**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**

July 16, 2021

Lynette Rhodes
Executive Director, Medical Assistance Plans
Georgia Department of Community Health
2 Peachtree Street, NW, 36th Floor
Atlanta, Georgia 30303- 3159

Dear Ms. Rhodes

The Centers for Medicare & Medicaid Services (CMS) completed its review of the state's Evaluation Design, which is required by the Special Terms and Conditions (STC) of Georgia's section 1115 demonstration, "Planning for Healthy Babies (P4HB)" (Project No:11-W-00249/4), effective through December 31, 2029. CMS has determined that the evaluation design, which was submitted on February 21, 2020 and revised on July 6, 2021, meets the requirements set forth in the STCs, and therefore, approves the state's P4HB Evaluation Design.

CMS has added the approved P4HB evaluation design to the demonstration's STCs as Attachment C. A copy of the STCs, which includes the new attachment, in 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.

CMS appreciates the state's commitment to a robust evaluation of the P4HB section 1115 demonstration. Please note that three interim evaluation reports, consistent with the approved Evaluation Design, are due to CMS per the timeline also outlined in this approved Evaluation Design. Additionally, if the state is seeking to extend the demonstration, the third draft interim evaluation report (for demonstration years 1 through 8) is due at the time of the extension application. 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 Georgia on the P4HB section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S Digitally signed by Danielle Daly -S Date: 2021.07.16 12:35:34 -04'00'

Andrea J. Casart -S Digitally signed by Andrea J. Casart -S Date: 2021.07.16 12:31:35 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

Andrea Casart
Director
Division of Eligibility and Coverage Demonstrations

cc: Etta Hawkins, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES**
**EXPENDITURE AUTHORITY**

**NUMBER:** **11-W-00249/4**

**TITLE:** **Georgia Planning for Healthy Babies (P4HB)**

**AWARDEE:** **Georgia Department of Community Health**

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Georgia for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from September 1, 2019, through December 31, 2029, unless otherwise specified, be regarded as expenditures under the State's title XIX plan.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the Georgia Planning for Healthy Babies demonstration, including the granting of the expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Act.

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

1. **Demonstration Population 1:** Expenditures for extending family planning and family planning-related services provided to uninsured women who are otherwise ineligible for Medicaid or the Children's Health Insurance Program (CHIP), ages 18 through 44, who have family income at or below 211 percent of the federal poverty level (FPL), including women who are losing Medicaid pregnancy coverage at the conclusion of the 60 day postpartum coverage period.

2. **Demonstration Population 2:** Expenditures for extending family planning, family planning-related, and interpregnancy care (IPC) services to women, ages 18 through 44, within three years of delivery of a very low birth weight (VLBW) baby (less than 1,500 grams or 3 pounds, 5 ounces), with income at or below 211 percent of the FPL, and who are not otherwise eligible for Medicaid or CHIP. Beneficiaries will be eligible for IPC services for two (2) years after the date of enrollment. Additional deliveries of subsequent VLBW babies will grant an additional two-year enrollment period to otherwise eligible beneficiaries.

**Demonstration Services 1:** Expenditures for extending Resource Mother Outreach services to women, ages 18 through 44, within three years of delivery of a VLBW baby, with income at or below 211 percent of the FPL, who are eligible for Medicaid under the Georgia Medicaid state plan. The Resource Mother Outreach services include but are not limited to, phone or in person visits to increase the adoption of healthy behaviors, including healthy eating choices and

smoking cessation, follow-up visits to make sure the baby receives regular "well-baby" check-ups and immunizations, and referrals to community resources.

**Requirements Not Applicable to the Demonstration Expenditures:**

**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 Demonstration Population 1.

**2. Eligibility Section** — **Section 1902(a)(10)(A)**

To the extent necessary to allow Georgia to not provide medical assistance for Demonstration Populations 1 and 2 until the individual has been enrolled in a managed care organization.

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

To the extent necessary to allow the State to offer Demonstration Population 1 a benefit package consisting only of family planning and family planning-related services and Demonstration Population 2 a benefit consisting only of family planning, family planning- related services, and IPC services.

**4. Freedom of Choice** — **Section 1902(a)(23)**

To the extent necessary to enable the State to limit freedom of choice of provider for Demonstration Populations 1 and 2. If a beneficiary qualifies for IPC services and was covered by Georgia Medicaid at the time of a VLBW birth, the beneficiary will be assigned to the care management organization (CMO) they were enrolled in at the time of the delivery of their VLBW baby.

**5. Retroactive Eligibility** — **Section 1902(a)(34)**

To the extent necessary to enable the State to not provide medical assistance to Demonstration Populations 1 and 2 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 all EPSDT services to Demonstration Populations 1 and 2.

# CENTERS FOR MEDICARE & MEDICAID SERVICES
# SPECIAL TERMS AND CONDITIONS

**NUMBER:** **11-W-00249/4**

**TITLE:** **Planning for Healthy Babies (P4HB)**

**AWARDEE:** **Georgia Department of Community Health**

## I. PREFACE

The following are the Special Terms and Conditions (STCs) for Georgia's "Planning for Healthy Babies" section 1115(a) Demonstration (hereinafter "demonstration") to enable the Georgia Department of Community Health (DCH) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted the state waiver and expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the State's obligations to CMS related to this demonstration. The "Planning for Healthy Babies" (P4HB) demonstration will be statewide and is approved from September 1, 2019 through December 31, 2029.

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. Monitoring
VIII. Evaluation of the Demonstration
IX. General Financial Requirements under Title XIX
X. Monitoring Budget Neutrality for the Demonstration

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

## II. PROGRAM DESCRIPTION AND OBJECTIVES

The Georgia section 1115(a) family planning demonstration, P4HB, has been operating since January 1, 2011. The demonstration has three components. The first component is the family planning program, which extends eligibility for family planning (FP) and family planning- related services to uninsured women, ages 18 through 44, who have income at or below 211 percent of the FPL, and who are not otherwise eligible for Medicaid or the CHIP, including

women who are losing Medicaid pregnancy coverage at the conclusion of the 60 day postpartum coverage period.

The second component, entitled Interpregnancy Care (IPC), offers, in addition to the family planning and family planning-related services described above, a limited benefit package of services to women who meet the same eligibility requirements described above and who deliver a very low birth weight (VLBW) baby (less than 1,500 grams or 3 pounds, 5 ounces).

The third component of the demonstration is the provision of Resource Mother Outreach services, as defined at V.28, to women ages 18 through 44, who have income at or below 211 percent of the FPL, who deliver a VLBW baby and who are eligible in the parent or caretaker relative with child(ren) eligibility group or an aged, blind, or disabled eligibility group under the Georgia Medicaid state plan.

Under this demonstration, Georgia expects to achieve the following to promote the objectives of title XIX:

- Reduce Georgia's Medicaid low birth weight (LBW) and VLBWrates;
- Reduce the number of unintended pregnancies in Georgia Medicaid;
- Reduce Georgia's Medicaid costs by reducing the number of unintended pregnancies by women who otherwise would be eligible for Medicaid pregnancy-related services;
- Provide access to IPC health services for eligible women who have previously delivered a VLBW baby; and
- Increase child spacing intervals through effective contraceptive use.

## III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with all applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), and the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (ACA).

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

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the changed provisions being changed is are explicitly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of

the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

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

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

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

6. **Changes Subject to the Amendment Process.** Changes related to 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 Act. The states must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

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

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

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

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

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

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

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

a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition

phase-out plan.

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

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

d. Transition and Phase-out Procedures: The state must comply with applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, and 431.213. In addition, the state must assure all applicable and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including §§ 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in the October 1, 2010 State Health Official letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

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

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

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

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

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

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

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

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

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

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this

demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program—including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs or procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

16. **Minimum Essential Coverage (MEC).** This demonstration is limited to the provision of services as described in Section V of the STCs and, consequently, is not recognized as Minimum Essential Coverage (MEC) as outlined in section 5000A(f)(1)(A)(ii) of the Internal Revenue Code of 1986. The state shall adhere to all applicable Internal Revenue Service reporting requirements with respect to MEC for demonstration enrollees.

## IV. ELIGIBILITY AND ENROLLMENT

**17. Eligibility Requirements.**

a. The state must enroll only individuals meeting the following eligibility criteria into the family planning component of the demonstration:

- Uninsured women, ages 18 through 44, who have family income up to and including 211 percent of the FPL, who are not otherwise eligible for Medicaid or CHIP, including women losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum.

b. The State must enroll only individuals meeting the following eligibility criteria into the IPC component of the Demonstration:

- Uninsured women ages 18 through 44, within three years of delivery of a VLBW baby, who have income up to and including 211 percent of the FPL, who are not otherwise eligible for Medicaid or CHIP.

c. The state will enroll individuals into the Resource Mothers Outreach component of the demonstration who are:

- Women, ages 18 through 44, who have income at or below 211 percent of the FPL, within three years of delivery of a VLBW baby , and who qualify under Medicaid State plan.

**18. Demonstration Enrollment.** Post-partum women who were on Medicaid coverage and enrolled in a Georgia Families Care Management Organization (CMO) at delivery will be automatically cascaded to the appropriate aid category and enrolled in the plan with which they were affiliated. These women will be afforded the opportunity to choose a new CMO if desired. The enrollment processes for each component of the Demonstration are described below:

a. **FP Component.** The state will follow applicable Federal law and regulations for determining eligibility and enrolling those determined eligible into one of the CMOs. Individuals must enroll in a managed care plan to receive family planning and family planning-related services.

b. **IPC Component.** Women in the IPC component must enroll in a managed care plan to receive Family Planning and IPCservices.

**c. Resource Mothers Outreach.**

i. Women ages 18 through 44 who are eligible under the Medicaid state plan and who are eligible for Resource Mothers Outreach services are auto-assigned or passively enrolled into a CMO. The member will have the opportunity to participate in a choice change period immediately after being auto-assigned.

ii. Women ages 18 through 44, within three years of delivery of a VLBW baby and who are eligible under the Medicaid State Plan, will receive Resource Mothers Outreach via a CMO. Eligible women will be allowed to choose a CMO through which they will receive only Resource Mothers Outreach services.

**19. Demonstration Disenrollment.**

a. If a woman becomes pregnant while enrolled in the demonstration, she may be determined eligible for Medicaid in the pregnant woman eligibility group in accordance with 42 CFR 435.916.

b. Women who choose to receive a sterilization procedure and complete all necessary follow-up procedures will be disenrolled from the demonstration.

c. Women receiving IPC services will be disenrolled from the IPC component of the demonstration and enrolled into the family planning-only component of the demonstration after 2 years of participation. Additional deliveries of subsequent VLBW babies will grant an additional two-year enrollment period in the IPC component of the demonstration to otherwise eligible beneficiaries.

d. Before disenrollment of any beneficiary eligible under the demonstration is effectuated, 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 prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 C.F.R. 435.916(f)(1).

