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

State Demonstrations Group

June 18, 2025

Stacie Weeks
Medicaid Administrator
Division of Health Care Financing and Policy
4070 Silver Sage Drive
Carson City, NV 89701

Dear Administrator Weeks:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the state's Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC #11.3 "Draft Evaluation Design" of the state's section 1115 demonstration, "Whole Mouth Whole Body Connection for Adults with Diabetes" (Project Number 11-W-00428/9), effective through June 30, 2029. CMS has determined that the Evaluation Design, which was submitted on December 5, 2024 and revised on April 18 and June 9, 2025, 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 C. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state's Medicaid website within 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 Nevada on the Whole Mouth Whole Body Connection for Adults with Diabetes 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: 2025.06.18 10:55:57 -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-00428/9

TITLE: Whole Mouth Whole Body Connection for Adults with Diabetes

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 July 1, 2024 through June 30, 2029, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. **Expenditures for Limited Dental Services for Adults with Diabetes**. Expenditures for Nevada to provide limited dental treatment services to non-pregnant diabetic adults (ages 21 through 64 years of age), otherwise ineligible for federal financial participation (FFP) under Nevada Medicaid.

Title XIX Requirements Not Applicable to the Demonstration Eligible Populations

All requirements of the Medicaid program expressed in law, regulation, and policy statement not expressly identified as not applicable to these expenditure authorities shall apply to the demonstration for the remaining period of this demonstration.

1. **Statewideness and Uniformity** **Section 1902(a)(1)**

   To permit the state to operate the demonstration on a less than statewide basis to the geographic area served by participating federally qualified health centers (FQHCs) and participating Tribal Health Centers.

2. **Freedom of Choice** **Section 1902(a)(23)**

   To permit the state to restrict enrollees' freedom of choice of provider for the dental services covered by the demonstration project to participating providers.

3. **Amount, Duration, and Scope and Comparability** **Sections 1902(a)(10)(B) and 1902(a)(17)**

To permit the State to offer a different package of services for dental care not otherwise available to other beneficiaries through Nevada Medicaid.

CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00428/9

TITLE: Whole Mouth Whole Body Connection for Adults with Diabetes

AWARDEE: Nevada Department of Health and Human Services

1. PREFACE

The following are the Special Terms and Conditions (STC) for the "Whole Mouth Whole Body Connection for Adults with Diabetes" 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 expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. The STCs set forth conditions and limitations on the expenditure authorities and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional expenditure authorities, nor expand upon those separately granted. The STCs related to the programs for those populations affected by the demonstration are effective from July 1, 2024 through June 30, 2029 unless otherwise specified.

The STCs have been arranged into the following subject areas:

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

2. PROGRAM DESCRIPTION AND OBJECTIVES

This demonstration provides expenditure authority for the state to offer a limited dental benefit to a subset of the Medicaid-eligible adult population enrolled in Nevada Medicaid, specifically non-pregnant diabetic adults (21 through 64 years of age). This demonstration limits eligible enrollees' freedom of choice in dental provider to participating federally qualified health centers (FQHCs) and participating Tribal Health Centers with dental clinics. This demonstration's limited dental benefit package includes diagnostic and preventative, restorative, endodontic, and periodontic dental services. To ensure spending under the demonstration remains budget neutral, the state is applying a limitation of no more than five encounters annually under the new dental benefit per demonstration-eligible recipient. Medicaid eligibility and cost-sharing policies remain unchanged for this demonstration. This demonstration furthers the objectives of Medicaid by improving access to dental services in Nevada for certain Medicaid-enrolled adults. Through these efforts, the state, in conjunction with CMS will be able to demonstrate the value of improved access to oral health care on enrollee health outcomes and in controlling expenditures for a high-risk adult diabetic population in Medicaid.

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

- Increase access to preventive dental services for participating enrollees
- Decrease hospital admissions for the demonstration population due to non-management of oral health needs
- Control or reduce the incidence of periodontal disease among the demonstration population
- Reduce emergency room visits related to non-management of diabetic conditions among the demonstration population
- Reduce levels of and management of A1c for the demonstration population

3. GENERAL PROGRAM REQUIREMENTS

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

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

3.3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid or CHIP programs that

occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

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

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

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

3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs,

including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 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.

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

3.11. **Adequacy of Infrastructure.** The state 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.

3.12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** In states with federally recognized tribes, the state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 3.6 or extension, are proposed by the state. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

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

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

3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the

requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

4. ELIGIBILITY AND ENROLLMENT

4.1. **Eligibility Groups Affected by This Demonstration.** Eligibility groups affected by this demonstration are listed in table 1 below.

Table 1		
Eligibility Group Name	Social Security Act and CFR Citations	Income Level
New Adult Group	Section 1902(a)(10)(A)(i)(VIII), 42 CFR 435.119	At or below 133% of FPL
Parents and Caretakers	Section 1931, 42 CFR 435.110	At or below 133% of FPL

4.2. **Eligibility Restrictions.** To be eligible for the demonstration Nevada Medicaid enrollees must qualify under one of the two eligibility groups listed above in table 1 and must also meet the following criteria:

- Have a medical diagnosis of type 1 or type 2 diabetes; and
- Be a patient of record at the demonstration participating FQHC or participating Tribal Health Centers providing the dental services.

