DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

April 30, 2025

Emma Sandoe
Medicaid Director
Oregon Health Authority
500 Summer Street NE, E35
Salem, OR 97301

Dear Director Sandoe:

The Centers for Medicare & Medicaid Services (CMS) is approving an amendment to Oregon's section 1115(a) demonstration titled "Oregon Contraceptive Care" (Project Number 11-W-00142/0) (the "demonstration"), in accordance with section 1115(a) of the Social Security Act ("the Act"). This amendment will be effective on the date of approval, through December 31, 2028, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.

CMS determined that this demonstration categorized sexually transmitted infection (STI)/sexually transmitted disease (STD) diagnosis services as a family planning service, which does not conform with State Medicaid Director Letters #10-013[1], #14-003[2], and #16-008[3]. In this guidance, CMS clarified that family planning related services are those services that are medical diagnosis services, including for STIs/STDs, that are provided pursuant to a family planning service. Family planning services must be for the purpose of preventing or delaying pregnancy. Therefore, in this amendment, CMS has identified only STI/STD screening services as a family planning service.

Budget Neutrality

There is no change to budget neutrality for this amendment.

Monitoring and Evaluation

There is no change to monitoring or evaluation requirement for this amendment.

Public Notice

Special Terms and Condition (STC) 3 gives CMS the right to amend the STCs to reflect changes

[1] https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD10013.pdf
[2] https://www.medicaid.gov/federal-policy-guidance/downloads/smd-14-003.pdf
[3] https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf

in Medicaid law, regulation, or policy without requiring the state to submit an amendment to the demonstration, as described in STC 7. The state was alerted to this change on February 26, 2025, more than 30 business days prior to approval and was given an opportunity to review the changes. Pursuant to STC 3, there was no state or federal public comment period needed.

Other Information

The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer for this demonstration is Amy Schlom, who is available to answer any questions concerning your section 1115 demonstration and her contact information is as follows:

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

If you have questions regarding this approval, please contact Jacey Cooper, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

[redacted]

Drew Snyder
Deputy Administrator and Director

Enclosure

cc: Nikki Lemmon, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00142/0**

TITLE: **Oregon Contraceptive Care (CCare) (Formerly Oregon Family Planning Program) Section 1115 Demonstration**

AWARDEE: **Oregon Health Authority**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Oregon for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration, be regarded as expenditures under the state's title XIX plan. All requirements of the Medicaid statute will be applicable to such expenditure authorities, except those specified below as not applicable to these expenditure authorities. All requirements of the Medicaid statute will be applicable to such expenditure authorities (including adherence to income and eligibility system verification requirements under section 1137(d) of the Act), except those specified below as not applicable to these expenditure authorities.

The following expenditure authorities and the provisions specified as "not applicable" enable Oregon to operate this section 1115 Medicaid family planning demonstration effective through December 31, 2028.

1. **Family Planning Services**. Expenditures for family planning services to individuals who are not otherwise eligible for Medicaid or the Children's Health Insurance Program (CHIP) and whose household income is at or below 250 percent of the Federal poverty level.

2. **Continuous Eligibility.** Expenditures for continued benefits for individuals who have been determined eligible who would otherwise lose coverage during an eligibility redetermination, except as noted in STC 16.b.

Medicaid Requirements Not Applicable to the Medicaid Expenditure Authorities:

All Medicaid requirements apply, except the following:

1. **Amount, Duration, and Scope of Services (Comparability) Section 1902(a)(10)(B)**

   To the extent necessary to allow the state to offer the demonstration population a benefit package consisting only of approved family planning services. The not applicable of comparability does not apply to non-emergency medical transportation (NEMT) services after December 31, 2024.

2. **Prospective Payment for Federally Qualified Health Centers Section 1902(a)(15) and Rural Health Centers and Rural Health Clinics**

The state will establish reimbursement levels to these clinics that will compensate them solely for family planning services.

3. Eligibility Procedures **Section 1902(a)(17)**

Parental income will not be included when determining a minor's (individual under age 18) eligibility for the demonstration.

4. Retroactive Coverage **Section 1902(a)(34)**

Individuals enrolled in the family planning demonstration will not be retroactively eligible.

5. Early and Periodic Screening, Diagnostic, and Treatment Section 1902(a)(43)(A) (EPSDT)

The state will not furnish or arrange for EPSDT services to the demonstration population.