**20. Redeterminations.** The states must ensure that redeterminations of eligibility for the demonstration are conducted no more frequently than every 12 months in accordance with 42 CFR 435.916(a).

**21. Primary Care Referral.** The states assures that providers of family planning services will make appropriate referrals to primary care providers, including providers practicing in Federally Qualified Health Centers (FQHCs and Rural Health Centers (RHCs)), as

medically indicated. The state also assures that individuals enrolled in this demonstration receive written materials and information about how to access primary care services. The written materials must explain to the participants how they can access primary care services.

## V. BENEFITS AND DELIVERY SYSTEMS

**22. Benefits.** Family planning services and supplies described in section 1905(a)(4)(C) of the Act are reimbursable at the 90 percent matching rate, including:

a. FDA-approved methods of contraception;

b. Sexually transmitted infection (STI)/sexually transmitted disease (STD) testing, Pap smears and pelvic exams. The laboratory tests done during an initial family planning visit for contraception include a Pap smear, screening tests for STIs/STDs, blood count, and a pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program, or provider. Additional laboratory tests may be needed to address a family planning problem or need during an inter-periodic family planning visit for contraception;

c. Drugs, supplies, or devices related to women's health services described above that are prescribed by a health care provider who meets the state's provider enrollment requirements, (subject to the national drug rebate program requirements); and,

d. Contraceptive management, patient education, and counseling.

**23. Family Planning-Related Benefits.** Family planning-related services and supplies are 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 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. The following are examples of family- planning related services:

a. Colposcopy (and procedures done with/during a colposcopy) or repeat Pap smear performed as a follow-up to an abnormal Pap smear which is done as part of a routine/periodic family planning visit.

b. Drugs for the treatment of STIs, except for HIV/AIDS and hepatitis, follow-up visit/encounter for the treatment/drugs and subsequent follow-up visits to rescreen for STIs based on the Centers for Disease Control and Prevention (CDC) guidelines may be covered.

c. Drugs 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 be covered.

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

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

   i. Treatment of a perforated uterus due to an intrauterine device insertion;
   ii. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
   iii. Treatment of surgical or anesthesia-related complications during a sterilization procedure.

24. **Primary Care Referrals.** Primary care referrals to other social service and health care providers as medically indicated are provided; however, the costs of those primary care services are only covered for women enrolled in the IPC component of the demonstration. These primary care services are not covered for enrollees who are not in the IPC component of this demonstration.

25. **Vitamins.** Participants will have access to folic acid, and/or a multivitamin with folic acid, which is crucial to a baby in the beginning of their development and this benefit will be reimbursable at the state's FMAP rate.

26. **Immunization Benefits.** Participants ages 19 and 20 will be eligible to receive the Hepatitis B, tetanus-diphtheria (Td), and combined tetanus, diphtheria, and pertussis (TdAP) vaccinations. Participants who are 18 years old are eligible to receive immunizations at no cost via the Vaccines for Children (VFC) Program. These services are reimbursable at the state's FMAP rate.

27. **IPC Component Benefits.** In addition to the family planning and family planning-related services described above, women who are enrolled in the IPC component of the Demonstration are also eligible for the benefits described in the table below. These services are reimbursable at the State's FMAP rate.

| Services | Notes/ Limitations |
|---|---|
| Primary care | Limited to 5 office/outpatient visits per year |
| Management and treatment of chronic diseases | |

| | |
|---|---|
| Substance use disorder treatment (detoxification and intensive outpatient rehabilitation) | |
| Limited Dental | Services are limited to exams and cleanings every six months; x-rays every 12 months; and simple extractions; and emergency dental services. |
| Prescription Drugs (non-family planning) | Prescription drug coverage is limited to the IPC formulary. |
| Non-emergency medical transportation | Only available for beneficiaries eligible under the IPC component of the demonstration. |
| Case management/Resource Mother Outreach | |

28. **Resource Mother Outreach.** Women served under the IPC and Resource Mother components of the demonstration will have access to Resource Mother Outreach. The purpose of the Resource Mother Outreach is to provide peer services in coordination with a nurse case manager. The Resource Mother provides a broad range of paraprofessional services to P4HB participants in the Interpregnancy Care component of the Planning for Healthy Babies Program and their families. The Resource Mother performs certain aspects of case management including the provision of assistance in dealing with personal and social problems and may provide supportive counseling to P4HB participants and their families and/or serve as a liaison for social services. The Resource Mother benefit is part of the CMO PMPM capitated rate.

**a.Q <u>ualifications and Technical Competencies</u>**

The CMOs will employ or contract with Resource Mothers who meet the following qualifications:

- High School diploma or GED with two-years' experience in social services related position or
- Bachelor's degree is a social services related field
- Valid Driver's license
- Reliable vehicle with motor vehicle insurance coverage
- Good communication skills

The Resource Mother must meet the Technical Competencies:

- Successfully complete Resource Mother training module and participate in ongoing in- service training as provided.
- Knowledge of agency policies and procedures.
- Ability to coordinate and organize the delivery services.
- Ability to interview clients and/or families using established techniques.
- Ability to develop client profile.
- Knowledge of agency confidentiality policies.

- Knowledge of state and federal confidentiality laws and regulations.
- Knowledge of available community resources.
- Ability to make appropriate referrals.
- Knowledge of crisis intervention
- Knowledge of what qualifies as an emergency situation.
- Ability to develop P4HB participant service plan to assist P4HB participant in attaining social, educational and vocational goals.
- Ability to contact health care professionals to obtain additional background information.
- Knowledge of target population.
- Knowledge of agency specific software.
- Knowledge of available databases.
- Ability to prepare reports and case history records.
- Knowledge of eligibility requirements.
- Knowledge of what qualifies as an emergency situation.

**b. Training**

The CMOs has the responsibility for training the Resource Mother and must utilize the standardized Resource Mother training Manual specified by the state.

**c. Supervision**

CMOs using Resource Mothers are required to provide supervision by a competent nurse case manager or similarly qualified program staff member. The amount duration and scope of supervision will vary depending on demonstrated competence and experience to provide peer support. The CMOs must ensure the Resource Mother Outreach is effective through monitoring of the Resource Mother's performance including an evaluation of the Resource Mother's P4HB participant contact activities and contact duration.

**d. Outreach Case Management Services**

RM Outreach must be coordinated within the contact of a comprehensive plan that addresses specific program goals of:

a. Increase the beneficiary's adoption of healthy behaviors such as healthy eating choices and smoking cessation;
b. Support the beneficiary's compliance with primary care medical appointments, including assisting with arranging non-emergency medical transportation;
c. Assist the mother of a VLBW baby to obtain regular preventive health visits and appropriate immunizations for her child;
d. Support the beneficiary's compliance with medications to treat chronic health conditions
e. Assist with coordination of social services support; and,
f. Assist with linking beneficiaries to community resources such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

29. **Delivery System.** Services provided through this demonstration are paid via a managed care delivery system via CMOs. Standard Medicaid managed care rules will apply including freedom of choice of provider for family planning services as specified in 42 CFR 431.51(a)(5).

## VI. GENERAL REPORTING REQUIREMENTS

30. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in an amount up to $1,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

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

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

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

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

e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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

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

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

b. Ensure all 1115, 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.

## VII. MONITORING

**33. Monitoring Reports.** The State must submit one (1) Semi-Annual Report and one (1) compiled Annual Report each DY. The Semi-Annual Reports are due no later than sixty (60) calendar days following the end of each demonstration six (6) month period. The compiled Annual Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a reference/bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and must be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports 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; updates on the state's financing plan and maintenance of effort described in STC 18.b; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports 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, grievances and appeals. The requiring monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. No later than 6 months after the end of each DY, or as soon thereafter as data are available, the state will calculate and report to CMS annual expenditure targets for the IPC component of the demonstration for the completed year. Administrative costs should be reported separately.

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

**34. Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

**35. Close-Out Report.** Within 120 calendar days of the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft close-out report must comply with the most current guidance from CMS.

b. 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 thirty (30) calendar 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 the penalties described in STC 30.

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

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.

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

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

**37. Post-Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the demonstration period in which the forum was held, as well as in its compiled Annual Report.

## VIII. EVALUATION OF THE DEMONSTRATION

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

administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 30.

39. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of data needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

40. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than 180 days after the approval of the demonstration. 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 draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

a. All applicable Evaluation Design guidance. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes of participants in the demonstration; the demonstration's progress on achieving its intended outcomes; and the financial impact of the demonstration.

b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a draft Evaluation Design.

41. **Evaluation Budget.** A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations, 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 designs are not sufficiently developed, or if the estimates appear to be excessive.

42. **Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Designs, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the

approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation process in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

**43. Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, 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 hypotheses. 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 Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by the National Quality Forum (NQF).

**44. Interim Evaluation Reports.** The State must submit an Interim Evaluation Report for the approved evaluation design for the completed years of the demonstration specified in subparagraph c, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Reports 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. The state must provide a draft Interim Evaluation Report for the corresponding years, no longer than one (1) year after completion of the measurement period, as described in i-iii below. The state must submit a final Interim Evaluation Report for each measurement period sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the documents to the state's website.

    i. A Draft Interim Evaluation Report for demonstration years 1-2 (calendar years 2020- 2021) will be due no later than December 31, 2022.
    ii. A Draft Interim Evaluation Report for demonstration years 3-5 (calendar years 2022- 2024) will be due no later than December 31, 2025.
    iii. A Draft Interim Evaluation Report for demonstration years 6-8 (calendar years 2025- 2027) will be due no later than December 31, 2028.

d. If the state is seeking to renew or extend the demonstration, the last draft Interim Evaluation Report, representing demonstration years 6-8 (calendar years 2025-2027) is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for the demonstration, as noted at subsection c.iii, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

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

**45. Summative Evaluation Report.** The draft Summative Evaluation Reports must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit the draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within sixty (60) calendar 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 thirty (30) calendar days of approval by CMS.

**46. Corrective Action Plan Related to Evaluation**. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may occur as part of a renewal process when associated with the state's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11.

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

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

**49. Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications

(including, for example, journal articles), by the state, contractor, or any third party directly connected to the demonstration. Prior to release of these reports, articles, or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

## IX. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

**50. Allowable Expenditures.** This demonstration project is approved for expenditure applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures so long as they do not exceed the pre-defined limits as specified in these STCs.[1]

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

[1] For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

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

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

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

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

53. **Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this 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. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at anytime. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.

b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

54. **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 states 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 the state share of title XIX 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 expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). 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 (IGT) to the extent that such funds are derived from state or local monies 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.

e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state 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.

