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

September 25, 2026

Trinity Wilson
Medicaid Director
Washington State Health Care Authority
626 8th Avenue SE, P.O. Box 45502
Olympia, WA 98504

Dear Director Wilson:

The Centers for Medicare & Medicaid Services (CMS) is making a conforming change to Washington's "Family Planning Only Program" demonstration (Project Number 11-W-00134/0) to align with recent changes to Medicaid and Children's Health Insurance Program (CHIP) statutes, regulation, and policy.

Public Law 119-21, which CMS refers to as the Working Families Tax Cut (WFTC) legislation, made changes to the Medicaid and CHIP provisions of the Social Security Act (the Act), including eligibility and financing changes. CMS has issued regulations and guidance implementing and interpreting many of the Medicaid and CHIP provisions of the WFTC legislation. Some of these statutory and related regulatory changes will affect this demonstration. Therefore, in this action, CMS is making a conforming change to the Washington Family Planning Only Program section 1115 demonstration during this demonstration period.

Specifically, in this action:

- We are changing the demonstration special terms and conditions (STCs) to conform with section 1903(v)(5) of the Act (added by section 71109 of the WFTC legislation) and guidance related to this section of the Act; this change is effective October 1, 2026, through June 30, 2030.

Unless renewed or amended, all authorities granted to operate this demonstration will expire on June 30, 2030.

The conforming change to the STCs is authorized under STC 3.3, titled "Changes in Medicaid and CHIP Law, Regulation, and Policy," which provides that the state must, within the timeframes specified in federal law, regulation, or policy statement, come into compliance with changes in law, regulation, or policy affecting the Medicaid program that occur during the demonstration approval period. Under STC 3.3, CMS may amend the STCs to reflect such changes without requiring the state to submit an amendment.

CMS has determined that this action for the Washington Family Planning Only Program demonstration is likely to assist in promoting the objectives of the Medicaid statute by aligning this section 1115 demonstration with new statutory requirements applicable to the Medicaid program and with how CMS has interpreted and implemented those requirements in regulations and guidance. The effective date of this action is intended to align with the implementation timeline of this new statutory requirement.

This section 1115(a) demonstration action is subject to the limitations specified in Attachment D below, which is appended to the demonstration's STCs, as changed and restated in our approval on August 11, 2026. Attachment D makes a conforming change to the demonstration's STCs as further specified therein, and governs any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The change in Attachment D of this letter should be considered as part of the broader set of STCs that were approved on August 11, 2026, for the Washington Family Planning Only Program demonstration and will be incorporated into the full STCs at a future approval action for this demonstration.

Program Integrity

As part of this action, CMS would like to remind the state about program integrity obligations. States are responsible for following all applicable federal law and regulations when they claim and use federal Medicaid funds and must fully comply with all applicable Medicaid laws and regulations under a section 1115 demonstration, except where specific provisions have been expressly waived or identified as not applicable for that demonstration. This obligation includes all requirements in Title XIX of the Act and implementing regulations governing provider screening and enrollment activities, pre- and post-payment review claiming, payment methodologies and rate-setting, utilization controls, and program integrity, including processes to identify, investigate, and refer suspected fraud and methods to receive complaints and identify questionable practices. States must maintain effective systems and safeguards to prevent, detect, and address any fraud, waste, or abuse (FWA) in the delivery of and payment for Medicaid services, including referrals to law enforcement, when appropriate.

States should have heightened monitoring and oversight mechanisms in place featuring robust internal controls to identify and remediate all vulnerabilities (including, but not limited to, FWA and beneficiary access issues) inherent in service areas approved as part of a demonstration. At any time, CMS may request that the state provide a plan detailing the state's systems and safeguards to prevent, detect, and address any FWA relative to this demonstration. Failure to meet program integrity obligations under federal statutes and regulations or under the terms and conditions of this demonstration approval may result in compliance actions or other enforcement measures that could include requirements to develop and implement corrective action plans, withholdings, deferrals, disallowances, and termination of demonstration authority.

Extent and Scope of Changes

Section 71109 – Alien Medicaid eligibility

Beginning October 1, 2026, sections 1903(v)(5) and 2107(e)(1)(R) of the Act, as added and amended, respectively, by section 71109 of the WFTC legislation, generally limit federal financial participation (FFP) for medical assistance (Medicaid) and child or pregnancy-related health assistance (CHIP), with limited exceptions, to U.S. citizens and U.S. nationals, lawful permanent residents (LPRs), Cuban/Haitian entrants, and Compact of Free Association (COFA) migrants.

Section 1903(v)(5) of the Act describes three exceptions to these FFP limitations: (1) care and services necessary for the treatment of an emergency medical condition as described in section 1903(v)(3) of the Act, (often referred to as "emergency Medicaid"), per section 1903(v)(2) of the Act; (2) full Medicaid and CHIP coverage provided to lawfully residing children and pregnant women under the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) 214 option, per section 1903(v)(4) of the Act, applicable to CHIP through a cross reference at section 2107(e)(1)(Q) of the Act; and (3) Health Services Initiatives (HSIs), which are programs that are designed to improve the health of low-income children, authorized under section 2105(a)(1)(D)(ii) of the Act. Washington elected the CHIPRA 214 option for Medicaid coverage of lawfully residing children and pregnant women.

On April 8, 2026, CMS issued State Health Official (SHO) letter #26-001, which provides policy and operational guidance to states related to implementation of the changes made by section 71109 of the WFTC legislation.[1] On August 17, 2026, CMS issued a letter to Washington describing CMS's determination that continuing previously approved policies in section 1115 demonstrations that authorize federal matching funds for expenditures for services furnished to individuals who will be subject to the FFP limitations in sections 1903(v)(5) and 2107(e)(1)(R) of the Act would not be likely to promote the objectives of the Medicaid or CHIP statutes, as applicable and as modified by the WFTC legislation.[2] In this action, CMS is making a conforming change to align with section 1903(v)(5) of the Act to the STCs of the demonstration. This change, which is further described below, is expected to protect program integrity, ensure accurate eligibility determinations, and ensure proper claiming of FFP in accordance.

Aligning section 1115 expanded continuous eligibility authorities with section 71109 changes

CMS has approved several demonstrations under the authority of section 1115(a) of the Act that provide expenditure authority for expanded continuous eligibility. On July 17, 2025, CMS issued a Dear Colleague letter indicating that CMS does not anticipate approving new requests for expanded continuous eligibility or renewing existing section 1115 demonstration authority for expanded continuous eligibility, beyond what is required or available under the Medicaid and CHIP statutes, as applicable.[3] CMS has provided technical assistance to assist states as they begin upgrading eligibility systems, notifying beneficiaries, and conducting an orderly phase out of expanded continuous eligibility where it has been approved under section 1115 demonstration authority.

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[1] https://www.medicaid.gov/federal-policy-guidance/downloads/sho26001.pdf
[2] https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/Washington_71109_Letter_08.17.26.pdf
[3] https://www.medicaid.gov/resources-for-states/downloads/contin-elig-ltr-to-states.pdf

CMS clarified in SHO Letter #26-001 that states must apply the FFP limitations under section 1903(v)(5) of the Act for the following: 1) children in a continuous eligibility period under the state plan or section 1115 demonstrations under section 1902(e)(12) of the Act; 2) individuals covered during a period of continuous postpartum coverage under the state plan or section 1115 demonstrations under section 1902(e)(16) of the Act; and 3) individuals receiving authority for an expanded continuous eligibility period under the terms of a section 1115 demonstration. For Medicaid applicants and current Medicaid beneficiaries who are not U.S. citizens or U.S. nationals, LPRs, Cuban/Haitian entrants, or COFA migrants, and are not lawfully residing children and pregnant women eligible under the state's election of the CHIPRA 214 option, FFP remains available for emergency Medicaid coverage for such individuals in accordance with section 1903(v)(5) of the Act beginning October 1, 2026, and for the remainder of the expanded continuous eligibility period.

In this action, consistent with its August 17, 2026, letter to Washington, CMS is making a conforming change to reflect that populations receiving expanded continuous eligibility under section 1115(a)(2) expenditure authority in Washington's Family Planning Only Program demonstration are subject to these new requirements beginning October 1, 2026. Specifically, CMS is adding subsection (4) to STC 4 to affirm that the FFP limitation under section 1903(v)(5) of the Act is applicable to Washington's expanded continuous eligibility authority in the Washington Family Planning Only Program demonstration.

Budget Neutrality

There is no change to budget neutrality for this action.

Monitoring and Evaluation

The state is required to conduct systematic monitoring and evaluation in accordance with the demonstration STCs and to incorporate, as appropriate, the conforming change specified in this letter and attachment into these activities. Monitoring and evaluation should identify and describe any observed changes in metrics or outcome measures, including relevant context, as well as associated operational updates. In addition to other required content, these activities—including required deliverables and monitoring calls—should address any anticipated or actual challenges, risks, and program integrity considerations related to implementation of the conforming change in this letter and attachment.