4.3. **Beneficiary Enrollment.** No enrollment limits apply to the eligibility groups participating in this demonstration. To identify demonstration participants, the state of Nevada, the Dental Benefits Administrator, participating FQHCs, and participating Tribal Health Centers, utilize claims data to identify eligible beneficiaries. Beneficiaries identified as eligible for the demonstration are provided notice from the Dental Benefits Administrator or state, depending on the beneficiary's assigned delivery system. Notified beneficiaries then are given the ability to opt into the new benefit program.

4.4. **Beneficiary Requirements for Participation in the Demonstration.** As part of the demonstration, beneficiaries will be encouraged to seek most of their annual primary, medical and dental care from the participating FQHC or Tribal Health Center to the extent feasible in order to maintain consistency in the demonstration. Participation in this request is voluntary and is not a condition of eligibility for the demonstration.

5. PROGRAM AND BENEFITS

5.1. **Covered Services.** Covered dental services include those approved in the State Plan for pregnant women.

5.2. **Encounter Limitations.** Each demonstration beneficiary will be eligible to receive five encounters with specified providers during the demonstration year. During these encounters there will be no limit on covered services completed, as clinically appropriate. Encounters may not be carried over to the following demonstration year and may not be shared between participants.

5.3. **Provider Restrictions.** This demonstration limits eligible enrollees' freedom of choice in dental provider to participating federally qualified health centers (FQHCs) and participating Tribal Health Centers with dental clinics. In the event that the beneficiary seeks dental care covered by this demonstration from a Medicaid-enrolled dental provider that is not a participating FQHC or Tribal Health Center, the services would not be eligible for Medicaid reimbursement.

6. COST SHARING

6.1. **Cost-Sharing.** There are no cost sharing or premium requirements for the services included this demonstration.

7. DELIVERY SYSTEM

7.1. **Delivery System.** This demonstration does not establish a new delivery system for services. The state's current delivery systems for providing services to this adult population are utilized for this demonstration. This demonstration utilizes a fee-for-service via state plan and a dental benefits administrator via a 1915(b) waiver for delivering services to the adult population eligible for the demonstration program. The eligible adults qualify as mandatory populations for Nevada managed care and the dental benefits administrator (PAHP) if they live in Clark and Washoe Counties. If a beneficiary is not part of a mandatory managed care population they receive their benefits through the state's fee- for-service delivery system via the state plan. Delivery system designations based on Medicaid eligibility group are shown in detail in Table 2 below.

	Table 2	
Medicaid Eligibility Group	Delivery System	Authority
Adults who live in urban Clark and Washoe Counties	Dental Benefit Administrator	1915(b)(1) & (4)
Adults who do not live in urban Clark and Washoe Counties	Fee for Service	State Plan

7.2. **Exceptions to Nevada Medicaid Managed Care County Mandate.** American Indian or Alaskan Native (AI/AN) who are members of a federally recognized tribe are not mandated to participate in managed care or the state's contracted dental administrator.

8. GENERAL FINANCIAL REQUIREMENTS

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

8.2. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the

Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

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

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

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

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

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

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

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51.

c. 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.

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

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

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

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

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

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

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

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

8.7. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 7.1. This report must include

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

8.8. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 9.

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.

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

8.10. **Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart in Table 3 provides a master list of MEGs defined for this demonstration.

Table 3: Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Dental Services	Hypo 1	X		X	All expenditures for dental benefits covered under this demonstration
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

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

8.11. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00428/9). 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 9, 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 STC 10.4, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods

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

Table 4: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
Dental Services	Report all medical assistance expenditures for the dental benefits allowed under the demonstration		Follow standard CMS-64.9 Category of Service Definitions	Date of service/Date of payment	MAP	Y	7/01/2024	6/30/2029
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality		Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	7/01/2024	6/30/2029

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

8.12. **Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in Table 5 below.

Table 5: Demonstration Years		
Demonstration Year 1	July 1, 2024 to June 30, 2025	12 months
Demonstration Year 2	July 1, 2025 to June 30, 2026	12 months
Demonstration Year 3	July 1, 2026 to June 30, 2026	12 months
Demonstration Year 4	July 1, 2027 to June 30, 2027	12 months
Demonstration Year 5	July 1, 2028 to June 30, 2029	12 months

8.13. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data,

using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in section 9. CMS will provide technical assistance, upon request.[1]

8.14. **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.

8.15. **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

[1] 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.

8.16. **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 8.17. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
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.

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

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

9. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

9.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 3, Master MEG Chart and Table 4, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

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

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

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

9.6. **Hypothetical Budget Neutrality Test 1: Dental 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. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6: 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
Dental Services	PC	Both	4.80%	$463.07	$485.29	$508.59	$533.00	$558.59

9.7. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be

known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

9.8. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the demonstration period, which extends from July 1, 2024 through June 30, 2029. 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.

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

Table 7: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
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 plus:	0.0 percent

10 MONITORING AND REPORTING REQUIREMENTS

10.1 **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter 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 for the 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.

In the event that either (1) 30 calendar days after the deliverable(s) were due if the state has not submitted a written request to CMS for approval of an extension as described below, within 30 calendar days after the deliverable was due, or (2) the state has not submitted a revised resubmission or a plan for corrective action to CMS within 30 calendar days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement including the information needed to bring the deliverable(s) into alignment with CMS requirements the following process is triggered:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay, and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request

c. If CMS agrees to an interim corrective process in accordance with subsection (b) above, and the state fails to comply with the corrective action plan or, still fails to submit the overdue deliverable(s) that meet the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

e. 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.