**55. Program Integrity.** The State must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that there is no duplication of Federal funding between the state's Maternal, Infant, and Early Childhood Home Visiting Program and the demonstration. In addition, the state must ensure that there is no duplication of Federal funding between the State's VFC Program and the Demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

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

tests and aggregate budget neutrality tests are further described and subject to the language in STCs 66-68 below.

| Table 1: Master MEG Chart | | | | | |
|---|---|---|---|---|---|
| **MEG** | **To Which BN Test Does This** | **Without Waiver (WOW) Per Capita** | **WOW Aggregate** | **With Waiver (WW)** | **Brief Description** |
| **Pregnant Women** | Main BN Test | | X | X | |
| **Infants 0-1** | Main BN test | | X | X | |
| **Family Planning** | Hypo 1 | X | | X | See Expenditure Authority #1 |
| **Resource Mother Services** | Hypo 2 | X | | X | See Expenditure Authority #3 |
| **IPC Services** | Main BN | | | X | See Expenditure Authority |

57. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W- 00249/4). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state must also report member months of eligibility for specified MEGs.

a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (Form CMS- 64.9P WAIVER) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any other cost settlements not attributable to this demonstration, the adjustment should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. Pharmacy Rebates. Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

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

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

a statement accompanying the annual report certifying the accuracy of this information.

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

**Table 2: MEG Detail for Expenditure and Member Month Reporting**

| MEG (Waiver Name) | Detailed Description | CMS-64.9 Line(s) To Use | How Expend. Are Assigned to DY | MAP or ADM | Report Member Months (Y/N) | MEG Start Date | MEG End Date |
|---|---|---|---|---|---|---|---|
| **Pregnant Women** | | 18A | Date of service | MAP | Y | 1/1/11 | 12/31/29 |
| **Infants 0-1** | | 18A | Date of service | MAP | Y | 1/1/11 | 12/31/29 |
| **Family Planning** | Family planning and family planning-related services (Expenditure Authority 1) | 18A | Date of service | MAP | Y | 1/1/11 | 12/31/29 |
| **IPC Services** | See Expenditure Authority 2 | 18A | Date of service | MAP | Y | 1/1/11 | 12/31/29 |
| **Resource Mother Services** | See Expenditure Authority 3 | 18A | Date of service | MAP | Y | 1/1/11 | 12/31/29 |

58. **Extent of FFP for Family Planning and Family Planning Related Services.** CMS shall provide FFP for services (including prescriptions) provided to women at the following rates:

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. Note: The laboratory tests performed during an initial family planning visit for contraception include a Pap smear, screening tests for STIs, blood counts, and pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program, or provider. Additional laboratory tests may be needed to address a family planning problem or needed during an inter-periodic family planning visit for contraception.

Allowable family planning expenditures eligible for reimbursement at the enhanced family planning match rate should be entered in Column (D) on the CMS 64 form on the appropriate waiver sheets.

b. In order for family planning-related services to be reimbursed at the FMAP rate they must be defined as those services generally performed as part of, or as follow-up to, a family planning service for contraception. Such services are provided because a "family planning-related" problem was identified/diagnosed during a routine/periodic family planning visit. These expenditures should be entered in Column (B) on the appropriate waiver sheets. Four kinds of family planning related services are recognized:

i. A colposcopy (and procedures done with/during a colposcopy) or repeat Pap smear performed as a follow-up to an abnormal Pap smear which is done as part of a routine/periodic family planning visit.

ii. Treatment/drugs for STIs, except for HIV/AIDS and hepatitis, where the STIs are identified/diagnosed during a routine/periodic family planning visit. A follow-up visit/encounter for the treatment/drugs may be covered at the applicable Federal matching rate for the State. Subsequent follow- up visits to rescreen for STIs based on the Centers for Disease Control and Prevention guidelines may be covered at the applicable Federal matching rate for the State.

iii. Treatment/drugs 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 be covered at the applicable Federal matching rate for the State.

iv. Treatment of major complications such as:

1. Treatment of a perforated uterus due to an intrauterine device insertion;
2. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
3. Treatment of surgical or anesthesia-related complications during a sterilization procedure.

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 family planning clinics or providers provide them. 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.

d. CMS will provide FFP at the appropriate 50 percent administrative match rate for general administration costs, such as, but not limited to, claims processing, eligibility assistance and determinations, outreach, program development, evaluation, and program monitoring and reporting.

59. **Extent of FFP for IPC Services.** CMS shall provide FFP for services described in STC 27 for women enrolled in the IPC component of the Demonstration at the state's regular federal matching rate.

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

**Table 3: Demonstration Years**

| Financial Reporting Crosswalk | Demonstration Year for the Current Approval Period | Demonstration Calendar Year | Time Frame |
|---|---|---|---|
| DY 9 | DY 9 | January 1, 2019 to December 31, 2019 | 12 months |
| DY 10 | DY 1 | January 1, 2020 to December 31, 2020 | 12 months |
| DY 11 | DY 2 | January 1, 2021 to December 31, 2021 | 12 months |
| DY 12 | DY 3 | January 1, 2022 to December 31, 2022 | 12 months |

| | | | |
|---|---|---|---|
| DY 13 | DY 4 | January 1, 2023 to December 31, 2023 | 12 months |
| DY 14 | DY 5 | January 1, 2024 to December 31, 2024 | 12 months |
| DY 15 | DY 6 | January 1, 2025 to December 31, 2025 | 12 months |
| DY 16 | DY 7 | January 1, 2026 to December 31, 2026 | 12 months |
| DY 17 | DY 8 | January 1, 2027 to December 31, 2027 | 12 months |
| DY 18 | DY 9 | January 1, 2028 to December 31, 2028 | 12 months |
| DY 19 | DY 10 | January 1, 2029 to December 31, 2029 | 12 months |

61. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in section X. CMS will provide technical assistance, upon request.[2]

62. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two (2) 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 (2) years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budgetneutrality.

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

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

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

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

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

## X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

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

a. Georgia shall be at risk for the per capita cost (as determined by the method described below in this section) for Medicaid eligible in the "Family Planning" eligibility group, but not for the number of demonstration eligibles in this group.

b. Georgia shall be at risk for both per capita costs and enrollment for the IPC Services group.

66. **Calculation of the Budget Neutrality Limits and How They Are Applied.** For each DY, two annual limits are calculated: one for the FP component of the Demonstration and one for the IPC and Resource Mother component of the Demonstration, as described in STCs 67 and 69 below. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

67. **Main Budget Neutrality Test.** The Main Budget Neutrality Test allows the state to show that demonstration waivers and expenditure authorities granted have not resulted in increased costs to Medicaid, and that expenditures for the IPC components of the demonstration are below the annual budget limit for the IPC components set as described below.

a. The aggregate financial cap for the IPC component is determined by applying state historical enrollment and cost trend rates to obtain annual budget limits for demonstration years ten (10) through twenty (20). The budget neutrality limit is determined using a births averted model, under which demonstration expenditures for the IPC MEG are not to exceed the total cost of pregnant women and infants under one (1) year of age absent the births averted by the demonstration, summed.

b. The budget neutrality limit for the IPC component will be for the total computable cost of $28,087,172,280, for the life of the demonstration, which is the sum of the ten (10) annual components shown in Tables 4 and 5 below. If the state chooses to operate the demonstration for fewer than ten (10) years, then the budget neutrality limit will be reduced on a pro rata basis to reflect the shortened approval period, and budget neutrality will be assessed based on the shortened period.

**Table 4: Main Budget Neutrality Test, IPC Services, DYs 9- 19**

| MEG Used to Calculate the Limit | PC or Agg[3] | WOW Only, WW Only, or Both | Enrollment Trend Rate | Cost Trend Rate | BASE YEAR: *2018* | DY 9/ CY 2019[4] | DY 10/ CY 2020 | DY 11/ CY 2021 | DY 12/ CY 2022 | DY 13/ CY 2023 |
|---|---|---|---|---|---|---|---|---|---|---|
| Pregnant Women | Agg. Annual Limit | Both | 8.70% | 0.00% | $ 810,730,567.00 | $881,264,126 | $957,934,105 | $1,041,274,372 | $1,131,865,243 | $1,230,337,519 |
| Infants 0-1 | Agg. Annual Limit | Both | 2.0% | 1.60% | $ 962,171,203.00 | $997,117,261 | $1,033,332,560 | $1,070,863,199 | $1,109,756,950 | $1,150,063,322 |
| Total | Agg. Annual Limit | Both | N/A | N/A | $ 1,772,901,770.00 | $1,878,381,387 | $1,991,266,665 | $2,112,137,571 | $2,241,622,193 | $2,380,400,841 |

| MEG Used to Calculate the Limit | PC or Agg[5] | WOW Only, WW Only, or Both | Enrollment Trend Rate | Cost Trend Rate | DY 14/ CY 2024 | DY 15/ CY 2025 | DY 16/ CY 2026 | DY 17/ CY 2027 | DY 18/ CY 2028 | DY 19/ CY 2029 |
|---|---|---|---|---|---|---|---|---|---|---|
| Pregnant Women | Agg Annual Limit | Both | 8.70% | 0.0% | $1,337,376,883 | $1,453,728,672 | $1,580,203,066 | $1,717,680,733 | $1,867,118,957 | $1,867,118,957.05 |

[3] PC = Per Capita, Agg = Aggregate
[4] The aggregate budget neutrality model outlined in these STCs is effective as of the date of approval of the demonstration's extension, June 25, 2019.
[5] PC = Per Capita, Agg = Aggregate

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Infants 0-1 | Agg. Annual Limit | Both | 2.0% | 1.60% | $1,173,064,589 | $1,215,670,295 | $1,259,823,440 | $1,305,580,227 | $1,352,998,901 | $1,352,998,900.99 |
| Total | Agg. Annual Limit | Both | N/A | N/A | $2,510,441,472 | $2,669,398,967 | $2,840,026,506 | $3,023,260,960 | $3,220,117,858 | $3,220,117,858 |

68. **Hypothetical Budget Neutrality.** CMS will determine budget neutrality pursuant to the methodology set out at STC 66. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees to offset that excess spending by savings elsewhere in the demonstration or to return the FFP to CMS.