Other Information

This action for the demonstration project is conditioned upon compliance with the previously approved expenditure authorities and STCs (as modified as stated in this letter and attachment) which set forth in detail the nature, character and extent of anticipated federal involvement in the project. In addition, this action is subject to CMS receiving written acceptance within 30 days of the date of this letter. Your project officer is Alex Desatoff, who is available to answer any questions concerning your section 1115 demonstration. Mr. Desatoff's contact information is as follows:

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

If you have questions regarding this action, please contact Sarah Aker, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at Sarah.Aker@cms.hhs.gov.

Sincerely,

Dan Brillman
Deputy Administrator, CMS
Director, Center for Medicaid and CHIP Services

Enclosure

cc: Edwin Walaszek, State Lead, Medicaid and CHIP Operations Group

Attachment D
CONFORMING CHANGES TO SPECIAL TERMS AND CONDITIONS

This Attachment D makes conforming changes to the STCs that were approved on April 30, 2025 and amended and restated on August 11, 2026, as follows. Language CMS is newly adding is in red text.

Edits to STC 4: Aligning section 1115 expanded continuous eligibility authorities with section 71109 changes

STC 4.4. Expanded Continuous Eligibility for Noncitizens Ineligible for FFP. For current Medicaid beneficiaries in an expanded continuous eligibility period, beginning October 1, 2026, the state must apply the FFP limitations under section 1903(v)(5) of the Act. FFP is limited to payment for emergency Medicaid coverage during the remainder of the expanded continuous eligibility period for such Medicaid beneficiaries who are not U.S. citizens or nationals, Lawful Permanent Residents (LPRs), Cuban/Haitian entrants, or Compact of Free Association (COFA) migrants and are not eligible as a child or pregnant woman who is lawfully residing in the U.S. under Washington's election of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) 214 option in accordance with section 1903(v)(4) of the Act.

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 11 -W-00134/0

TITLE: Washington "Family Planning Only Program" Section 1115 Demonstration

AWARDEE: Washington Health Care Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Washington for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from May 1, 2025, through June 30, 2030, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. **Family Planning Services.** Expenditures for extending Medicaid eligibility for family planning services and family planning related services with 12 months of continuous eligibility to women and men capable of producing children who meet one of the following criteria:

    a. Women and men with family income at or below 260 percent of the FPL who are not otherwise enrolled in Medicaid or the Children's Health Insurance Program (CHIP); and,

    b. Individuals up to and including age 26 and domestic violence victims who need confidential family planning services and have individual income at or below 260 percent of the FPL.

<u>Medicaid Requirements Not Applicable to the Medicaid Expenditure Authorities:</u>

All Medicaid requirements apply, except the following:

1.	**Methods of Administration: Transportation**	**Section 1902(a)(4) insofar as it incorporates 42 CFR431.53**

To the extent necessary to enable the state to not assure transportation to and from providers for the demonstration population.

2. 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 and family planning-related services.

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

To the extent necessary for the state to establish reimbursement levels to these clinics that will compensate them solely for family planning and family planning-related services.

4. Eligibility Procedures Section 1902(a)(17)

To the extent necessary to allow the state to not require a person found income-eligible upon application to report changes in income or household size for the 12-month period of coverage under the family planning demonstration.

5. Retroactive Coverage Section 1902(a)(34)

To the extent necessary to enable the state to not provide medical assistance to the demonstration population for any time prior to when an application for the demonstration is made.

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

To the extent necessary to enable the state to not furnish or arrange for EPSDT services to the demonstration population.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: 11 -W-00134/0

TITLE: Washington "Family Planning Only Program" Section 1115 Demonstration

AWARDEE: Washington State Health Care Authority

1. PREFACE

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

The STCs related to the programs for those populations affected by the demonstration are effective from May 1, 2025, through June 30, 2030, unless otherwise specified.

The STCs have been arranged into the following subject areas:

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

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	Evaluation Design

2. PROGRAM DESCRIPTION AND OBJECTIVES

The Washington Family Planning Only Program section 1115(a) Medicaid demonstration extends Medicaid eligibility for family planning and family planning related services to women and men capable of producing children who meet one of the following criteria: Women and men capable of producing children with family income at or below 260 percent of the FPL who are not otherwise enrolled in Medicaid or the Children's Health Insurance Program (CHIP); or, individuals up to and including age 26 and domestic violence victims who need confidential family planning services and have individual income at or below 260 percent of the FPL.

Historical Context and Objectives

The Washington family planning demonstration was originally approved on March 6, 2001, with an effective date of July 1, 2001. The demonstration has been consistently extended since that date. The original Washington "TAKE CHARGE" demonstration expanded Medicaid coverage for family planning services to men and women with family income at or below 200 percent of the FPL. Beginning October 1, 2012, the state had approval to increase eligibility to individuals with income up to 250 percent of the FPL. With the implementation of the Affordable Care Act's requirement to transition to the use of Modified Adjusted Gross Income (MAGI) for determining Medicaid income eligibility, the state's comparable income limit increased to 260 percent of the FPL effective October 1, 2013. Women losing pregnancy related coverage after 60-days postpartum were auto-enrolled in the demonstration, however in July 2022 Washington implemented a separate postpartum program, eliminating the need to cover this population. The state has not had any other program changes. On November 24, 2017, Washington submitted a request to extend the demonstration for a five-year period with the only program change being that the name of the demonstration will now be the "Family Planning Only Program." On May 9, 2018, the state received approval for renewal of the demonstration for five years (through June 2023), and the name of the demonstration was changed to "Family Planning Only Program."

On November 30, 2022, the state submitted a five-year request to extend the demonstration. On June 15, 2023, CMS approved a temporary extension of the demonstration through June 30, 2024. On June 21, 2024, CMS approved a second temporary extension through June 30, 2025, to allow for additional time for the state and CMS to continue to work on the extension request.

Effective May 1, 2025, CMS amended the STCs to identify STI/STD screening services as a family planning service and STI/STD diagnosis and treatment services as a family planning related service.

CMS and Washington expect that approval of this demonstration extension will promote Medicaid program objectives by:

- Improving access to family planning and family planning-related services;
- Decreasing unintended pregnancies; and
- Reducing state and federal Medicaid expenditures by averting births from unintended pregnancies.

3. GENERAL PROGRAM REQUIREMENTS

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

3.2. Compliance with Medicaid 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 expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3.3. Changes in Medicaid and CHIP Law, Regulation, and Policy. The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

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

the state may seek an amendment to the demonstration (as per STC 3.7 of this section) as a result of the change in FFP.

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

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

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

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

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

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

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

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

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

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

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

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

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

activities the state will undertake to notify affected beneficiaries, including community resources that are available.

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

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

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

f. Enrollment Limitation during Demonstration Phase-Out: If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

3.10 Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waiver 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 must 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.

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

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

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

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

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

4. ELIGIBILITY AND ENROLLMENT

4.1 Eligibility for the Demonstration. Family planning and family planning related services are provided to eligible individuals as defined below for a 12-month period. As a function of the 12-month coverage period, an individual found eligible will not be required to report changes in income or household size for the 12-month period of eligibility. Individuals will reapply for coverage at the expiration of the 12-month coverage period and are not limited in how many times they can reapply for coverage. Eligible individuals are women and men capable of producing children who meet one of the following criteria:

a. Women and men with family income at or below 260 percent of the FPL who are not otherwise enrolled in Medicaid or the Children's Health Insurance Program (CHIP); and,

b. Individuals up to and including age 26 and domestic violence victims who need confidential family planning services and have individual income at or below 260 percent of the FPL.

4.2 Eligibility Determination Process.

a. Application. In addition to providing the single streamlined application to beneficiaries who wish to apply for full Medicaid or CHIP benefits, the state will use a separate application to determine eligibility for the Family Planning Only Program. The Family Planning Only Program application will be available online for fax submission, by phone submission, by mail submission, and available at designated provider sites for submission in person.

b. Notices: In addition to complying with content requirements at 42 CFR 435.917, the state will provide the following information on the beneficiary eligibility determination notice:

i. Eligibility will be for a 12-month period without a requirement to report a change in income or household size.
ii. The eligibility determination notice will also serve as advance notification of termination of family planning coverage after the 12-month period of eligibility.
iii. Individuals will need to re-apply for family planning coverage at the expiration of the 12-month period of eligibility. Individuals are not limited in how many times they can reapply for coverage.
iv. How individuals will receive program notices in accordance with 42 CFR 435.918. Individuals up to and including age 26 and domestic violence victims who need confidential family planning services will receive notices at the clinic of their choice. Applicants that opt for a clinic to receive notices regarding their eligibility are expected to make

arrangements with the clinic as to when and how to get notices at the provider site.

c. Coordination with other Insurance Affordability Programs. Individuals applying through the family planning only application must be provided information about potential eligibility for full-scope Medicaid or CHIP coverage and be provided facilitated access to apply for full-scope Medicaid or CHIP coverage. If individuals indicate they have not applied, but wish to apply for more comprehensive coverage, individuals must be directed to or assisted with applying through the single streamlined application. The state must receive written attestation on the family planning only application from individuals indicating they have recently been denied full-scope Medicaid/CHIP coverage or are making an informed choice to not apply for full-scope Medicaid/CHIP coverage and are only seeking family planning only coverage.