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

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

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

b. Ensure all section 1115 demonstration, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and

c. Submit deliverables to the appropriate system as directed by CMS.

10.4 **Monitoring Reports.** The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each demonstration year (DY). The fourth-quarter information that would ordinarily be provided in a separate Quarterly Monitoring 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 Annual Monitoring Report (including the fourth-quarter information) and 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 will include all required elements as per 42 CFR 431.428 and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Quarterly and Annual Monitoring Reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. **Operational Updates.** Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. 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.** The performance metrics will provide data to demonstrate how the state's is progressing toward meeting the demonstration's goals. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration on beneficiaries' utilization of services, outcomes of care, quality and cost of care, and access to care. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

   The state and CMS will work collaboratively to finalize the list of metrics to be reported on in Annual Monitoring Reports. The required monitoring and performance metrics must be included in the Monitoring Reports and will follow the CMS framework provided by CMS to support federal tracking and analysis. The reporting of the

monitoring metrics must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

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

10.5 **Corrective Action Plan Related to 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 preventive services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

10.6 **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 11.7 and 11.8, respectively.

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

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

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

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 10.1.

10.7 **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, enrollment and access, budget neutrality, and progress on evaluation activities.

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

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

10.8 **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (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 thirty (30) days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its Medicaid 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 Annual Monitoring Report associated with the quarter in which the forum was held.

11. EVALUATION OF THE DEMONSTRATION

11.1. **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 10.1.

11.2. **Independent Evaluator.** Upon approval of the demonstration, 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 accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

11.3. **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 Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs, and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 11.7 and 11.8.

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 approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

In the event of demonstration extensions, for components that are continuing from the prior demonstration approval period, the state's Evaluation Design must reframe and refocus as needed the evaluation hypotheses and research questions to appropriately factor in where it can reasonably expect continued improvements, and where the demonstration's role might be more to help stabilize outcomes. Likewise, for continuing policies, the state must revisit its analytic approaches compared to those used in the prior approval period evaluation activities, to ensure that the evaluation of those policies taps into the longer implementation time span.

11.4. **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.

11.5. **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, if any. 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 Medicaid website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the 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.

11.6. **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 its effectiveness in achieving the goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of preventive services. Proposed measures should be selected from nationally-recognized sources and national measure sets, where possible. Measures sets could include those from the Dental Quality Alliance;[2] CMS's Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by National Quality Forum (NQF).

[2] https://www.ada.org/resources/research/dental-quality-alliance/dqa-dental-quality-measures

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

Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography), and by demonstration component, to the extent feasible. Such stratified analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes and help inform how the demonstration's various policies might support reducing such disparities.

11.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension of the demonstration, the Interim Evaluation Report should be posted to the state's Medicaid 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, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report may include an evaluation of the authority, to be collaboratively determined by CMS and the state.

c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for the extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting an extension for a demonstration, the Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit the revised Interim Evaluation Report sixty (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 Report) of these STCs.

11.8. **Summative Evaluation Report.** The state must submit to CMS a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (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. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Summative Evaluation Report within sixty (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 Report to the state's Medicaid website within thirty (30) calendar days.

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

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

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

11.12. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration, over which the state has control. Prior to release of these reports, articles or

other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) calendar days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

12. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 8: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
180 calendar days after demonstration approval	Draft Evaluation Design	STC 11.3
60 days after receipt of CMS comments	Revised Evaluation Design	STC 11.5
June 30, 2024, or with renewal application	Draft Interim Evaluation Report	STC 11.7.c
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 11.7.d
Within 18 months after June 30, 2025	Draft Summative Evaluation Report	STC 11.8
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 11.8.a
Monthly Deliverables	Monitoring Calls	STC 10.7
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 10.4
	Quarterly Expenditure Reports	STC 8.2
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 10.4

ATTACHMENT A

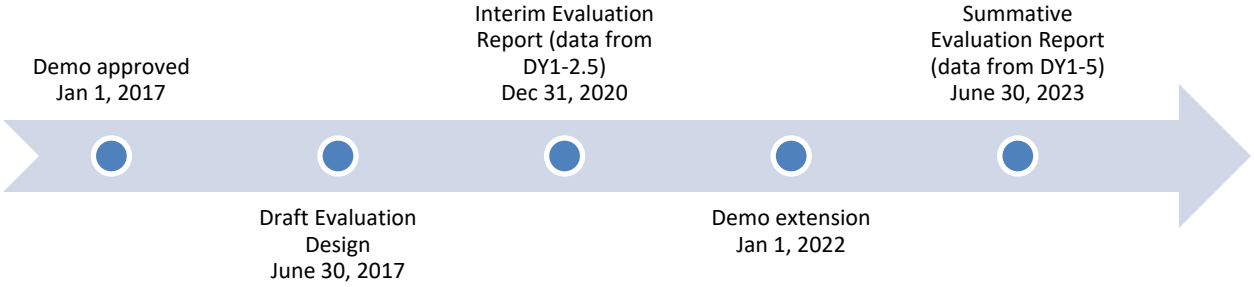
Preparing the Evaluation Design

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. 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 those from the Dental Quality Alliance;[3] 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.

[3] https://www.ada.org/resources/research/dental-quality-alliance/dqa-dental-quality-measures

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

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

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.