69. **Hypothetical Budget Neutrality: Family Planning and Resource Mothers Components.** The table below identifies the MEGs that are used for Hypothetic Budget Neutrality Tests 1 and 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

**Table 5: Hypothetical Budget Neutrality Tests 1 and 2, DYs 9- 13**

| MEG | PC or Agg * | WOW Only, WW Only, or Both | BASE YEAR | TREND | DY9/ CY 2019 | DY 10/ CY 2020 | DY11/ CY 2021 | DY 12/ CY 2022 | DY 13/ CY 2023 |
|---|---|---|---|---|---|---|---|---|---|
| **Family Planning** | PC | Both | 2018 | 2.7% | $31.80 | $32.66 | $33.54 | $34.45 | $35.38 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Resource Mothers** | PC | Both | 2018 | 4.6% | $206.42 | $215.92 | $225.85 | $236.24 | $247.11 |

| Table 5: Hypothetical Budget Neutrality Tests 1 and 2, DYs 14- 19 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **MEG** | **PC or Agg*** | **WOW Only, WW Only, or Both** | **BASE YEAR** | **TREND** | **DY 14/ CY 2024** | **DY 15/ CY 2025** | **DY 16/ CY 2026** | **DY 17/ CY 2027** | **DY 18/ CY 2028** |
| **Family Planning** | PC | Both | 2018 | 2.7% | $36.34 | $37.32 | $38.33 | $39.36 | $40.42 |
| **Resource Mothers** | PC | Both | 2018 | 4.6% | $258.48 | $270.37 | $282.81 | $295.82 | $309.43 |

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

71. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from September 1, 2019 to December 31, 2029. The Main Budget Neutrality Test may incorporate net savings, 26, 988,680, from the immediately prior demonstration period of 2014 through 2017 (but not from any earlier approval period). If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

72. **Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and

approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

**Main Budget Neutrality Test**

| Table 6: Main Budget Neutrality Test Mid-Course Correction Calculations for IPC & RM Components | | | |
|---|---|---|---|
| Financial Reporting Crosswalk | Demonstration Year | Cumulative Target Definition | Percentage |
| DY 9 | DY 9 | Cumulative budget neutrality limit plus: | 2.0 percent |
| DY 9 through DY 10 | DY 9 through DY 1 | Cumulative budget neutrality limit plus: | 1.5 percent |
| DY 10 through DY11 | DY 1 through DY 2 | Cumulative budget neutrality limit plus: | 1.0 percent |
| DY 11 through DY 12 | DY 2 through DY 3 | Cumulative budget neutrality limit plus: | 0.5 percent |
| DY 12 through DY 19 | DY 3 through DY 10 | Cumulative budget neutrality limit plus: | 0.0 percent |

**Hypothetical Budget Neutrality Test**

| Table 7: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations for FP Only | | | |
|---|---|---|---|
| Financial Reporting Crosswalk | Demonstration Year | Cumulative Target Definition | Percentage |
| DY 9 | DY 9 | Cumulative budget neutrality limit plus: | 2.0 percent |
| DY 9 through DY 10 | DY 9 through DY 1 | Cumulative budget neutrality limit plus: | 1.5 percent |
| DY 10 through DY 11 | DY 1 through DY 2 | Cumulative budget neutrality limit plus: | 1.0 percent |
| DY 11through DY 12 | DY 2 through DY 3 | Cumulative budget neutrality limit plus: | 0.5 percent |
| DY 12 through DY 19 | DY 3 through DY 10 | Cumulative budget neutrality limit | 0.0 percent |

**ATTACHMENT A**
**Developing the Evaluation Design**

## Introduction

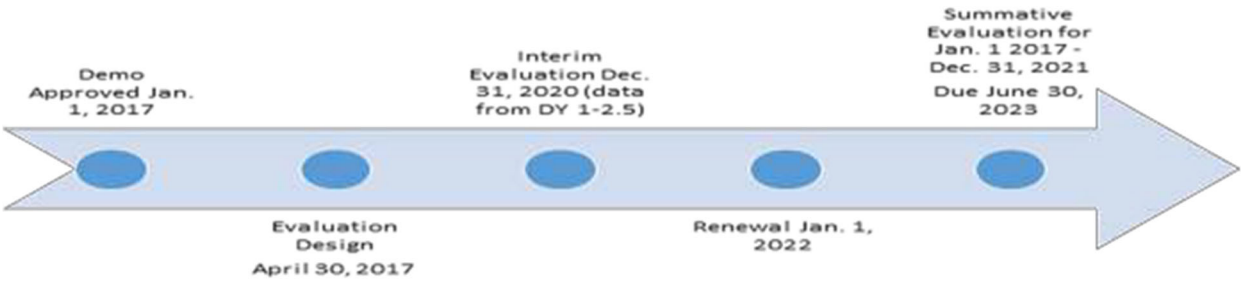
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs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

## Expectations for Evaluation Designs

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

**The format for the Evaluation Design is as follows:**
General Background Information; Evaluation
Questions and Hypotheses; Methodology;
Methodological Limitations; Attachments.

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




**Required Core Components of All Evaluation Designs**
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

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

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

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

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

**C. Methodology** – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

    If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys

must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

   d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

**D Methodological Limitations** – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

**E. Attachments**

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

## Introduction

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

## Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

## Intent of this Guidance

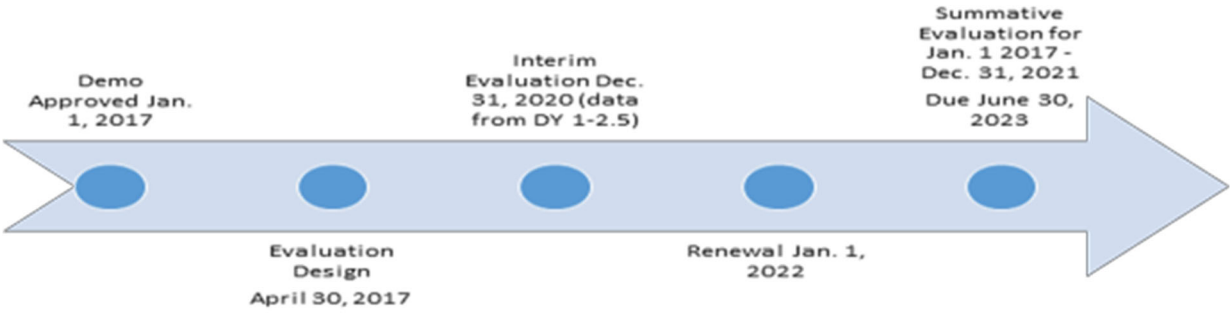
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

**Submission Timelines**

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



**Required Core Components of Interim and Summative Evaluation Reports**
The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

**A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

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

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

    **A. Methodological Limitations** - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

    **B. Results** – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

    **C. Conclusions** – In this section, the state will present the conclusions about the evaluation results.

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

**D. Interpretations, Policy Implications and Interactions with Other State Initiatives –** In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

**E. Lessons Learned and Recommendations –** This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

**F. Attachment -** Evaluation Design: Provide the CMS-approved Evaluation Design

# Family Planning Section 1115 Demonstration
# Evaluation Design for Georgia's Planning for Healthy Babies (P4HB) Program

## Introduction:

Women who use contraceptives consistently and correctly throughout the course of any given year account for only 5% of all unintended pregnancies [1]. Births resulting from unintended pregnancies are twice as likely to be publicly financed as those that are intended, costing taxpayers approximately $11 billion annually through the Medicaid program for maternal prenatal, labor and delivery, and postpartum care and infant first year of life care [2, 3]. Data from the National Survey of Family Growth (2006-2010) demonstrate that more than half of the unintended pregnancies experienced by US parous women occur within two years post-delivery, with 70% occurring within the first year post-delivery. Not surprisingly, the use of less effective methods of contraception increases the risk for unintended pregnancy post-delivery, as does younger maternal age, lower maternal education, and Medicaid vs. private health insurance [4]. Increasing women's access to health insurance has the potential to reduce unintended pregnancy by reducing financial barriers to contraceptive use [1, 5-7]. Publicly funding family planning services are cost-effective, saving nearly $4 in Medicaid expenditures for pregnancy-related care for every $1 spent. [8] Despite many policies aimed at decreasing the number of unintended births almost half of all pregnancies in the United States were characterized as unintended in 2011. [9]

From 1972 until the implementation of the Affordable Care Act (ACA), states did not have the option to provide family planning services and supplies under their Medicaid state plans to individuals otherwise ineligible for Medicaid, including parents with incomes above state eligibility levels and non-disabled adults who were not caring for children. Because the provision of family planning services has been found to be cost effective for the Medicaid program [10], the Secretary of Health and Human Services has and continues to grant Section 1115 program authority to permit states to cover family planning services and supplies for individuals not otherwise eligible for Medicaid. Currently 26 states have either Section 1115 waivers or State Plan Amendments (SPA) that cover family planning and related services for women (and sometimes, men) not otherwise eligible for Medicaid. [11]

Beginning on January 1, 2011, Georgia's Planning for Healthy Babies Program (P4HB), Georgia's section 1115(a) Medicaid Demonstration, expanded the provision of family planning services to low income and uninsured women. The P4HB program was designed to meet primary and reproductive health care needs of women deemed eligible by meeting the following criteria: 1) U.S. citizens or person with qualified proof of citizenship; 2) residents of Georgia; 3) otherwise uninsured and not eligible for Medicaid; 2) 18 through 44 years of age; 3) not pregnant but able to become pregnant; and 4) with incomes at or below 200% of the Federal Poverty Level (FPL) [now 211% FPL]. The P4HB program has a unique component which provides Interpregnancy Care (IPC) services, inclusive of nurse case management/Resource Mother outreach, to women who meet the above eligibility criteria and recently delivered a very low birth weight (VLBW) infant (<1500 grams or < 3 pounds 5 ounces). This interpregnancy care (IPC) component provides coverage for primary health care services, limited dental services, management of chronic health conditions, mental health or substance abuse treatment and detoxification, and case management services in addition to family planning services. P4HB also offers nurse case management/Resource Mother outreach services to women enrolled in the Georgia LIM (Low Income Medicaid) or ABD (Aged, Blind and Disabled) Medicaid programs who delivered a very low birth weight infant on or after January 1, 2011. In the last P4HB Annual Report, Georgia summarized the findings regarding the goals of P4HB as provided from their outside evaluator:

The P4HB program was granted multiple temporary extensions through August 29, 2019 and the Center for Medicare and Medicaid Services (CMS) extended the P4HB waiver program effective September 1, 2019 through December 31, 2029. The approval of P4HB is based on the determination that the continued demonstration is likely to promote the objectives of Title XIX by "improving access to high-quality, person-centered family planning services that produce positive health outcomes for individuals." It is also likely to lead to positive health outcomes through its unique program component of Interpregnancy Care (IPC) which provides targeted benefits for physical and behavioral health services postpartum to otherwise uninsured women that have delivered very low birth weight (VLBW) infants in Georgia.

The postpartum period is a critical window for initiating contraception, preventive, and disease management services for women with a VLBW baby. Women are motivated to prevent pregnancy and short interpregnancy intervals [12, 13], both of which increase the risk for adverse maternal and infant health outcomes in a subsequent pregnancy [14]and are much more likely to occur among women who do not initiate contraception [15,16]. For women with chronic medical conditions and/or who experienced complications of pregnancy such as gestational hypertension or gestational diabetes, the period after pregnancy is an important period for secondary prevention and/or disease management to improve the woman's future health; for these women who will have another pregnancy, interpregnancy care also optimizes health before a subsequent pregnancy [17]. The postpartum period is also a particularly important period for women to seek treatment for perinatal mood and anxiety disorders and substance use disorders that may be not be addressed during pregnancy and which can cause adverse maternal [18] and infant health outcomes.