Individuals applying through the Washington Health Benefit Exchange who are determined ineligible for full-scope Medicaid or CHIP coverage must be provided information on the written notice about potential eligibility for family planning only coverage and how to apply for such coverage.

Any changes to the state's applications, notices, program outreach materials, administrative procedures, or any other associated operational processes for full-scope Medicaid/CHIP coverage or family planning only coverage necessary to comply with the requirements in this STC shall be provided to CMS for review and concurrence at least 15 days prior to the state's intended implementation of such changes. The state must submit revised drafts addressing any CMS comments received on such materials for final CMS review and approval prior to implementation.

4.3 Demonstration Disenrollment. If a woman becomes pregnant while enrolled in the demonstration, she may be determined eligible for Medicaid under the state plan. The state must not submit claims under the demonstration for any woman who is found to be eligible under the Medicaid state plan. In addition, women and men who receive a sterilization procedure and complete all necessary follow-up procedures will subsequently be disenrolled from the demonstration.

5. PROGRAM AND BENEFITS

5.1. Family Planning Benefits. Individuals 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. Screening for sexually transmitted infection (STI) or sexually transmitted disease (STD) during a family planning visit, Pap smears and pelvic exams;

   Note: The 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.

b. One comprehensive family planning preventive visit per year (once every 12 months) based on nationally recognized clinical guidelines which must have a primary focus and diagnosis of family planning which includes counseling, education, and initiation or management of contraceptive methods.

c. Contraceptives including:

   i. FDA-approved methods of prescription and nonprescription contraceptives;

   ii. Over-the-counter (OTC) family planning drugs, devices, and drug-related supplies; and,

   iii. Education and supplies for FDA-approved contraceptives, natural family planning and abstinence.

d. Sterilization procedures and devices, the office visits or physical exams related to and necessary for sterilization or long-acting reversible contraception, laboratory testing necessary to complete a sterilization or long-acting reversible contraception insertion, and approved prescription medication to treat anxiety and pain in relation to the sterilization procedure. All prescription medications must be directly related to the sterilization procedure and align with the State's preferred drug list.

e. Drugs, supplies, or devices related to family planning services described above that align with the State's preferred drug list and are prescribed by a health care provider who meets the state's provider enrollment requirements (subject to the national drug rebate program requirements).

5.2 Family Planning-Related Benefits. Individuals eligible under this demonstration will also receive family planning-related services and supplies defined as those services provided as part of or as follow-up to a family planning visit for diagnosis and treatment pursuant to a family planning visit such as contraceptive counseling and are reimbursable at the state's regular Federal Medical Assistance Percentage (FMAP) rate. Examples of family planning-related services and supplies include:

a. Treatment of STIs/STDs, except for HIV/AIDS and hepatitis, when the STI/STD is identified during a screen pursuant to a routine or periodic family planning visit. A follow-up visit/encounter for the treatments, such as drugs and

subsequent follow-up visits to rescreen for STIs/STDs based on the Centers for Disease Control and Prevention guidelines may be covered.

b. STI/STD diagnosis and treatment pursuant to a family planning visit such as contraceptive counseling.

c. Drugs/treatment for vaginal infections/disorders, other lower genital tract and genital skin infections/disorders, and urinary tract infections, where these conditions are identified/diagnosed during a routine/periodic family planning visit. A follow-up visit/encounter for the treatment/ drugs may also be covered, and align with the State's preferred drug list.

d. Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services.

e. Treatment of major complications arising from a family planning procedure such as:

   i. Treatment of a perforated uterus due to an intrauterine device insertion;

   ii. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or,

   iii. Treatment of surgical or anesthesia-related complications during a sterilization procedure.

5.3 Minimum Essential Coverage (MEC). The Washington family planning demonstration is limited to the provision of services as described in STCs 5.1 and 5.2. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC).

5.4 Primary Care Referrals. Primary care referrals to other social service and health care providers as medically indicated will be 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 enrollees and must assure CMS that written materials concerning access to primary care services are distributed to demonstration enrollees. The written materials must explain to enrollees how they can access primary care services.

6. COST SHARING

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

7. DELIVERY SYSTEM

7.1 Delivery of Services. Enrollees will receive family planning demonstration services on a fee-for-service (FFS) basis. Beneficiary freedom of choice of which provider to see for family planning services shall not be restricted.

8. MONITORING AND REPORTING REQUIREMENTS

8.1. General Financial Requirements. The state must comply with all general financial requirements under title XIX and as set forth in section 10.

8.2. Reporting Requirements Relating to Budget Neutrality. The state must comply with all reporting requirements for monitoring budget neutrality as set forth in section 11.

8.3. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

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

b. For each deliverable, the state may submit 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, the steps the state has taken to address such issue(s), and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) that meet the terms of this agreement, CMS may proceed with the issuance of a deferral against

the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

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

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.

8.4. Submission of Post-Approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs unless CMS and the state mutually agree to another timeline.

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

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

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

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

8.7. Annual Monitoring Reports. The state must submit one Annual Monitoring Report each demonstration year (DY) that is due no later than 90 calendar days following the end of the DY. The state must submit a revised Annual Monitoring Report within 60 calendar days after receipt of CMS' 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 Report must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed and/or evolve, and will be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates - Per 42 CFR §431.428, Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and how challenges are being addressed. 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 the state's progress toward meeting the goals and milestones of the demonstration initiatives, including relative to their projected timelines. Per 42 CFR §431.428, the Monitoring Reports must document the impact of the demonstration on providing family planning to beneficiaries, as well as access to utilization of care, outcomes of care, and quality and cost of care Specifically:

   The demonstration's metrics reporting must cover categories including, but not limited to: eligibility, appeals and grievances, utilization of services, unpaid medical bills at application or medical debt, and quality of care and health outcomes. The state must report metrics for all demonstration populations.

   Monitoring reports should include the results of beneficiary satisfaction or experience of care surveys, if conducted.

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

demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the Form CMS-64.

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

8.8. 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 corrective action plan could include a temporary suspension of implementation of demonstration initiatives in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

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

a. The draft 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 9.5 and 9.7, respectively.

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

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

e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.
f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.3.

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

9. EVALUATION OF THE DEMONSTRATION

9.1. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design Framework no later than 180 calendar days after the approval of the demonstration. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 9.5 and STC 9.7.

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

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

9.3. Evaluation Design Approval and Updates. The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR §431.424(c), the state will publish the approved Evaluation Design to the state's Medicaid website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each Monitoring Report. 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 wish to include updates to the Evaluation Design in monitoring reports.

9.4. Evaluation Questions and Hypotheses. Consistent with Attachments A and B ("Developing the Evaluation Design" and "Preparing the Interim and Summative Evaluation Reports") of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the demonstration's goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study 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 metrics 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 measure sets, where possible. Measures sets could include CMS's Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set), 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 National Quality Forum (NQF).

Specifically, evaluation hypotheses must focus on the impact of the demonstration in helping eligible beneficiaries access family planning and tobacco cessation 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 method and percentage of beneficiaries who utilized any contraception by method effectiveness) and tobacco cessation services, and maternal health and birth outcomes (e.g., unintended pregnancies, teen birth rates, and the rate of preterm and low birthweight births. 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 medical debt and provider uncompensated care costs. The demonstration evaluation must also assess the effects of the not applicable of NEMT and test evaluation hypotheses related, but not limited, to unmet needs for medical transportation and missed medical appointments.

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with access to and quality of care.

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

a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.

b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report 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 the extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and a description of how the design was adapted should be included. If the state is not requesting an extension for a

demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any.

e. The Interim Evaluation Report must comply with Attachment B ("Preparing the Evaluation Report") of these STCs.

9.6. Cooperation with Federal Evaluators. As required under 42 CFR §431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR §431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.3.

9.7. Summative Evaluation Report. The state must submit to CMS a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.

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

9.8. 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 accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved

methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

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

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

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

9.12. Additional Publications and Presentations. For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given 30 days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

10. GENERAL FINANCIAL REQUIREMENTS

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

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

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

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

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

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

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

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share

for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.

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

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

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

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

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

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

b. For non-risk-based PIHPs and PAHPs, arrangements comply with the upper payment limits specified in 42 CFR §447.362, and if payments exceed the cost of services, the state will recoup the excess and return the federal share of the excess to CMS.

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

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

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

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

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

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

10.7. State Monitoring of Non-federal Share. If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 8.3. This report must include:

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;

b. Number of providers in each locality of the taxing entities for each locality tax;

c. Whether or not all providers in the locality will be paying the assessment for each locality tax;

d. The assessment rate that the providers will be paying for each locality tax;

e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;

f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

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

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.

