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



State Demonstrations Group

March 30, 2021

MaryAnne Lindeblad Director Washington Health Care Authority 626 8th Avenue, PO Box 45502 Olympia, WA 98504-5050

Dear Ms Lindeblad:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Family Planning Evaluation Design, which is required by the Special Terms and Conditions (STC) of Washington's section 1115 demonstration, "Family Planning Only Program" (Project No: 11-W-00134/0), effective through June 30, 2023. CMS determined that the revised evaluation design submitted on October 25, 2019 meets the requirements set forth in the STCs, and therefore, approves the state's evaluation design. We sincerely appreciate the state's commitment and its collaboration with CMS in finalizing the evaluation design.

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

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

Page 2 – MaryAnne Lindeblad

We appreciate our continued partnership with the state on the Washington Family Planning Only Program section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly Digitally signed by Danielle Daly -S Date: 2021.03.30 13:41:26 -04'00'

Danielle Daly
Director

Division of Demonstration Monitoring and Evaluation Andrea J.

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Andrea Casart Director

Division of Eligibility and Coverage Demonstrations

cc: Courtenay Savage, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

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 of this demonstration extension, be regarded as expenditures under the state's title XIX plan. All requirements of the Medicaid statute will be applicable to such expenditure authorities (including adherence to income and eligibility system verification requirements under section 1137(d) of the Act), except those specified below as not applicable to these expenditure authorities.

The following expenditure authority and the provisions specified as "not applicable" enable Washington to operate its demonstration effective as of the date of the approval letter through June 30, 2023:

- Expenditures for extending Medicaid eligibility for family planning and family planningrelated services through a targeted application and enrollment process to women and men capable of producing children that meet one of the following criteria:
 - a) Women losing Medicaid pregnancy-related coverage after their 60-day post maternity coverage ends;
 - b) Women and men with family income at or below 260 percent of the Federal poverty level (FPL) who are not otherwise enrolled in Medicaid or the Children's Health Insurance Program (CHIP); and,
 - c) Teens and domestic violence victims who need confidential family planning services and have individual income at or below 260 percent of the FPL.

Medicaid Requirements Not Applicable to the Medicaid Expenditure Authorities:

All Medicaid requirements apply, except the following:

1. Methods of Administration: Transportation Section 1902(a)(4) insofar as it incorporates 42 CFR §431.53

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 family planning services and family planning-related services.

3. Prospective Payment for Federally Qualified Health Centers and Rural 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)(A)

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

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Washington section 1115(a) Medicaid demonstration entitled the, "Family Planning Only Program" (hereinafter "demonstration"). The parties to this agreement are the Washington State Health Care Authority (hereinafter "state") and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs are effective as of the date of the accompanying CMS award letter through June 30, 2023. All previously approved STCs, waivers, and expenditure authorities are superseded by the STCs set forth below and the associated expenditure and non-applicable authorities.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Benefits and Delivery Systems
- VI. General Reporting Requirements
- VII. General Financial Requirements
- VIII. Monitoring Budget Neutrality
- IX. Evaluation
- X. Schedule of State Deliverables during the Demonstration

Appendix A: Template for Quarterly and Annual Monitoring Reports

Appendix B: Evaluation Design Plan

II. PROGRAM DESCRIPTION AND HISTORICAL CONTEXT

Effective through June 30, 2023, 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 have family income at or below 260 percent of the federal poverty level (FPL), women losing Medicaid pregnancy coverage at the conclusion of the 60-day postpartum eligibility period, and teens and domestic violence victims who need confidential family planning services because they are covered under their perpetrators' or parents' health insurance and have individual income

at or below 260 percent of the FPL, and who are not otherwise enrolled in Medicaid or the Children's Health Insurance Program (CHIP).

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. 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."

CMS and Washington expect this demonstration program will promote Medicaid program objectives by:

- Improving access to family planning and family planning-related services;
- Decreasing unintended pregnancies;
- Reducing state and federal Medicaid expenditures by averting births from unintended pregnancies; and,
- Lengthening intervals between pregnancies and births to improve positive birth and women health outcomes.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes. The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
- 2. Compliance with Medicaid Law, Regulation, and Policy. All requirements of the Medicaid programs expressed in law, regulation, and policy statement not expressly waived or identified as not applicable in the expenditure authority document (which is a part of these terms and conditions), must apply to the demonstration.
- **3.** Changes in Medicaid Law, Regulation, and Policy. The state must, within the timeframes specified in law, regulation, court order, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is explicitly waived or identified as not applicable.

- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy Statements.
 - 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. The modified agreement will be effective upon the implementation of the change.
 - b) If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.
- 5. Changes Subject to the Amendment Process. Changes related to demonstration features such as eligibility, enrollment, benefits, 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 Act). The state must not implement changes to these demonstration elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 6 below.
- **6. Amendment Process.** Requests to amend the demonstration must be submitted to CMS in writing for approval no later than 120 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 reports and other deliverables in a timely fashion according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
 - a) A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - b) A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality expenditure limit;
 - c) An explanation of the public process used by the state consistent with the requirements of STC 14; and,
 - d) If applicable, a description of how the evaluation design must be modified to incorporate the amendment provisions.

- 7. Extension of the Demonstration. States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than 12 months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 Code of Federal Regulations (CFR) §431.412(c) or a transition and phase-out plan consistent with the requirements of STC 8.
- **8. Demonstration Transition and Phase-Out.** The state may suspend or terminate this demonstration, in whole or in part, at any time prior to the date of expiration.
 - a) Notification of Suspension or Termination: The state must promptly notify CMS in writing of the effective date and reason(s) for the suspension or termination. At least six months before the effective date of the demonstration's suspension or termination, the state must submit to CMS its proposed transition and phase-out plan, together with intended notifications to demonstration enrollees. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with the requirements of STC 14. Once the 30-day public comment period has ended, the state must provide a summary of public comments received, the state's response to the comments received, and how the state incorporated the comments received into the transition and phase-out plan submitted to CMS.
 - b) Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities, including community resources that are available.
 - c) <u>Phase-out Plan Approval:</u> The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of phase-out activities. Implementation of phase-out activities must be no sooner than 14 days after CMS approval of the phase-out plan.
 - d) Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR §431.206, §431.210 and §431.211. In addition, the state must assure all appeal and hearing rights are afforded to demonstration participants as outlined in 42 CFR §431.220 and §431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as found in 42 CFR §435.916.

- e) Exemption from Public Notice Procedures 42 CFR §431.416(g): CMS may expedite or waive the federal and state public notice requirements in the event it determines that the objectives of titles XIX or XXI would be served or 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.
- g) <u>Federal Financial Participation (FFP)</u>: If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.
- 9. CMS Right to Amend, Suspend, or Terminate. CMS may amend, suspend or terminate the demonstration, in whole or in part, at any time before the date of expiration, whenever it determines, following a hearing, that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the amendment, suspension or termination, together with the effective date.
- **10. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of \$1,000,000 per deliverable (federal share) when items required by these STCs (e.g., monitoring reports, evaluation design documents, required data elements and analyses, presentations, and any other deliverable 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. Specifically:
 - a) Thirty days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
 - b) For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).
 - i. CMS may decline the extension request.
 - ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.
 - iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.

