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.

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 -S
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Date: 2021.03.30 13:41:26 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

Andrea J. Casart -S
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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

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 coverage • No 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 Component	Evaluation Question	Evaluation Hypotheses	Measures (to be reported for each Demonstration Year)		Data Source	Analytic Approach	Time Periods
			Numerator	Denominator			
Demonstration Objective 1: Ensure access to and utilization of family planning and/or family planning-related services for individuals not otherwise eligible for Medicaid.							
Process	How did beneficiaries utilize covered health services?	Enrollees will utilize family planning services and/or family planning related services.	Number of beneficiaries who had a family planning or family planning related service encounter in each year of the demonstration	Total number of beneficiaries	ProviderOne and First Steps Database (FSDB)	Descriptive statistics (frequencies and percentages)	Compute for each year of the demonstration extension and calculate annual rates for each measures specified.
			Number of family planning services utilized	Total number of beneficiaries			
			Number of female beneficiaries who utilized any contraceptive in each year of the demonstration	Total number of female beneficiaries			
			Number of female beneficiaries who utilized long-acting reversible contraceptives in each year of the demonstration	Total number of female beneficiaries			
			Number of beneficiaries tested for any sexually transmitted disease (by STD)	Total number of beneficiaries			
			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	Evaluation Question	Evaluation Hypotheses	Measures (to be reported for each Demonstration Year)		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 demonstration increase the use of more effective contraceptive methods among FPO beneficiaries?	Beneficiaries will have a higher rate of using more effective contraceptive methods compared to other members of Medicaid beneficiaries.	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.
			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 Component	**Evaluation Question**	**Evaluation Hypothesis**	**Measures (to be reported for each Demonstration Year)**		**Data Source**	**Analytic Approach**	**Time Periods**
			Numerator	**Denominator**			
Outcome/ Impact	Does the demonstration improve health outcomes? [Calculate for target	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 significance testing (chi-squared of	Calculate annual and biannual rates for each measures specified and conduct a trend analysis after year three.
			Number of low birth weight babies born to beneficiaries	Total number of babies born to beneficiaries			

	population and similar population from Medicaid within-state]		Number of premature babies born in the beneficiaries	Total number of babies born to beneficiaries		the proportions); trend analysis when applicable.	

Demonstration Objective 3: Reduce the number of unintended pregnancies in the waiver population.							
Outcome/Impact	Does the demonstration 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 (chi-squared of the proportions); trend analysis when applicable.	Calculate annual and biannual rates for each measures specified and conduct a trend analysis after year three.

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 Objective #1 (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 Objective #2 (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 Objective #3 (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.

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.

ProviderOne: 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.

First Steps Database (birth certificates linked to Medicaid clients): All Washington birth certificates are linked at the individual level to Medicaid claims and eligibility history. FSDB begins with births in August 1988 and currently contains linked birth certificates through 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 objective #1 (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 re-enrollment for at least the second spell of coverage three years prior to and three years post the current enrollment year.

For objective #2 (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.

WA State Measure 1: 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

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.

WA State Measure 2: 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 Objective #3 (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 CMS for comment	December 31, 2021	51(a-e)
HCA receives comments from CMS		51(a-e)
HCA submits final Interim Evaluation Report to CMS (with 60 calendar days of receipt of comments)		51(a-e)
Annual Monitoring Report	September 31, 2022	30(d)
HCA submits draft Summative Evaluation Report to CMS for comment	Provide a summative evaluation 18 months following the end of the approval period (approval period will end 06/30/2023; summative evaluation due approximately December 31, 2024.	53(a-b)
HCA receives comments from CMS		
HCA submits final Summative Evaluation Report to CMS		53(a-b)

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