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

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

Table 1: Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Family Planning	Hypo 1	X		X	All expenditures for the transportation benefit under the family planning demonstration population.
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

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

10.11. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00134/0). 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. To assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset

against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

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

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the MEG Charts and in the STCs in section 10, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

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

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

Table 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	Expenditures for approved demonstration services for the demonstration population	N/A	Follow standard CMS-64.9 Category of Service Definition s	Date of Service	MAP	Y	7/1/98	6/30/30
ADM	Administrative costs that are directly attributable to the demonstration	N/A	Follow standard CMS-64.10 Category of Service Definition s	Date of Payment	ADM	N	7/1/98	6/30/30

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

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

Table 3: Demonstration Years

Demonstration Year 25	May 1, 2025, to June 30, 2026	14 months
Demonstration Year 26	July 1, 2026, to June 30, 2027	12 months
Demonstration Year 27	July 1, 2027, to June 30, 2028	12 months
Demonstration Year 28	July 1, 2028, to June 30, 2029	12 months
Demonstration Year 29	July 1, 2029, to June 30, 2030	12 months

10.13. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality

expenditure limits described in section 11. CMS will provide technical assistance, upon request. [1]

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

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

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

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

c The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded

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

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

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

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 10.16.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 3.7 . CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

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

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

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

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

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

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

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

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.

11. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

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

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

11.4. 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 "Supplemental". Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS

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

11.6. Hypothetical Budget Neutrality Test 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 25	DY 26	DY 27	DY 28	DY 29
Family Planning	PC	Both	6.2%	$12.16	$12.99	$13.80	$14.66	$15.57

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

11.8. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 5/1/25 to 6/30/30. If at the end of the demonstration approval period the Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

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

Table 5: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 25	Cumulative budget neutrality limit plus:	2.0 percent
DY 25 through DY 26	Cumulative budget neutrality limit plus:	1.5 percent
DY 25 through DY 27	Cumulative budget neutrality limit plus:	1.0 percent
DY 25 through DY 28	Cumulative budget neutrality limit plus:	0.5 percent
DY 25 through DY 29	Cumulative budget neutrality limit plus:	0.0 percent

12. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Timeline	Deliverable	STC
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
Periodic	Monitoring Calls	8.6
30 calendar days after the end of each quarter	Quarterly Expenditure Reports (CMS 64)	10.2
60 calendar days after the end of each quarter, except for Q4 which is submitted with Annual Report	Quarterly Budget Neutrality Reports	10.12
90 calendar days after end of each demonstration year	Annual Monitoring Reports (including Q4 monitoring information)	8.7
60 calendar days after receipt of CMS comments	Revised Monitoring Report	8.7
No later than 180 calendar days after demonstration approval.	Draft Evaluation Design	9.1
60 calendar days after receipt of CMS comments	Revised Evaluation Design	9.3
One year prior to current demonstration expiration date, or when the extension application is submitted, whichever is sooner.	Draft Interim Evaluation Report	9.5c
60 calendar days after receipt of CMS comments	Final Interim Evaluation Report	9.5
No later than 18 months after the end of the demonstration approval period.	Draft Summative Evaluation Report	9.6
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	9.6b

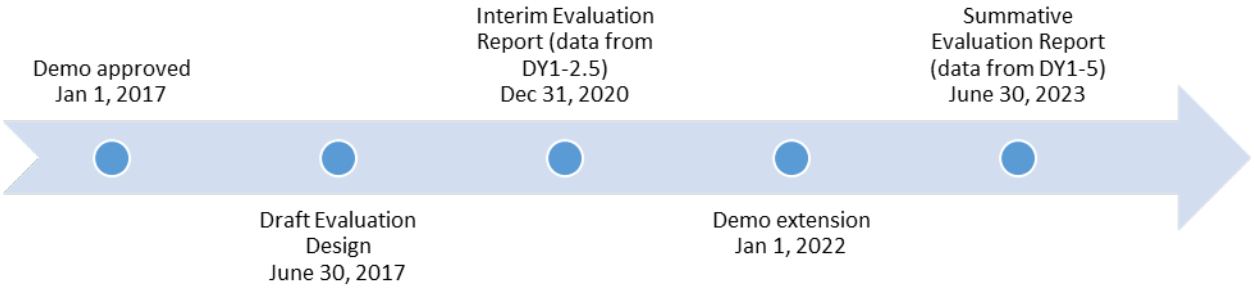
ATTACHMENT A
Developing the Evaluation Design

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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus 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 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 issues that the state is trying to address with the approved section 1115 demonstration waivers and expenditure authorities, the potential magnitude of the issues, and why the state selected this course of action to address the issues (e.g., a narrative on why the state submitted a section 1115 demonstration application).

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, or expansion of, the demonstration.

5. For extensions, 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 XXI.

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

4. Include a Logic Model or 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 goal, the primary drivers that contribute directly to achieving the goal, 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.

5. Include implementation evaluation questions to inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

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. The evaluation approach should also consider principles of equitable evaluations, and involve partners such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in developing an evaluation approach. The state's Request for Proposal for an independent evaluator, for example, could encourage research teams to partner with impacted groups.

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. *Focus and Comparison Populations* – Describe the characteristics of the focus 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.

   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 Core Set of Health Care Quality Measures for Medicaid–Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, 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 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.

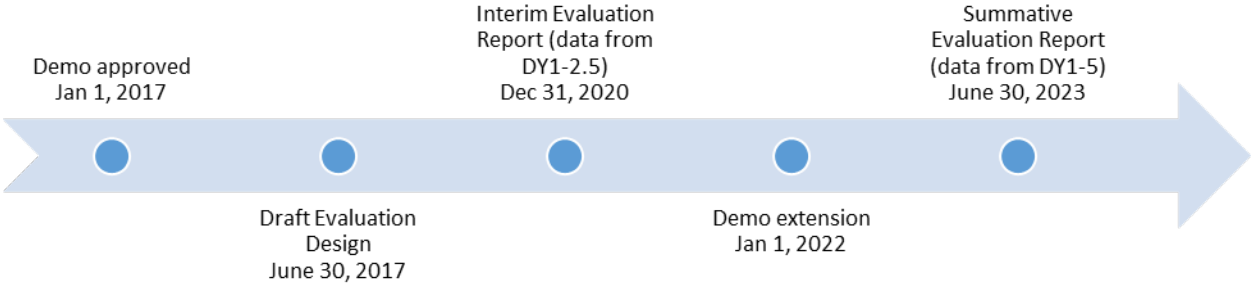
ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus 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 30 calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). The already–approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When submitting an application for renewal, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.
CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section–1115–demonstrations/1115–demonstration–monitoring–evaluation/1115–demonstration–state–monitoring–evaluation–resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

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

Required Core Components of Interim and Summative Evaluation Reports
The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy.
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 issues that the state is trying to address with the approved section 1115 demonstration waivers and expenditure authorities, how the state became aware of the issues, the potential magnitude of the issues, 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, or expansion of, the demonstration.
5. For extensions, 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 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 Logic Model or 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. *Focus and Comparison Populations* – Describe the focus 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. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

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
Evaluation Design

Washington State's 1115(a) Medicaid Family Planning Only (FPO) Demonstration Waiver

Evaluation Design Plan

As required by the Centers for Medicare and Medicaid Services (CMS), STC 9.1

Demonstration Approval Period: May 1, 2025 – June 30, 2030

Project Number: 11-W-00134/0

February 3, 2026

Washington State Health Care Authority

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General Background Information

Since July 1, 2001, the Washington State's Family Planning Only (FPO) Demonstration waiver (formerly Take Charge) has been operating continuously state-wide toward the goals of: 1) improving the reproductive health[1] of low-income Washingtonians through appropriate health screens and treatment and 2) reducing state and federal Medicaid expenditures for births from unintended pregnancies. The FPO Demonstration is administered through a fee-for-service (FFS) delivery model and covers every FDA approved birth control method and a narrow range of family planning and family planning-related services that help clients use their contraceptive methods safely and effectively to avoid unintended pregnancy.

From the previous demonstration period there have been changes to eligibility criteria and covered services. FPO formerly offered 10-months of Demonstration services to recently pregnant persons who lost Medicaid coverage 60-days post-pregnancy. However, with the July 2022 implementation of the After-Pregnancy Coverage program extending full-benefits to 12-months post-pregnancy, the FPO waiver no longer enrolls postpartum (formly known as FPO-pregnancy-related) clients. Given these changes to eligbility, the demonstration objectives no longer include evaluation metrics on birth intervals or birth outcomes. Family planning-related covered services were expanded in January 2024 to include screening, testing, and treatment for additional sexually transmitted infections (STIs). Changes to clarification of STI covered services has prompted the evaluation to include objectives on assessing treatment.