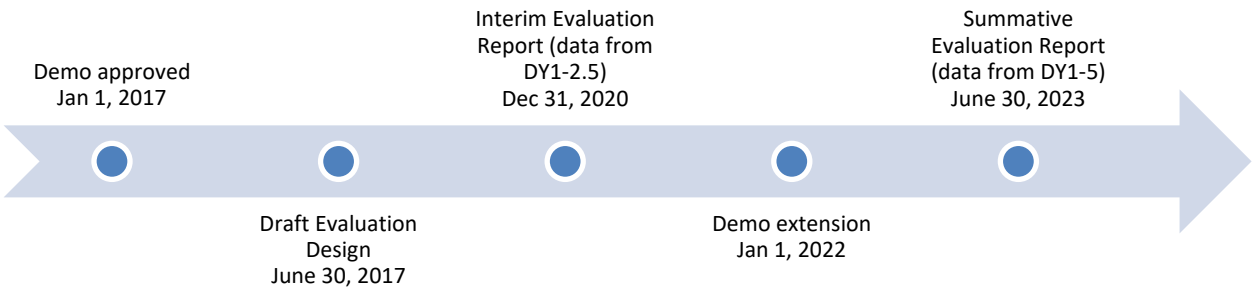
ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

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 – Evaluation Design

Nevada's Section 1115 Demonstration

Whole Mouth Whole Body Connection for Adults with Diabetes

(Project Number: 11-W-00428/9)

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

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

Joe Lombardo
Governor
State of Nevada

Richard Whitley, MS
Director
Department of Health and Human Services

Table of Contents

SECTION A: GENERAL BACKGROUND INFORMATION

Demonstration Information

The purpose of the Nevada Medicaid Section 1115 Whole Mouth Whole Body Connection for Adults with Diabetes Demonstration is to provide expenditure authority for the state to offer a limited dental benefit to a subset of the Medicaid-eligible adult population enrolled in Nevada Medicaid, specifically nonpregnant diabetic adults (21 through 64 years of age). The Nevada Department of Health Care Financing and Policy (DHCFP) received authority for a Medicaid Section 1115 Demonstration Project from the Centers for Medicare & Medicaid Services (CMS) on June 21, 2024, to implement a new section 1115 demonstration to offer a limited dental benefit to non-pregnant diabetic adults (21 through 64 years of age). The authorities granted to operate this demonstration will be effective through June 30, 2029, unless extended or otherwise amended.

This demonstration limits eligible enrollees' freedom of choice in dental providers to participating federally qualified health centers (FQHCs) and participating Tribal Health Centers with dental clinics. This demonstration's limited dental benefit package includes diagnostic and preventative, restorative, endodontic, and periodontic dental services.

The state is proposing no changes in eligibility procedures for populations eligible for Nevada Medicaid under the demonstration. The state will continue to use the same standards and methodologies to determine Medicaid eligibility for all populations in the demonstration as used in the State Plan. The state expects that all enrollees eligible to participate in the demonstration to be otherwise eligible for Nevada Medicaid, and that any eligible adults who are enrolled in Medicaid seeking or receiving services from a participating FQHC provider would be included in this demonstration's population as described in more detail below. No enrollment limits will apply for this demonstration including the expansion adult populations under this demonstration.

Demonstration Goals

The goal of this waiver is to test the impact of improved access to dental benefits on the health outcomes for the adult diabetic population who are enrolled in the state's Medicaid program. The proposed demonstration will further the objectives of Title XIX of the Social Security Act by improving access to dental services in Nevada for certain Medicaid-enrolled adults. Through these efforts, the state will be able to demonstrate the value of improved access to oral health care on enrollee health outcomes and in controlling expenditures for a subset of the state's eligible nonpregnant, adult and parent population, specifically high-risk adult population with a diagnosis of type 1 or 2 diabetes

Brief Description and History of Implementation

Currently, Nevada does not offer diagnostic, preventive, periodontal, and restorative dental benefits for its Medicaid-enrolled, non-pregnant adult population as permitted by federal law. Nevada ranks among the bottom half of states with respect to overall oral health and dental care and below the national average for the percentage of adults who receive annual dental visits. The state also ranks 43rd among the states with the highest percentage of adults who have poor-to-fair oral health conditions. A lack of dental coverage coupled with chronic provider shortages may explain Nevada's low rankings in oral health when compared to other states.

Oral health is integral to overall physical health and has been linked to several chronic diseases, including diabetes. Poor management of diabetes and other chronic diseases can also affect one's oral health. For example, periodontal disease has long been considered a complication of diabetes. The chronic hyperglycemia present in diabetics exaggerates the immune-inflammatory response in general, and to oral pathogens in specific. This "attack" leads to rapid and severe destruction of periodontal (gum) tissues which results in infections and tooth loss. Elevated A1c results (>7) correspond to stronger immune-inflammatory reactions. This impacts multiple systems and causes increased medical expenditures, poorer quality of life, and overall deterioration of the body.

Improving access to dental care for non-pregnant adults with diabetes who are enrolled in Nevada's Medicaid program will improve and address unmet oral health needs, thereby improving health outcomes and lowering overall costs. Offering new dental benefits for this population should result in a reduction in expenditure for hospital admissions and emergency room visits related to poor oral health. It is also reasonable to expect some savings with respect to chronic dental disease states for this population that result in emergency dental services (including fewer extractions and removable prostheses) that are covered today by Nevada's Medicaid program.

