emphasis on the provision of 24-hour crisis care, utilization of evidence-based practices, care coordination, and integration with physical health care.

Future State:

This waiver will allow Nevada to expand and improve care coordination efforts for individuals transitioning between levels of care. It will ensure and support successful treatment for individuals with SUD and complement Nevada's increased access to residential levels of care provided. The ability to create and implement integrated care plans, ensure access to an array of linked services, and the exchange of information among consumers, family members, and providers will be necessary not only in outpatient settings, like CCBHCs, but also residential and inpatient levels of care.

Nevada will consider financial incentives for care coordination across health care professional types including behavioral health counselors and other non-physicians in specialty and non-specialty settings. Allowing providers to receive reimbursement for a collaborative, team-based care model provides a pathway for primary care offices to deliver sustainable, high-quality, evidence-based treatment. If legislative authority, Nevada will have budgetary authority to move this forward.

As part of Nevada's 1115 application, Nevada plans to further expand the targeted case management benefit to include a specific target group for individuals with an SUD only diagnosis ensuring residential and outpatient providers will have reimbursement incentive to effectively support individuals transitioning between levels of care.

Table 7. Milestone #6: Improved Care Coordination and Transitions between Levels of Care

Milestone Criteria	Current State	Future State	Summary of Actions
			Needed
Implementation of	Current Medicaid	Redefining discharge	Redefine discharge
policies to ensure	Service Manual	criteria and transitions	criteria specific for
residential and	discharge policy criteria	of care standards	residential treatment
inpatient facilities link	requires providers to	across DPBH Division	providers and develop
beneficiaries with	include a discharge	Criteria and Medicaid	transition of care
community-based	plan within an	policy to include but	standards across DPBH
services and supports	individual's treatment	not limited to, support	Division Criteria and
following stays in	plan and includes	with setting follow up	Medicaid policy to
these facilities	requirements for	appointments with	include but not limited
	providers to	community-based	to, support with setting
	recommend aftercare	providers prior to	follow up
	services for goals that	discharge, referral	appointments with
	were both achieved	options provided to	community based
	and not achieved	individual at time of	providers prior to
	during the duration of	discharge, ASAM score	discharge, referral
	the treatment plan.	at time of discharge,	options provided to
	Discharge criteria also	statement of progress	individual at time of
	requires providers to	made during treatment	discharge, ASAM score
	identify available	between residential	at time of discharge,
	agencies and	and outpatient levels	statement of progress
	independent providers	of care. This will	made during treatment

to provide aftercare services and the purpose of each for the recipient's identified needs under the treatment plan to ensure the recipient has access to supportive aftercare.

Providers are expected to transition clients to lower levels of care once their residential needs are met. ASAM provides a robust continuum of care based on a personcentered need where the client moves through the continuum from higher levels to lower levels. During certification reviews, a sample of clinical records by level of care are reviewed to ensure providers are accurately moving clients through the continuum.

The current contract with MCO includes care management. Care Management consists of both Level 1 Care Coordination and Level 2 Case Management. Care Coordination is designed to assist members with social determinants of health needs, challenges in accessing health and community resources or other member needs that fragment

support individuals with a full continuum of support and lead to enhanced provider network communication to support successful treatment outcomes.

within new Medicaid Service Manual policy for substance treatment providers and Division Criteria (Timeline: 12 -24 months)

If provided budgetary authority, Nevada will integrate a new SUD-only target group within the targeted case management benefit to support case management activities for individuals transitioning between residential and outpatient SUD services. (Timeline: 24-36 months)

	the member's care or lead to poor health outcomes. Case Management is designed to support members, regardless of age, based on an individualized assessment of health and social determinant of health needs. Case Management must be offered to members identified as high-risk, including members with SED/SMI, members with comorbid medical and behavioral health conditions, including substance abuse disorders, and members experiencing		
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	a high-risk pregnancy. Nevada policies to ensure coordination of care for co-occurring physical and mental health conditions are outlined within our Certified Community Behavioral Health Centers (CCBHCs) which includes coordinating all behavioral/mental and physical health activities regardless if the care is provided directly by the CCBHC and its DCO or through referral or other affiliation outside of the CCBHC delivery model.	Develop MSM and Division Criteria standards for coordination of care for co-occurring physical and mental health conditions for residential levels of care transitioning to outpatient levels of care. Explore collaborative care model and consider adoption within Medicaid Services Manual policy and State Plan.	Develop MSM and Division Criteria standards for coordination of care for co-occurring physical and mental health conditions for residential levels of care transitioning to outpatient levels of care. (Timeline: 18- 24 months) If provided legislative authority, integrate the collaborative care model within state plan and MSM. (Timeline: 24-36 months)

<u>Section II – Implementation Administration</u>

The Division's point of contact for the Implementation Plan is:

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Section III – Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

SUPPORT Act Grant Sustainability Plan

SUPPORT Act Grant Strategic Plan

SUPPORT Act Grant Infrastructure Assessment Report

Attachment A - SUD Health Information Technology (IT) Plan

Section I.