6. Enrollment Simplification and Coordination with State Health Insurance Exchanges **Section 1943**

To the extent necessary to allow the state to transition to compliance, for the period prior to December 31, 2028, with respect to family planning services to individuals who are not otherwise eligible for Medicaid or the Children's Health Insurance Program (CHIP) and whose household income is at or below 250 percent of the Federal poverty level.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00142/0**

TITLE: **Oregon Contraceptive Care (CCare) (Formerly Oregon Family Planning Program) Section 1115 Demonstration**

AWARDEE: **Oregon Health Authority**

I. PREFACE

The following are the Special Terms and Conditions (STC) for the "Oregon Contraceptive Care" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Oregon Health Authority (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on the expenditure authority, 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 demonstration will be statewide and is approved through December 31, 2028, unless otherwise specified.

The STCs have been arranged into the following subject areas:

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

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

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: Approved Evaluation Design (Reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

Effective through December 31, 2028, the Oregon CCare section 1115(a) Medicaid demonstration expands the provision of family planning services to individuals who are not otherwise eligible for Medicaid or the Children's Health Insurance Program (CHIP) and whose household income is at or below 250 percent of the Federal Poverty Level (FPL).

Historical Context and Objectives

On October 14, 1998, CMS approved the precursor to this Medicaid section 1115(a) demonstration proposal titled "Oregon Family Planning Expansion Project" (now known as "Oregon Contraceptive Care" or "CCare"), designed to expand the availability of Medicaid-supported contraceptive management services to a wider population base. The program was implemented on January 1, 1999 and has been consistently extended by CMS since that date.

On July 7, 2021, the state submitted a five-year request to extend the demonstration with no programmatic changes. The demonstration was scheduled to expire on December 31, 2021, but on December 15, 2021, CMS approved a temporary extension of the demonstration until June 30, 2022, to allow for additional time for the state and CMS to continue to work on finding an amenable approval path for the extension request. A subsequent temporary extension was approved on June 8, 2022, which extended the demonstration period until June 30, 2023. A third temporary extension was approved on June 23, 2023, to extend the demonstration through December 31, 2023. The current extension of this demonstration is being granted for an additional five years through December 31, 2028.

Approval of this demonstration extension will allow the state to continue to expand access to family planning services and increase the chances of more healthy outcomes for Medicaid recipients and will align the continued eligibility period with the 24-month period approved in the Oregon Health Plan demonstration.

On April 30, 2025, CMS amended the STCs to identify STI/STD screening services as a family planning service.

III. GENERAL PROGRAM REQUIREMENTS

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

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

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or written policy affecting the Medicaid and/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 thirty (30) calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or written 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 and/or a modified allotment neutrality worksheet for the demonstration 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) as a result of the change in FFP.

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

5. **State Plan Amendments.** The state will not be required to submit title XIX or title 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 may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements authorized through these STCs 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 or begin operational changes to these demonstration elements without prior approval. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for amendments to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3 or otherwise specified in the STCs.

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 herein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

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

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

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

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

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

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

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six (6) 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 thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the thirty (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 transition and 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 administrative reviews 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 fourteen (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 category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1) or for children in CHIP consider eligibility for other insurance affordability programs under 42 CFR 457.350. The state must comply with all applicable notice requirements for Medicaid found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214 or for CHIP found at 42 CFR 457.340(e), including information about a right to review consistent with 42 CFR 457.1180. In addition, the state must assure all applicable Medicaid appeal and hearing rights are afforded to Medicaid beneficiaries in the demonstration as outlined in 42 CFR, part 437 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 (6) months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved

Medicaid state plan.

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

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

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

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

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

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

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

entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

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

IV. ELIGIBILITY AND ENROLLMENT

16. Eligibility Requirements.

Eligibility for this demonstration is limited to individuals who are not otherwise eligible for Medicaid or the Children's Health Insurance Program (CHIP), whose household income is at or below 250 percent of the FPL, and who meet all other eligibility requirements.