The continued approval of WA FPO is based on the determination that the continued demonstration is designed to promote the objectives of Title XIX of the Social Security Act (establishing the Medicaid program), by increasing and strengthening reproductive health, reducing unintended pregnancies, reducing health inequities, and improving maternal and child health outcomes by providing access to family planning services and supplies to eligible, low-income indviduals. On May 1, 2025, the waiver was approved for another five years through June 30, 2030.

Program Eligibility and Enrollment

The eligibility criteria for FPO Demonstration extends benefits for family planning services and family planning-related services to uninsured individuals for these two populations:

- Women and men with family incomes at or below 260% federal poverty level (FPL) who seek family planning coverage to prevent an unintended pregnancy; and
- Individuals up to age 26 years and domestic violence victims who need confidential family planning services and are at or below 260% FPL.

Eligibility will be for a 12-month period and during this time reporting changes to income or household size will not be required. Individuals can re-apply for coverage after the 12-month eligibility period ends and are not limited in how many times they can reapply for coverage.

[1] Reproductive health refers to the physical (e.g., functional condition of reproductive organs), mental (e.g., emotional well-being related to sexuality, reproductive decisions, and parenthood), and social (e.g., access to healthcare, information, and support related to reproductive issues) well-being of individuals related to their reproductive systems and processes.

Demonstration Covered Services

The FPO Demonstration provides health and family planning services at no cost to eligible individuals in Washington state. FPO Demonstration covered services can be categorized into two benefit types outlined in the FPO Demonstration Special Terms and Contiditions (STCs)[2] and clarified in State Medical Director Letter #16-008[3].

Family Planning Benefits. Beneficiaries eligible under this Demonstration will receive family planning services and supplies whose primary purpose is to prevent or delay pregnancy as described in section 1905(a)(4)(c) of the Social Security Act, including:

- Annual comprehensive family planning preventive visit with primary focus to include:
    - Initation and management of contraceptive method management,
    - Patient education and counseling;
- FDA-approved methods of contraception;
- Pelvic examinations and Pap smears with a family planning visit;
- Sterilization procedures and devices;
- Sexually transmitted infections (STI)/sexual transmitted disease (STD) screening services; and
- Drugs, supplies, or devises related to health services desribed above.

Family Planning-Related Benefits. Beneficiaries eligible under this Demonstration will also receive family planning-related services and supplies defined as those services provided as part of or as follow-up to a family planning visit. Such services are provided because a "family planning-related" problem was identified and/or diagnosed during a routine or periodic family planning visit. Examples of family planning-related services and supplies provided under this Demonstration include:

- STI/STD diagnosis and treatment services;
- Drugs for vaginal infections/disorders, other lower genital tract or genital skin infections/disorders, and urinary tract infections;
- Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services in a family planning setting;
- Treatment of major complications arising from a family planning procedure such as:
    - Treatment of a perforated uterus due to an intraurtine device insertion;
    - Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
    - Treatment of surgical or anesthesia-related complications during a sterilization procedure.

2 https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/wa-family-planning-only-program-ca-04302025.pdf
3 https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf

Evaluation Questions and Hypotheses

Demonstration Goals

The goals of the FPO Demonstration are to:

1) increase access and utilization to family planning services via person-centered contraceptive care to avert unintended pregnancies, positively impacting reproductive health outcomes,
2) increase access and utilization to family planning-related services, including screenings and treatment to prevent severe health complications from untreated STIs/STDs, positively impacting reproductive health outcomes,
3) Reduce the overall cost of publicly funded health care by providing low-income Washingtonians access to safe, effective services that are consistent with these goals.

The Driver Diagram and Evaluation Design include evaluation questions and hypotheses examining all goals of the FPO Demonstration.

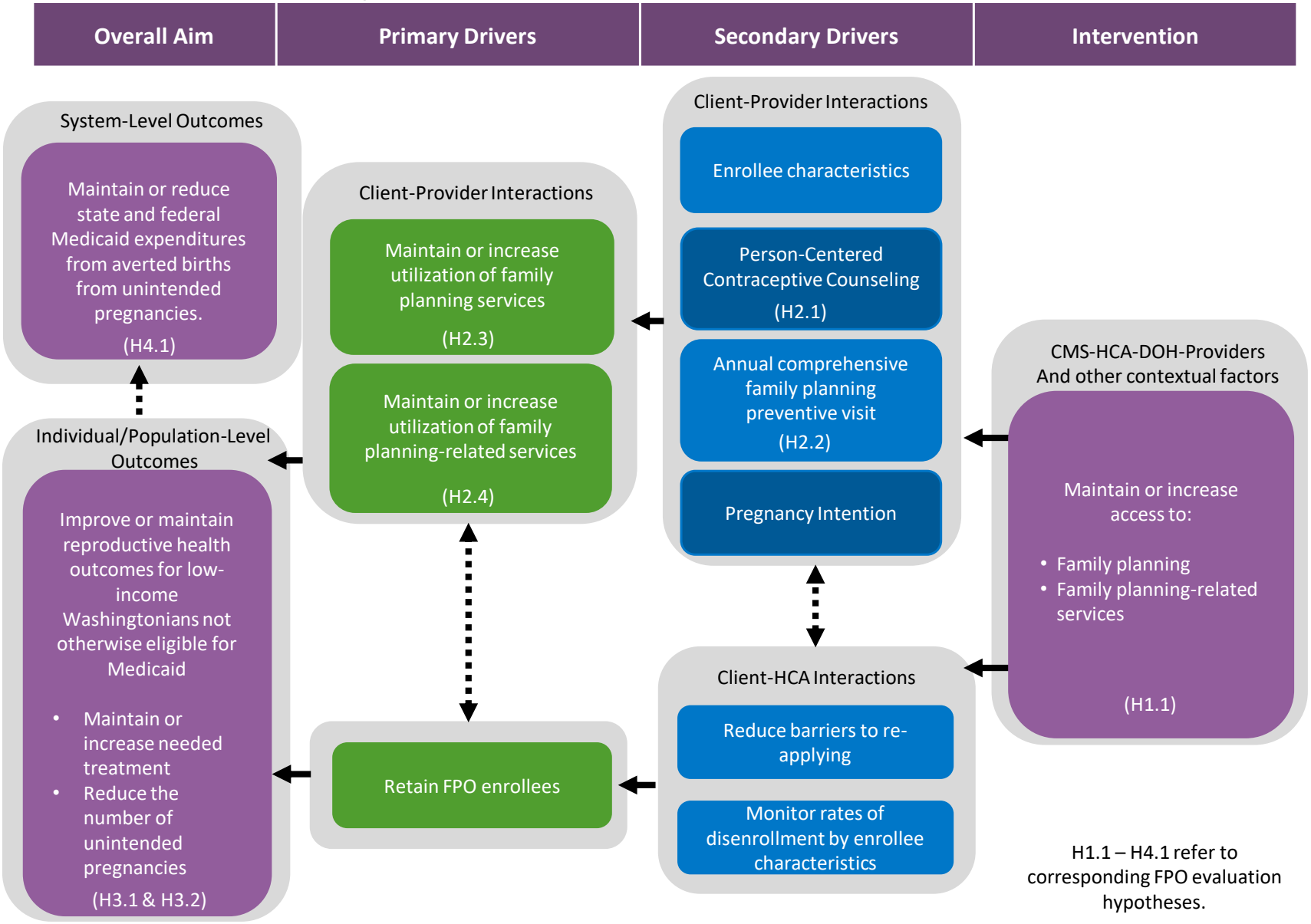
Driver Diagram

The design and implementation of an intervention demonstration are usually based on a set of explicit or implicit assumptions by stakeholders about what action is required to solve a social problem and why the problem will respond to this action. The driver diagram explains why the intervention demonstration is expected to work, focusing on the causal pathways to the overarching aim of demonstration.

Figure 1 describes the relationship between each waiver goal and the primary and secondary drivers necessary to achieve the **overall aim**, to maintain or improve reproductive health outcomes for low-income Washingtonians as a result of access to family planning and/or family-related services. Consistent with other CMS Driver Diagrams, the projected causal pathway moves from right to left, beginning with the **intervention**, the provision of services, maintaining or increasing access to family planning and/or family planning-related services. The intervention (i.e., access) is expected to motivate utilization of family planning/family planning-related services (i.e., **primary drivers**), however **secondary drivers** (e.g. person-centered contraceptive care, immediate and long-term pregnancy goals), actions necessary to achieve primary drivers, were also chosen to be evaluated.

Driver diagrams are included for the demonstration goal to provide a summary and rationale behind the cause and effect of various waiver components and intended outcomes. The driver diagram demonstrates the provision of coverage for family planning and family planning-related services under the FPO Demonstration.

FIGURE 1: FPO Demonstration Driver Diagram



Evaluation Questions and Hypotheses

Four evaluation questions guide this study. The proposed evaluation questions are designed to assess the goals of the FPO Demonstration. Each evaluation question is addressed through a minimum of one corresponding hypothesis that aligns with the interventions, drivers, and outcomes in the FPO Demonstration Driver Diagram (Figure 1). Subsequent sections operationalize the evaluation hypotheses through a series of measures, study populations, data sources, and analytic methods intended to translate the evaluation questions into quantifiable targets of program performance.

