

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

September 17, 2024

Stacie Weeks  
Medicaid Administrator  
Division of Health Care Financing and Policy  
1100 East William Street, Suite 101  
Carson City, NV 89701

Dear Director Weeks:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC #36 “Draft Evaluation Design” of Nevada’s section 1115 demonstration, “Nevada’s Treatment of Opioid Use Disorder (OUD) and SUD Transformation Project” (Project No: 11-W-00409/9), effective through December 31, 2027. CMS has determined that the Evaluation Design, which was submitted on October 20, 2023 and May 30, 2024, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state’s Evaluation Design.

CMS has added the approved Evaluation Design to the demonstration’s STCs as Attachment E. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state’s Medicaid website within 30 days. CMS will also post the approved Evaluation Design as a standalone document, separate from the STCs, on Medicaid.gov.

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

We appreciate our continued partnership with the state on Nevada's Treatment of Opioid Use Disorder (OUD) and SUD Transformation Project section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

**Danielle Daly -S** Digitally signed by Danielle Daly -S  
Date: 2024.09.17 14:16:39 -04'00'

Danielle Daly  
Director  
Division of Demonstration Monitoring and Evaluation

cc: Cecilia Williams, State Monitoring Lead, CMS 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: Reserved for 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. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 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. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

- 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. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
- iii. Patient Placement. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
- iv. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. Currently, residential 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. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
- vi. Standards of Care. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

- vii. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/ODU. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
  - viii. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/ODU. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
  - ix. Improved Care Coordination and Transitions between levels of care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.
  - x. SUD Health IT Plan. Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics are detailed in STC 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 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.<sup>1</sup> 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/>).

---

<sup>1</sup> *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.gov/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. Performance Metrics. Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress toward meeting the demonstration's annual goals and overall targets as 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. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR § 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly 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. Evaluation Activities and Interim Findings. Per 42 CFR § 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of

evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

- e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 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	Hypo 1	X		X	Beneficiaries receiving services through the state's Managed Care Delivery System
FFS IMD Services	Hypo 2	X		X	Beneficiaries receiving services through the state's Fee for Service Delivery System

<b>ADM</b>	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.
------------	-----	--	--	--	---

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

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

- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the MEG Charts and in the STCs in section 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. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

**Table 2: MEG Detail for Expenditure and Member Month Reporting**

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
<b>IMD Services Managed Care MEG</b>	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
<b>IMD Services FFS</b>	Beneficiaries receiving IMD	See STC #20	Follow CMS 64.9 Base		MAP	Y	01/01/2023	12/31/2027

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

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.

<b>Table 3: Demonstration Years</b>		
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.<sup>2</sup>

- 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

---

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

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:
- i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,
  - ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

## 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 Services	PC	Both	4.3%	\$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.

<b>Table 6: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations</b>		
<b>Demonstration Year</b>	<b>Cumulative Target Definition</b>	<b>Percentage</b>
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:
- 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.
  - 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

<b>Table 7: Schedule of Deliverables for the Demonstration Period</b>		
<b>Date</b>	<b>Deliverable</b>	<b>STC</b>
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 quarter, except 4 <sup>th</sup> quarter.	Quarterly Monitoring Reports, including implementation updates	STC 28
	Quarterly Expenditure Reports	STC 28(c)
Annual Deliverables - Due 90 calendar days after end of each 4 <sup>th</sup> quarter	Annual Monitoring Reports	STC 28

## ATTACHMENT A

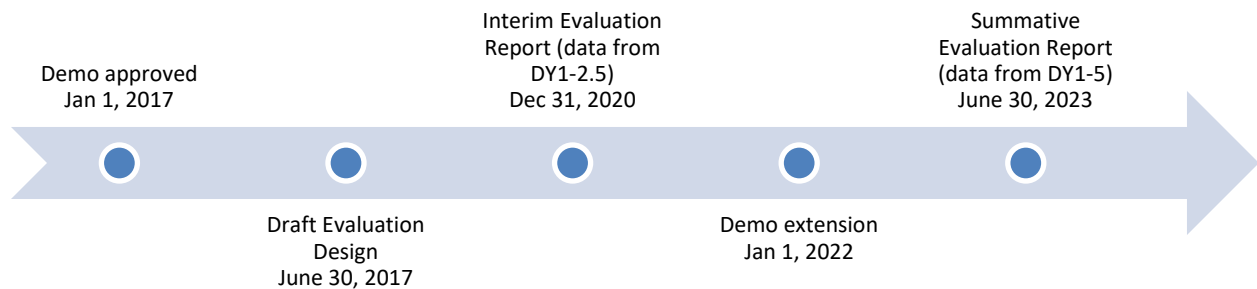
### Preparing the Evaluation Design

#### 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-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with 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-in-differences 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**

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

**D. Methodological Limitations** – This section provides 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**

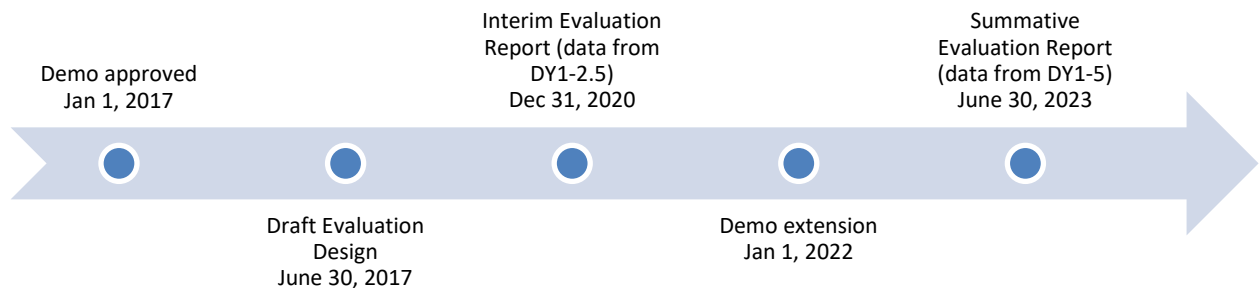
### **Preparing the Interim and Summative Evaluation Reports**

#### **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-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>. If the state needs technical assistance using this outline or developing the evaluation 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

**ATTACHMENT C**  
**Reserved for SUD Implementation Plan and Health IT Plan**

**ATTACHMENT D**  
**Reserved for SUD Monitoring Protocol**

**ATTACHMENT E**  
**Evaluation Design**

**Nevada's Section 1115 Demonstration**

***Treatment of Opioid Use Disorders (OUDs) and Substance Use Disorders (SUDs) Transformation Project***

**(Project Number: 11-W-00409/9)**



*State of Nevada*  
*Division of Health Care Financing & Policy*  
*Department of Health and Human Services*