For an individual found to be income-eligible for this demonstration upon initial application or annual redetermination, the state will provide twenty-four (24) months continuous eligibility during which the state will not terminate coverage based on a change in circumstance.

a. Continuous Eligibility. The continuous eligibility period begins on the effective date of the individual's eligibility determination or the effective date of the most recent renewal of eligibility. Given individuals are continuously eligible regardless of changes in circumstances (except as provided under STC 16.b.), the state will conduct renewals of eligibility at the end of the individual's continuous eligibility period. The state will continue to redetermine eligibility during a period of continuous eligibility in limited circumstances, if appropriate, as described in STC 16.b.

b. Continuous Eligibility Exceptions. Notwithstanding STC 16.a, if any of the following circumstances occur during an individual's designated continuous eligibility period, the individual's Medicaid eligibility shall be redetermined or terminated:
    i. The individual becomes pregnant or otherwise eligible for Medicaid or CHIP;
    ii. The individual is no longer an Oregon resident;
    iii. The individual requests termination of eligibility;
    iv. The individual dies; or
    v. The agency determines that eligibility was erroneously granted at the most

recent determination, redetermination or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the individual.

17. **Streamlined Application and Eligibility Determination Process.** Application and enrollment processes for this demonstration must comply with section 1943 of the Act and implementing regulations at 42 CFR part 435. Transition to full compliance must be completed no later than December 31, 2028.

    a. Mitigation Work Plan and Timeline. The state must submit for CMS review and approval a work plan describing the changes the state will make to its demonstration application and enrollment processes that meet the intent of section 1943 of the Act and regulations at 42 CFR part 435 (referred to herein as mitigations) and the timeline for implementing the mitigations. The work plan must be submitted to CMS no later than 120 calendar days after approval of this demonstration extension. The state must implement all mitigations no later than a date mutually agreed to by CMS and the state through the mitigation work plan review and approval. The mitigation work plan must address each of the following areas:
        i. Application
        ii. Eligibility Hierarchy and Determination Cascade
        iii. Opportunity to Apply
        iv. Verification
        v. Renewals of eligibility
        vi. Notices
        vii. Coordination with Other Insurance Affordability Programs
        viii. Fair Hearings

    b. Systems coordination and full compliance with section 1943 and implementing regulations at 42 CFR part 435. The state must achieve compliance with section 1943 of the Act and implementing regulations at 42 CFR part 435. The state must specifically address the following issues: coordination between the family planning program and the full benefit Medicaid program application processes such that individuals can file a single application to be considered for all bases of eligibility; integrating family planning eligibility into the state's Medicaid eligibility hierarchy; redetermining a beneficiary's Medicaid eligibility on all bases of eligibility and without re-application; conducting verification in accordance with 42 CFR 435.916 and 42 CFR 435.956; providing all applicants and beneficiaries with timely and adequate written notice in accordance with 42 CFR 435.917 and 42 CFR 435.918; and maintaining a fair hearing system that meets the requirements of 42 CFR 431.205 and 431.220-246. The state must be in full compliance with applicable statute and regulations no later than December 31, 2028.
        i. *Documentation*. The state must notify CMS in writing when it achieves full compliance with applicable statute and regulations. This notification must include documentation to demonstrate the state's compliance.

ii. *CMS Review*. Upon receipt of the documentation in STC 17(b)(i), CMS will review the information and work with the state to verify compliance with applicable statute and regulations.

A delay in implementing the processes necessary to align with section 1943 of the Act (and implementing federal regulations at 42 CFR part 435) may subject the state to the penalty described in STC 10.

18. **Demonstration Disenrollment.** If an individual becomes pregnant while enrolled in the demonstration, they may be determined eligible for Medicaid under the state plan. The state must not submit claims under the demonstration for any individual who is found to be eligible under the Medicaid state plan.

V. PROGRAM BENEFITS

19. **Family Planning Benefits.** Beneficiaries eligible under this demonstration will receive family planning services and supplies as described in section 1905(a)(4)(C) of the Act, which are reimbursable at the 90 percent Federal matching rate and are limited to those services and supplies whose primary purpose is family planning to prevent or delay pregnancy. The specific family planning services provided under this demonstration are as follows:

    a. FDA approved methods of contraception;
    b. Screening for sexually transmitted infection (STI) or sexually transmitted disease (STD) during a family planning visit, Pap smears and pelvic exams.
    Note: Laboratory tests done during an initial family planning visit for contraception include a Pap smear, screening tests for STIs/STDs, blood count and pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program or provider. Additional laboratory tests may be needed to address a family planning problem or need during an inter-periodic family planning visit for contraception;
    c. Drugs, supplies, or devices related to women's health services described above that are prescribed by a health care provider who meets the state's provider enrollment requirements, subject to the national drug rebate program requirements;
    d. Contraceptive management, patient education, and counseling; and
    e. Vasectomies for men over the age of 21.