As part of a section 1115 demonstration authority, the state must conduct an evaluation of the demonstration, and provide regular monitoring reports to CMS to inform policy decisions. States must submit an evaluation design, interim and summative evaluation reports, and annual monitoring reports as per 42 CFR 431.424. Since its implementation in 2011 and under the original STCs from CMS the outside evaluator has completed quarterly and annual reports on key outcomes, available a: https://medicaid.georgia.gov/planning-healthy-babies-quarterly-reporting-0. The original evaluation design was based on a quasi-experimental, pre/post analysis of key outcomes. Below is a short summary of these findings:

- P4HB was associated with the following positive outcomes for Georgia's Medicaid population:
    - decreased unintended pregnancies;
    - decreased teen births;
    - decreased very short (< 6 months) interpregnancy intervals; and
    - increased age at first birth.

- Implementation of P4HB was not associated with changes in the rates of VLBW and LBW and the percent LBW and VLBW Medicaid paid births has increased 2009 (pre-P4HB) to 2018 (post-P4HB) period.

- P4HB enrollees who utilize covered services are less likely to conceive quickly and have improved outcomes in subsequent pregnancies relative to Right from the Start (RSM) women who do not enroll and to P4HB enrollees who do not utilize services.

- Women enrolled in IPC *and* participating were less likely to have clinically inappropriate interpregnancy intervals (< 12 or 18 months) than eligible women who do not enroll.

- Women enrolled in IPC and participating were significantly *less likely* to have an adverse outcome (fetal death, stillbirth, VLBW or LBW infant) in subsequent deliveries than RSM women not enrolling.

- Low-income Medicaid mothers who participate in RM only benefits are far less likely to have a repeat pregnancy within 12 to 18 months postpartum.

Currently, Georgia has not expanded Medicaid under the Affordable Care Act (ACA) and an estimated 405,000 Georgia women of reproductive age remained uninsured in 2017. [19] Roughly 20% of these uninsured women are in the age range targeted by P4HB. The highest rates of uninsured are among Hispanics, single mothers, those with income < 138% Federal Poverty Level (FPL) and unemployed. [18]. The P4HB program remains a critically important source of partial coverage for women of reproductive age not otherwise insured.

### A. Demonstration Objectives/Goals

In general, the purpose of a family planning demonstration is to provide Medicaid coverage for family planning and/or family planning-related services in states that have not elected to include these benefits in their state plan through the new eligibility group authorized in section 1902(a)(10)(A)(ii)(XXI) of the Social Security Act (the Act). As noted, Georgia has not expanded to this new eligibility group.

The minimum goals generally held by CMS for family planning demonstrations include:

1. **Ensure access** to family planning and/or family planning-related services for low-income individuals not otherwise eligible for Medicaid; and

2. **Improve or maintain health outcomes** for the target population because of access to family planning services and/or family planning-related services.

Under its initial and extended demonstration period, the P4HB program in Georgia goes beyond the minimum goals generally held for family planning demonstrations by specifying the following objectives:

3. Reduce Georgia's Medicaid low birth weight (LBW) and VLBW rates;
4. Reduce the number of unintended pregnancies in Georgia Medicaid;
5. Reduce Georgia's Medicaid costs by reducing the number of unintended pregnancies by women who otherwise would be eligible for Medicaid pregnancy-related services;

6. Provide access to IPC services for eligible women who have previously delivered a VLBW infant; and
7. Increase child spacing intervals through effective contraceptive use.

The evaluation design outlined below includes quantitative data collection, including survey data with open ended qualitative questions to examine the effects of the P4HB program on key process and outcomes measures.

### B. Drivers of Outcomes and Evaluation Questions/Hypotheses

#### B.1Primary and Secondary Drivers of Outcomes

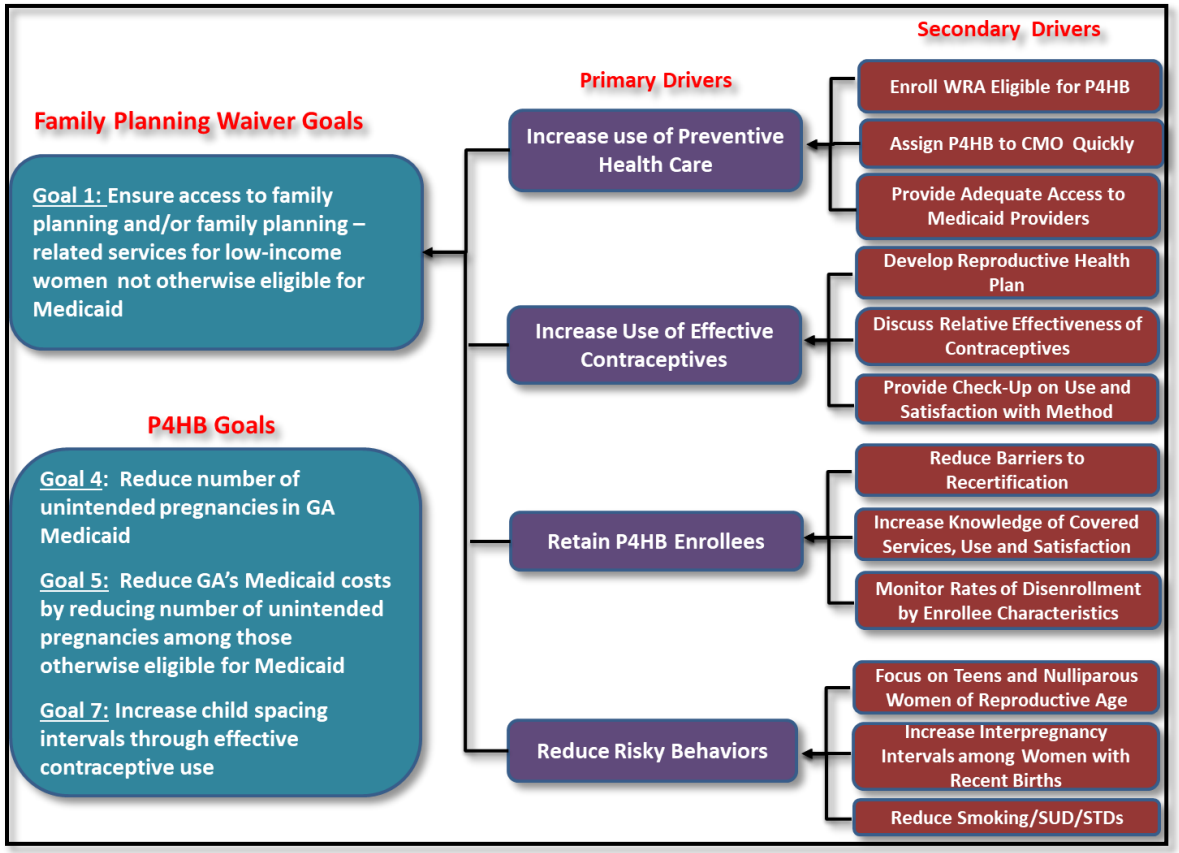
Our approach to the conceptual framework follows that proposed and refined by Andersen [21]. This model asserts that the use of health care services is driven by the predisposing (e.g., age, race/ethnicity, and education level), enabling (e.g. income, insurance) and need (health risks) characteristics of individuals within the context of the health care system and external environment in which their behavior is determined. Their use of health

care services and personal health practices are hypothesized to result in the final outcomes of health status and consumer satisfaction. Our overriding hypothesis is that insurance and hence, reduced out-of-pocket costs through the P4HB program components, lead to increased use of primary and family planning services by women 18-44 and otherwise uninsured in Georgia. In turn, this leads to decreased rates of unintended or mistimed pregnancies. In addition, the receipt of expanded case management/social support services through the IPC and RM components leads to increased use of post-partum health care services and improved health outcomes and any subsequent pregnancy/delivery.

In the Driver Diagrams below, we state the overall aims and related outcomes as well as the primary and secondary drivers to meet these aims and achieve the anticipated outcomes of the P4HB program. Given the differences in the eligible women and the services covered by the FP only and IPC/RM only components, we present separate driver diagrams for each. This allows us to highlight the different aims and 'drivers' specific to these program components. For brevity, we denote the women of reproductive age [18 to 44] who are eligible for P4HB as women of reproductive age (WRA) in the following diagrams.

**Family Planning Only Diagram**

The overall goal of Medicaid family planning waivers is to ensure access and use of family planning services among persons not otherwise eligible for Medicaid. This is a similar overarching goal of the FP component of P4HB for low-income women ages 18-44. Related to this overall goal, specific goals of P4HB are to reduce unintended pregnancies among Georgia Medicaid live births and their related costs as well as increase child spacing through effective contraceptive use. The following driver diagram shows the primary and secondary drivers to achieving these goals within the FP only component.



A primary driver with the FP only component is the increased use of preventive services (e.g., STD testing/treatment, family planning visits). Secondary drivers that affect this use is enrollment of a significant portion of eligible women of WRA into P4HB and once enrolled, assignment to one of the four Medicaid CMOs. The CMOs provide access to a network of primary and specialty providers that accept Medicaid and can provide family planning and family planning-related services. A primary driver to reducing unintended pregnancies is the use of contraceptives that are known to be effective if used appropriately; in our evaluation we use the WHO tiers of effectiveness which emphasize the use of long-acting reversible contraceptives (LARCs). Secondary drivers in increasing the use of effective contraceptives include providers' development of reproductive health plans with WRA in P4HB, discussion of the relative effectiveness of contraceptives and follow-up with enrollees on their satisfaction and appropriate use.