***Revised Final – May 31, 2024***

**Stacie Weeks, JD MPH**  
*Administrator*  
*Division of Health Care Financing and Policy*

**Joe Lombardo**  
*Governor*  
*State of Nevada*

**Richard Whitley, MS**  
*Director*  
*Department of Health and Human Services*

## Table of Contents

<u>SECTION A: GENERAL BACKGROUND INFORMATION</u> .....	55
<u>Demonstration Information</u> .....	55
<u>Demonstration Goals</u> .....	55
<u>Brief Description and History of Implementation</u> .....	60
<u>Population Groups Impacted</u> .....	61
<u>SECTION B: EVALUATION QUESTIONS AND HYPOTHESES</u> .....	62
<u>Driver Diagram</u> .....	62
<u>Evaluation Questions and Hypotheses and Measures</u> .....	67
<u>SECTION C: METHODOLOGY</u> .....	76
<u>Evaluation Design</u> .....	76
<u>Target Population and Comparison Groups</u> .....	76
<u>Evaluation Period</u> .....	77
<u>Evaluation Measures</u> .....	77
<u>Data Sources</u> .....	77
<u>Analytic Methods</u> .....	78
<u>SECTION D: METHODOLOGICAL LIMITATIONS</u> .....	80
<u>Attachment 1 – Independent Evaluator</u> .....	82
<u>Attachment 2 – Evaluation Budget, Timeline and Milestones</u> .....	83



## SECTION A: GENERAL BACKGROUND INFORMATION

### Demonstration Information

The purpose of the Nevada Medicaid Section 1115 Substance Use Disorder and Behavioral Health Program (SUD-BHP) Demonstration is to expand statewide access to comprehensive behavioral health services to Medicaid and CHIP eligible Nevadans with OUD/SUD. The Nevada Department of Health and Social Services (DHSS) has received authority for a Medicaid Section 1115 Demonstration Project from the Centers for Medicare & Medicaid Services (CMS) on December 29, 2022 to implement a new section 1115 demonstration program to offer a full continuum of SUD treatment services consistent with the American Society of Addiction Medicine (ASAM) criteria; including authority to provide treatment and withdrawal management services for SUD to program beneficiaries who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

### Demonstration Goals

Under the demonstration, Nevada will implement a series of proposed strategies and evidence-based interventions aimed at more effectively addressing the needs of each of the selected target populations. A major consideration in designing the demonstration program is to recognize the anticipated benefits, such as reduced use of acute, and costly services, that should result by conducting universal screenings; intervening early, when symptoms are first identified; utilizing sub-acute, community-based step-up/step-down clinical services as alternatives to residential and inpatient services; and developing community-based supports to maintain recovery, health, and wellness. Overall, increasing efforts early on, regarding prevention and early intervention, as opposed to greater emphasis on acute, residential, crisis, emergency care, should lead not only to cost savings, but also to improved care and outcomes for Nevadans. New Medicaid-covered services under the demonstration will establish a robust continuum of care designed to anticipate and address the range of behavioral health needs of the target populations. Specifically, the demonstration provides 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 provided through the demonstration, Medicaid and CHIP beneficiaries will be able to receive the appropriate treatment needed when they are determined to need ASAM residential/inpatient level of care within an IMD. With this new demonstration authority, 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.

The States' 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.

Nevada seeks to achieve these goals through demonstration activities aimed at improving access to evidence-based SUD treatment (including Medication Assisted Treatment (MAT), improving the quality of available SUD treatment, increasing treatment adherence and retention, and improved access to high quality of care across the continuum of SUD and other care services. In 2014, Nevada adopted an integrated behavioral health clinic model to provide mental health and SUD treatment using ASAM criteria as the framework for levels of care and intensity of needs determination for placement. 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. Through these efforts, the state offered the state plan benefits to Medicaid and CHIP eligibles as found in **Exhibit 1**.

**Exhibit 1: Nevada Medicaid and CHIP State Plan SUD Benefits by ASAM Level of Care**

ASAM Level of Care	State Plan 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
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

However, these efforts have not gone far enough, and Nevada still experiences significant challenges in expanding access and quality of community-based residential treatment and/or withdrawal management services. Through the SUD demonstration, Nevada will be able to supplement the above listed Medicaid and CHIP State Plan SUD state plan benefits with additional demonstration services that will permit the state to offer a full continuum of services consistent with the ASAM criteria. Additionally, Nevada will continue to engage in improvement efforts as outlined in the CMS-approved SUD Implementation Plan for each of the CMS-required SUD program milestones to improve Medicaid beneficiaries' access to high quality, evidence-based treatment services for addiction to opioids or other substances, ranging from acute withdrawal management to on-going chronic care for these conditions,

in cost-effective treatment settings while also improving care coordination and care for co-morbid physical and mental health conditions. A summary of the State's planned activities to this aim as articulated in the CMS-approved SUD Implementation Plan is found in **Exhibit 2**.

**Exhibit 2: Nevada Planned Activities in Support of CMS-required Program Milestones**

Milestone Criteria	State Planned Actions
<b>Milestone #1: Access to Critical Levels of Care for OUD and Other SUDs</b>	
Coverage of Outpatient Services	Review all substance use treatment service definitions and staff qualifications to ensure alignment with ASAM. (Timeline 12-18 months)
	Amend State Plan to define substance use treatment services aligned with ASAM levels of care. (Timeline 12-18 months)
	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. (Timeline 12- 18 months)
Coverage of Intensive Outpatient Services	Continue to enroll Intensive Outpatient and Partial Hospitalization providers to expand this level of care across the state. (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)	Remove policy requirements from MSM for providers to have a Data 2000 or X-waiver for prescribing buprenorphine. (Timeframe: 6-12 months)
	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)
Coverage of Intensive levels of care in residential and inpatient settings	Provide enrollment opportunity for IMDs under the 1115 demonstration and training support for residential treatment providers. (Timeline 6-12 months)
	Amending the State Plan to define substance use treatment services in alignment with intensive levels of care in residential and inpatient settings that meet ASAM criteria. (Timeline 12-24 months)
	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)
	Define reimbursement for residential levels of care as well as evaluate and collaborate with the Nevada Division of Public and Behavioral Health (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	Amend the State Plan 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)
	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

Milestone Criteria	State Planned Actions
<b>Milestone #1: Access to Critical Levels of Care for OUD and Other SUDs</b>	
	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)

Milestone Criteria	State Planned Actions
<b>Milestone #2: Use of Evidence-based, SUD-specific Patient Placement Criteria</b>	
Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines.	Amend the 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.	Leverage the SUPPORT Act post planning demonstration grant activities to support growth in increased provider capacity at every ASAM level of care. (Timeline: 6 – 18 months)
	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.	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, non-covered services, etc. (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.	Utilize a QIO-like contracted vendor that currently uses ASAM criteria and MSM policy to determine medical necessity for placement in residential treatment IMD settings. (Timeframe: 6-12 months)

Milestone Criteria	State Planned Actions
<b>Milestone #3: Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities</b>	
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance in alignment with program standards in the ASAM Criteria or other nationally recognized, SUD-specific program Standards.	MMIS will incorporate system enhancements to enroll substance use treatment providers that are licensed or certified as individual Medicaid providers and will be able to link to a substance use treatment provider agency (Timeline: 6 -12 months)

Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards	The State already implemented, and no further action required.
Implementation of requirement that residential treatment facilities offer MAT onsite or facilitate access off site.	Update Medicaid Service Manual policy to include requirement of offering all FDA-approved MAT on-site or facilitate access to off-site MAT. (Timeline: 12-18 months)