Population Groups Impacted

To be eligible for the waiver demonstration, Nevada Medicaid enrollees who qualify as one of the two eligibility groups below (i.e., Medicaid-enrolled parents and/or adults without children) must also meet the following criteria

1. Have a medical diagnosis of type 1 or type 2 diabetes; and
2. Be a patient of record at the participating FQHC providing dental services.

The eligibility groups affected by this demonstration include those listed in the table below.

Eligibility Group Name	Social Security Act and CFR Citations	Income Level
Adults without children	Section 1902(a)(10)(A)(i)(VIII) 42 CFR 435.119	At or below 138% of FPL
Parents and caretakers	Section 902(a)(10)(A)(i)(I) and 1931 42 CFR 435.110	At or below 138% of FPL

Section B: Evaluation Questions & Hypothesis

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 beginning on the following page was developed using Nevada's goal (Aim) to test the impact of improved access to dental benefits on the health outcomes of specified waiver recipients in the adult diabetic population enrolled in the states Medicaid Program. The driver diagram serves as an informative framework, recognizing the interrelationships between goals, primary drivers, and secondary drivers and may at times be multidirectional.

Aim	Primary Drivers	Secondary Drivers
Test the impact of improved access to dental benefits on the health outcomes for the adult diabetic population enrolled in the state's Medicaid Program.	• Decrease hospital admissions for the eligible enrollees by receiving regular dental care. • Reduce emergency room visits related to non-management of diabetic conditions by providing regular preventive dental care. • Increased control of A1c	• Increase access to preventive dental services. • Reduce A1c lab results by allowing the participating enrollees to have regular dental care. • The demonstration will result in improvements in quality of life through regular/ preventive dental care for the intended demonstration population.

In this section, the demonstration's core evaluation questions, hypotheses and recommended measures are presented. 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. To increase the robustness of the design, multiple quantitative approaches were utilized, as well as both internal pre-post comparisons and, as appropriate, comparisons between demonstration populations and state and national data if available.

	Evaluation Questions (Q)		Hypothesis (H)
Q1	Will the demonstration increase access to preventive dental services for the specified waiver recipients?	H1	The demonstration will increase access to preventive dental services for the specified waiver recipients.
Q2	Will the demonstration decrease hospital admissions for the specified waiver recipients due to non-management of oral health needs?	H2	The demonstration will decrease hospital admissions for the specified waiver recipients by receiving regular/ preventive dental care.
Q3	Will the demonstration reduce emergency room visits related to non-management of diabetic conditions among the specified waiver recipients?	H3	The demonstration will reduce emergency room visits related to non-management of diabetic conditions by providing regular/ preventive dental care and check-ups
Q4	Will the demonstration result in reduced A1c lab results for the specified waiver recipients?	H4	The demonstration will reduce A1c lab results by allowing the specified waiver recipients to have regular dental care and dental cleanings which will help lower overall A1c levels.
Q5	Will the demonstration result in improvements in quality of life for the specified waiver recipients?	H5	The demonstration will result in improvements in quality of life through regular/ preventive dental care for the specified waiver recipients.

Evaluation Questions and Measures

Evaluation Question #1: Will the demonstration increase access to dental services for specified waiver recipients and parents/caretakers with diabetes who are enrolled in Medicaid and served by participating FQHC's and participating Tribal Health Centers with dental clinics?

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Approach
The demonstration will increase dental claims for the specified waiver recipients	State Identified	The count of specified waiver recipients who receive an annual preventative dental service exam as compared to the count of the specified waiver recipients who receive an annual preventive dental service exam in waiver year 1. Waiver Year 1 will serve as a baseline year for this measure for evaluating improvements in access over time.	All specified waiver recipients	Diabetic adults not a patient of record at 1115 participating clinics	MMIS (claims) data	Descriptive statistics, pre/post, ITS regression

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Approach
Adults with Diabetes Oral Examination	2025 Dental Quality Alliance (DQA)[4] Adult Measures User Guide	Specified waiver eligibles receiving procedure codes D0150 or D0120	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics; pre/post
Non-surgical ongoing periodontal care for adults with gingivitis or periodontitis	2025 Dental Quality Alliance (DQA)	Specified waiver eligibles receiving procedure codes D1110, D4341, D4342, D4346, D4910	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics; pre/post

[4] American Dental Association Dental Quality Measures (Adult) Available at DQA Dental Quality Measures | American Dental Association

Evaluation Questions #2: Will the demonstration decrease hospital admissions for the specified waiver recipients due to non-management of oral health needs?

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Methods
The demonstration will result in fewer hospital admissions for the specified waiver recipients and nonmanagement of the oral needs.	State Identified	Over the course of the waiver, admissions for non-traumatic dental conditions or dental-related emergency procedures among the specified waiver recipients. CPT Codes: 99281-99285 ICD-10-CM Codes: ICD- codes 520, 520.6, 521, 523, and 525, ICD-10 codes K00, K01.0-K01.1, K02-K06, K08, M27.6	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	MMIS data Statewide hospital admissions data	Descriptive statistics, pre/post, ITS regression
Non-traumatic dental admission to hospital	EDV-A-A 2025 (DQA) Adult Measures User Guide	Specified waiver recipients with hospital admission claims with the following ICD-codes: 520, 520.6, 521, 523, and 525, ICD-10 codes K00, K01.0-K01.1, K02-K06, K08, M27.6	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics, Paired t-test

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Methods
Reduced costs related to non-traumatic dental admission to hospital	State identified	Claims costs related to specified waiver recipients with hospital admission claims with the following ICD codes: 520, 520.6, 521, 523, and 525, ICD-10 codes K00, K01.0-K01.1, K02-K06, K08, M27.6	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics

Evaluation Question #3. Will the demonstration reduce emergency room visits related to non-management or diabetic conditions among the specified waiver recipients?