20. **Transportation.** As of January 1, 2025, non-emergency transportation to covered family planning services.

21. **Minimum Essential Coverage (MEC).** The CCare demonstration is limited to the provision of family planning services as described in STC 22; thereby, the demonstration is not recognized as MEC as communicated by CMS in its February 12, 2016 correspondence to the state regarding our designation of MEC for the state's section 1115 demonstrations.

Primary Care Referrals. Primary care referrals to other social service and health care providers as medically indicated are provided; however, the costs of those primary care services are not covered for enrollees of this demonstration. The state must facilitate access to primary care services for participants, and must assure CMS that written materials concerning access to primary care services are distributed to demonstration participants. The written materials must explain to the participants how they can access primary care services.

VI. COST SHARING

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

VII. DELIVERY SYSTEM

23. Delivery System. All demonstration beneficiaries will continue to receive services through the same delivery system arrangements as currently authorized in the state. Services under this demonstration are provided through a fee-for- service (FFS) delivery system.

VIII. MONITORING AND REPORTING REQUIREMENTS

24. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, 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 are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

In the event that either (1) the state has not submitted a written request to CMS for approval of an extension, as described below, within thirty (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 thirty (30) calendar days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement including the information needed to bring the deliverable 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 to the state's request, a corresponding extension of the deferral process 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 plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, 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 with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the 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.

25. Submission of Post-Approval Deliverables. The state must submit all required analyses, reports, design documents, presentations, and other items specified in these STCs ("deliverables"). The state shall use the processes as stipulated by CMS and within the timeframes outlined within these STCs.

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

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

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

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

27. Annual Monitoring Reports. The state must submit one (1) Annual Monitoring Report each demonstration year (DY) that is due no later than ninety (90) calendar days following the end of the DY. The state must submit a revised Annual Monitoring Report within sixty

(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 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, 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 is progressing towards meeting the demonstration's goals. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing family planning services to beneficiaries, as well as access to and utilization of care, outcomes of care, and quality and cost of 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 demonstration's monitoring metrics must cover categories to include, but not limited to, enrollment, utilization of services, unpaid medical bills at application, and quality of care and health outcomes. The state should also report payment-related and provider-level metrics, if applicable. The state must undertake robust reporting of quality of care and health outcomes metrics aligned with the demonstration's policies and objectives to be reported for all demonstration populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race and 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.

   The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration.

The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements Section X 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 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 must include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

28. 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 family planning services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

29. Close-Out Report. Within one hundred twenty (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 41 and 42, respectively.

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

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

e. The final Close-Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 27.

30. 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.

31. 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 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 year in which the forum was held.

IX. EVALUATION OF THE DEMONSTRATION

32. 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; providing data and analytic files to CMS; 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 27.

33. **Independent Evaluator.** The state must use an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved 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.

34. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs, 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 41 and 42.

    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 one hundred eighty (180) calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the Monitoring Reports. The amendment components of the 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.

35. **Evaluation Budget.** A budget for the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and

cleaning, analyses, and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

36. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' 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 website within thirty (30) calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the 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.

37. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) 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 of the demonstration's impact and its effectiveness in achieving the demonstration's goals.

    The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must cover outcomes, such as enrollment, 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 family planning services. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Maternal and Perinatal Health Care Quality Measures for Medicaid and CHIP Consumer Assessment of Health Care Providers and Systems (CAHPS) the National Survey of Family Growth (NSFG), the Pregnancy Risk Assessment Monitoring System (PRAMS), and/or measures endorsed by the National Quality Forum (NQF).

    Specifically, evaluation hypotheses must focus on the impact of the demonstration in helping eligible beneficiaries access family planning services. Hypotheses must include, but not be limited to, outcomes such as beneficiary access to and utilization of family planning services (e.g., percentage of beneficiaries reporting difficulty obtaining preferred contraceptive and percentage of beneficiaries who utilized any contraceptives by method effectiveness) and maternal health and birth outcomes (e.g., unintended pregnancies, teen birth rates, and the rate of preterm and low birthweight births), with a focus on addressing any demographic disparities. The state must also collect necessary data to accommodate

CMS's evaluation expectations to assess the effects of not providing retroactive eligibility on beneficiaries and providers, for example, by examining outcomes such as beneficiary financial status, including changes in incidence of medical debt and provider uncompensated care costs.