Milestone Criteria	State Planned Actions
<b>Milestone #4: Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD</b>	
Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT.	Integrate intensive crisis stabilization services within the State Plan and MSM to support individuals experiencing a substance use disorder crisis in need of stabilization. With this new provider type and specialty, the Medicaid enrollment checklists will include language to participate in statewide crisis response system. Once NBHCCCH is effective, these providers can be integrated into the response system for individuals experiencing a mental health or substance use crisis. (Timeframe: 6-12 months)
	Update MCO vendor contracts to include time and distance standard ratios for providers delivering services under this demonstration. (Timeline: 6-12 months)
	Utilize data gathered 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 demonstration program)
	Further develop and refine the SUD Data Book developed through the DHHS's Office of Analytics. (Timeline: 12-24 months)

Milestone Criteria	State Planned Actions
<b>Milestone #5: Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD</b>	
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	The State already implemented, and no further action required.
Expanded coverage of, and access to, naloxone for overdose reversal	This milestone is met, as statewide access to naloxone is already in place. Nevada will continue work across DHHS to support access, training, and awareness of coverage through increased provider communication through web announcements and monthly SUD treatment provider engagement meetings. (Timeline: 6 months - Demonstration Period)
	Nevada will further increase access to naloxone by adding pharmacists as an approved prescriber under a collaborative practice agreement (CPA) with other licensed prescribing healthcare providers like physicians, 'standing orders' issued by the state. (Timeline: 24-36 months)
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	Evaluate dashboard capabilities (Timeframe: Throughout Demonstration Period)

Milestone Criteria	State Planned Actions
<b>Milestone #6: Improved Care Coordination and Transitions between Levels of Care</b>	
Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities	Redefine discharge criteria specific for residential treatment providers and develop transition of care standards across DPBH Division Criteria and Medicaid policy to include but not limited to, support with setting follow up appointments with community based providers prior to discharge, referral options provided to individual at time of discharge, ASAM score at time of discharge, statement of progress made during treatment within new Medicaid Service Manual policy for substance treatment providers and Division Criteria (Timeline: 12 -24 months)
	If the state authorizes 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)
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	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)
	Effective July 1, 2024, integrate the collaborative care model within state plan and MSM. (Timeline: 24-36 months)

## Brief Description and History of Implementation

Per Mental Health America ([MHA](#))<sup>3</sup>, in 2023, Nevada ranked 42nd nationally for adults that have a higher prevalence of mental illness and a lower rate of access to care. This measure includes adults with substance use disorder (SUD) within the past year. In 2023, MHA reported 360,000 adult Nevadans with a SUD within the past year; representing 14.9% of the population in Nevada and slightly lower than the national average of 15.3%. Related to the SUD statistics, Nevada currently ranks 24th, with 21.3% or 508,000 people experiencing mental illness, including SUD as a comorbidity. Nevada, like so many other

<sup>3</sup> [State of Mental Health in America 2023 | Mental Health America \(mhanational.org\)](#)

states, has been severely impacted by the opioid epidemic declared by the U.S. Department of Health and Human Services in 2017.

As reported in the CMS-approved Implementation Plan, 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 ASAM criteria as the framework for levels of care and intensity of needs determination for placement. 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.

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 sought and received approval from CMS to implement a new section 1115 demonstration program to offer a full continuum of SUD treatment services consistent with the ASAM criteria; including authority to provide treatment and withdrawal management services for SUD to program beneficiaries who are short-term residents in facilities that meet the definition of an IMD.

### Population Groups Impacted

The demonstration will target all mandatory and optional eligibility groups approved for full benefit coverage under the Nevada Medicaid and CHIP State Plans, who need OUD/SUD treatment services. Nevada Medicaid and CHIP State Plan eligibility is as follows:

- All Medicaid beneficiaries with full scope state plan coverage with income at or below 138% of the federal poverty level (FPL).
- All CHIP (including separate title XXI) beneficiaries with income at the qualifying eligibility level as outlined below.

Eligible CHIP Population	Eligibility Income Level
Medicaid Expansion CHIP Children ages 0-5	Up to 160% of the FPL
Medicaid Expansion CHIP Children ages 6-18	Up to 133% of the FPL
Separate CHIP for Uninsured Children ages 0-18	Up to 200% of the FPL

\*5% FPL disregard not reflected in above percentages.

The State expects to serve approximately 28,501 Medicaid beneficiaries and 3,850 CHIP beneficiaries over the 5-year duration of the demonstration.

## SECTION B: EVALUATION QUESTIONS AND HYPOTHESES

### Driver Diagram

The driver diagram depicts the relationship between the demonstration's goal/purpose/aim, identifying the primary drivers that contribute to realizing that purpose, and the secondary drivers that are necessary to achieve the primary drivers. The diagram found in **Exhibit 3** (beginning on the following page) was developed using the six CMS goals, Nevada's three additional goals and serves as an informative framework, recognizing the interrelationships between goals, primary drivers, and secondary drivers may at times be multidirectional. The primary drivers identified in the evaluation design include the following:

- Universally screen all Medicaid and CHIP recipients using SUD-specific, multi- dimensional evidenced based assessment tools aligned with ASAM that are used universally throughout the Nevada substance use treatment system of care.
  - Use the ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.
  - Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.
  - Improve SUD provider infrastructure and capacity utilizing industry- recognized standards for certification and ongoing accountability, leveraging work developed through both phases of the SUPPORT Act Planning and Post Planning Grants (with emphasis on rural providers, residential providers that offer MAT, but across the board).
  - Improve SUD workforce by carefully reviewing existing certification requirements and modifying as appropriate to align with Medicaid, CHIP, and industry- recognized credentialing standards.
  - Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.
  - Improve care coordination of services to support better care transition upon discharge.
-



**Exhibit 3: Driver Diagram for Nevada's Section Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration**

#	CMS Goals	Primary Drivers (Major themes through which Nevada may accomplish the CMS goals and three state specified additional goals)	Secondary Drivers (from Nevada's Implementation Plan, utilizing key milestones identified by CMS)
1	Increase rates of identification, initiation, and engagement in treatment for SUD	<ul style="list-style-type: none"> <li>• Universally screen all Medicaid and CHIP recipients using SUD-specific, multi- dimensional evidenced based assessment tools aligned with ASAM that are used universally throughout the Nevada substance use treatment system of care.</li> <li>• Use the ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.</li> <li>• Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> </ul>	<ul style="list-style-type: none"> <li>• Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>• Milestone #2: Use of Evidence-Based, SUD- Specific Patient Placement Criteria</li> <li>• Milestone #5: Implementation of Comprehensive Treatment &amp; Prevention Strategies to Address Opioids</li> <li>• Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>
2	Increase adherence to and retention in treatment	<ul style="list-style-type: none"> <li>• Use the ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.</li> <li>• Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> </ul>	<ul style="list-style-type: none"> <li>• Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>• Milestone #2: Use of Evidence-Based, SUD- Specific Patient Placement Criteria</li> <li>• Milestone #5: Implementation of Comprehensive Treatment &amp; Prevention Strategies to Address Opioids</li> <li>• Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>