- c) When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
- d) As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from extending a demonstration or obtaining a new demonstration.
- e) CMS will consider with the state an alternative set of operational steps for implementing the deferral associated with this demonstration to align the process with any existing deferral process the state is undergoing (e.g., the quarter the deferral applies to and how the deferral is released).
- **11. Finding of Non-Compliance.** The state does not relinquish its rights to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.
- 12. Withdrawal of Waiver/Expenditure Authority. CMS reserves the right to amend or withdraw waiver and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS must promptly notify the state in writing of the determination and the reasons for the amendment or 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 or amended, 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 participants.
- **13. 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 applicable to the demonstration; compliance with cost sharing requirements to the extent they apply; and reporting on financial and other demonstration components.
- **14. 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.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR §431.408(b), State Medicaid Director Letter #01-024, or contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

15. Federal Financial Participation (FFP). No federal matching funds for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter.

IV. ELIGIBILITY AND ENROLLMENT

- **16. 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 as follows:
 - a) Recently pregnant women who lose Medicaid coverage after their 60-day post maternity coverage ends;
 - b) Uninsured women and men with family income at or below 260 percent of the FPL; and,
 - c) Teens and domestic violence victims who need confidential family planning services and have individual income at or below 260 percent of the FPL.
- **17. Eligibility Determination Process.** The state will develop and implement enrollment procedures in accordance with the following processes:
 - 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. Teens 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.

18. 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.

V. BENEFITS AND DELIVERY SYSTEMS

- **19. 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. The specific family planning services provided under this demonstration are as follows:
 - a) 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.

- b) The following services if they occur during a visit focused on family planning:
 - i. Pregnancy testing;
 - ii. Cervical cancer screening according to schedules established by nationally recognized clinical guidelines;
 - iii. Gonorrhea and chlamydia screening according to nationally recognized clinical guidelines based on age (only covered for women 13-25);
 - iv. Assessment and management of family planning or contraceptive problems, when medically necessary; and,
 - v. STI and STD testing and treatment when medically indicated by symptoms or report of exposure and medically necessary for the client's safe and effective use of the client's chosen contraceptive method.
- 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, the office visits or physical exams related to and necessary for sterilization, laboratory testing necessary to complete a sterilization, and approved prescription medication to treat anxiety and pain in relation to the sterilization procedure.
- e) Additional screening tests may be performed depending on the method of contraception desired based on nationally recognized guidelines. Additional laboratory tests may be needed to address a family planning problem or need during an inter-periodic family planning visit for contraception;
- 20. 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 and are reimbursable at the state's regular Federal Medical Assistance Percentage (FMAP) rate. 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 include:
 - a) Drugs for the treatment of STIs/STDs, except for HIV/AIDS and all forms of hepatitis, when the STI/STD is identified/diagnosed during a routine/periodic family planning visit and is not medically necessary for the client's safe and effective use of the client's chosen contraceptive method. A follow-up visit/encounter for the treatment/drugs and subsequent follow-up visits to rescreen for STIs/STDs based on

the Centers for Disease Control and Prevention guidelines may be covered. 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.

- b) Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services in a family planning setting.
- c) 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.
- **21. Minimum Essential Coverage (MEC).** The Washington family planning demonstration is limited to the provision of services as described in STCs 19 and 20. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) as indicated by CMS in its February 12, 2016 correspondence from Vikki Wachino to MaryAnne Lindeblad, Washington State Medicaid Director, regarding the designation of MEC for the state's section 1115 demonstration.
- 22. 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.
- **23. 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.

VI. GENERAL REPORTING REQUIREMENTS

- **24. General Financial Requirements.** The state must comply with all general financial requirements under title XIX and as set forth in section VII.
- **25. Reporting Requirements Relating to Budget Neutrality.** The state must comply with all reporting requirements for monitoring budget neutrality as set forth in section VII.
- **26. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

- **27. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
 - a) Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b) Ensure all 1115, 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.
- **28. Quarterly Monitoring Reports.** The state must submit three quarterly monitoring reports and one combined fourth quarter/annual monitoring report for each demonstration year according to the scheduled listed below. The quarterly monitoring reports are due no later than 60 days following the end of each demonstration quarter. The combined fourth quarter/annual monitoring report is due no later than 90 days following the end of the demonstration year as described in STC 30. The combined fourth quarter/annual report monitoring should distinctly describe the information associated with the fourth quarter of the demonstration year. The state's demonstration quarterly reporting cycle is outlined below:

| Demonstration Begin Date | | End Date | Quarterly Report | |
|--------------------------|-------------|----------------|----------------------------|--|
| Quarter | | | Due Date | |
| Q1 | July 1st | September 30th | November 29 th | |
| Q2 | October 1st | December 31st | March 1 st | |
| Q3 | January 1st | March 31st | May 30 th | |
| Q4 & Annual | April 1st | June 30th | September 30 th | |
| Monitoring | | | | |
| Report | | | | |

The state must submit quarterly monitoring reports through CMS' designated system using the framework incorporated in these STCs as "Attachment A." The intent of these reports is to present the state's data along with an analysis of the status of key operational areas under the demonstration. The quarterly monitoring report must include all required elements outlined below and in the format provided in Attachment A. The quarterly monitoring report should not direct readers to links outside the report, except if listed in a reference/bibliography section. Quarterly monitoring reports must include, but are not limited to:

a) A summary of current notable program activity during the quarter. This includes highlights of the state's progress with implementation of STC 17 with supporting documentation, progress of addressing MBES/CBES Schedule C reporting adjustments on the CMS-64 as outlined in STC 34(c), and key operational milestones anticipated to occur in the near future. Notable program activity

- includes, but is not limited to, program operations such as provider participation and education, health care delivery, benefits, eligibility, enrollment, beneficiary complaints, quality of care, access, state share of financing and pertinent legislative activity;
- b) Quarterly unduplicated enrollment for demonstration enrollees (defined as any individual who obtains a covered family planning service through the demonstration) as required to evaluate compliance with the budget neutral agreement;
- c) Program outreach and education activities conducted and an assessment of the effectiveness of these outreach and education activities;
- d) Program integrity and related audit activities, including an analysis of point-ofservice eligibility procedures; and,
- e) Grievances and appeals made by beneficiaries, providers, or the public and actions being taken to address any significant issues.
- 29. Quarterly Monitoring Calls. CMS and Washington will participate in quarterly conference calls following receipt of the quarterly/annual monitoring reports, unless CMS determines that more frequent calls are necessary to adequately monitor the demonstration. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Areas to be addressed include, but are not limited to, the state's progress with implementation of STC 17; the state's progress with completing MBES/CBES Schedule C reporting adjustments on the CMS-64; and significant program issues or changes related to health care delivery, enrollment, quality of care, access, benefits, anticipated or proposed changes in payment rates, audits, lawsuits, changes in state sources of funding for financing this demonstration, evaluation of the demonstration, state legislative developments, and any demonstration amendments the state is considering submitting. CMS will update the state on any Washington Family Planning Only Program actions under review as well as federal policies and issues that may affect any aspect of the demonstration. Washington and CMS will jointly develop the agenda for the calls.
- **30. Annual Monitoring Report.** No later than 90 days following the end of each demonstration year, the state must submit an annual monitoring report that represents the status of the demonstration's various operational areas and any state analysis of program data collected for the demonstration year. As specified in STC 28, the state may combine its fourth quarter monitoring update with the annual monitoring report for each demonstration year. The combined fourth quarter/annual monitoring report will serve as the state's annual report that include an end of year summary of the program elements as reported in each quarterly report. The annual monitoring report will include all elements required by 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 state must submit the annual monitoring report through CMS' designated

system using the framework incorporated in these STCs as "Attachment A," 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. Each annual monitoring report must minimally include the following:

- a) Operational Updates Per 42 CFR §431.428, the annual monitoring report must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; descriptions of any public forums held, and a summary of program integrity and related audit activities for the demonstration. The annual monitoring report should also include a summary of all public comments received through the post-award public forum required per 42 CFR §431.420(c) regarding the progress of the demonstration.
- b) Performance Metrics Per 42 CFR §431.428, the annual monitoring report must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys (if conducted) and grievances and appeals. The required monitoring and performance metrics must be included in writing in the annual monitoring report, and will follow the framework provided by CMS to support federal tracking and analysis.
- c) <u>Budget Neutrality and Financial Reporting Requirements</u> Per 42 CFR §431.428, the annual monitoring report must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every annual monitoring report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including a total annual member month count for the demonstration population, total annual expenditures for the demonstration population, and the resulting "per member, per month" calculation. The annual monitoring report must also include the submission of corrected budget neutrality data upon request.
- d) Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the annual 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.
- **31. Program Integrity.** The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration. The state must

confirm its process for ensuring there is no duplication of federal funding in each annual monitoring report as specified in STC 30(a).

- **32. Draft and Final Close-out Report.** Within 120 days after the expiration of the demonstration, the state must submit a draft Close-out Report to CMS for comments.
 - a) The draft report must comply with the most current guidance from CMS.
 - b) The state will present to and participate in a discussion with CMS on the close-out report.
 - c) The state must take into consideration CMS' comments for incorporation into the final close-out report.
 - d) The final close-out report is due to CMS no later than 30 days after receipt of CMS' comments.
 - e) A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 10.

VII. GENERAL FINANCIAL REQUIREMENTS

This project is approved for title XIX expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

- **33. Quarterly Expenditure Reports.** The state must provide quarterly expenditure reports to report total expenditures for services provided under this Medicaid section 1115(a) demonstration following routine CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. CMS must provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined cost limits specified in STC 43.
- **34. Reporting Expenditures Subject to the title XIX Budget Neutrality Agreement.** The following describes the reporting of expenditures subject to the budget neutrality limit:
 - a) Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES). All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS and the two digit project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made (e.g., For reporting expenditures with dates of services made in demonstration year 17 (7/1/2017 6/30/2018), the state would use "17" as the project number extension).
 - b) <u>Use of Waiver Forms</u>. The state must report demonstration expenditures on separate forms CMS-64.9 Waiver and/or 64.9P Waiver each quarter to report title XIX expenditures for demonstration services. The state will continue to use the waiver

- name "Family Planning (Take Charge)" to report expenditures in the MBES/CBES and in the budget neutrality workbook required to be submitted with the Annual Monitoring Report per STC 30.
- c) MBES/CBES Schedule C Reporting Adjustments. The state must submit prior period adjustments subsequent to the routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual to report actual expenditures incurred for demonstration services in DY12 (7/2012 6/2013) through DY17 (7/2017 6/2018). The state must complete similar adjustments to separately report administrative costs that are directly attributable to the demonstration for DY12 through DY17. The state shall complete these reporting adjustments within 12 months of the date of CMS' approval of this extension and provide written certification of the accuracy of the adjusted expenditures upon completion. The state must provide an update on the progress of these adjustments during the CMS monitoring calls described in STC 29 and the quarterly and annual monitoring reports described in STC 28 and 30.
- d) <u>Cost Settlements</u>. For monitoring purposes, cost settlements attributable to the demonstration must be recorded 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.
- **35. Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must separately track and report administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on Form CMS-64.10.
- **36. Claiming Period.** All claims for expenditures subject to the budget neutrality agreement (including any cost settlements) must be made 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 must 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.
- **37. Reporting Member Months.** The following describes the reporting of member months for the demonstration:
 - a) For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the Annual Monitoring Report required per STC 30, the actual number of eligible member months for all demonstration enrollees. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
 - b) 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 each eligible for two months, each contribute two eligible member months, for a total of four eligible member months.

- 38. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must 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 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 must 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 set out in STC 10, 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.
- **39.** Extent of Federal Financial Participation (FFP) for the Demonstration. CMS shall provide FFP for family planning and family planning related services at the applicable federal matching rates as described in STCs 19 and 20, subject to the limits and processes described below:
 - a) For procedures or services clearly provided or performed for the primary purpose of family planning (i.e., contraceptive initiation, periodic or inter-periodic contraceptive management, and sterilizations), and which are provided in a family planning setting, FFP will be available at the 90 percent federal matching rate. Reimbursable procedure codes for office visits, laboratory tests, and certain other procedures must carry a primary diagnosis or a modifier that specifically identifies them as a family planning service.
 - Allowable family planning expenditures eligible for reimbursement at the enhanced family planning match rate of 90 percent, as described in STC 20, should be entered in Column (D) on the CMS-64.9 Waiver Form.
 - b) Pursuant to 42 CFR §433.15(b)(2), FFP is available at the 90 percent administrative match rate for administrative activities associated with administering the family planning services provided under the demonstration including the offering, arranging, and furnishing of family planning services. These costs must be allocated in accordance with OMB Circular A-87 cost allocation requirements. The processing of claims is reimbursable at the 50 percent administrative match rate.
 - c) FFP will not be available for the costs of any services, items, or procedures that do not meet the requirements specified above, even if provided by eligible Medicaid providers. For example, in the instance of testing for STIs as part of a family planning visit, FFP will be available at the 90 percent federal matching rate. The match rate for the subsequent treatment would be paid at the applicable federal

- matching rate for the state. For testing or treatment not associated with a family planning visit, no FFP will be available.
- **40. Sources of Non-Federal Share.** The state must certify that matching the non-federal share of funds for the demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
 - a) CMS shall review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the timeframes set by CMS.
 - b) Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- **41. State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
 - a) Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.
 - b) To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
 - c) To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
 - d) The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments. Under all circumstances, health care providers must retain 100 percent of the claimed expenditure. Moreover, no pre-arranged agreements (contractual or otherwise) exist between health care providers and state and/or local government to

return and/or redirect any portion of the Medicaid payments. 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.

VIII. MONITORING BUDGET NEUTRALITY

The following is the method by which budget neutrality will be monitored for the Washington Family Planning Only Program section 1115(a) Medicaid demonstration.