The state should ideally undertake a well-designed beneficiary survey, which would significantly strengthen the demonstration's evaluation. Finally, to the best extent feasible, the state must collect data to support analyses stratified by key subpopulations of interest (e.g., by sex, age, race and ethnicity, primary language, disability status, and geography). Such stratified analyses will provide a fuller understanding of existing shortcomings or disparities in access to and quality of care and health outcomes and help inform how the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

38. **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 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 component within the demonstration that expires prior to the overall demonstration's expiration date, and depending on the timeline of the expiration/phase-out, the Interim Evaluation Report must 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 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 the demonstration, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

    d. The state must submit the final Interim Evaluation Report sixty (60) calendar days after receiving CMS 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 thirty (30) calendar days.

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

39. **Summative Evaluation Report.** The state must submit the 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 Report) 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.

    b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within thirty (30) calendar days.

40. **Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

41. **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.

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

43. **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. 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 on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

X. GENERAL FINANCIAL REQUIREMENTS

44. 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.

45. 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 thirty (30) days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter that 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.

46. 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.

47. 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 are met:

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

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

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

d. Under all circumstances, health care providers must retain one hundred (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.

48. 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.

49. 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 Act, 42 CFR 433.66, and 42 CFR 433.54.

50. 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 XX. 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.

51. 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 X:

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 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.

52. 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.

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

demonstration.

Table 1: Master MEG Chart					
MEG	**Which BN Test Applies?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
Family Planning	Hypo	X		X	Eligible individuals who are not otherwise eligible for Medicaid or CHIP and whose household income is at or below 250 FPL.
ADM	N/A				All additional administrative costs that are not directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

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

54. 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-0036/2). 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 DY 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 Master MEG Chart table and in the STCs in section X, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in Section X, 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 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, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 2: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
Family Planning	Report all expenditures related to those eligible individuals under this demonstration.	**[PO Instructions: Discuss with the state if any exclusions should be listed]**	Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	01/01/1999	12/30/2028
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		

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

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

Table 3: Demonstration Years		
Demonstration Year 26	January 1, 2024 to December 31, 2024	12 months
Demonstration Year 27	January 1, 2025 to December 31, 2025	12 months
Demonstration Year 28	January 1, 2026 to December 31, 2026	12 months
Demonstration Year 29	January 1, 2027 to December 31, 2027	12 months
Demonstration Year 30	January 1, 2028 to December 31, 2028	12 months

55. **Budget Neutrality Monitoring Tool.** The state must provide CMS with annual 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 demonstration's actual expenditures to the budget neutrality

expenditure limits described in Section X. CMS will provide technical assistance, upon request.[1]

56. 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.

57. 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

[1] Per 42 CFR 431.420(a)(2) provides that 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.

data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

58. **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 60.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside 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 statue or regulations, not directly associated with Medicaid, which impact expenditures;

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

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

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

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

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

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

ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

60. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1 Master Meg Chart and Table 2, MEG Detail for Expenditure and Member Months 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.

61. **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.
62. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests, including "capped hypotheticals". Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
63. **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.

64. **Hypothetical Budget Neutrality Test 1:** Family Planning. 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 4: Hypothetical Budget Neutrality Test 1								
MEG	**PC or Agg**	**WOW Only, WW Only, or Both**	**Trend Rate**	**DY 26**	**DY 27**	**DY 28**	**DY 29**	**DY 30**
Family Planning	PC	Both	5.3%	$27.50	$39.89	$42.00	$44.23	$46.57

65. **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.

66. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2024 through December 31, 2028. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

67. **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 5: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
Demonstration Year	**Cumulative Target Definition**	**Percentage**
DY 26	Cumulative budget neutrality limit plus:	2.0 percent
DY 26 through DY 27	Cumulative budget neutrality limit plus:	1.5 percent
DY 27 through DY 28	Cumulative budget neutrality limit plus:	1.0 percent
DY 28 through DY 29	Cumulative budget neutrality limit plus:	0.5 percent
DY 29 through DY 30	Cumulative budget neutrality limit plus:	0.0 percent

XII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 6: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
180 calendar days after approval date	Draft Evaluation Design	STC34
60 calendar days after receipt of CMS comments	Revised Evaluation Design	
120 calendar days after approval date	Mitigation Work Plan and Timeline	STC 17
One year prior to demonstration expiration, or with extension application	Draft Interim Evaluation Report	STC 38
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 38
No later than 18 months after expiration of this demonstration period	Draft Summative Evaluation Report	STC 39
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 39
No later than 120 calendar days after the end of the demonstration, applicable only if not to be extended	Draft Close-Out Report	STC 29
30 calendar days after receiving CMS comments	Revised Close-Out Report	STC 29

Annually		
90 calendar days after the end of each demonstration year	Draft Annual Monitoring Report	STC 27
60 calendar days after receiving CMS comments	Revised Annual Monitoring Report	STC 27

The state is held to all reporting requirements as outlined in the STCs. This schedule of deliverables should serve only as a tool for informational purposes.

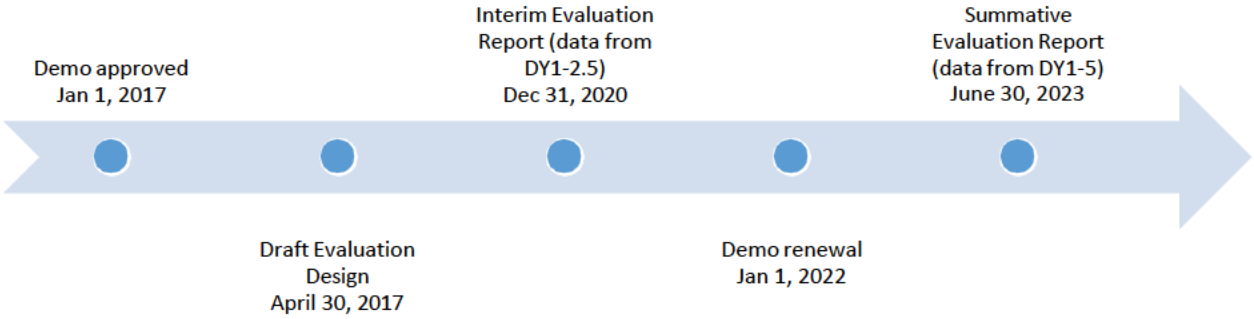
ATTACHMENT A
Developing the Evaluation Design

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

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

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

The format for the Evaluation Design is as follows:

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

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

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
5. For renewals, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss

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

2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured. 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.

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

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

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

care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate. The state also should include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

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

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
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.

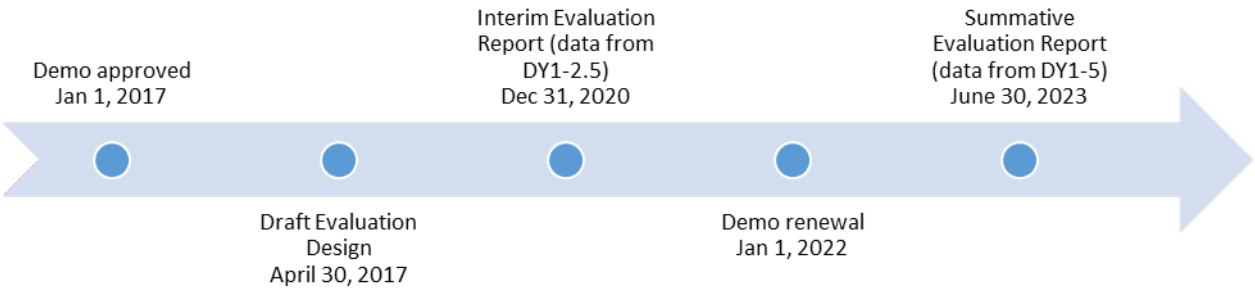
Attachment B:
Preparing the Interim and Summative Evaluation Reports

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 deliverables 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 Design, 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.

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

A. 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?

2. If the state did not fully achieve its intended goals, why not?
3. 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?

ATTACHMENT C
Reserved (Evaluation Design)

Attachment D
Mitigation Plan (Reserved)