**Exhibit 3: Driver Diagram for Nevada's Section Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration**

#	CMS Goals	Primary Drivers (Major themes through which Nevada may accomplish the CMS goals and three state specified additional goals)	Secondary Drivers (from Nevada's Implementation Plan, utilizing key milestones identified by CMS)
3	Reduce overdose deaths, particularly those due to opioids	<ul style="list-style-type: none"> <li>• Universally screen all Medicaid and CHIP recipients using SUD-specific, multi- dimensional evidenced based assessment tools aligned with ASAM that are used universally throughout the Nevada substance use treatment system of care.</li> <li>• Use the ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.</li> <li>• Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> <li>• Improve SUD provider infrastructure and capacity utilizing industry- recognized standards for certification and ongoing accountability, leveraging work developed through both phases of the SUPPORT Act Planning and Post Planning Grants (with emphasis on rural providers, residential providers that offer MAT, but across the board).</li> <li>• Improve SUD workforce by carefully reviewing existing certification requirements and modifying as appropriate to align with Medicaid, CHIP, and industry-recognized credentialing standards.</li> </ul>	<ul style="list-style-type: none"> <li>• Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>• Milestone #2: Use of Evidence-Based, SUD-Specific Patient Placement Criteria</li> <li>• Milestone #3: Use of Nationally Recognized SUD-specific Program Standards for Residential Treatment Facility Provider Qualifications</li> <li>• Milestone #4: Sufficient Provider Capacity at Critical Levels of Care</li> <li>• Milestone #5: Implementation of Comprehensive Treatment &amp; Prevention Strategies to Address Opioids</li> <li>• Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>

**Exhibit 3: Driver Diagram for Nevada's Section Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration**

#	CMS Goals	Primary Drivers (Major themes through which Nevada may accomplish the CMS goals and three state specified additional goals)	Secondary Drivers (from Nevada's Implementation Plan, utilizing key milestones identified by CMS)
4	Reduce utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	<ul style="list-style-type: none"> <li>Continue to use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.</li> <li>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> <li>Improve SUD provider infrastructure and capacity utilizing industry- recognized standards for certification and ongoing accountability, leveraging work developed through both phases of the SUPPORT Act Planning and Post Planning Grants (with emphasis on rural providers, residential providers that offer MAT, but across the board).</li> </ul>	<ul style="list-style-type: none"> <li>Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>Milestone #2: Use of Evidence-Based, SUD-Specific Patient Placement Criteria</li> <li>Milestone #3: Use of Nationally Recognized SUD-specific Program Standards for Residential Treatment Facility Provider Qualifications</li> <li>Milestone #4: Sufficient Provider Capacity at Critical Levels of Care</li> <li>Milestone #5: Implementation of Comprehensive Treatment &amp; Prevention Strategies to Address Opioids</li> <li>Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>
5	Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	<ul style="list-style-type: none"> <li>Continue to use the ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.</li> <li>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> <li>Improve SUD provider infrastructure and capacity utilizing industry- recognized standards for certification and ongoing accountability, leveraging work developed through both phases of the SUPPORT Act Planning and Post Planning Grants (with emphasis on rural providers, residential providers that offer MAT, but across the board).</li> </ul>	<ul style="list-style-type: none"> <li>Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>Milestone #2: Use of Evidence-Based, SUD-Specific Patient Placement Criteria</li> <li>Milestone #3: Use of Nationally Recognized SUD-specific Program Standards for Residential Treatment Facility Provider Qualifications</li> <li>Milestone #4: Sufficient Provider Capacity at Critical Levels of Care</li> <li>Milestone #5: Implementation of Comprehensive Treatment &amp; Prevention Strategies to Address Opioids</li> <li>Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>

**Exhibit 3: Driver Diagram for Nevada's Section Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration**

#	CMS Goals	Primary Drivers (Major themes through which Nevada may accomplish the CMS goals and three state specified additional goals)	Secondary Drivers (from Nevada's Implementation Plan, utilizing key milestones identified by CMS)
6	Improve access to care for physical health conditions among beneficiaries with SUD	<ul style="list-style-type: none"> <li>• Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</li> <li>• Improve SUD provider infrastructure and capacity utilizing industry- recognized standards for certification and ongoing accountability, leveraging work developed through both phases of the SUPPORT Act Planning and Post Planning Grants (with emphasis on rural providers, residential providers that offer MAT, but across the board).</li> <li>• Improve SUD workforce by carefully reviewing existing certification requirements and modifying as appropriate to align with Medicaid, CHIP, and industry-recognized credentialing standards.</li> <li>• Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</li> <li>• Improve care coordination of services to support better care transition upon discharge.</li> </ul>	<ul style="list-style-type: none"> <li>• Milestone #1: Access to Critical Levels of Care for SUD Treatment</li> <li>• Milestone #2: Use of Evidence-Based, SUD-Specific Patient Placement Criteria</li> <li>• Milestone #3: Use of Nationally Recognized SUD-specific Program Standards for Residential Treatment Facility Provider Qualifications</li> <li>• Milestone #4: Sufficient Provider Capacity at Critical Levels of Care</li> <li>• Milestone #6: Improved Care Coordination and Transitions Between Levels of Care</li> </ul>

## Evaluation Questions and Hypotheses and Measures

The evaluation questions and hypotheses found in **Exhibit 4** were derived from and organized based on the Driver Diagram. In this section, the demonstration's core evaluation questions, hypotheses and recommended measures are presented in **Exhibit 5**. Nevada's Evaluation Design includes both outcome and process measures. Where possible, Medicaid specific metrics sets were given preference over other national sets and data, and SUD core monitoring metrics were leveraged in the evaluation as appropriate. To increase the robustness of the design, mixed methods were utilized, including both quantitative and qualitative approaches, as well as both internal pre-post comparisons and, as appropriate, comparisons between demonstration populations and state and national data if available.

### Exhibit 4: Evaluation Questions and Hypotheses Developed for the Evaluation of Nevada's SUD Demonstration

Evaluation Questions (Q)		Hypotheses (H)	
Q1	Does the demonstration increase access to and utilization of substance use disorder treatment services?	H1	The demonstration will increase the number of beneficiaries who are referred to and engage in treatment for substance use disorders.
		H2	The demonstration will decrease utilization of emergency department, inpatient, or institutional settings within the beneficiary population.
		H3	The demonstration will increase the percentage of beneficiaries who adhere to treatment for substance use disorders.
Q2	Do enrollees receiving substance use disorder services experience improved health outcomes?	H4	The demonstration will increase the percentage of beneficiaries with substance use disorder who experience care for comorbid conditions.
		H5	The demonstration will decrease the rate of drug overdose and overdose deaths due to opioids.
Q3	Does the demonstration maintain or reduce the total cost of Medicaid and CHIP for Nevada and the Federal Government?	H6	The demonstration will maintain or reduce Nevada's Medicaid and CHIP SUD and total cost of care.