- **42. Limit on Title XIX Funding.** The state shall be subject to a limit on the amount of federal title XIX funding it may receive on approved demonstration service expenditures incurred during the period of demonstration approval. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the approved demonstration period. Actual expenditures subject to budget neutrality expenditure limit shall be reported by the state using the procedures described in STC 34.
- **43. Budget Neutrality Annual Expenditure Limits.** For each demonstration year, an annual budget limit will be calculated for the demonstration. The Washington Family Planning Only Program annual demonstration cycle is July 1 through June 30 as originally approved. The state's demonstration years are as follows:

```
Demonstration Year 11 = July 1, 2011 – June 30, 2012
Demonstration Year 12 = July 1, 2012 – June 30, 2013
Demonstration Year 13 = July 1, 2013 – June 30, 2014
Demonstration Year 14 = July 1, 2014 – June 30, 2015
Demonstration Year 15 = July 1, 2015 – June 30, 2016
Demonstration Year 16 = July 1, 2016 – June 30, 2017
Demonstration Year 17 = July 1, 2017 – June 30, 2018
Demonstration Year 18 = July 1, 2018 – June 30, 2019
Demonstration Year 19 = July 1, 2019 – June 30, 2020
Demonstration Year 20 = July 1, 2020 – June 30, 2021
Demonstration Year 21 = July 1, 2021 – June 30, 2022
Demonstration Year 22 = July 1, 2022 – June 30, 2023
```

The budget limit is calculated as the projected per member/per month (PMPM) cost times the actual number of member months for the demonstration multiplied by the Composite Federal Share.

<u>PMPM Cost</u>. The following table provides the approved demonstration cost trend (based on the state's historical rate of growth) and the PMPM (total computable) ceiling for each demonstration year.

| PMPM Ceilings for Family Planning Services | | | | |
|---|---------|--|--|--|
| DY18 \$15.57 | | | | |
| DY19 \$15.57 | | | | |
| DY20 \$15.57 | | | | |
| DY21 \$15.57 | | | | |
| DY22 | \$15.57 | | | |

- a) Composite 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, as reported on the forms listed in STC 34 above, by total computable demonstration expenditures for the same period as reported on the forms. Should the demonstration be terminated prior to the end of the approval period (see STC 8), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable Composite Federal Share may be used.
- b) <u>Structure</u>. The demonstration's budget neutrality model is structured as a "pass-through" or "hypothetical" expenditure population. Therefore, the state may not derive savings from the demonstration.
- c) <u>Risk</u>. Washington shall be at risk for the per capita cost (as determined by the method described in this section) for demonstration enrollees, but not for the number of demonstration enrollees. By providing FFP for eligible enrollees, Washington shall not be at risk of changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs for enrollees in the demonstration, CMS assures that federal demonstration expenditures do not exceed the level of expenditures that would have occurred had there been no demonstration.
- d) Application of the Budget Limit. The budget limit calculated above will apply to demonstration expenditures reported by the state on the CMS-64 forms. If at the end of the demonstration period, the costs of the demonstration services exceed the budget limit, the excess federal funds will be returned to CMS. If the costs of the demonstration services do not exceed the budget limit, the state may not derive or utilize any such savings.
- **44. Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.
- **45. Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality over the life of this demonstration extension approval period. No later than 90 days after the end of

each demonstration year, the state will calculate and report to CMS an annual cumulative expenditure target for the completed year as part of the Annual Monitoring Report described in STC 30. This amount will be compared with the actual cumulative amount the state has claimed for FFP through the completed year. If cumulative spending exceeds the cumulative target by more than the indicated percentage, the state will submit a corrective action plan to CMS for approval. The state will subsequently implement the approved plan.

| Year | Cumulative Target Expenditures | Percentage |
|------|--|-------------------|
| DY18 | DY18 budget limit amount plus: | 2 percent |
| DY19 | DY18 through DY19 combined budget limit amount plus: | 1.5 percent |
| DY20 | DY18 through DY20 combined budget limit amount plus: | 1 percent |
| DY21 | DY18 through DY21 combined budget limit amount plus: | 0.5 percent |
| DY22 | DY18 through DY22 combined budget limit amount plus: | 0 percent |

46. Exceeding Budget Neutrality. The state, whenever it determines that the demonstration is not budget neutral or is informed by CMS that the demonstration is not budget neutral, must immediately collaborate with CMS on corrective actions, which includes submitting a corrective action plan to CMS within 21 days of the date the state is informed of the problem. While CMS will pursue corrective actions with the state, CMS will work with the state to set reasonable goals that will ensure that the state is in compliance.

If at the end of the demonstration approval period, the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

IX. EVALUATION

- **47. Draft Evaluation Design.** The draft evaluation design must be developed in accordance with CMS' separately provided guidance for family planning demonstrations. The state must submit, for CMS comment and approval, a draft evaluation design with an implementation timeline by no later than 120 days after the effective date of these STCs. Any modifications to an existing approved evaluation design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of an independent party in the development of the draft evaluation design.
- **48. Evaluation Budget.** A budget for the evaluation shall be provided with the draft evaluation design. It will include the total estimated cost as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design

or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

- **49. Evaluation Design Approval and Updates.** The state must submit a revised draft evaluation design within 60 days after receipt of CMS' comments. Upon CMS approval of the final evaluation design, the document will be included as "Attachment B" to these STCs. Per 42 CFR 431.424(c), the state will publish the approved final evaluation design within 30 days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each Annual Monitoring Report as required by STC 30, including any required rapid cycle assessments specified in these STCs. 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.
- 50. Evaluation Questions and Hypotheses. Consistent with CMS' separately provided guidance entitled, "Developing the Evaluation Design" and "Preparing the Evaluation Report," the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- **51. 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, the interim evaluation report should be posted to the state's website with the application for public comment.
 - a) The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
 - b) For demonstration authority that expires prior to the overall demonstration's expiration date, the interim evaluation report must include an evaluation of the authority as approved by CMS.
 - c) If the state is seeking to extend the demonstration, the draft interim evaluation report is due when the application for extension is submitted. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting an extension of the demonstration, the draft 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 final interim evaluation report 60 days after receiving CMS comments on the draft interim evaluation report and post the document to the state's website.
- e) The interim evaluation report must comply with CMS' separately provided guidance entitled, "Preparing the Evaluation Report."
- **52.** Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall 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 shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR §431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 10.
- **53. Summative Evaluation Report.** The draft summative evaluation report must be developed in accordance with CMS' separately provided guidance entitled, "Preparing the Evaluation Report." The state must submit a draft summative evaluation report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The summative evaluation report must include information as outlined in the approved evaluation design.
 - a) Unless otherwise agreed upon in writing by CMS, the state shall submit the final summative evaluation report within 60 days of receiving comments from CMS on the draft.
 - b) The final summative evaluation report must be posted to the state's Medicaid website within 30 days of approval by CMS.
- **54. 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 state's interim evaluation, and/or the summative evaluation.
- **55. Public Access**. The state shall post the final documents (e.g., monitoring reports, approved evaluation design, interim evaluation report, summative evaluation report, and close-out report) on the state's Medicaid website within 30 days of approval by CMS.

56. 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.

X. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

| Deliverable | Timeline | STC Reference |
|---------------------------------|---|---------------|
| Quarterly Monitoring Report | Within 60 days following the end of each quarter | STC 28 |
| Annual Monitoring Report | Within 90 days following the end of each demonstration year | STC 30 |
| Draft Evaluation Design Plan | Within 120 days after the approval of the demonstration extension | STC 47 |
| Final Evaluation Design Plan | Within 60 days following receipt of CMS comments on Draft Evaluation Design | STC 49 |
| Summative Evaluation Report | Within 18 months following the end of this demonstration extension period | STC 53 |

ATTACHMENT A: Family Planning Section 1115 Demonstration Template for Quarterly and Annual Monitoring Reports

Purpose and Scope of Quarterly and Annual Reports:

In accordance with STCs 28 and 30, the intent of these reports is to present the states' analysis of collected data and the status of the various operational areas, reported by month in the demonstration year. The report should also include a discussion of trends and issues over the year, including progress on addressing any issues affecting access, quality, or costs.

Each quarterly report must include, at a minimum, the following program elements:

- A. Executive Summary
- B. Utilization Monitoring
- C. Program Outreach and Education
- D. Program Integrity
- E. Grievances and Appeals

In addition to elements A - E above, the state's combined fourth quarter/annual monitoring report shall also include the following elements:

- F. Annual Post Award Public Forum
- G. Budget neutrality
- H. Demonstration evaluation activities and interim findings.

QUARTERLY MONITORING REPORT FAMILY PLANNING SECTION 1115 DEMONSTRATIONS

| State: | |
|--|-------------|
| Demonstration Reporting Period: | |
| Demonstration Year: | |
| Approved start and end date of the Demonstration | |

A. Executive Summary

- 1. Synopsis of the information contained in the report
- **2.** Program Updates
 - **a.** Current Trends and Significant Program Activity
 - i. Narrative describing administrative and operational activities occurring in the quarter including any changes to demonstration processes related, but not limited to, eligibility and enrollment, provider education, systems,

- health care delivery, benefits, quality of care, anticipated or proposed changes in payment rates, and outreach changes.
- ii. Narrative on any demonstration changes, such as notable changes in enrollment, service utilization, and provider participation (up or down 10 percent). Discussion of any action plan if applicable.
- iii. Narrative on the existence of or results of any audits, investigations, or lawsuits that impact the demonstration.

3. Policy Issues and Challenges

- **a.** Narrative of any operational challenges or issues the state has experienced.
- **b.** Narrative of any policy issues the state is considering, including pertinent legislative/budget activity, and potential demonstration amendments.
- **c.** Discussion of any action plans addressing any policy, administrative or budget issues identified, if applicable.

B. Utilization Monitoring

The state will summarize utilization through a review of claims/encounter data for the demonstration population in the subsequent tables. This includes the following:

Table 1. Utilization Monitoring Measures

| Topic | Measure [reported for each month included in the report] |
|---|---|
| | Unduplicated Number of Enrollees by Quarter |
| Unduplicated Number of Beneficiaries with any Claim by Quarter (by ke | |
| TT.*11 | demographic characteristics such as age, gender, and income level) |
| Utilization | Utilization by Primary Method and Age Group |
| Monitoring | Total number of beneficiaries tested for any sexually transmitted disease |
| | Total number of female beneficiaries who obtained a cervical cancer screening |
| | Total number of female beneficiaries who received a clinical breast exam |

Table 2: Unduplicated Number of Enrollees by Quarter

| | Number of Female Enrollees by Quarter | | | | | | | |
|---------------------|---------------------------------------|------------------------------|---------------------------------|----------------------------------|----------------------------|--|--|--|
| | 14 years old | 15-20 years | 21-44 years | Over 45 years | Total Unduplicated | | | |
| | and under | old | old | old | Female Enrollment* | | | |
| Quarter 1 | | | | | | | | |
| Quarter 2 | | | | | | | | |
| Quarter 3 | | | | | | | | |
| Quarter 4 | | | | | | | | |
| | | | | | | | | |
| | N | umber of Male | es Who Utilize S | ervices by Age and | l Quarter | | | |
| | No. 14 years old | umber of Male 15-20 years | es Who Utilize S 21-44 years | ervices by Age and Over 45 years | Quarter Total Unduplicated | | | |
| | | | | | | | | |
| Quarter 1 | 14 years old | 15-20 years | 21-44 years | Over 45 years | Total Unduplicated | | | |
| Quarter 1 Quarter 2 | 14 years old | 15-20 years | 21-44 years | Over 45 years | Total Unduplicated | | | |
| _ | 14 years old | 15-20 years | 21-44 years | Over 45 years | Total Unduplicated | | | |

Table 3: Unduplicated Number of Beneficiaries with any Claim by Age Group and Gender per Quarter in the Demonstration Year (to date)

| | Number of Females Who Utilize Services by Age and Quarter | | | | | | |
|---------------------|---|--------------------|--------------------|----------------------|-------------------------|--|--|
| | 14 years old and under | 15-20 years old | 21-44 years old | Over 45 years old | Total Female Users * | Percentage of Total Unduplicated Female Enrollment | |
| Quarter 1 | | | | | | | |
| Quarter 2 | | | | | | | |
| Quarter 3 | | | | | | | |
| Quarter 4 | | | | | | | |
| | | Number o | of Males Who | Utilize Servi | ces by Age and (| Quarter | |
| | 14 years old and under | 15-20 years old | 21-44 years old | Over 45 years old | Total Male Users* | Percentage of Total Unduplicated Male Enrollment | |
| Overton 1 | | | | | | | |
| Quarter 1 | | | | | | | |
| Quarter 1 Quarter 2 | | | | | | | |
| | | | | | | | |

^{*}Total column is calculated by summing columns 2-5.

Table 4: Utilization by Primary Method and Age Group per Demonstration Year (to date)

| | Total Users | | | | | |
|----------------------------|------------------------|----------------------|----------------------|------------------------------|--------|------------------------------|
| Primary Method | 14 years old and under | 15 – 20 years old | 21 – 44 years old | 45 years old and older | Total* | Percent of All Devices |
| Sterilization | | | | | | |
| Emergency Contraception | | | | | | |
| Intrauterine Device (IUD) | | | | | | |
| Hormonal Implant | | | | | | |
| 1-Month Hormonal | | | | | | |
| Injection | | | | | | |
| 3-Month Hormonal Injection | | | | | | |
| Oral Contraceptive | | | | | | |
| Contraceptive Patch | | | | | | |
| Vaginal Ring | | | | | | |
| Diaphragm | | | | | | |
| Sponge | - | | | _ | | |
| Female Condom | | | | | | |
| Male Condom | | | | | | |

^{*}Total column is calculated by summing columns 2-5.

Table 5: Number Beneficiaries Tested for any STD by Demonstration Year (to date)

| | Female Tests | | Male Tests | | Total Tests | |
|---|--------------|------------------|------------|------------------|--------------------|------------------|
| Test | Number | Percent of Total | Number | Percent of Total | Number | Percent of Total |
| Unduplicated number of beneficiaries who obtained an STD test | | | | | | |

Table 6: Total Number of Female Beneficiaries who obtained a Cervical Cancer Screening (to date)

| Screening Activity | Number | Percent of Total Enrolled Females |
|--|--------|--------------------------------------|
| Unduplicated number of female beneficiaries who obtained a cervical cancer screening | | |

Table 7: Breast Cancer Screening (to date)

| Screening Activity | Number | Percent of Total Enrolled Females |
|--|--------|--------------------------------------|
| Unduplicated number of female beneficiaries who received a Breast Cancer Screening | | |

C. Program Outreach and Education

- 1. General Outreach and Awareness
 - **a.** Provide information on the public outreach and education activities conducted this demonstration quarter; and,
 - **b.** Provide a brief assessment on the effectiveness of these outreach and education activities.
- **2.** Target Outreach Campaign(s) (if applicable)
 - **a.** Provide a narrative on the populations targeted for outreach and education campaigns and reasons for targeting; and,
 - **b.** Provide a brief assessment on the effectiveness of these targeted outreach and education activities.