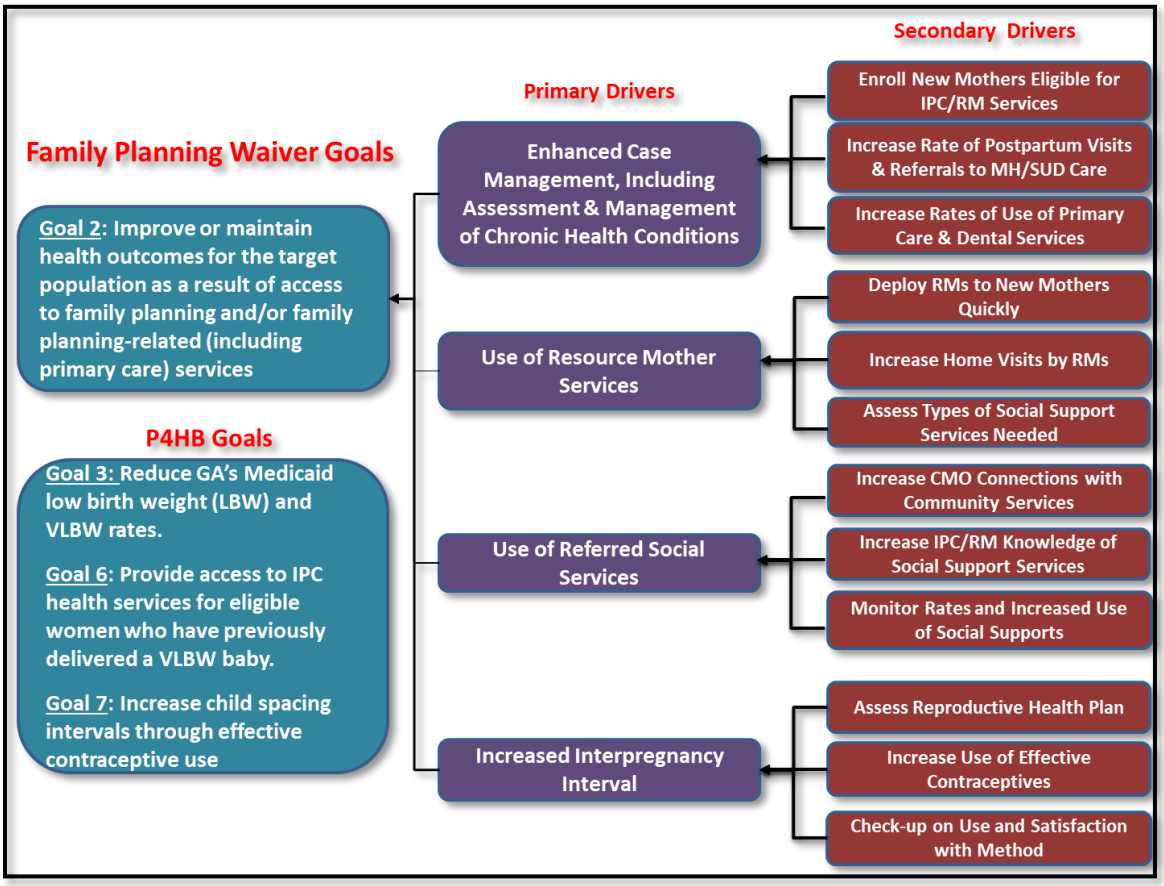
A primary driver to achieving the aim of increased use of family planning services among P4HB enrollees is their retention in the program as long as they are eligible. Recertification of eligibility can create barriers to retention and in turn, disrupt their use of effective family planning services. Secondary drivers therefore include reducing these barriers, increasing knowledge of covered services and monitoring reasons for disenrollment to assure that uninsured eligible women do not lose access to effective contraceptives. Since a large portion of the VLBW infants born to Medicaid insured women are first births a primary driver of reductions in LBW/VLBW is the reduction of risky behaviors including teen births/first births. Secondary drivers include reductions in other risks such as smoking and substance abuse. Among teens or other WRA with a recent birth, reductions in short (<18 months) interpregnancy intervals is an important secondary driver.

**IPC/RM Only Diagram**

Another overall goal of family planning waivers is to improve or maintain health outcomes for the target population because of access to family planning or family planning-related services. Specific to P4HB, the goals of the IPC/RM only components of P4HB are to increase the use of primary care (inclusive of family planning services) as well as the additional RM and related social support services needed by these women. Their eligibility is predicated on a recent VLBW infant and they are deemed to be at high-risk for a repeat poor birth outcome. If this goal is achieved for these women, the expected outcomes are better managed chronic conditions, optimal interpregnancy intervals and fewer maternal morbidities for those with a subsequent pregnancy. The ultimate outcomes would be a higher rate of full-term infants and lower rates of LBW/VLBW infants among births to these Medicaid insured women. The following driver diagram shows the primary and secondary drivers to achieving these goals within the IPC/RM only component.

A primary driver to reducing risks among these women is the enhanced case management included in their benefit package. This entails the assessment of chronic conditions such as hypertension or diabetes and provision of health care services postpartum that can better manage them. This applies to physical as well as mental health conditions; referrals to providers able to treat mental health and substance abuse disorders (SUD) is a secondary driver. Secondary drivers that affect the ability of the program to meet its goals are the enrollment of new mothers of VLBW infants soon after delivery. Once enrolled, increased rates of any postpartum visit as well as rates of use of primary care are secondary drivers.

The RM component of P4HB is designed to help these mothers get to their health care provider, make connections to social services in their community and remain connected to the provider system. The RMs are deployed by the CMOs but less is known about the process of employment and/or deployment of this important resource or their use by P4HB enrollees. An important secondary driver is a contact by the RM soon after delivery and enrollment in IPC/RM only components. Other secondary drivers include increasing the rate of contact between the RM and P4HB enrollee as well as a clear assessment of the types of social services needed.




The RM component should help reduce the barriers these women face due to social determinants of health in their personal and community lives. A primary driver is the use of referred social services that can address such needs. Secondary drivers include clear connections between the CMO providers and community service entities, increased knowledge about these supporting entities among the IPC/RM only women and data on the rate at which the RMs increase use of needed social support services. A primary driver is an increase in interpregnancy intervals for the IPC/RM only women. Included in the services these women should receive is a reproductive health plan that makes them aware of the risks of a short or non-optimal interpregnancy interval (<18 months); this is a secondary driver. Increasing the use of contraceptives that are known to be effective if used appropriately (e.g., LARCs) is a key secondary driver. As the use of LARCs is increased the goals of lower maternal morbidities in subsequent pregnancies and lower rates of preterm and LBW/VLBW births can potentially be achieved.

### B.2 Evaluation Questions and Analysis

In **Table 1** below we state the research questions, hypothesized effects, and the data sources we propose to use to address the research questions in the evaluation of P4HB. Each of six core research questions are aligned within the seven goals of either family planning waivers generally or the specific goals of P4HB as noted earlier. Under each goal, we include the: 1) associated research question, 2) hypothesis, 3) data sources, 4) brief analytic approach and 5) description of treatment and control groups where applicable. We include both process measures (e.g., enrollment, receipt of medically appropriate care) and outcome measures (e.g. birth weight, interpregnancy intervals) in this table. A detailed description of the analytic approaches is included in section C: Methodology. We note that our proposed evaluation goes beyond the basic measures noted by CMS for evaluation of family planning demonstrations and includes data, measures, and analyses specific to the unique IPC and RM only components of P4HB.

We confirm that state-specific files (e.g., Medicaid administrative and financial data, vital records and Pregnancy Risk Assessment Monitoring System or PRAMS) will be made available to the outside evaluator. We also include data and analyses from publicly available sources where helpful in completing this evaluation.

**Table 1. Key Evaluation Questions, Hypotheses, Measures, Data Sources and Analytic Approach by Demonstration Goals**

| Summary of Key Evaluation Questions, Hypotheses, Measures, Data Sources and Analytic Approach by Demonstration Goals | | | | |
|---|---|---|---|---|
| **Hypotheses** | **Anticipated Measures** | **Data Sources** | **Analytic Approach** | **Treatment / Control Groups** |
| **Demonstration Goal 1: Ensure access to family planning and/or family planning-related services for individuals not otherwise eligible for Medicaid.** | | | | |
| **Research Question 1: How did beneficiaries utilize covered health services?** | | | | |
| P4HB enrollees will utilize FP services and/or FP related services at desired rates. | Number (and % of total enrolled) FP only and IPC/RM enrollees who had a FP and/or FP related service encounter in the year. | Medicaid administrative data on enrollment, encounters. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| P4HB enrollees will utilize FP services and/or FP related services at desired rates inclusive of contraceptive methods. | Number (and % of total enrolled) FP only and IPC/RM enrollees who used any contraceptive method in the year. | Medicaid administrative data on enrollment, encounters, and drug files. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| P4HB enrollees will use contraceptive methods of high effectiveness. | Number (and % of total FP only and IPC/RM enrolled family planning users who used contraceptive methods) by WHO tier of effectiveness. | Medicaid administrative data on enrollment, encounters, and drug files. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| P4HB enrollees will receive guideline concordant screening services. | Number (and % of total enrolled) FP only and IPC/RM enrollees who received age-appropriate STI screening, cervical cancer screening, vaccinations during their enrollment. | Medicaid administrative data on enrollment, encounters, and drug files. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| Uninsured women in Georgia < 211% FPL will be more likely to have access to primary care and receive guideline concordant screening services than similar women in comparison states. | Numbers (and % of all women uninsured < 211% FPL) reporting: personal doctor, primary care visit within past year, ever received a Pap, Pap test within past 3 years, flu shot in past 12months, ever tested for HIV. | Behavioral Risk Factor Surveillance System (BRFSS) for women in Georgia and women in states which have also not expanded Medicaid. | Multivariate logit regression analysis of the probability of reporting access to primary care and preventive services controlling for socioeconomic factors (e.g., age, education, marital status, race/ethnicity). | Treatment Group: Georgia Uninsured Women 18-44 < 211% FPL<br><br>Comparison Group: Uninsured Women 18-44 < 211% FPL in SE States without Medicaid Expansion or changes to Family Planning waivers |
| **Research Question 2: Do P4HB enrollees maintain coverage for 12 months or longer? How do sociodemographic, county, and economic factors affect the probability of disenrollment?** | | | | |
| Beneficiaries will maintain coverage for one or more 12-month enrollment period. | Number (and percent of total enrolled) of FP only and IPC/RM enrollees who completed one period of 12-month enrollment/total number of beneficiaries | Medicaid administrative data on enrollment by month and eligibility | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |

| | | | | |
|---|---|---|---|---|
| | | category. | | |
| Individual sociodemographic, county, economic and enrollment barriers affect probability of disenrollment from P4HB. | Monthly data on enrollment by individual P4HB enrollee. | Medicaid administrative data on enrollment by month and eligibility category linked to county level data from Area Resource File (ARF) and American Community Survey (ACS) data | Multivariate logit regression analysis of the probability of disenrollment controlling for sociodemographic (e.g., age, race/ethnicity) and county level determinants (e.g. employment levels, access to providers, Marketplace premiums, rurality). | Treatment Group: P4HB enrollees who use any P4HB service (by family planning and other service categories) in year<br><br>Comparison Group: P4HB enrollees who do not use any service (by family planning and other service categories) in year |
| **Demonstration Goal 2: Improve or maintain health outcomes for the target population because of access to family planning and/or family planning-related services.** | | | | |
| **Research Question 3a: Do health outcomes (e.g., severe maternal morbidities) improve among beneficiaries using program services?** | | | | |
| The P4HB program will reduce the rate of severe maternal morbidities in pregnancy among women participating vs. not participating in the FP program. | Rate of severe maternal morbidity among pregnancies (#/1000) among Medicaid women and those ever vs. never participating in P4HB FP program. | Medicaid administrative data on enrollment, encounters linked to hospital discharge data and *vital records.* | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups; regression analysis of participants versus non-participants. | Treatment Group: Participants in the FP component<br><br>Comparison Group: Women eligible for P4HB FP component but not participating |
| The P4HB program will reduce the rate of severe maternal morbidities in the postpartum period of the index VLBW birth and/or in subsequent pregnancies among IPC/RM enrollees. | Rate of severe maternal morbidity (#/1,000) in the 12 months following the index VLBW birth and/or during any subsequent pregnancies to IPC/RM enrolled women. | Medicaid administrative data on enrollment, encounters and hospital discharge data linked to *vital records*. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups; regression analysis of participants versus non-participants. | Treatment Group: Participants in the IPC/RM component of P4HB<br><br>Comparison Group: Women eligible for P4HB IPC/RM component but not participating |
| Management of chronic conditions among IPC/RM beneficiaries will improve their health. | Rate of severe maternal morbidity (#/1,000) in the 12 months following the index VLBW birth and/or during any subsequent pregnancies to IPC/RM enrollees with conditions known to impact women's health and/or subsequent pregnancy outcomes. | Medicaid administrative data on enrollment, encounters linked to *vital records.* | Descriptive statistics (frequencies and %s) of IPC/RM with evidence of complications of pregnancy or chronic health conditions (e.g., gestational hypertension, gestational diabetes, chronic hypertension, chronic diabetes, mental health conditions, substance use disorders), stratified according to receipt of recommended clinical screenings and follow-up management of these conditions. | Not Applicable |
| The P4HB program will increase the percentage of women with a Medicaid paid birth whose next delivery is privately insured. | Number (and % of all subsequent deliveries to P4HB enrollees) in which the payer is private insurance. | Medicaid administrative data on enrollment, encounters linked to *vital records using the maternal long-ID.* | Descriptive statistics (frequencies and %s); regression analysis of the probability of private insurance in subsequent delivery controlling for socioeconomic factors (e.g., age, education, marital status). | Treatment Group: Medicaid insured Mothers participating in P4HB<br><br>Comparison Group: Medicaid insured Mothers eligible for P4HB but not participating |
| **Demonstration Goal 3: Reduce Georgia's Medicaid low birth weight (LBW) and VLBW rates.** | | | | |
| **Research Question 3b: Do health outcomes (e.g., birth outcomes) improve among beneficiaries using services?** | | | | |