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
<b>Evaluation Question #1: Does the demonstration increase access to and utilization of substance use disorder treatment services?</b>						
<b>Evaluation Hypothesis #1: The demonstration will increase the number of beneficiaries who are referred to and engage in treatment for substance use disorders.</b>						
Number of beneficiaries screened for symptoms of SUD using industry recognized, evidence- based screening instruments (Annual)	State-identified	Number of beneficiaries screened for symptoms of SUD using industry recognized, evidence- based screening instruments	--	Claims Data	Descriptive statistics; Pre/post	Universally screen all Medicaid and CHIP recipients using SUD-specific, multi-dimensional evidenced based assessment tools.  Use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.
Number of Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis (CMS SUD Metric #2) (Month)	CMS-constructed	Number of unique beneficiaries who receive MAT or have qualifying facility, provider, or pharmacy claims with a SUD diagnosis and a SUD-related treatment service, but not in the three months before	--	Claims Data	Descriptive statistics; ITS Regression	Universally screen all Medicaid and CHIP recipients using SUD-specific, multi-dimensional evidenced based assessment tools.  Use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.
Number of beneficiaries with a claim for inpatient/ residential treatment for SUD in an IMD during the measurement period (CMS SUD Metric #5) (Annual)	CMS-constructed	Number of unique beneficiaries who received inpatient/ residential treatment in an IMD for a SUD diagnosis	--	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Universally screen all Medicaid and CHIP recipients using SUD-specific, multi-dimensional evidenced based assessment tools.  Use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (NQF 0004) (CMS SUD Metric #15) (Annual)	NCQA	<b>Initiation:</b> Number of patients who began initiation of treatment within 14 days of the index episode start date  <b>Engagement:</b> Initiation of treatment and two or more defined SUD visits within 34 days of the initiation visit	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 ½ months of the measurement year  Same as above	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.  Use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.

**Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration**

Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
Follow up after discharge from emergency department visits for SUD, and specifically for OUD, by setting (NQF 2605), (FUA-AD), (CMS SUD Metric #17(1)) (Annual)	NCQA	Members who had a follow-up visit to an ED visit with a SUD indicator within 30 days of discharge within the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months.	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Improve care coordination of services to support better care transition upon discharge.
Number of providers who were enrolled in Medicaid and CHIP, qualified to deliver SUD services during the measurement period (Annual)	CMS-constructed (CMS SUD Metric #13)	Total number of eligible SUD providers enrolled and qualified to deliver SUD services	--	Provider enrollment records	Descriptive statistics; Pre/post	Improve SUD provider infrastructure and capacity.
Number of providers who were enrolled in Medicaid and CHIP, qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT (Annual)	CMS-constructed (CMS SUD Metric #14)	The total number of SUD providers who meet the standards to provide buprenorphine or methadone as part of MAT	--	Provider enrollment records	Descriptive statistics; Pre/post	Improve SUD provider infrastructure and capacity.
Providers' reported experience, including barriers before, during, and shortly following expansion of SUD services	State-constructed	--	--	Provider key informant interviews	Qualitative synthesis & thematic analysis	Improve SUD workforce.
Nevada tribal entities reported changes in quality of care and access to care following expansion of SUD services	State-constructed	--	--	Provider key informant interviews	Qualitative synthesis & thematic analysis	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
<b>Evaluation Question #1: Does the demonstration increase access to and utilization of substance use disorder treatment services by increasing access to treatment services?</b>						
<b>Evaluation Hypothesis #2: The demonstration will decrease utilization of emergency department, inpatient, or institutional settings within the beneficiary population.</b>						
Emergency department utilization for SUD per 1,000 Medicaid and CHIP beneficiaries (CMS SUD Metric #23) (Month)	CMS-constructed	The number of ED visits for SUD during the measurement period	Number of beneficiaries in the population of interest	Claims Data	Descriptive statistics; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.  Improve SUD provider infrastructure and capacity.
Inpatient admissions for SUD per 1,000 Medicaid and CHIP beneficiaries (CMS SUD Metric #24) (Month)	CMS-constructed	The number of inpatient discharges related to a SUD stay during the measurement period	Number of beneficiaries in the population of interest	Claims Data	Descriptive statistics; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.  Improve SUD provider infrastructure and capacity.
Average length of stay in IMDs (CMS SUD Metric #36) (Annual)	CMS-constructed	The total number of days in an IMD for inpatient/residential discharges for SUD	The total number of discharges from an IMD for beneficiaries with an inpatient or residential treatment stay for SUD. Limit to IMDs receiving FFP	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.  Improve SUD provider infrastructure and capacity.
30-day readmission rate to inpatient facilities following hospitalization for an SUD related diagnosis, by setting (CMS SUD Metric #25) (Annual)	CMS-constructed	The count of 30-day readmissions: at least one acute readmission for any diagnosis within 30 days of the Index Discharge Date	The count of Index Hospital Stays	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Use ASAM Criteria to match individuals with SUD with the services and tools necessary for recovery.  Improve care coordination of services to support better care transition upon discharge.



Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
<b>Evaluation Question #1: Does the demonstration increase access to and utilization of substance use disorder treatment services by increasing access to treatment services?</b>						
<b>Evaluation Hypothesis #3: The demonstration will increase the percentage of beneficiaries who adhere to treatment for substance use disorders.</b>						
Number of beneficiaries with a SUD diagnosis including those with OUD who used services in the last month or year, by service or benefit type (CMS SUD Metric #3) (Month)	CMS-constructed	The number of unique beneficiaries who receive MAT or have qualifying facility, provider, or pharmacy claims with a SUD diagnosis and a SUD-related treatment service during the measurement period and/or in the 11 months before	--	Claims Data	Descriptive statistics; ITS Regression	<p>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</p> <p>Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</p>
Time to treatment, by service type (National Behavioral Health Quality Framework [NBHQF] Goal 1) (Annual)	NBHQF	The total number of days from IESD, i.e., within 14 days.	The total number of claims for initiation within 14 days of the diagnosis among demonstration beneficiaries	Claims Data	Descriptive; Pre/post	<p>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</p> <p>Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</p>
Continuity of pharmacotherapy for opioid use disorder (NQF 3175) (CMS SUD Metric #22) (Annual)	USC	Number of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous pharmacotherapy treatment	Number of adults 18 years of age and older with an OUD	Claims Data	Descriptive statistics; Pre/post; ITS Regression	<p>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</p> <p>Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</p>

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
<b>Evaluation Question #2: Do enrollees receiving substance use disorder services experience improved health outcomes?</b>						
<b>Evaluation Hypothesis #4: The demonstration will increase the percentage of beneficiaries with substance use disorder who experience care for comorbid conditions.</b>						
Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD (CMS SUD Metric # 32) (Annual)	NCQA	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Number of beneficiaries with a SUD diagnosis	Claims Data	Pre/post	<p>Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.</p> <p>Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</p> <p>Improve care coordination of services to support better care transition upon discharge.</p>
Screening for chronic conditions relevant to state Medicaid and CHIP population (Annual)	State-constructed	The number of unique demonstration beneficiaries screened for a chronic condition	The total number of unique demonstration beneficiaries	Claims Data	Pre/post	<p>Universally screen all Medicaid and CHIP recipients using SUD-specific, multi-dimensional evidenced based assessment tools.</p> <p>Increase access to medical and community-based services for pregnant and parenting individuals in an IMD.</p> <p>Improve care coordination of services to support better care transition upon discharge.</p>

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
Screening for co- morbidity of behavioral health and substance use disorders within the demonstration population compared to the total Medicaid and CHIP population (Annual)	State-constructed	<p><u>Rate Indicator 1</u>: Number of unique beneficiaries with a SUD diagnosis screened for symptoms of BH</p> <p><u>Rate Indicator 2</u>: Number of unique beneficiaries with a BH diagnosis screened for symptoms of SUD</p>	<p><u>Rate Indicator 1</u>: Number of unique beneficiaries who receive MAT or have qualifying facility, provider, or pharmacy claims with a SUD diagnosis and a SUD-related treatment service in the measurement period and/or in the 11 months before</p> <p><u>Rate Indicator 2</u>: Number of unique beneficiaries enrolled in the measurement period diagnosed with a BH disorder</p>	Claims Data	Pre/post	Improve SUD provider infrastructure and capacity.