Specifications:

SUD Demonstration Milestone 5.0, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

The specific milestones to be achieved by developing and implementing an SUD Health IT Plan include:

- Monitoring the Health IT functionality to support Prescription Drug Monitoring Program (PDMP) interoperability; and working to support the Board of Pharmacy.
- Monitoring clinicians in their usage of the state's PDMP.

Current State-

Nevada's Pharmacy Board currently shares data nationwide with 40 States and Military Health System through an interstate data sharing agreement. This allows Nevada to share more complete data records of patient's-controlled substance medication history to healthcare providers in making decisions for their patients. Interstate data sharing varies based on each state's regulation policies.

Nevada shares prescription data across stateliness via PMP InterConnect® and RxCheck hubs. The data sharing hubs allow participating state PMPs to be linked and provide a more effective means of combating drug diversion and drug abuse nationwide. The PMP staff analyzes controlled substance prescription data to identify high prescribers and patients who are doctor shoppers. Currently the Board of Pharmacy Prescription Monitoring Program (PMP) staff submits a biannual report to each licensing board to alert them of their licensees who are identified on the high prescriber's report.

In addition, the Pharmacy Board currently utilizes Bamboo Health's PMP Gateway integration service and Electronic Health Records (EHRs) and Pharmacy Management Systems (PMS). The Pharmacy Board uses patient-clustering algorithms that result in 99.8% accurate patient matching, leading to more reliable prescribing and dispensing. Instead, the EHR or PMS will automatically initiate a patient query, which will return the patient's-controlled substance prescription records directly within the clinical workflow.

Nevada has a Health Information Exchange (HIE) but there is no requirement for data submission or data quality. DHCFP currently has no initiatives for HIE before legislature and does not have any intentions of doing any connectivity or innovations with the HIE as the data is unreliable and unusable.

Future State-

Nevada will support sharing data with the additional 10 States, based on the contingency of the other states processes and policies for interstate data sharing. Additional outreach efforts will occur with clinicians, providers, and other states.

DHCFP will encourage prescribers through the DHCFP website to utilize the Board of Pharmacy's resources and encourage the integration of the EHR or pharmacy management system, even though it is not mandatory. Nevada will encourage providers and pharmacies to integrate the NV PMP with their EHR or pharmacy management system but does not have any incentives or initiatives.

Milestone	Current State	Future State	Summary of
Criteria			Actions
			Needed
Prescription Drug	Monitoring Program (PDMP) Functionali	ties	
Enhanced	Nevada currently shares data	Data sharing	Review the
interstate data sharing in order to better track patient specific prescription data	nationwide with 40 states, as well as the Military Health System. Interstate data sharing efforts have increased the availability of a more complete record of a patient's-controlled substance medication history to health care providers to assist them in making the best decision for their patients and deterring drug diversion. Interstate data sharing varies based on each state's statutory limitations.	with the additional 10 states will be pursued. This will be contingent on other states' processes and policies for interstate data sharing.	remaining 10 states polices and statutory regulations for interstate data sharing and identify any limitations. For the states without policy or statutory limitations, data sharing will be a challenge.
Enhanced "ease of use" for prescribers and other state and federal stakeholders	Nevada shares prescription data across stateliness via PMP InterConnect® and RxCheck hubs. The data sharing hubs allow participating state PMPs to be linked and provide a more effective means of combating drug diversion and drug abuse nationwide. Interstate data sharing allows physicians and pharmacists to help identify patients with prescription drug abuse and misuse problems, especially those	Nevada currently has 8562 prescribers and 610 pharmacies enrolled in interstate data sharing with the PMP	Evaluate possible outreach efforts to prescribers and other eligible state and federal stakeholders through 12/2027.

	patients who cross state lines to obtain	InterConnect	
	drugs.	and RxCheck hubs.	Update DHCFP Pharmacy website to utilize the Board of Pharmacy's resources and encourage them to integrate the EHR or pharmacy management system, even though it is not mandatory through 12/2027.
Enhanced	The Nevada PMP is not connected to	Nevada has a	No actions
connectivity	the state Health Information Exchange	Health	necessary.
between the	(HIE).	Information	
state' PDMP and		Exchange (HIE)	
any statewide, regional or local		but there is no	
health		requirement	
information		for data	
exchange		submission or	
		data quality.	
		At this time,	
		DHCFP currently has	
		no initiatives	
		for HIE before	
		legislature and	
		does not have	
		any intentions	
		of doing any	
		connectivity	
		or innovations	
		with the HIE	
		as the data is	
		unreliable and	
		unusable.	