| | | | | |
|---|---|---|---|---|
| The P4HB program will increase the rate of full term, healthy birth weight infants among women participating in the FP program and using services. | Rate (percent) of full-term normal weight birth infants among all Medicaid births and among those to women ever participating in P4HB. | Medicaid administrative data on enrollment, encounters and drug files linked to *vital records*. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups; regression analysis of the probability of healthy birth outcomes controlling for socioeconomic factors (e.g., age, education, marital status, parity) use of family planning services and length of P4Hb enrollment. | Treatment Group: Women participating in the FP only program postpartum<br><br>Comparison Group: Women eligible for FP program only program postpartum but not participating |
| The P4HB program will increase the rate of full term, healthy birth weight infants in subsequent pregnancies among IPC/RM enrollees participating in the program and using services. | Rate (percent) of full term, normal weight birth infants among subsequent deliveries to IPC/RM enrollees. | Medicaid administrative data on enrollment, encounters and drug files linked to *vital records.* | Descriptive statistics (frequencies and %s); regression analysis of the probability of healthy birth outcomes controlling for socioeconomic factors (e.g., age, education, marital status, parity) use of family planning services and length of P4Hb enrollment. | Treatment Group: Medicaid Mothers of VLBW infants participating in IPC/RM components<br><br>Comparison Group: Medicaid Mothers of VLBW infants eligible for IPC/RM components but not participating |
| **Demonstration Goal 4: Reduce the number of unintended pregnancies in Georgia Medicaid.** | | | | |
| **Research Q4: Was P4HB associated with a reduction in the share of unintended pregnancies among Medicaid live births?** | | | | |
| Implementation of P4HB reduced the share of Georgia's Medicaid live births that are unintended pregnancies. | Number (and percentage of total births) reported as an unintended pregnancy for women uninsured pre-pregnancy but Medicaid insured at delivery. | Pregnancy Risk Assessment Monitoring System (PRAMS) survey data for Georgia and comparison states with weighted data as compiled by CDC | Updated multivariate regression analysis of the probability of unintended pregnancy among Medicaid insured births in Georgia 2018-2019. | Treatment Group: Births in Georgia among women uninsured pre-pregnancy but Medicaid insured at delivery to proxy those who are eligible for Medicaid pregnancy-related services<br><br>Comparison Group: Births among women uninsured pre-pregnancy but Medicaid insured at delivery to proxy those who are eligible for Medicaid pregnancy-related services in comparison states |
| **Demonstration Goal 5: Reduce Georgia's Medicaid costs by reducing the number of unintended pregnancies by women who otherwise would be eligible for Medicaid pregnancy-related services.** | | | | |
| Implementation of P4HB reduced the costs to the Medicaid program due to reduced unintended pregnancies among women who would have been eligible for Georgia Medicaid if pregnant. | Costs (amounts paid to providers of services) at delivery and during first year of life for births among Medicaid insured women in the Right from the Start (RSM) eligibility category. | Pregnancy Risk Assessment Monitoring System (PRAMS) survey data for Georgia and Medicaid administrative data on enrollment, encounters and drug files linked to *vital records* | Simulation of costs to Georgia Medicaid 'as if' the estimated difference in unintended pregnancies between Georgia and comparison states found in PRAMS analysis had reduced the number of births to RSM women. | Not Applicable |

| | | | | |
|---|---|---|---|---|
| **Demonstration Goal 6: Provide access to IPC services for eligible women who have previously delivered a VLBW baby.** | | | | |
| **Research Questions 5: Is the P4HB program providing the IPC services to IPC and RM only women as originally envisioned?** | | | | |
| P4HB enrollees in the IPC/RM component will receive services to manage chronic health conditions. | Number (and % of total enrolled IPC/RM women with diagnoses of chronic conditions known to impact reproductive health and pregnancy outcomes (e.g. chronic or gestational diabetes and hypertension, mental health conditions, substance use disorders) receiving medically appropriate preventive and disease management services postpartum. | Medicaid administrative data on enrollment, encounters and drug files linked to *vital records*. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| P4HB enrollees in the IPC/RM component will receive case management and referrals to social support services. | Number (and % of total IPC/RM women enrolled) receiving case management, home visits, coordination of services and referrals to community resources/social support services. | Medicaid administrative data on enrollment, encounters linked to vital records *and individual file on RM contacts and referrals.* | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| P4HB enrollees in the IPC/RM component will receive needed social support services | Number (and % of total IPC/RM women enrolled) receiving peer support/mentoring and social support services. | Medicaid administrative data on enrollment, encounters linked to vital records and *individual file on receipt of social services in the community.* | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. | Not Applicable |
| **Demonstration Goal 7: Increase child spacing intervals through effective contraceptive use.** | | | | |
| **RQ 3c: Do health outcomes (e.g. optimum interpregnancy intervals) improve among beneficiaries using services?** | | | | |
| Among FP enrollees who enroll following birth, the P4HB program will increase the percentage with optimum interpregnancy intervals | Number (and % of all subsequent pregnancies to FP enrollees who enrolled post-birth) with an interval of 18 months or longer. | Medicaid administrative data on enrollment, encounters and drug files linked to *vital records*. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups; regression analysis of participants versus non-participants. Among those participating, regression analysis of users versus non-users of P4HB services. | <u>Treatment Group:</u> Participants in the FP only component; within this group, users versus non-users of services<br><br><u>Comparison Group:</u> Women eligible for P4HB FP component but not participating |
| The P4HB program will increase the percentage of IPC/RM enrollees with optimum interpregnancy intervals. | Number (and % of all subsequent pregnancies to IPC/RM enrolled) with an interval of 18 months or longer. | Medicaid administrative data on enrollment, encounters and drug files linked to *vital records*. | Descriptive statistics (frequencies and %s); Chi-square or T-test of differences across CMO, racial/ethnic and age groups; regression analysis of participants versus non-participants. Among those participating, regression analysis of users versus non-users of P4HB services. | <u>Treatment Group:</u> Participants in the P4HB IPC/RM component<br><br><u>Comparison Group:</u> Women eligible for P4HB IPC/RM component but not participating |

## C. Methodology

1. Evaluation design: The evaluation design will utilize a post-only assessment with a comparison group for **most** of the outcomes that will be analyzed. The timeframe for the post-only period will begin when the current demonstration period began (September 1, 2019) and will end when the current demonstration period ends (December 31, 2029).

   For **selected outcomes** that have not been examined in a previous pre/post analysis, we will test for significant effects from the initial P4HB implementation pre (2008-2010) and post periods (2012-2019). In this analysis we will focus on pre/post analysis of: 1) guideline concordant screening services, and 2) severe maternal morbidities among first and repeat Medicaid pregnancies/deliveries.

2. Data Collection and Sources: The data used in the proposed evaluation will include data collected both retrospectively and prospectively.

   **Administrative Data.** Most of the data outlined in the above table for use in the evaluation will be retrospective in nature and come from DCH and its vendor IBM Watson. The latter entity uses the raw claims/enrollment data to create uniform research files for the outside evaluator. Medicaid eligibility and claims data are received annually in August covering claims through June 30 of that year.

   These files include all eligibility and delivery claims paid by Medicaid and CHIP and nine months of claims pre-delivery and 12 months post-delivery; all eligibility and claims for infants born to all women whose deliveries were paid by Medicaid and CHIP; crosswalk linking Medicaid ID of mother with Medicaid ID of infant (85% linkage rate); all eligibility and claims for women receiving at least one family planning service; all Medicaid and CHIP eligible females ages 10 through 50; and all eligibility and claims data for all women enrolled in the Medicaid 1115 Demonstration (aid categories 180-183).

   Additionally, every November, IBM Watson delivers a crosswalk file that links the mother's Medicaid claims/enrollment data to the prior year's vital records (birth, fetal death) from the Department of Public Health (DPH). The prior year's vital records are also received every November from DPH. Approximately 92% of mothers have a valid Medicaid-vital records link. We treat the vital records as the 'gold standard' in measuring birthweight and hence, reporting on this outcome as well as multivariate analysis of this outcome, will be completed in annual and interim reports.

   A new file from DCH will be used to assess the receipt of RM services by IPC and RM only enrollees. This file was updated beginning in 2016 and provides a measure of number of RM contacts/services and referrals to needed social support services. DCH will send a linking ID to the evaluator so that these files can be analyzed in conjunction with the receipt of medically appropriate preventive and disease management services postpartum among IPC/RM women. Initial review of these files indicates a high linkage percentage (~75%) even before aligning the women's enrollment periods between files.

   **Survey Data.** In the proposed evaluation, survey data will continue to be collected through a vendor chosen by the CMOs who serve P4HB enrollees.

   The outside evaluator will work with DCH to revise the P4HB survey tool such that it maximizes the responses rate (i.e. annual text based surveys) and obtains select qualitative information about P4HB beneficiaries through open-ended questions about recommendations for improvement. The evaluator will analyze weighted survey data on questions which can be summarized quantitatively and will summarize 'themes' from the open-ended questions for reporting in semi-annual reports to CMS.

**Publicly Available Data.** Publicly available data to be used in the proposed evaluation include: Pregnancy Risk Assessment Monitoring System (PRAMS) data; Behavioral Risk Assessment Monitoring System (BRFSS), American Community Survey (ACS).