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
Evaluation Question #2: Do enrollees receiving substance use disorder services experience improved health outcomes?						
Evaluation Hypothesis #5: The demonstration will decrease the rate of drug overdose and overdose deaths due to opioids.						
Rate of overdose deaths, specifically overdose deaths due to any opioid (CMS SUD Metric #27) (Annual)	CMS-constructed	The number of overdose deaths among beneficiaries in the population of interest	Number of beneficiaries in the population of interest	Vital Statistics  CDC – NCHS	Descriptive Statistics; Pre/post	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.
Use of Opioids at High Dosage in Persons Without Cancer (NQF 2940) (CMS SUD Metric #18) (Annual)	NCQA	The number beneficiaries aged 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more	All Medicaid beneficiaries within the eligible population defined in the measure steward's specifications	Claims Data	Pre/post	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.

Exhibit 5: Evaluation Questions, Hypotheses and Measures for Nevada's Treatment of Opioid Use Disorders (OUD) and SUD Transformation Demonstration						
Measure Description	Measure Steward	Numerator	Denominator	Data Source	Analytic Approach	Primary Driver
<b>Evaluation Question #3: Does the demonstration maintain or reduce the total cost of Medicaid and CHIP for Nevada and the Federal Government?</b>						
<b>Evaluation Hypothesis #6: The demonstration will maintain or reduce Nevada's Medicaid and CHIP SUD and total cost of care.</b>						
Per-member-per-month (PMPM) cost for SUD treatment (Annual)	CMS-constructed	Total expenditures related to the diagnosis and treatment of SUD incurred under the demonstration by DY (split out by SUD and non-SUD costs)	Total beneficiary eligible member months for SUD treatment during the demonstration by DY	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.
Total PMPM costs for Beneficiaries with SUD (Annual)	CMS-constructed	Total expenditures related to treatment cost drivers for Beneficiaries with SUD (split out by type of care)	Total beneficiary eligible member months for SUD treatment during the demonstration by DY	Claims Data	Descriptive statistics; Pre/post; ITS Regression	Increase SUD treatment options for Medicaid and CHIP recipients, particularly parenting individuals, and their children in transitional and residential IMD settings.

## SECTION C: METHODOLOGY

### Evaluation Design

Across the three evaluation questions and six hypotheses, the evaluation will employ mixed methods to evaluate the demonstration's impact on improving access to SUD treatment services, improving health outcomes, and maintaining or reducing the total cost of Medicaid and CHIP for Nevada and the Federal Government. Quantitative analysis will utilize descriptive statistics, trends over time, key informant interviews, and interrupted time-series (ITS) analysis of pre- and post-demonstration periods. For all measures, the unit of analysis is number of beneficiaries submitting a claim for the service being evaluated (e.g., ED, inpatient, outpatient, and IMD services). For cost measures, the unit of analysis is dollars is either PMPM or PBPM. All modeling approaches will include covariates to control for demographic characteristics, including age, race, gender, and/or behavioral or physical health comorbidities.

Descriptive statistical methods will be used to generate summary tables of population size and characteristics, and outcomes for demonstration beneficiaries. Data will be analyzed using standard tests such as rates, proportions, and frequencies to develop a quantitative picture of the demonstration population to identify characteristics and trends and inform ITS analyses.

ITS regression of claims and administrative data will be used to compare the trend in each outcome during the 24-month pre-demonstration period to the period from demonstration launch until the end of the demonstration. Unlike a simple pre-post design, ITS can analyze trends over time in outcome variables. This will allow for greater sensitivity to changes in outcomes that may have been increasing or decreasing at baseline. Additionally, stratification by region, demographics, and other populations of interest will be used to investigate whether disparities exist and if so whether they have been reduced. Subgroup analysis will be performed for gender, race/ethnicity, parents, pregnant women, and presence of a co-occurring mental health diagnosis. ITS will be used when a comparison group is not feasible.

The methodology for conducting analyses to assess changes in costs to the Medicaid and CHIP programs will be a hybrid ITS/pre-post testing approach for estimating different linear effects of the pre-demonstration and post-demonstration periods. Demonstration data will include all beneficiaries who were enrolled during the quarter, regardless of duration. Two years of claims data prior to the demonstration period will be used to identify individuals to be included in the pre-demonstration period, to identify beneficiaries more accurately with an SUD condition.

### Target Population and Comparison Groups

The population studied will be adult Medicaid and CHIP beneficiaries up to age 64 who have an SUD diagnosis. Because all Medicaid and CHIP beneficiaries with full scope State Plan coverage are eligible for services under the demonstration, no true comparison population is available for this demonstration; thereby, necessitating the ITS approach utilizing pre- and post- demonstration trends as described above. For additional context, comparisons of statewide outcomes to national trends and other states will be made, but are not considered a true counterfactual, as other states are different at baseline, and many also are implementing similar programs.

## Evaluation Period

The evaluation period will include 24 months prior to the January 1, 2023, effective date of the demonstration as a baseline, as found in **Exhibit 6**. The evaluation period will end at the close of the initial 5-year demonstration period, i.e., December 31, 2027, resulting in a 60-month post-intervention period.

**Exhibit 6: Evaluation Period**

Evaluation Period	Timeframe	Duration
Pre-Intervention	January 1, 2021 – December 31, 2022	24 months
Post Intervention	January 1, 2023 – December 31, 2027	60 months

## Evaluation Measures

The measures that will be utilized in the evaluation, as outlined in **Exhibit 5**, are drawn from CMS-required measures for monitoring and evaluation and measurement data will be drawn from claims (either managed care or fee-for-service as applicable) for the specific SUD services listed. Capacity measures will be drawn from the state's provider enrollment database and from service claims reporting to determine numbers of Medicaid and CHIP enrolled facilities providing SUD services. Key informant interviews of providers will be used to investigate the demonstration's perceived impact on key demonstration goals such as improved quality of OUD/SUD treatment, impacted OUD/SUD treatment adherence, or the state's increased capacity for providing SUD treatment services during the demonstration through the provision of OUD/SUD treatment services in IMD facilities. Overdose deaths will be derived from CDC reports, as the state does not track this information in sufficient detail. This will not allow the identification of Medicaid or CHIP beneficiaries so the rate will be for the state rather than the demonstration target population.

## Data Sources

The data to evaluate performance in meeting the measures will be mostly derived from administrative data, Medicaid and CHIP claims/encounter data, member enrollment and eligibility data, provider enrollment data and will be reported to CMS as part of the approved SUD demonstration monitoring protocol. As indicated above, overdose mortality data will be obtained from the CDC/National Center for Health Statistics.