Enhanced	TI DAID : (())		C
Enhanced identification of	The PMP staff analyzes controlled	Monitoring of	Create reports
	substance prescription data to identify	fee for service	for monitoring
long-term opioid	high prescribers and patients who are	claims and	purposes
use directly	doctor shoppers. The Board of	Managed Care	through
correlated to	Pharmacy PMP staff submits a biannual	encounter	12/2027.
clinician	report to each licensing board to alert	claims.	
prescribing	them of their licensees who are		
patters (see also "use of PDMP"	identified on the high prescribers		
	report. If a doctor shopper is identified,		
#2 below)	they are referred to law enforcement.		
Current and Futu	re PDMP Query Capabilities		
Facilitate the	The Nevada PMP utilizes Bamboo	Due to the	No actions
state's ability to		Due to the	No actions
· -	Health's patient matching services	high	necessary.
properly match patients	which uses patient-clustering	percentage	
receiving opioid	algorithms that result in 99.8% accurate	accuracy rate	
prescriptions	patient matching, leading to more	of 99.8% using	
with patients in	reliable prescribing and dispensing.	Bamboo	
the PDMP (I.e the		Health's	
state's master		patient	
patient index		matching	
(MPI) strategy		services,	
with regard to		further	
PDMP query)		enhancements	
T Divir query,			
		are not being	
		considered at	
		this time.	
	upporting Clinicians with Changing Office	_	
Develop	The Nevada Prescription Drug	Nevada will	Evaluate
enhanced	Monitoring Program (PDMP) allows	encourage	possible
provider	healthcare facilities to integrate data	providers to	outreach efforts
workflow /	into approved Electronic Health	integrate the	to clinicians
business	Records (EHRs) and Pharmacy	NV PMP with	through
processes to	Management Systems (PMS). The	their EHR or	12/2027.
better support	PDMP utilizes Bamboo Health's PMP		
clinicians in	Gateway integration service.	pharmacy	
accessing the	Prescribers and pharmacists will no	management	
PDMP prior to prescribing an	longer need to navigate to the state	system.	
opioid or other	Nevada PMP website, log in, and enter		
controlled		The Nevada	
substance to	their patient's information. Instead, the	Prescription	
address the	EHR or PMS will automatically initiate a	•	
issues which	patient query, which will return the	Monitoring	
follow	patient's-controlled substance	Program (NV	
.011044	prescription records directly within the	PMP) has	
	clinical workflow.		

partnered with Appriss Health to integrate NV PMP data into Nevada electronic health records (EHR) and Nevada pharmacy management systems via Appriss Health's PMP Gateway platform. This empowers clinicians at the point of care with information that can help the clinician make better informed prescribing decisions. Integration is NOT mandatory. PMP data can still be accessed through the NV PMP web portal. Integration of the NV PMP data into the

		clinician's EHR or pharmacy management system is not mandatory but is available at no cost.	
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	Nevada Revised Statute 639.23507, implemented in 2017, requires practitioners to query a patient's PMP report prior to prescribing a controlled substance list in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance.	No further enhancements are being considered at this time due to the requirements in Nevada Revised Statute 639.23507 which requires practitioners to query a patient's PMP report prior to prescribing a control substance list in schedule II, III, IV or an opioid that is a controlled substance listed in schedule V at least once every 90 days thereafter for the duration of the course of treatment using the	No actions necessary.

		controlled	
		substance.	
	dex/Identify Management		
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	Ambulatory Detox / Rehabilitation Residential Current Funded Programs: Ambulatory, intensive outpatient Ambulatory, non-intensive outpatient Detox, 24-hour, Free-Standing residential Detox, 24-hour Hospital inpatient Rehabilitation/ Residential, Hospital Rehabilitation/ Residential, Long Term>=30 days Rehabilitation/ Residential, Short Term <= 30 days Unknown	Continue with ongoing services that are in place	Hired TEDS Health Program Specialist and TEDS Business Process Analyst with SAPTA with the aim to aid in analyzing datasets as well as communicating with substance abuse treatment centers to identify barriers and gaps in reporting, in order to facilitate better data. The analyst from the Department of Behavioral Health is directly communicating with substance facilities and working with them on reporting gaps in the data.
	for Enhancing PDMP Functionality & Inte		
Leverage the	(2017) Nevada Revised Statute	No further	No actions
above	639.23507 requires practitioners to	enhancements	necessary.
functionalities / capabilities /	query a patient's PMP report prior to prescribing a controlled substance list	are being considered at	

supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribingand to ensure that Medicaid does not inappropriately pay for opioids

in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 thereafter for the duration of the course of treatment using the controlled substance.

this time due to the requirements in Nevada Revised Statute 639.23507 which requires practitioners to query a patient's PMP report prior to prescribing a control substance list in schedule II, III, IV or an opioid that is a controlled substance listed in schedule V at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance.

Attachment A, Section II – Implementation Administration

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

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Attachment A, Section III – Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

ATTACHMENT D Reserved for SUD Monitoring Protocol

ATTACHMENT E Reserved for SUD Evaluation Design