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Methods

The demonstration will result in fewer emergency room visits related to nonmanagement of diabetic conditions for this population.	State Identified	Over the course of the waiver, diabetic patients within the waiver who have diabetic related emergency room visits. CPT Code: 99281-99285, ICD-10-CM Codes: E08-E13	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	MMIS data Statewide hospital admissions data	If the data is sufficient, parametric tests of statistical significance will be utilized to explore whether differences are statistically significant. The specific test or tests to be used will be determined once data are received, cleaned and assessed.
Ambulatory Care Sensitive Emergency Department Visits for Non-Traumatic Dental Conditions in Adults	EDV-A-A 2025 (DQA)1 Adult Measures User Guide	Specified waiver recipients with ER code claims with non-traumatic dental ICD- codes 520, 520.6, 521, 523, and 525, ICD-10 codes K00, K01.0-K01.1, K02-K06, K08, M27.6	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics, paired t-test

Reduced costs related to emergency room and ambulatory care visits for non-traumatic dental conditions in adults	State Identified	Claims costs related to specified waiver recipients with hospital admission claims with the following ICD codes:	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	Waiver Enrollment and MMIS/claims data	Descriptive statistics

Evaluation Question #4. Will the demonstration result in reduced A1c lab result levels for the specified waiver recipients?

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Methods
Hb A1c results	2025 (DQA) Adult Measures User Guide	Average Hb A1c of Eligibles after treatment subtracted from average Hb A1c before receiving dental treatment	Average Hb A1c of specified waiver recipients before receiving dental treatment	Year to year change of overall A1c levels among specified waiver recipients	Quarterly A1c Reports from participating clinics	Descriptive statistics, Paired t-test

Evaluation Question #5. Will the demonstration result in improvements in quality of life for the specified waiver recipients?

Measure Description	Measure Steward	Numerator	Denominator	Comparison Group	Data Source	Analytic Methods
Quality of Life Survey (QOLS)[5]	2025 (DQA) Adult Measures User Guide	Average numeric score on QLS survey after treatment in year 1 subtracted from the average numeric score on QLS survey before dental treatment.	Average numeric score on QOLS survey before dental treatment.	Year to year change of overall QOLS survey among specified waiver recipients	Yearly QOLS report from clinics/members	Descriptive statistics, Paired t-test

[5] The Quality of Life Scale (QOLS): Reliability, Validity, Utilization https://pmc.ncbi.nlm.nih.gov/articles/PMC269997/

Periodontal Evaluation in Adults with Periodontitis	2025 (DQA) Adult Measures User Guide	The number of specified waiver recipients who received a periodontal evaluation.	All specified waiver recipients	Diabetic adults who are not patients at waiver-participating clinics	MMIS/claims data	Descriptive statistics
Non-Surgical Ongoing Periodontal Care for Adults with Periodontitis	2025 (DQA) Adult Measures User Guide	The number of specified waiver recipients who received non-surgical ongoing periodontal care	All specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health centers	MMIS/claims data	Descriptive statistics
Topical Fluoride for Adults at Elevated Caries Risk	2025 (DQA) Adult Measures User Guide	The number of specified waiver recipients who received topical fluoride treatment	The total number of specified waiver recipients	Other Medicaid eligible adults with diabetes diagnosis who are not on record as patients at participating health center	MMIS/ claims data	Descriptive statistics

SECTION C: METHODOLOGY

Methodological Design

Across the fourteen **(14)** measure descriptions the evaluation will employ quantitative methods to evaluate the demonstration's impact on improving the dental outcomes for the specified waiver recipients under this waiver and maintaining or reducing the total cost to Medicaid for Nevada and the Federal Government. Quantitative analysis will utilize descriptive statistics, trends over time, beneficiary surveys, and interrupted time-series (ITS) analysis of pre- and post-demonstration periods.

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

Target Population and Comparison Groups

This demonstration provides limited dental benefits to a subset of the Medicaid-eligible adult population enrolled in Nevada Medicaid, specifically nonpregnant diabetic adults (21 through 64 years of age). Since there is no historical comparison group due to the addition of novel dental benefits for this specific population, data from WY 1 will be used as a comparison group for specific analytical measures as appropriate. Where applicable to the specific waiver question, otherwise eligible diabetic members located at nonparticipating clinics will be used as a comparison group (n= 9,092).

Evaluation Period

The evaluation period will run from July 1, 2024, or once the system is implemented and claims reimbursed through its five-year demonstration period timeline, June 30, 2029.

Evaluation Measures

The measures that will be utilized in this evaluation are derived from the Dental Quality Alliance (DQA) Adult Measures user guide as well as unique state identified measures to round out the questions and measures to ensure that the goals set forth in this demonstration can be properly evaluated. Measurement data will be drawn from claims (either managed care or fee-for-service as applicable) for the specific dental services listed. Participating clinics will provide a quarterly A1C report for participating members.

A quantitative survey distributed to the specified waiver recipients will be utilized to collect data that is not captured through Medicaid claims or provider reports, such as Quality of Life measures.