As indicated in the CMS-approved Implementation Plan, Nevada is developing a process to collect quality measures from OUD/SUD providers. The State will leverage its enhanced Medicaid Management Information System (MMIS) to ensure the state is able to capture data needed to calculate the required quality measures (e.g., all cause readmissions, identification of follow up care, initiation of substance use diagnosis and engagement in treatment).

Use of fee-for-service (FFS) claims, and managed care encounters will be limited to final, paid status claims/encounters. Interim transaction and voided records will be excluded from all evaluations because these types of records introduce a level of uncertainty (from matching adjustments and third-party liabilities to the index claims) that can impact reported rates and cost calculations.

Qualitative data will be gathered through document review and key informant interviews, conducted in accordance with the timelines and milestones as illustrated **Table B of Attachment 2**. Semi-structured key informant interviews will be conducted by phone or videoconference, with privacy protections in accordance with CMS guidelines. Interviews will be recorded and transcribed. Interview guides will be developed by the Independent Evaluator in collaboration with Nevada DHHS.

## Analytic Methods

### Descriptive statistics

The evaluation will use descriptive statistical methods to generate summary tables of population size and characteristics, outcomes for the pre- and post- demonstration periods, and distribution of outcomes by demographic characteristics and relevant subgroupings. Data will be analyzed using standard tests as rates, proportions, frequencies, and measures of central tendency (e.g., mean, median, mode). These tables will be used to develop a quantitative picture of the population, to describe raw trends, and to identify characteristics that will be included as covariates in regression modeling.

### Pre/Post Testing

For measures and time periods for which there is no contemporaneous comparison group, and which have too few observations to support an interrupted time series analysis, average rates during the pre-demonstration period will be compared against average rates during the demonstration period using a Chi-square test, t-test, or other statistical analysis given the data. Specifically, comparisons will be made using this model:  $Y = \beta_0 + \beta_1 * post$  where Y is the rate of the outcome being measured each year,  $\beta_0$  captures the average rate in the baseline years, and the coefficient  $\beta_1$  for the dummy variable, post, representing the evaluation years, captures the change in average outcome between the baseline and evaluation time periods. Binomial logistic regression will be utilized to evaluate measures that are binary outcomes or presented as rates, and Poisson regression and negative binomial regression will be utilized to evaluate measures that have count outcomes.

### ITS regression modeling

When a suitable comparison group cannot be found and data can be collected at multiple points in time before and after the implementation of the program, an ITS methodology can be used. This analysis is quasi-experimental in design and will compare a trend in outcomes between the baseline period and the evaluation period for those who were subject to the program.

In ITS, the measurements taken before a demonstration was initiated are used to predict the outcome if the demonstration did not occur. The measurements collected after the demonstration are then compared to the predicted outcome to evaluate the impact the demonstration had on the outcome.

The evaluation will use ITS analysis to test for different linear effects in the pre-demonstration and post-demonstration periods. An example ITS function for outcome C is found in **Exhibit 7** on the following page.



**Exhibit 7: Interrupted Time Series Function for Outcome C – Illustrative Only**

Equation	
$C = \beta_0 + \beta_1 * TIME + \beta_2 * POST + \beta_3 * TIME * POST + \beta_i * COVAR + \varepsilon$	
Variable	Description
C	Outcome of interest for the time period
TIME	A count variable that starts with the first quarter pre-demonstration period data and ends with the last quarter of post-demonstration period data as found in Exhibit
POST	An indicator variable that equals 1 if the month occurred on or after demonstration start date.
COVAR	A set of covariates or observed confounding variables that may account for the differences between the intervention and comparison groups. For ITS analyses utilizing aggregate-level data, confounding variables will take the form of average values in the population, such as average age, average risk score, or percent female. For analysis utilizing individual-level data, control variables may include age, sex, race/ethnicity, county of residence, or duration of Medicaid enrollment.

The marginal effect and standard error for each term will be derived and reported. The average marginal effect of the interaction term ( $\beta_3 * TIME * POST$ ) represents the apparent difference between the pre- and post-demonstration periods.

Assuming measurements taken after the implementation of the demonstration would have been equal to the expectation predicted from the measurements taken before the demonstration in the absence of the intervention, any changes in the observed rates after implementation can be attributed to the program. However, as the ITS approach relies on a pre- and post-period, it is unable to differentiate between mechanisms that may have impacted observed changes; it is possible that external events could have occurred simultaneously with the demonstration and influenced the outcomes of interest. The independent evaluator will rely on best practices to mitigate the potentially confounding effect of simultaneously occurring confounding events such as the COVID-19 PHE as well as post-pandemic Medicaid “unwinding” by including the use of dummy variables for each time-period.

Furthermore, the Independent Evaluator will consider several sensitivity analyses to test the robustness of the main model results. For example, as the demonstration overlaps with the COVID-19 PHE as well as post-pandemic Medicaid “unwinding”, the Independent Evaluator will explore how the results change when excluding the years most impacted by these external events, or when estimating program effects separately by each year, rather than aggregating baseline years and evaluation years. A similar approach will be taken to account for the “unwinding” period in which the Medicaid continuous enrollment condition authorized ended and Nevada began redeterminations of eligibility.

**Qualitative analysis**

Qualitative analysis will be used for key informant interview transcripts. The goal is to identify perceptions of providers and administrators regarding the ways the demonstration did or did not achieve the program goals of increased access and improved outcomes. These perceptions will be used in combination with quantitative analysis to understand the impact of the demonstration and to identify challenges or potential course corrections for consideration by the state.

## SECTION D: METHODOLOGICAL LIMITATIONS

### Lack of a true comparison group

The target population for the demonstration is Nevada Medicaid and CHIP beneficiaries with OUD/SUD. A true comparison group for this demonstration would be an equivalent population of Medicaid or CHIP beneficiaries who are not offered the services provided through the demonstration. Because all beneficiaries with SUD are eligible for the demonstration, a true comparison group is not available. Nevada residents not eligible for Medicaid or CHIP, and residents of other states, are different in demographics and acuity, and will have access to a varied range of OUD/SUD services depending on their coverage or uninsured status. The most rigorous method available is the ITS regression (without control group), which will compare trends during the demonstration period to trends in the pre-intervention time period.

Note that due to the lack of a true comparison group, as part of the focused evaluation on covering OUD/SUD services for Medicaid and CHIP beneficiaries residing in IMDs, the independent evaluator will be responsible for the final measure selection and methodological approaches used to assess the 1115 program. The independent evaluator will continue to research for other comparison groups and comparable sources of data as well as assess the data approaches identified in the current design for measuring any changes in data overtime. Evaluation approaches may be slightly adjusted as necessary, including conducting additional key informant interviews, to address study questions with the best available data at the time of analysis.

### Sample size

The number of Nevada Medicaid and CHIP beneficiaries with OUD/SUD is estimated at an average of 6,470 unique individuals per year during the demonstration period (i.e., 770 CHIP beneficiaries and 5700 Medicaid beneficiaries). While the Independent Evaluator will assess sample size and the ability to conduct subgroup power calculations for key outcomes, the estimated number of beneficiaries with OUD/SUD may still not be large enough to conduct statistical analysis on all subgroups of interest.