Evaluation Question 1*: Did the FPO Demonstration maintain or increase access to family planning and/or family planning-related services for low-income individuals not otherwise eligible for Medicaid?*

- Hypothesis 1.1: The FPO Demonstration will maintain or increase access to family planning and/or family planning-related services.

Evaluation Question 2*: Did the FPO Demonstration maintain or increase utilization of family planning and/or family planning-related services for the target population.*

- Hypothesis 2.1: The FPO Demonstration will maintain or increase person-centered contraceptive care.
- Hypothesis 2.2: The FPO Demonstration will maintain or increase annual comphrensive family planning visits.
- Hypothesis 2.3: The FPO Demonstration will maintain or increase utilization to family planning services.
- Hypothesis 2.4: The FPO Demonstration will maintain or increase utilization to family planning-related services.

Evaluation Question 3**:** *Did the FPO Demonstration maintain or improve reproductive health outcomes for the target population as a result of access to family planning and/or family planning-related services.*

- Hypothesis 3.1: The FPO Demonstration will maintain or increase the treatment rate for waiver participants diagnosed with treatment need.
- Hypothesis 3.2: The FPO Demonstration will maintain or reduce the number of unintended pregnancies among enrollees.

Evaluation Question 4*: Did FPO Demonstration maintain or reduce state and federal Medicaid expenditures for averted births from unintended pregnancies.*

- Hypothesis 4.1: The FPO Demonstration will remain at or below the CMS-specified annual expenditure limits and total expenditures will be significantly lower than the cost of pregnancies averted for the FPO population.

Methodology

The evaluation of the FPO Demonstration is guided by four evaluation questions and eight hypotheses that examine the impact of the FPO Demonstration on access, utilization, and reproductive health outcomes. This section summarizes the evaluation design, study populations, and evaluation period for the FPO evaluation. Subsequent sections provide detailed information for each evaluation question, including study populations, data sources, analytic methods, evaluation measures, and methodological limitations.

Data, analytic methods, and reporting will meet the traditional standards of scientific and academic rigor, as appropriate and feasible for each aspect of the FPO evaluation.

Evaluation Design

A general challenge to Washington's FPO Demonstration evaluation is the similarity of the current renewal to previous waiver periods. Washington State has offered waiver services for more than two decades; while the FPO Demonstration seeks to expand access to these services, it currently does not substantively change them or the populations receiving them. The proposed evaluation design attempts to capture changes resulting from the FPO Demonstration Waiver but observed changes are likely to be modest given the similarity of the counterfactual condition.

With this methodological challenge in consideration, most FPO Demonstration measures are evaluated using a **one-group posttest only** design due to the longstanding nature of the FPO Demonstration. While the one-group posttest design is the most vulnerable to threats to validity, it is only used when pre-Demonstration and comparison group data are unavailable. Table 1 lists which measures will be evaluated through a one-group posttest design using descriptive trend analysis (DTA). Benchmark and subgroup analyses will be leveraged where feasible to support interpretation of findings. The timeframe for the post-only period will begin when the current demonstration period begins on 05/01/2025 and ends when the current demonstration period ends on 06/30/2030.

In the event of approved FPO Demonstration waiver amendments and/or state/federal exogenous events/policy changes affecting the demonstration population, the FPO evaluation will explore the feasibility of an additional quasi-experimental design: **one-group pretest-posttest design** to evaluate the impact of interventions (i.e., policies, programs). A one-group pretest-posttest design relies on repeated observations to monitor changes before and after waiver amendments and/or state/federal exogenous events/policy changes. Table 1 lists which measures may be evaluated through a one-group pretest-posttest design using descriptive trend analysis (DTA). To strengthen DTA, the evaluation will also leverage benchmarks and subgroup analyses where feasible to substantiate and contextualize observed trends. At minimum, FPO eligible beneficiaries/utilization measures under Hypothesis 2.3 will be evaluated using interrupted time series (ITS) analysis if a minimum of data points each for the pretest-posttest periods is reached. Further details on quasi-experimental methods can be found under Quantitative Analysis.

Evaluation Populations

The target population for the FPO evaluation includes all clients enrolled in the FPO Demonstration. If feasible, each measure will be stratified by different program income eligibility populations. However, given the program majority is women, we may exclude some sub-populations (e.g., males, teens, and

domestic violence victims) due to data availability and small sample sizes which would lead to less power to detect statistical differences.

The FPO evaluation includes client-, provider-, and system-level analyses. For most measures, population-level data (rather than a sample) will be used to assess process and outcome measures. These data are available at the individual level for both clients and providers, which are the primary units of analyses. Measures relating to clients and providers may be stratified into key demographic subgroups, such as age, race/ethnicity, region, or provider type, where applicable.

In addition to population-level client and provider data, the evaluation will draw on survey data from the FPO Client Survey, which was pilot tested last year (Washington State Institutional Review Board (WSIRB) Project #2024-006). There were no statistically significant differences between survey respondents and non-respondents, suggesting results are representative to the FPO Demonstration population.

Evaluation Measures

TABLE 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches

Demonstration Goal 1: Maintain or increase access to family planning and/or family planning-related services					
Evaluation Question	**Evaluation Hypotheses**	**Measures (to be reported for each Demonstration Year)**	**Data Source**	**Analytic Approach**	**Time Periods**
Did demonstration increase access to family planning and/or family planning-related services?	1.1 Enrollees will maintain or increase access to family planning and/or family planning-related services.	Provider-to-enrollee ratio = Total number of participating providers: Total number of beneficiaries	ProviderOne	Descriptive statistics (frequencies and percentages); time trend analysis; subgroup analysis	Compute for each year of the demonstration extension and calculate for each measure specified.
		Network adequacy of beneficiaries to providers		Descriptive statistics of drive time and distance (frequencies and percentages); time trend analysis; subgroup analysis	

Demonstration Goal 2: Maintain or increase utilization of family planning and/or family planning-related services for the target population.						
Evaluation Question	**Evaluation Hypotheses**	**Measures (to be reported for each Demonstration Year)**		**Data Source**	**Analytic Approach**	**Time Periods**
		Numerator	**Denominator**			
Did the FPO Demonstration maintain or increase utilization of family planning and/or family planning-related services for the target population.	2.1: The FPO Demonstration will maintain or increase person-centered contraceptive care.	Number of FPO Waiver participants rating all four PCCC-RS items as "Excellent" (i.e., topbox score)	Total number of survey female respondents	FPO Client Survey	Descriptive statistics (frequencies and percentages); time trend analysis; subgroup analysis; benchmark comparison to FPO pilot results	Administer survey monthly for at least 3 demonstration years
	2.2: The FPO Demonstration will maintain or increase annual comprehensive family planning visits.	Number of annual comprehensive family planning visits	Total number of beneficiaries	ProviderOne	Descriptive statistics (frequencies and percentages); time trend analysis; subgroup analysis; benchmark comparison to CMS Core Set	Compute for each year of the demonstration extension and calculate annual rates for each measure specified.
	2.3: The FPO Demonstration will maintain or increase utilization to family planning services.	Number of family planning services utilized	Total number of beneficiaries			
		Number of beneficiaries who utilized any contraceptive in each year of the demonstration	Total number of beneficiaries			
		Number of female beneficiaries who utilized long-acting reversible contraceptives in each year of the demonstration	Total number of female beneficiaries			
	2.4: The FPO Demonstration will maintain or increase utilization to family	Number of beneficiaries tested for any sexually transmitted infection or disease	Total number of beneficiaries	ProviderOne	Descriptive statistics (frequencies and percentages); time trend analysis;	Compute for each year of the demonstration extension and calculate annual rates for each measure specified.