Data Sources

The data used to evaluate the performance in meeting the measures will be derived from administrative data, Medicaid claims/encounter data, member enrollment data, survey data, quarterly A1C reports from participating providers and will be reported to CMS as part of the approved Dental Demonstration Waiver monitoring protocol.

A quantitative Quality of Life Survey (QOLS) will be distributed to the specified waiver recipients at the end of each demonstration year. The survey will be a web-based, self-administered questionnaire produced with the Research Electronic Design Capture (REDCap)[6] software. The QOLS will contain statements that describe how access to dental care has positively or negatively influenced certain aspects of the participant's life. Questions will be designed for participants to rate their agreement, disagreement, or neutrality with these statements using a Lickert-type scale. Each response on the Lickert-type scale will be associated with a numeric value that will then be summed into a QOL (quality of life) score. Higher scores will be indicative of a higher quality of life. Participants' individual scores and the average score among the total survey participants will be compared throughout the demonstration years in order to observe any changes between demonstration years.

Analytic Methods

A combination of quantitative statistical methods will be used for the analysis. Specific measures will be utilized for each demonstration as detailed in goal 1 and 2 tables above. While the Demonstration seeks to increase dental care provisions and promote quality care, observed changes may be attributed to the Demonstration itself and/or external factors, including other State- or national-level policy or market changes or trends. For each Demonstration activity, a conceptual framework will be developed depicting how specific Demonstration goals, tasks, activities, and outcomes are causally connected to serve as the basis for the evaluation methodology. Methods chosen will attempt to account for any known or possible external influences and their potential interactions with the Demonstration's goals and activities. The evaluation will seek to isolate the effects of the Demonstration on the observed outcomes in several ways.

[6] Can be found at https://project-redcap.org/

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 relative subgroupings. Data will be analyzed using standard tests such 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 are no contemporaneous comparison groups, 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: $Y= \beta_0 + \beta_1 \times post$ where Y is the rate of the outcome being measured each year, β_0 captures the average rate in the baseline years, and the coefficient β_1 for the dummy variable, post, representing the evaluation years, captures the change in average outcome between the baseline and the 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 used to evaluate measures that have count outcomes.

ITS regression modeling

Interrupted time series (ITS) regression modeling will be used 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, and ITS methodology can be used. This analysis is a 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 them compared to the predicted outcome to evaluate the impact the demonstration had on the outcome.

This analysis will utilize hospital/ER claims data from DY1 as the baseline comparison for the ITS regression model. It is appropriate to use this demonstration year as the baseline as there are no waiver claims expected in DY1 due to system delays in the implementation of shadow billing required for tracking, and monitoring, of the new dental benefits. Therefore, only hospital/ER claims data for beneficiaries who would have been eligible for DY 1 will be available to be considered “pre-intervention.” In addition, it will not be possible to collect Hb A1c “pre-intervention” data as the state will rely on participating clinics to report A1c levels of beneficiaries once they attend the clinic to begin receiving waiver services. Once that baseline data is reported to the state it will be utilized for subsequent evaluation periods.

SECTION D: METHODOLOGICAL LIMITATIONS

Due to Nevada utilizing two different sources for data collection, claims data and surveys, the first potential limitation is ensuring each individual analysis is based on unduplicated data. There will need to be a sufficient sample size pulled to ensure it is representative and can be generalized to a larger population. Given the unique design of this demonstration and the lack of adult dental experience in Nevada, DHCFP is not able to use historic data on dental outcomes for diabetic adults, requiring the methodology to utilize data from waiver year 1 as a baseline. Bias may also be a limitation due to the use of a survey for collecting data on certain measures. While it is impossible to eradicate all biases, the survey will be designed to minimize biases that may arise, such as response bias, recall bias, and sampling bias. The survey may be improved or streamlined throughout the waiver evaluation period to reduce bias.

Sample size

The number of Nevada Medicaid beneficiaries that would qualify for this expanded dental coverage is estimated to be **1,576** unique individuals per waiver year during the demonstration period. Office of Analytics (OOA) will assess sample size and the ability to conduct calculations for key outcomes. The estimated number of beneficiaries who qualify for this expanded dental benefit may not be large enough to conduct the needed statistical analysis.

Lack of historical data

Due to the novel benefits this waiver provides, there is no historical data to compare against the current eligible population. As a result, the evaluation plan relies on using some data from Waiver Year 1 as a baseline for certain measures.

ATTACHMENT 1 – INDEPENDENT EVALUATOR

Nevada Medicaid (DHCFP) will utilize The Department of Human and Health Services Office of Analytics (OOA) to assist in executing its Waiver for Adults with Diabetes demonstration evaluation plan. The OOA will also have the responsibility of conducting the mid-point assessment of the program's effectiveness and overall performance. The Department of Healthcare Financing and Policy (DHCFP) Federal Waiver Team will retain primary responsibility for monitoring the demonstration, with support from the OOA, as necessary. To mitigate any potential conflict of interest, the OOA 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

ATTACHMENT 2 – EVALUATION BUDGET, TIMELINE AND MILESTONES

Evaluation Budget, assuming no Demonstration amendments or changes to the Evaluation Design, are expected to be $335,102.80 over the project period 2024-2029. Please see budget breakdown below illustrated in Table 3.