D. Program Integrity

Provide a summary of program integrity and related audit activities for the demonstration.

E. Grievances and Appeals

Provide a narrative of grievances and appeals made by beneficiaries, providers, or the public, by type and highlighting any patterns. Describe actions being taken to address any significant issues evidenced by patterns of appeals.

The below program elements are to be included only in the state's combined fourth quarter/annual monitoring report at the end of each demonstration year:

F. Annual Post Award Public Forum

Provide a summary of the annual post award public forum conducted by the state as required by 42 CFR §431.420(c) that includes a report of any issues raised by the public and how the state is considering such comments in its continued operation of the demonstration.

G. Budget Neutrality

- 1. Please complete the budget neutrality workbook.
- 2. Discuss any variance noted to the estimated budget, including reasons for variance in enrollment and/or in total costs, and/or in per enrollee costs. Describe any plans to mitigate any overages in budget neutrality by the end of the demonstration period.

H. Demonstration Evaluation Activities and Interim Findings

- 1. Please provide a summary of the progress of evaluation activities, including key milestones accomplished. Include:
 - **a.** Status of progress against timelines outlined in the approved Evaluation Design.
 - **b.** Any challenges encountered and how they are being addressed.
 - **c.** Status of any evaluation staff recruitment or any RFPs or contracts for evaluation contractual services (if applicable).
- 2. Description of any interim findings or reports, as they become available.

Attachment B

Washington State Family Planning Only 1115 Demonstration

Evaluation Design for Waiver Period 07-01-2018 through 06-30-2023

A. Demonstration Objectives/Goals

The purpose of the Family Planning Only 1115 Demonstration (FPO) is to provide Medicaid coverage for family planning (FP) and/or family planning-related services for low income individuals not otherwise eligible for Medicaid. The program's goals are to improve the health of women, children, and families by decreasing unintended pregnancies and lengthening intervals between births and reducing state and federal Medicaid expenditures for births from unintended pregnancies.

The FPO 1115 Demonstration serves individuals from these three populations: 1) recently pregnant women who lose Medicaid coverage after their pregnancy coverage ends; 2) uninsured women and men with family incomes at or below 260% federal poverty level (FPL) who seek FPO services to prevent an unintended pregnancy; and 3) teens and domestic violence victims who need confidential FPO services and are covered under their perpetrator's or parent's health insurance and are at or below 260% (FPL) (**Table 1**).

The specific objectives of the Washington State FPO program that will be evaluated include:

- Ensure access to FP services and/or FP-related services.
- Improve or maintain health outcomes for the target population as a result of access to FP services and/or FP-related services.
- Reduce the number of unintended pregnancies in the waiver population.

B. Evaluation Questions and Hypotheses

The demonstration's core evaluation questions, hypothesis, data sources, and analytic approaches are provided in **Table 2**.

TABLE 1 Program Description

| Program Goals | Improve access to family planning and family planning related-services. Decrease the number of unintended pregnancies. Increase the use of contraceptive methods. Increase the interval between pregnancies and births to improve positive birth and women's health outcomes. Reduce state and federal Medicaid expenditures for averted births from unintended pregnancies. | | | | | |
|--|--|--|--|--|--|--|
| Historical demonstration population name | Family Planning Only Extension | Take Charge | | | | |
| Current demonstration population name | Family Planning Only – Pregnancy Related (Effective 7/1/19) | Family Planning Only (Effective 7/1/19) | | | | |
| Income eligibility | Income at or below 198% of the federal poverty level (FPL) | Income at or below 260% of the FPL | | | | |
| Target population | Recently pregnant women who lose Medicaid coverage after their 60-days post pregnancy coverage ends, regardless of pregnancy outcomes and not eligible for Apple Health (Medicaid) coverage. | Uninsured women and men seeking to prevent unintended pregnancy and not eligible for Apple Health (Medicaid) coverage. Teens and domestic violence victims who need confidential family planning services. | | | | |
| Coverage period | Additional 10-month coverage following Medicaid 60-days post-pregnancy coverage. When coverage ends must apply for Medicaid or Family Planning Only | 12-month coverageNo limit on how many times they can reapply for coverage. | | | | |
| Program coverage | Family planning-related services for women include an annual comprehensive family planning preventive medicine visit, screening for gonorrhea and chlamydia for women ages 13 through 25, cervical cancer screening, and services directly related to successfully using a chosen method of contraception | Family planning-related services for women include an annual comprehensive family planning preventive medicine visit, screening for gonorrhea and chlamydia for women ages 13 through 25, cervical cancer screening, and services directly related to successfully using a chosen method of contraception Family planning-related services for men include an annual counseling session for reducing the risk of unintended pregnancy, condoms and spermicides, and services directly related to vasectomies. | | | | |

C. Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches

TABLE 2
Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches

| Evaluation | Evaluation Evaluation Measures (to be reported for each Demonstration | | h Demonstration | Data Source | Analytic | Time Periods | |
|---|---|--|--|--------------------------------------|---|---|--|
| Component | Question | Hypotheses | Year) Numerator | Denominator | | Approach | |
| Demonstration | • | Ensure access to an | d utilization of family planning and/ | or family planning- | related services | for individuals | not otherwise |
| | | | Number of beneficiaries who had a family planning or family planning related service encounter in each year of the demonstration | Total number of beneficiaries | and First statistics Steps (frequencie Database and | | extension and calculate annual |
| | | | Number of family planning services utilized | Total number of beneficiaries | | | |
| beneficiaries utilize fa utilize planning so covered and/or fa Process health planning r | beneficiaries utilize covered health | ciaries utilize family ze planning services red and/or family planning related | Number of female beneficiaries who utilized any contraceptive in each year of the demonstration | Total number of female beneficiaries | | Descriptive statistics | |
| | | | Number of female beneficiaries who utilized long-acting reversible contraceptives in each year of the demonstration | Total number of female beneficiaries | | (frequencies | |
| | | | Number of beneficiaries tested for any sexually transmitted disease (by STD) | Total number of beneficiaries | | | specified. |
| | | Number of female beneficiaries who obtained a cervical cancer screening | Total number of female beneficiaries | | | | |
| | Do beneficiaries maintain | Beneficiaries will maintain coverage for one | Number of beneficiaries who completed one spell of 12 month enrollment | Total number of beneficiaries | ProviderOne | Descriptive statistics (frequencies | Available on a monthly basis approximately 1 |

| Evaluation Component | | | Data Source | Analytic Approach | Time Periods | | |
|----------------------|--|---|---|---|-------------------------|---|--|
| | | | Numerator | Denominator | | | |
| | coverage long-term (12 months or more)? | or more 12 month enrollment period. | Number of beneficiaries re-enrolled for at least their second spell of coverage | Total number of beneficiaries | | and percentages) | month after the end of each quarter |
| Process | Does the demonstratio n increase the use of more effective contraceptive methods | Beneficiaries will have a higher rate of using more effective contraceptive methods compared to | Number and type of contraceptive methods used prior to (or on) first FPO visit compared to number and type of contraceptive methods used by the end of the client's eligibility period. | Total number of beneficiaries | ProviderOne and FSDB | Descriptive statistics (proportions) and significance testing (Chi² test) | Annual rates available for statistical testing. |
| | among FPO beneficiaries? | other members of Medicaid beneficiaries. | Number of LARC continuations | Total number of beneficiaries using LARCs | | Survival analysis (e.g., Kaplan-Meier) | Waiver period 07/01/2018 through 06/30/2021 |