Demonstration Goal 2: Maintain or increase utilization of family planning and/or family planning-related services for the target population.						
Evaluation Question	**Evaluation Hypotheses**	**Measures (to be reported for each Demonstration Year)**		**Data Source**	**Analytic Approach**	**Time Periods**
		Numerator	**Denominator**			
	planning-related services.	Number of female beneficiaries who obtained a cervical cancer screening	Total number of female beneficiaries		subgroup analysis; benchmark comparison to CMS Core Set	

Demonstration Goal 3: Maintain or improve reproductive health outcomes for the target population as a result of access to FP services and/or FP-related services.						
Evaluation Question	**Evaluation Hypothesis**	**Measures (to be reported for each Demonstration Year)**		**Data Source**	**Analytic Approach**	**Time Periods**
		Numerator	**Denominator**			
Does the demonstration improve reproductive health outcomes?	3.1: Maintain or increase the treatment rate for waiver participants diagnosed with treatment need.	Number of beneficiaries receiving treatment	Beneficiaries diagnosed for any sexually transmitted infection or disease	ProviderOne	Descriptive statistics (proportions) and significance testing (chi-squared of the proportions); trend analysis when applicable.	Calculate annual and biannual rates for each measures specified and conduct a trend analysis after year three.
		Number of female beneficiaries receiving follow-up visits	Number of female beneficiaries who obtained a cervical cancer screening diagnosis			
	3.2: Reducing the number of unintended pregnancies among FPO Demonstration enrollees.	Number of births	Total number of survey respondents stratified by pregnancy and fertility goals	FPO Client Survey and FSDB		

Demonstration Goal 4: Maintain or reduce state and federal Medicaid expenditures for averted births from unintended pregnancies.					
Evaluation Question	**Evaluation Hypothesis**	**Measures (to be reported for each Demonstration Year)**	**Data Source**	**Analytic Approach**	**Time Periods**
Did FPO Demonstration maintain or reduce state and federal Medicaid expenditures for averted births from unintended pregnancies.	4.1: The FPO Demonstration will remain at or below the CMS-specified annual expenditure limits and total expenditures will be significantly lower than the cost of pregnancies averted for the FPO population.	Cost benefit analysis to Medicaid from expenditures related to prenatal, delivery, and newborn services up to 1-year of age	ProviderOne, FPO Client Survey, and FSDB	Descriptive statistics (proportions) and significance testing (chi-squared of the proportions); trend analysis when applicable.	Estimate savings cost for the waiver period; benchmark comparison when benchmark is available

Potential Comparison Group

Because the FPO Demonstration is available statewide and clients are placed in the most comprehensive program for which they are eligible, there are no truly comparable clients in other HCA programs. However, in keeping with the rigor of the proposed evaluation design, HCA assessed the viability of the Apple Health (AH) Medicaid clients as a potential comparison group. AH includes a potential comparison group of clients of reproductive age (and non-pregnant) with benefits that include family planning and family planning-related services. However, AH as a comparison group have lower incomes (up to 133% FPL) than FPO Demonstration and receive more comprehensive services under the Medicaid state plan. Therefore, positive outcomes observed in the FPO population would likely be due to population characteristics (i.e., selection bias) rather than the FPO benefits. Due to substantial validity issues arising from these differences (i.e., different eligibility requirements, program structures, and funding mechanism) and technical challenges related to client identification and selection bias – no viable comparison group exists for the FPO evaluation as a whole.

Evaluation Period

The study period for the FPO Demonstration evaluation is May 1, 2025 through June 30, 2030. This timeframe corresponds to the current FPO Demonstration waiver period and ensures the population, services, and data sources are comparable. WA State HCA has decided to exclude waiver extension years (July 1, 2023 – April 31, 2025) from the current evaluation period and include them in the previous evaluation period (May 9, 2018- June 30, 2023) (Summative Evaluation Report due December 31, 2026).

Data Sources and Collection

Data Sources

The FPO Demonstration will leverage several administrative data sources collected by HCA for reporting and payment purposes to assess the impact of the FPO Demonstration. Primary data collection will also be used to explore client perspectives on patient-centered contraceptive care and pregnancy intention related to the FPO Demonstration

Secondary Data Collection

Administrative data for the evaluation will be collected retrospectively quarterly, annually, and at the end of the demonstration period.

Data for evaluation are based on eligibility, birth certificates, and linked claims file with vital records also known as the First Steps Database (FSDB) (WSIRB Project #D-092711-A). Claims and eligibility data are available for all Medicaid clients.

ProviderOne-Enrollment: The client-level enrollment files contain information about clients' age, race/ethnicity, county, and beginning and end dates of FPO eligibility.

ProviderOne-FFS claims data: FFS claims data contain information on client diagnoses, procedures provided under the FFS delivery model, including Current Procedure Terminology (CPT) codes; International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes, provider identification numbers (National Provider Identifier (NPI)); and other information necessary to calculate individual-level measures.

Contraceptive methods will be grouped by efficacy into clinically meaningful tiers: 1) most effective, 2) moderately effective, and 3) least effective. For clients using multiple methods concurrently, the method with the highest effectiveness will be selected.

1) Most effective contraception consists of reversible methods (e.g., implants or intrauterine devices) and permanent methods (e.g., sterilization) that have experienced less than 1 pregnancy per 100 women within the first year of use.

2) Moderately effective contraception consists of hormonal or barrier reversible methods (e.g., oral contraceptive pill, injectables, etc.) that rely on correct use and where women have experienced approximately 6-12 pregnancies per 100 women within the first year of use.

3) Least effective contraception consists of barrier reversible methods (e.g., female/male condom, natural family planning, etc.) that rely on correct use or abstinence and where women have experienced approximately 18 or more pregnancies per 100 women within the first year of use.

LARC effectiveness years vary by type (e.g., copper IUD (~10 years) versus implants (~3 years)) and brand. The utilization measure is "Number of female beneficiaries who utilized long-acting reversible contraceptives in each year of the demonstration/total beneficiaries", the proposed measure is intended to evaluate long-term use of contraceptive methods. Continuous use of IUDs has been shown to be cost-neutral at 2.1 years and it is of interest to other states and CMS to report continuation rates and characteristics of women who continue versus discontinue.

ProviderOne-Pharmacy claims data: Client-level pharmacy claims contain information about filled prescriptions, including drug code name, dose, date filled, number of days prescribed, and refill information. Even though these data are highly reliable and valid, claims data are subject to more interpretation as providers submitting claims do not necessarily conform to uniform standards for the finer details describing services provided; in some cases, claims may reflect contraceptive methods provided, not the method in use by the client as clients may discontinue methods.

First Steps Database (birth certificates linked to Medicaid clients): All Washington birth certificates are linked at the individual level to Medicaid claims and eligibility history. FSDB begins with births in August 1988 and currently contains linked birth certificates through 2024. The annual unduplicated count of FPO eligible clients is linked to the FSDB by ProviderOne ID. The First Steps Database is maintained biannually.

External Data Sources

Benchmark data. The evaluation leverages ongoing reporting of state and national benchmarks. Importantly, benchmarks at the state or national level may not be representative of FPO clients and may not be available at the subgroup level (e.g., race/ethnicity, or age) or at the same time intervals as the FPO Demonstration. The sources below may be used to develop evaluation-specific benchmarks, where available and applicable.

- National Survey of Family Growth (NSFG)
- Pregnancy Risk Assessment Monitoring System (PRAMS) survey
- CMS Core Set of Health Care Quality Measures for Children/Adults in Medicaid and CHIP

Primary Data Collection

The perspectives of FPO Demonstration participants offer valuable insight into the FPO Demonstration client-provider interaction not otherwise available through administrative or publicly available data sets.

The FPO Client Survey will include the Retrospective Person-Centered Contraceptive Counseling (PCCC-RS) scale and items assessing pregnancy and fertility goals. The PCCC-RS[4] is a validated[5] four-item patient reported outcome measure designed to assess if the contraceptive counseling and contraceptive methods were person-centered, or focused on the patient's own needs, values, and preferences. The FPO Client Survey will be administered monthly to any waiver participant meeting inclusion criteria via text with an online survey link or via telephone interview. PCCC-RS is intended to be administered within six months from the date of a waiver service. Based on the FPO waiver pilot test (WSIRB Project #2024-006) a 30 percent response rate was achieved and there were no statistically significant differences between survey respondents and non-respondents, suggesting responses are representative of the broader FPO Demonstration population.

Data Analysis Strategy

Access, utilization, and reproductive health outcomes will be evaluated using a series of quantitative and qualitative methods. This section describes the proposed analytic strategies for examining the measures presented in Table 1. Subgroup analyses (i.e., age, race/ethnicity, FPO Demonstration income groups, and geography) will focus on identifying any changes to FPO eligible and participant populations over the waiver period that would impact access, utilization, and reproductive health outcomes. If statistically significant subgroup changes are observed for FPO eligible and participant populations, these results could contextualize observed trends in measures where subgroup analysis may not be currently feasible (e.g., LARC utilization and Cervical Cancer screening).

Quantitative Analysis

For administrative (i.e., eligibility enrollment, claims), vital records, and survey quantitative results will be analyzed using descriptive statistics, descriptive trend analysis (DTA), and interrupted time series (ITS) to examine most of the evaluation questions. **Descriptive statistics** assess the characteristics of FPO eligible and participant populations. Descriptive statistics include estimates of central tendency and dispersion. Potential inferential analyses include bivariate statistics, parametric tests (e.g., *t*-tests or chi-squared tests), and non-parametric tests (e.g., McNemar's test, Wilcoxon signed-ranked test). **Descriptive trend analysis (DTA)** will be used if there are no intervention/changes observed for the measure and the recommended minimum measurement time points for ITS are not available. (i.e., eight pre- and eight post-FPO Demonstration measurement time points). Univariate or bivariate statistics will be calculated on the measure population at two or more points in time to determine if a trend exists. Unadjusted trend analyses will be used to present the change of process and impact outcomes measures over time. The analyses may be further stratified by subgroups (e.g., age, race/ethnicity, sex, income groups, and geography). Generalized linear and/or logistic regressions may be used to test the variations in the trends for the entire demonstration population and across different subgroups. Finally, **ITS analysis**, which uses aggregate data collected over equally spaced intervals before and after an intervention/policy change (including state/federal exogenous events/policy changes), may be used to evaluate the success, failure, or unintended consequences of interventions/policies on measures. A key assumption of ITS is that data trends before the intervention/change can be extrapolated to predict trends had the intervention/policy

[4] University of California San Francisco Person-Centered Contraceptive Counseling Measure https://pcccmeasure.ucsf.edu/retrospective-pccc

[5] Partnership for Quality Measurement validation endorsement status https://p4qm.org/measures/4825

change not occurred. A major advantage of ITS methodology is that a control site or comparison group is not required, both conditions which are not feasible due to the statewide FPO Demonstration. The ITS method allows the target population to serve as its own comparison group in the pre/post analysis.