Table 3. Evaluation Budget Overview

Evaluation Task	2024	2025	2026	2027	2028	2029	Total Cost
Data analytic plan and timeline	$4,661.07	$15,908.27	$10,655.68	$5,150.09	5,365.00	5,606.74	$47,346.84
Retrospective data analysis	$6,991.61	$23,862.41	$14,207.57	$7,725.13	$5,365.00	$5,606.74	$63,758.45
Beneficiary survey data collection, including follow up	$2,330.54	$7,954.14	$7,103.78	$5,150.09	5,365.00	$5,606.74	$33,510.28
Quantitative data analysis and cleaning	$6,991.61	$23,862.41	$24,863.24	$18,025.31	$18,777.50	$19,623.58	$112,143.64
Draft and Final Interim Reports	$2,330.54	$7,954.14	$14,207.57	$10,300.18	$10,730.00	$5,606.74	$51,129.15
Draft and Final Summative Reports	$0.00	$0.00	$0.00	5,150.09	$8,047.50	$14,016.84	$27,214.43
Total	$23,305.36	$79,541.36	$71,037.84	$51,500.88	$53,650.00	$56,067.36	$335,102.80

Table 4. Waiver Deliverable Timeline and Milestones

Schedule of Deliverables	2024	2025	2026	2027	2028	2029	2030
Quarterly narrative/ expenditure report	29-Nov	Quarterly	Quarterly	Quarterly	Quarterly	Quarterly	
Draft evaluation design due	18-Dec						
Annual Deliverables due:		31-Mar	31-Mar	31-Mar	31-Mar	31-Mar	
Post Award Forum due: Within 6 months of waiver implementation		To be determined					
Interim Evaluation Report due: 1 year prior to end of demonstration or submitted with extension application. (if applicable)					30-Jun		
Summative Evaluation Report due:			30-Dec				

Milestones

80th Nevada Legislative Session Assembly Bill 223 was passed in 2019, 10/07/2022 State application for whole Body Whole Mouth Connection for Adults with Diabetes received by CMS, 10/20/2022 CMS Completeness Letter, June 21st, 2024, waiver approval, Effective period 07/01/2024-06/30/2029.
02/21/2024 Department of Healthcare Financing and Policy (DHCFP) met with Gainwell (NV's QIO Vendor) to discuss shadow billing as it related to Federally Qualified Health Center (FQHC)s and Tribal Health Centers in general and for the 1115 waiver.
04/24/2024 Gainwell started research for shadow billing regarding FQHC's billing in general for all services, this research was not focused on the 1115 waiver system just what is applicable to the shadow billing requirement.
07/03/2024 meeting with the Dental Director for NV Health Centers and the Dental Director of Community Health Alliance (CHA). Received feedback from CHA that they have a provider capacity limitation and opening additional days in the clinic could be difficult for adults with diabetes. Both clinics reported that if their sister FQHC medical only clinics or partner Managed Care Organizations (MCO) directed diabetic patients to their clinics they do not have the providers to care for them. Discussed with the FQHC's that we pulled the eligibles from only those clinics that had a dental service. As we are not interested in overwhelming their clinics as dental services will best serve patients if they are able to take advantage of all five encounters per year. Discussed reporting and comprehensive exams and that periodontal charting should be completed to satisfy that coding and reimbursement. They discussed the administrative burden of the WRAP reporting to DHCFP.
07/03/2024- **Milestone: Independent Evaluator for 1115.** Engaged with the Office of Analytics at DHHS about their ability to support the 1115 waiver as a third-party evaluator. Discussed personnel that will be working on this project.
07/29/2024- Meeting with participating tribes and DHCFP's QIO vendor Gainwell to discuss billing mechanisms and potential reporting metrics for the 1115 waiver. They were very enthusiastic and excited about starting and reported that quarterly A1c reporting would not be overly burdensome.
7/30/2024- Engaged CMS regarding our ability to eliminate the WRAP payments for the FQHCs and instruct the PAHP Liberty to pay the Prospective Payment System (PPS) rate to the FQHC dental clinics. It was determined that timing would not work in this initial year for capitation rate and SPA changes, but it is still a priority for leadership and moving forward for calendar year 2026.
8/28/2024- Meeting with Owyhee Tribe to discuss the 1115 waiver as they were not able to attend the July 29th meeting with the other participating tribes. Discussed billing and reporting for the 1115 waiver. The clinical manager reported that many members seek care in Idaho and that they have difficulty getting dentists reliably to their clinic to provided care.
10/7/2024- Weekly meetings began with the federal waiver team, dental officer, Managed Care Quality Assurance, and Office of Analytics to support 1115 project deliverables.

11/5/2024- State Dental Officer met with a Gainwell representative and reviewed various system questions about the implementation of the Fee for service build. The Gainwell representative provided July of 2025 as a forecast for when the system would go live. The possibility of allowing interested clinics in providing services before implementation and back dating claims was sent to CMS for discussion as reporting metrics may be complicated.
11/25/2024- First quarterly narrative and budget neutrality workbook submitted to CMS.
12/6/2024- Initial submission of the Draft Evaluation Design to CMS

Acronym Definitions

CFR: Code of Federal Regulations

CHA: Community Health Alliance

DHCFP: Department of Health Care Financing and Policy

DQA: Dental Quality Alliance

FQHC: Federally Qualified Health Centers

ITS: Interrupted Time Series

MMIS: Medicaid Management Information System

OOA: Office of Analytics

QIO: Quality Improvement Organization

QOLS: Quality of Life Survey

ATTACHMENT D

ATTACHMENT E