Demonstration Objective 2: Improve or maintain health outcomes for the target population as a result of access to family planning and family planning-related services.

| | | Evaluation Hypothesis | Measures (to be reported for each Year) | Demonstration | Data Source | Analytic Approach | Time Periods |
|--------------------|--|--|--|--|-------------------------|---|---|
| | | | Numerator | Denominator | | | |
| Outcome/ Impact | Does the demonstratio n improve health | Health outcomes will improve as a result of the demonstration. | Number of subsequent live births that occurred at an interval of 18 months or longer | Total number of subsequent live births | ProviderOne and FSDB | Descriptive statistics (proportions) and | Calculate annual and biannual rates for each measures specified and |
| | outcomes? [Calculate for target | | Number of low birth weight babies born to beneficiaries | Total number of babies born to beneficiaries | | significance testing (chi- squared of | conduct a trend analysis after year three. |

| Outcome/I mpact | Does the demonstratio n decrease the number of unintended pregnancies? | The number of women reporting unintended pregnancy will decrease. | Number of respondents who reported pregnancy was unintended | Total number of survey respondents | Pregnancy Risk Assessment Monitoring System (PRAMS) | Descriptive statistics (proportions) and significance testing (chisquared of the proportions); trend analysis when applicable. | Calculate annual and biannual rate for each measures specified and conduct a trend analysis after year three. |
|--------------------|--|---|---|------------------------------------|--|--|---|
|--------------------|--|---|---|------------------------------------|--|--|---|

D. Methodology

Evaluation Design

The evaluation design will utilize a post-only assessment with a comparison group. The timeframe for the post-only period will begin when the current demonstration period begins on 7/1/2018, and ends when the current demonstration period ends on 06/30/2023.

There will be annual evaluation updates (STC.30(d) and Attachment A.(H)) during the waiver period with an interim evaluation report (STC.51) due with any application to extend the demonstration and a summative evaluation report (STC.53) due 18-months after the demonstration period ends. We will construct a comparison group when applicable for various evaluation processes.

Evaluation population and comparison group

We plan on evaluating process and outcome measures over the waiver period for FPO recipients compared to statistically matched comparison peers. Matched peers will be selected from a pool of other women of reproductive ages 15-44 years who were Medicaid eligible, but were not participating in the FPO program. If feasible, two comparison groups will be matched for 1) postpartum women in FPO to postpartum women in Medicaid and 2) uninsured women in FPO with Medicaid women.

Propensity score methods will be used to establish a matched cohort for analyses of measures for both waiver objectives. Propensity scoring is a method of matching that uses available background information on the characteristics of the study waiver populations to establish a matched pairs of treated participants and controls.

For <u>Objective #1</u> (Ensure access to and utilization of family planning and/or family planning-related services for individuals not otherwise eligible for Medicaid), those selected for the comparison group will be matched on demographics and baseline medical utilization similar to those women who participated in the FPO waiver.

For <u>Objective #2</u> (Improve or maintain health outcomes for the target population as a result of access to family planning and family planning-related services), those selected for the comparison group will be matched on demographics, baseline medical utilization, family planning utilization services, and prenatal care utilization similar to those women who participated in the FPO waiver.

For <u>Objective #3</u> (Reduce the number of unintended pregnancies in the waiver population), waiver population and comparison group will be determined by linking PRAMS survey respondents to Medicaid and FPO clients. Those selected for the comparison group will be non-FPO demonstration waiver survey respondents. Results will be stratified by sub-populations of interest (e.g., age, mother's education), if available.

If feasible, each measure will be stratified by different program population summarized in Table 1. 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.

Evaluating the impact of FPO on key outcomes is complicated by the longevity of the waiver and lack of experimental comparison. By using propensity scores, we attempt to simulate a comparison group, however, the differences between FPO and Medicaid women could prove difficult to statistically match. If a comparison group cannot be constructed via propensity score methodology, we propose to describe the process and outcome measures over time for the FPO beneficiaries only.

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Evaluation Design Data Collection and Sources

Data collection

Administrative data for the evaluation will be collected retrospectively quarterly, annually, and at the end of the demonstration period. Pregnancy Risk Assessment Monitoring System (PRAMS) survey data will be collected retrospectively every year and at the end of the demonstration period.

Data Sources

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

<u>ProviderOne</u>: HCA's claims file contains a record for every claim submitted for reimbursement. For all FPO eligible clients, the FSDB staff obtains a service history for appropriate time periods for each client. ProviderOne services history data are used to describe the types of FP services provided. ProviderOne is updated monthly.

<u>First Steps Database</u> (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 2016. The annual unduplicated count of FPO eligible clients is linked to the FSDB by ProviderOne ID. The First Steps Database is created biannually.

Pregnancy Risk Assessment Monitoring System (PRAMS) survey: To evaluate the program goal of reducing the number of unintended pregnancies, Washington will rely on the PRAMS survey to describe unintended pregnancy rates. PRAMS survey results will be individually linked to Medicaid and FPO clients so the survey results can be reported for the waiver population of the family planning waiver. PRAMS is a surveillance survey by the Centers for Disease Control and Prevention (CDC) developed to report maternal attitudes and experiences before, during, and shortly after pregnancy. As of 2018, forty-seven states participated in PRAMS, covering approximately 83 percent of all live births in the United States. These data can be used to identify groups of women and infants at high risk for health problems, monitor changes in health status, and to measure progress towards goals in improving the health of mothers and infants. PRAMS data allows WA State to compare state-specific rates against national trends and Healthy People 2020 goals.

Data Analysis Strategy

Methods

For <u>objective #1</u> (Ensure access to and utilization of family planning and/or family planning-related services for individuals not otherwise eligible for Medicaid), we will apply descriptive methods of frequency and proportions to demonstrate service utilization of FPO beneficiaries compared to statistically

matched Medicaid beneficiaries for all the service utilization measures as specified in table 2. The monthly enrollment into the programs will be the key indicator for measuring 1) whether the beneficiaries maintain coverage long term, i.e., continues enrollment of 10 or 12 months or more, and 2) whether there is a reenrollment for at least the second spell of coverage three years prior to and three years post the current enrollment year.