### Identification of beneficiaries with OUD/SUD

Individuals will be included in the evaluation if they have an OUD/SUD diagnosis on a claim within the previous 12 months, based on CMS guidelines. Individuals with an SUD that has not resulted in a diagnosis or treatment will not be detected. Because some beneficiaries transition on and off Medicaid (or CHIP), a full 12 months of claims may not be available for all individuals, and there is a risk of missing individuals who have OUD/SUD due to incomplete data. This is likely to lead to an under identification of beneficiaries with an OUD/SUD but is preferable to excluding individuals who lack 12 months of continuous data. The failure to detect individuals who have SUD but are not identified due to incomplete data has a similar effect as failure to detect individuals with undiagnosed OUD/SUD. Incomplete identification will reduce the sample size, and could alter the characteristics of the population, which should be considered in interpretation of the results. While the Independent Evaluator will comment on any apparent and likely systematic differences between the identified and unidentified beneficiaries with SUD and the likely direction of the resulting bias in its estimates, it is possible that there will be some differences that are not detectable.

### **Data availability**

Overdose mortality was not tracked in Nevada during the pre-demonstration period, so no baseline is available in state data. CDC data will be used to measure fatal overdose to produce a rate for the state adult population overall, rather than rates for Medicaid or CHIP beneficiaries. As such, any benchmark comparisons to other states would be limited to aggregate rates for adults and will not be specific for Medicaid or CHIP beneficiaries.

### **COVID-19 PHE**

The COVID-19 PHE impacted the healthcare industry and the entire population on a global scale, requiring substantial changes to the processes used in the delivery of healthcare. In Nevada, as in other locations, healthcare utilization was significantly reduced in 2020 (and to a lesser extent in 2021) and could impact results observed in this evaluation. Given that the beginning of the pre-intervention period in January 2021 coincides with the relaxing of COVID-19 restrictions in Nevada, it is possible that any impact of the COVID-19 PHE on the evaluation may be minimal. To assess any potential impact of the COVID-19 PHE, the independent evaluator will compare monthly outcomes in 2021 to monthly outcomes in 2022 (when the impact of COVID-19 is expected to be lower). The independent evaluator will consider if any differences between the monthly outcomes in 2021 and monthly outcomes in 2022 are consistent with the expected impacts of COVID-19. If any of these differences are observed, adjustments will be made to account for its confounding impact. For measures analyzed using ITS, knowledge of state-specific case counts, shutdowns, and stay-at-home orders will be incorporated into the model to account for the effect of the COVID-19 PHE by controlling for affected quarters or years in the regression analyses. If the evaluator observes no potential impact of the COVID-19 PHE on 2021 monthly rates, no further adjustments for COVID will need to be implemented.

## Attachment 1 – Independent Evaluator

Nevada will follow its procurement guidelines to contract with an independent evaluator to assist the State in executing its SUD demonstration evaluation plan. The independent evaluator will also have the responsibility of conducting the mid-point assessment of the program's effectiveness and overall demonstration performance. The State will retain primary responsibility for monitoring the SUD demonstration, with support from the independent evaluator, as necessary. To mitigate any potential conflict of interest, the independent evaluator is responsible for:

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

As part of the focused IMD evaluation, the independent evaluator is responsible for final measure selection, identifying, if viable, other State systems that may serve as comparisons, conducting all data analysis, measuring change overtime, and developing sensitivity models as necessary to address study questions.

Consistent with the requirements of 42 CFR 431.420, Nevada will select and retain an independent evaluator to complete the independent evaluation of the demonstration required under 42 CFR 431.424. Accordingly, Nevada has selected Health Services Advisory Group, Inc. to serve as the Independent Evaluator to perform the independent evaluation of any federally approved section 1115 demonstration related to funding IMDs, specifically regarding the impact of the IMD expenditure authority on health care service delivery, quality, health outcomes, and cost effectiveness and any other federally required areas of evaluation.

## Attachment 2 – Evaluation Budget, Timeline and Milestones

**Table A: Estimated cost for evaluation activities over the demonstration period.**

Nevada Section 1115 Demonstration -Evaluation Budget Breakout							
Task	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	SFY2029	SFY2030
Project Management	\$ 2,247	\$ 6,515	\$ 34,786	\$ 33,850	\$ 3,463	\$ 52,669	\$ 17,259
MPA - Semi-Structured Interviews	\$ 5,617	\$ 9,773	\$ -	\$ -	\$ -	\$ -	\$ -
MPA - Quantitative Data Collection and Analysis	\$ 14,605	\$ 9,773	\$ 52,179	\$ -	\$ -	\$ -	\$ -
MPA Report Synthesis and Production	\$ -	\$ 9,773	\$ 52,179	\$ -	\$ -	\$ -	\$ -
Interim Report - Semi-Structured Interviews	\$ -	\$ 9,773	\$ 34,786	\$ 16,925	\$ -	\$ -	\$ -
Interim Report - Quantitative Data Collection and Analysis	\$ -	\$ 19,544	\$ 173,927	\$ 118,475	\$ -	\$ -	\$ -
Interim Report Synthesis and Production	\$ -	\$ -	\$ -	\$ 169,250	\$ -	\$ -	\$ -
Summative Report - Semi-Structured Interviews	\$ -	\$ -	\$ -	\$ -	\$ 6,926	\$ 52,669	\$ 8,630
Summative Report - Quantitative Data Collection and Analysis	\$ -	\$ -	\$ -	\$ -	\$ 17,313	\$ 316,016	\$ 43,148
Summative Report - Synthesis and Production	\$ -	\$ -	\$ -	\$ -	\$ 6,926	\$ 105,340	\$ 103,553
<b>TOTAL COSTS PER YEAR</b>	<b>\$ 22,469</b>	<b>\$ 65,151</b>	<b>\$ 347,857</b>	<b>\$ 338,500</b>	<b>\$ 34,628</b>	<b>\$ 526,694</b>	<b>\$ 172,590</b>
<b>TOTAL EVALUATION BUDGET</b>							<b>\$ 1,507,889</b>

**Table B: Expected timeline and milestones for completing evaluation**

Task	SFY2023				SFY2024				SFY2025				SFY2026				SFY2027				SFY2028				SFY2029				SFY2030
	CY2023				CY2024				CY2025				CY2026				CY2027				CY2028				CY2029				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
<b>Data Collection</b>																													
Obtain Nevada Medicaid claims/encounters																													
Obtain Nevada Medicaid member, provider, and eligibility/enrollment data																													
Obtain financial data																													
Integrate data; generate analytic dataset																													
<b>Conduct Analysis</b>																													
<i>Key Informant Interviews</i>																													
Develop protocols																													
Conduct interviews																													
Conduct analyses																													
<i>Measure Calculation and Analysis</i>																													
Prepare and calculate metrics																													
Conduct statistical testing and comparison																													
<b>Report Development</b>																													
Mid-Point Assessment																													
Final Mid-Point Assessment																													
Draft Interim Evaluation Report																													
Final Interim Evaluation Report																													
Draft Summative Evaluation																													
Final Summative Evaluation Report																													
Note: SFY: State fiscal year, CY: Calendar Year, Q: Quarter																													