Qualitative Analysis

Thematic content analysis will be used to evaluate salient responses to open-ended questions from the FPO Client Survey. Through this method, evaluators will begin with a detailed and systematic reading of the responses, making brief notes about analytic ideas and reflections. Evaluators will code the responses independently and identify patterns of meaning across codes that represent central, coherent ideas and coalesce coded segments together. The grouping of these codes may use inductive or deductive reasoning as initial themes emerge. Evaluators will review and discuss divergences, and the questions below (modified from Braun & Clarke[6]) will be used to review and refine initial themes into final core themes:

1. Is this a theme that represents a pattern across participants?
2. Does this theme tell us something about the needs of FPO clients?
3. Does this theme include or exclude many coded segments?
4. Is there enough data to support that this is a strong theme?

Methodological Limitations and Considerations

Limitations inherent to the evaluation design can be divided into two categories: methodological concerns such as bias in survey responses; and contextual and environmental concerns such as changes to provider participation and other external pressures on access to care.

Survey responses. Several of our key outcomes rely on self-report data from the FPO client Survey. Bias can be introduced into survey analysis in a few distinct ways, two of which are particularly relevant to this survey. First, sample selection and survey response rates can lead to bias if the eventual survey respondent sample is not representative of the FPO enrollee population. As mentioned, pilot test respondents were statistically compared to non-respondents demographic information, eligibility characteristics, and FPO waiver utilization. No statistically significant differences between respondents and non-respondents were found, suggesting survey respondents were representative of the FPO Demonstration female population. Second, given the highly sensitive survey questions around contraceptive care and pregnancy intentions, responses may be subject to social desirability bias, whereby respondents give answers that they believe to be more socially acceptable, rather than those that are accurate. Again, pilot test respondents were compared to benchmarks for the PCCC-RS scale. Evaluators will continue to test for biases.

Provider participation. The network of clinics providing services to FPO enrollees includes Local Public Health Agencies (LPHAs), Federally Qualified Health Centers (FQHCs), stand-alone family planning clinics (e.g., Planned Parenthood), and school-based or university health centers. In recent analysis, Planned Parenthood provides a majority of FPO services. Any exogenous changes impacting the number and feasibility of the FPO Demonstration provider network could affect some evaluation outcomes of interest,

[6] Braun, V., & Clarke, V. (2022). *Thematic analysis: A practical guide*. SAGE.

such as enrollment rates, churn, and continuity of care, and could diminish the value of pre-demonstration period FPO enrollees as a potential comparison group.

Client acceptability and utilization of contraceptives. While pharmacy claims data will be used to analyze contraceptive methods prescribed, it cannot measure acceptability or adherence.

External pressures on access to care. Several current health care infrastructure, policy, and political issues may impact access to care for FPO enrollees in ways that are difficult to isolate from the effects of the demonstration. As with impacts from COVID-19, evaluators included federal and state policy dates, noting contextual data in trend analysis to help interpret and contextualize FPO Demonstration utilization changes in the prior waiver period.

Special Methodological Considerations. A general challenge to Washington's FPO Demonstration evaluation is the similarity of the current renewal to previous waiver periods. Washington State has offered waiver services for more than two decades; while the FPO Demonstration seeks to expand access to these services, it does not substantively change them or the populations receiving them. Accordingly, the FPO Demonstration meets the definition of a "long-standing, non-complex, [or] unchanged" program, as described in Attachment A of the STCs (see "Special Methodological Considerations")[7]. The proposed evaluation design attempts to capture changes resulting from the FPO Demonstration Waiver but observed changes are likely to be modest given the similarity of the counterfactual condition.

[7] Section 1115 Demonstrations. Developing the Evaluation Design. https://www.medicaid.gov/medicaid/downloads/developing-the-evaluation-design.pdf

Appendix A - Independent Contractor

All analyses and reporting related to the Washington State HCA Family Planning Demonstration Waiver, Family Planning Only, will be completed using research staff within the HCA DATA First Steps Database (FSDB) Team (in-house), as well as collaboration with the FPO Program Manager, and survey team contracted with the Department of Social and Health Services (DSHS) Research and Data Analysis (RDA) Division. FSDB provides valid, rigorous, and policy-relevant analyses of government-funded social and health services in the State of Washington. Since FSDB staff have performed previous 1115 Family Planning Only waiver evaluations, along with other maternity and family-planning-related studies, they are very knowledgeable about Medicaid programs in general and the family planning waiver program previously called TAKE CHARGE, in particular.

Simplified Evaluation Budget:

As required by CMS STC 9.2, Evaluation Budget, the proposed budget shell includes total estimated cost, estimated staff, administrative, and other costs for all aspects of the evaluation. The estimated budget will cover all evaluation expenses, including salary, fringe, administrative costs, conference calls, as well as indirect costs and those related to quantitative and qualitative data collection and analyses, travel expenses related to primary data collection, results dissemination, and report development. The required budget will consist of the following line items:

TABLE 2

Proposed Evaluation Budget

Category	**DY 2026**	**DY 2027**	**DY 2028**	**DY 2029**	**DY 2030**	**Total (All Years)**
Personnel (evaluation design, project management, data collection, analysis, reporting, WSIRB, and all other tasks) and fringe benefits	$145,000	$145,000	$145,000	$145,000	$164,000	$744,000
FPO Client Survey (DSHS RDA)	$37,025	$40,728	$44,800			$122,553
Other (e.g., software, printing)	$7,385	$7,386	$7,387	$7,388	$7,389	$36,935
Travel	$6,000	$6,000	$6,000	$6,000	$6,000	$30,000
Administrative and indirect costs	$19,000	$19,000	$19,000	$19,000	$22,000	$98,000
Total Evaluation Cost	$214,410	$218,114	$222,187	$177,388	$199,389	$1,031,488

Appendix B - Schedule of Evaluation Deliverables

TABLE 3

Deliverable	Date	STC reference
Draft Evaluation Design	October 28, 2025	9.1
Annual Monitoring Report	December 31, 2025	8.7(d)
HCA receives comments from CMS on Draft Evaluation Design		
HCA submits final Evaluation Design Plan	Provide a final evaluation design plan within 60 calendar days after receipt of CMS's comments.	9.3
Annual Monitoring Report	December 31, 2026	8.7(d)
Annual Monitoring Report	December 31, 2027	8.7(d)
Annual Monitoring Report	December 31, 2028	8.7(d)
Interim Evaluation draft submitted to CMS for comment	June 30, 2029	9.5(a-e)
HCA receives comments from CMS on Interim Evaluation draft		9.5(a-e)
HCA submits final Interim Evaluation Report to CMS (with 60 calendar days of receipt of comments)		9.5(a-e)
Annual Monitoring Report	December 31, 2029	8.7(d)
HCA submits draft Summative Evaluation Report to CMS for comment	Provide a summative evaluation 18 months following the end of the approval period (approval period will end 06/30/2030; summative evaluation due approximately December 31, 2031.	9.7
HCA receives comments from CMS on draft Summative Evaluation Report		9.7(a)
HCA submits final Summative Evaluation Report to CMS	Provide a final evaluation design plan within 60 calendar days after receipt of CMS's comments.	9.7(a)

Appendix C – Document History Log

TABLE 4 – the purpose of this table is to document changes to the evaluation design plan as requested through FPO Demonstration amendments or CMS review and feedback.

Version	Effective Date	Description
Baseline	October 28, 2025	Original Draft Evaluation Design Plan (STC 9.1)
Revision	February 3, 2026	Updated based on CMS feedback received December 4, 2025

Appendix D – Acronyms

AH	Apple Health
CMS	Center for Medicare and Medicaid Services
FDA	U.S. Food and Drug Administration
FFS	Fee-for-service
FPL	Federal Poverty Limit
FPO	Family Planning Only
FQHC	Federally Qualified Health Center
HCA	Health Care Authority
PCCC-RS	Person-centered contraceptive counseling-retrospective survey
STC	Special Terms and Conditions
STD	Sexually transmitted disease
STI	Sexually transmitted infection