For <u>objective #2</u> (Improve or maintain health outcomes for the waiver population as a result of access to family planning and family planning-related services), most of the data analyses for the outcome measures specified will be descriptive that utilizes basic statistic tests of Chi-squared statistics for comparison on the differences in frequencies or proportions between groups and Cochran-Armitage test for examining the changes in proportion of the outcomes over time among FPO program beneficiaries when applicable. For the outcome measures of birth span, low birth weight and premature babies, the differences in proportions of the outcomes will be tested at an annual basis. We will also calculate the proportions of these outcome measures at a biannual basis and therefore, Cochran-Armitage test for trend can be conducted when applicable.

Washington State added Evaluation Questions

Examining the program's role in transitioning clients to more effective methods is a measure for monitoring how programs support contraceptive choice and use. Washington State has added the evaluation question: "Does the demonstration increase use of more effective contraceptive methods?," we are proposing the following study design and analysis.

<u>WA State Measure 1</u>: Number and type of contraceptive methods used prior to (or on) first FPO visit compared to number and type of contraceptive methods used by the end of the client's eligibility period. 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.

We will examine changes in contraceptive use by comparing the method clients obtain before or at the start of their FPO visit and compare it with the method they are using at the end of their eligibility period. Our four study outcomes include:

- 1) Moving from least effective method to a moderately effective method by the end of the client's eligibility period.
- 2) Moving from least effective method to a most effective method by the end of the client's eligibility period.
- 3) Moving from a moderately effective method to most effective method by the end of the client's eligibility period.
- 4) Moving from moderately/most effective method to a least effective method by the end of the

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client's eligibility period.

This new measure is intended to evaluate the quality of contraceptive choice by comparing FPO Demonstration Waiver to age or waiver subgroups and/or if feasible, to comparable Medicaid populations.

<u>WA State Measure 2</u>: Track women who received a LARC insertion longitudinally over the length of the waiver period to identify and describe continuation rates among FPO clients.

LARC effectiveness years vary by type (e.g., copper IUD (~10 years) versus implants (~3 years)) and brand. In contrast to the utilization measure: "Number of female beneficiaries who utilized long-acting reversible contraceptives in each year of the demonstration/total beneficiaries", the proposed state measure seeks to follow FPO beneficiaries over the length of the waiver period (in months). We plan on conducting survival analysis for LARC continuation, calculating the survival probability as the number of FPO clients continuing to use LARCs divided by the number of FPO LARC users.

This new 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.¹

For <u>Objective #3</u> (Reduce the number of unintended pregnancies in the waiver population), pregnancy intentions on the PRAMS survey are obtained by asking respondents to think back to the time just before their pregnancy and to recall how they felt about becoming pregnant at that time. The pregnancy intention question is a part of the "core" set of questions, asked in each participating state's uniform set of questions. The PRAMS questionnaire is mailed to women who have had a recent live birth (usually within 2 to 6 months after delivery), with each state's sample drawn from vital records, and including oversampling by specific characteristics to create annual, representative data at the state level of all women delivering in that year.²

Respondents may choose one of five response options: 'I wanted to be pregnant sooner', 'I wanted to be pregnant later', 'I wanted to be pregnant then', 'I didn't want to be pregnant then or any time in the future', or 'I wasn't sure what I wanted'. Beginning in 2012, the last response, 'I wasn't sure what I wanted' was added to the responses. As a result, unintended pregnancy rates computed from 2013 onward are not directly comparable to those prior to 2013.

Traditionally, respondents who select, 'I didn't want to be pregnant then or any time in the future' are defined as unwanted pregnancies. To evaluate the program goal of reducing the number of unintended pregnancies, Washington will rely on the PRAMS survey to describe unintended pregnancy rates. PRAMS survey results will be individually linked to Medicaid and FPO clients so the survey results can be reported for the waiver population of the family planning waiver.

E. Independent Contractor:

HCA has contracted with the Department of Social and Health Services (DSHS) Research and Data Analysis (RDA) Division to conduct the FPO waiver extension evaluation. RDA provides valid, rigorous, and policy-relevant analyses of government-funded social and health services in the State of Washington. Since RDA staff have performed previous 1115 Family Planning Only waiver evaluations, along with other maternity

¹ Trussell, J., Hassan, F., Lowin, J., Law, A., Filonenko (2015). Achieving cost-neutrality with long-acting reversible contraceptive methods. Contraception, 91(1), 49-56.

² Center for Disease Control. PRAMS model surveillance protocol, 2015 version. 2015. https://www.cdc.gov/prams/methodology.htm.

and family-planning-related studies, they are very knowledgeable about Medicaid programs in general and the family planning waiver program called TAKE CHARGE in particular. They are prepared to begin evaluation activities for the coming five-year period promptly, upon approval of the extension and the evaluation design.

Simplified Evaluation Budget:

As required by CMS Section IX of the STCs, Section 48 (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 amount will cover all evaluation expenses, including salary, fringe, administrative costs, other direct costs such as travel for data collection, conference calls, as well as indirect costs and those related to quantitative and qualitative data collection and analyses, and report development. The required budget will consist of the following line items:

- 1. Computer programming (cost per hour x hours);
- 2. Analysis of the data (cost per hour x hours);
- 3. Preparation of the report (cost per hour x hours);
- 4. Other (specify work, cost per hour, and hours). If work is outside the requirements of the basic evaluation this should be identified in the draft evaluation design along with justification for an increased budget match.

TABLE 3
Proposed Evaluation Budget

| Category | Hours | Cost per hour | Total |
|-------------------------------|-------|---------------|-----------|
| | | | |
| Computer programming | 1,500 | \$46.60 | \$69,900 |
| Data Analyses | 1,280 | \$46.60 | \$59,648 |
| Report preparation | 1,760 | \$56.60 | \$99,616 |
| Reviewing and Reporting | 300 | \$56.60 | \$16,980 |
| | | | |
| Benefits | | | \$72,254 |
| Miscellaneous (cost recovery) | | | \$31,994 |
| Total Evaluation Cost | | | \$350,392 |

Schedule of Evaluation Deliverables for current demonstration period

TABLE 4
Schedule of Evaluation Deliverables

| Deliverable | Date | STC reference |
|--------------------------|--------------------|---------------|
| Annual Monitoring Report | September 30, 2019 | 30(d) |
| Annual Monitoring Report | September 30, 2020 | 30(d) |
| Annual Monitoring Report | September 31, 2021 | 30(d) |

| Interim Evaluation draft submitted to | December 31, 2021 | 51(a-e) |
|---|-----------------------------|---------|
| CMS for comment | | |
| HCA receives comments from CMS | | 51(a-e) |
| HCA submits final Interim Evaluation | | 51(a-e) |
| Report to CMS (with 60 calendar days of | | |
| receipt of comments) | | |
| Annual Monitoring Report | September 31, 2022 | 30(d) |
| HCA submits draft Summative Evaluation | Provide a summative | 53(a-b) |
| Report to CMS for comment | evaluation 18 months | |
| | following the end of the | |
| | approval period (approval | |
| | period will end 06/30/2023; | |
| | summative evaluation due | |
| | approximately December 31, | |
| | 2024. | |
| HCA receives comments from CMS | | |
| HCA submits final Summative Evaluation | | 53(a-b) |
| Report to CMS | | |

HCA=Health Care Authority, CMS = Centers for Medicare and Medicaid Services.