Data Analysis Strategy: In the text that follows the analytic methods proposed to address the core research questions enumerated in Table 1 are described. We note that virtually all of the proposed analysis is quantitative in nature.

- **Quantitative Methods:** For each of the evaluation questions, we describe the statistical and analytical methods that will be employed to test for effects of P4HB and changes in those effects over time. The research questions are designed to address key process and outcome measures for the three groups of women affected by access to and use of P4HB covered services. These groups are women enrolled in the: 1) family planning only (FP only); 2) Interpregnancy Care Component (IPC); and 3) Resource Mother only (RM only) components of P4HB.

**RQ1**: **How did beneficiaries utilize covered health services?**

Data and Analysis: The primary data source of data will be the administrative data on enrollment/claims. Total numbers of users and rates of use of family planning and contraceptive services, receipt of covered primary and preventive care among all enrollees and medically appropriate preventive and disease management among IPC/RM enrollees will be estimated for each demonstration year. Service receipt will include an assessment of enrollees' receipt of guideline-concordant screening services (e.g. STI screening and treatment, vaccinations).

To assess a broader view of access to primary and preventive services we will use data from the BRFSS for uninsured women ages 18 to 44 in Georgia and other states in the Southeast or nation to assess the levels and changes in the level of receipt of preventive care (age-appropriate STI screening and treatment, cervical cancer screening, vaccinations) for uninsured women of reproductive age under 211% FPL in Georgia compared to other states. This analysis will be multivariate and include state and year fixed effects; age; race/ethnicity; education; work status; marital status; household size; health status; and urban/rural county. This analysis will use women in states that have not expanded Medicaid or changed their family planning programs significantly over the years studied as a comparison group of women to those eligible for P4HB in Georgia.

We will test for effect of P4HB pre (2008-2010) and post (2011-2013) its initial implementation. Since the implementation of the Affordable Care Act (ACA) allowed many lower income women otherwise served by Medicaid and P4HB to obtain subsidized insurance through the Marketplace and expanded funding for safety net providers that serve the uninsured, we will also test for changes in the receipt of these preventive services among this group of women post 2014.

**RQ2: Do P4HB enrollees maintain coverage for 12 months or longer? How do sociodemographic, county, and economic factors affect the probability of disenrollment**?

Data and Analysis: The primary data source will be the administrative data on enrollment for all P4HB enrollees but analysis will be subset to the three enrollee groups in the: 1) family planning only (FP only); 2) Interpregnancy Care Component (IPC); and 3) Resource Mother only (RM only) components of P4HB.

We will provide descriptive statistics (frequencies and percentages) of the total and total consecutive months enrolled, percentage enrolled < 12 months and 12-24 months and the distribution of disenrollment by movement to: 1) RSM; 2) LIM or 3) no Medicaid enrollment. We will use Chi-square or T-test of differences across 1) the four CMOs, 2) racial/ethnic and 3) age groups of women within each P4HB component.

We will construct a file of month to month enrollment for women in the family planning only group and estimate proportional Hazard rate models on time to disenrollment or the odds of disenrollment by 12 months and by 24 months. This will be a multivariate model that will incorporate covariates to control for: 1) age; 2) race/ethnicity; 3) user/non-users of P4HB services; 4) CMO; and 5) county characteristics (employment, percent uninsured, poverty, urban/rural). We will present odds ratios in reports and Issue Briefs for DCH as these are more easily interpreted by policymakers.

This type of model will also be estimated for the IPC and separately, the RM only enrollees. Since these women have recently given birth the control variables will include those listed above as well as measures such as: 1) parity; 2) evidence of chronic conditions and 3) use of any (and categories such as primary care, disease management, family planning) services postpartum.

**RQ3 a, b & c: Do health outcomes (a: severe maternal morbidities; b: birth outcomes; c: optimum interpregnancy intervals) improve among beneficiaries using services?**

Data and Analysis: The primary data source for Research Questions 3 a, b & c will be the administrative data on Medicaid enrollment and claims linked to vital records as well as county level data where available. These analyses are highly interrelated but have been organized under P4HB Goals 2, 4 and 7 in Table 1 and are discussed as separate research questions here.

**Analysis of RQ 3a.** Lower income women entering Medicaid due to pregnancy are at higher risk of poor maternal and infant outcomes. The Right from the Start (RSM) Medicaid eligible women for example, are not eligible pre-pregnancy, often delay prenatal care and due to being lower income may have generally higher health risks. Women in the IPC/RM only component are at increased risk of repeat pregnancies at short intervals and even higher risks of subsequent poor outcomes.

In RQ 3a the dependent variable will be the probability of severe maternal morbidities (SMM) in a pregnancy. SMM are defined based on any one of 21 indicators and corresponding ICD codes which will be found in the claims data for both the FP only and IPC/RM P4HB enrollees. See https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/severe-morbidity-ICD.htm for further detail on the codes to be used.

Using this outcome measure we will estimate the following type of logistic regression model:

3a) $$y_{it} = \alpha + \beta^1 Part_i + \beta^2 SES_i + \beta^3 CE_i + \beta^4 \tau_i + \varepsilon_{it}$$

Where $y_{it}$ represents the outcome of severe maternal morbidity (SMM) for the i$^{th}$ woman at time of outcome $t$ (e.g. SMM at delivery). The variable $Part_i$ is a 0/1 indicator for participation by the i$^{th}$ woman in the FP only or IPC/RM only components of P4HB. Among the women in the RSM eligibility category who delivered an infant on Georgia Medicaid in the *post P4HB years* we will identify those who have enrolled/participated in P4HB as a 'treatment' group ($Part_i$= 1) and those not enrolling as a 'control' group ($Part_i$= 0). Similarly, we will use those eligible for and participating in the IPC/RM only components of P4HB as the treatment group and those eligible but not participating, as the control group. The *SES* vector will include age, race/ethnicity, month/year of index birth, parity, and pregnancy complications. We will

also include a *CE* vector of county environment measures (e.g. employment, percent uninsured, and poverty). Since the data are linked to vital records we will test models with a fuller set of demographic and clinical determinants (education, parity, pre-pregnancy chronic conditions) but the samples will be smaller given a linkage rate of ~90-95%. The variable $\tau_i$ measures the number of months enrolled in the FP only or IPC/RM only components of P4HB.

**Analysis of RQ 3b**. When analyzing the effect of P4HB on birth outcomes we will again use multivariate logistic regression but here the dependent variable is the probability of full term, normal weight live births. We will use multivariate logistic regression to assess the difference in this probability. The generic logistic equation for this analysis is again shown below:

3b) $$y_{it} = \alpha + \beta^1 Part_i + \beta^2 SES_i + \beta^3 CE_i + \beta^4 \tau_i + \varepsilon_{it}$$

Where $y_{it}$ represents a live birth for the i[th] woman at time of outcome $t$ (Medicaid paid live birth in month *t*). The variable $Part_i$ is a 0/1 indicator for participation by the i[th] woman in the FP only or IPC/RM only components of P4HB. For the FP only women we will use the comparison group of RSM women who could have participated in P4HB but did not. For the IPC women we will use those with a VLBW infant delivered on Medicaid but not enrolling in IPC and for the RM only group we will use LIM women with a VLBW infant not enrolling in the RM only component of P4HB. Control variables will again include those noted in RQ 3a.

Separate analysis will be completed on those participating and using P4HB services ('treatment') versus those not using P4HB services ('control'). Categories of use (e.g. primary care, family planning, effective contraceptives) and intensity of use (e.g. number of visits or amounts paid) will also be tested.

**Analysis of RQ 3c.** When analyzing the effect of P4HB on optimum interpregnancy intervals we will again use multivariate logistic regression. The dependent variable here is the probability of conceiving within 6, 12 or 18 months after enrollment in, for example, the IPC/RM only component. We will use the generic logistic equation for this analysis as shown below:

3c) $$y_{it} = \alpha + \beta^1 Part_i + \beta^2 SES_i + \beta^3 CE_i + \beta^4 \tau_i + \varepsilon_{it}$$

Where $y_{it}$ represents a subsequent pregnancy for the i[th] woman at time of outcome $t$ (e.g. repeat pregnancy at month *t*). The variable $Part_i$ is a 0/1 indicator for participation by the i[th] woman in the IPC/RM only component of P4HB. For the IPC women we will use a comparison group of RSM women with a VLBW infant delivered on Medicaid but not enrolling in IPC and for the RM only group we will use LIM women with a VLBW infant not enrolling in RM only component of P4HB. Control variables will be as presented in RQ 3 a.

Both the IPC/RM women are at increased risk of short interpregnancy intervals. The dependent variable will be the probability of a very short (< 6 months) or suboptimum (< 18 months) interpregnancy interval. Since these women have recently delivered a VLBW infant the 'start time' for the subsequent outcomes will be the month of their index birth or enrollment in IPC/RM after that index birth. Separate analysis will be completed on those IPC/RM enrolling and using P4HB services ('treatment') versus those enrolling and not using P4HB services ('control'). Here, we will focus on the use of any family planning services and in turn, the use of more effective (Tier 1) contraceptives with a focus on the use of long-acting reversible contraceptives (LARCs).

If we find a sufficient sample of women in LIM with a VLBW infant prior to P4HB (e.g. 2008-2010) we will test a Pre/Post P4HB indicator *Post* = 1 and interact this with $Part_i$. This particular model would use an individual fixed-effects and omit demographics.

An additional set of analyses will use the maternal long ID in the linked Medicaid and vital records to analyze whether the probability of any subsequent birth to a P4HB enrollee being Medicaid or private insured. The hypothesis here is that participation in P4HB and receipt of family planning and related services has served to increase the woman's health and ability to plan the timing of their pregnancies such that they are able to remain in the labor force and access to private insurance.

**RQ4: Was P4HB associated with a reduction in the share of unintended pregnancies among Medicaid live births?**

Data and Analysis: The primary data source will be the Pregnancy Risk Assessment Monitoring System (PRAMS) data available to the outside evaluator through and existing DUA with the CDC. Survey data with appropriate weights are made available for states with adequate response rates (generally greater than 60%).

*Unintended Birth*: Unintended birth is a key outcome of interest that we can only measure with survey data. In prior work we tested the effect of P4HB on several measures of unintended pregnancy/birth. For years 2008-2010, the PRAMS data asked the question: *"Thinking back to just before you got pregnant with your new baby, how did you feel about becoming pregnant?"* and included as possible responses the following options: 1) *I wanted to be pregnant sooner*, 2) *I wanted to be pregnant later*, 3) *I wanted to be pregnant then*, and 4) *I didn't want to be pregnant then or at any time in the future*. In 2012, however, a fifth response choice was added: 5) *I was not sure what I wanted.* We therefore will continue to teste several measures of unintended pregnancy/birth. The first will classify mothers as having an unintended pregnancy/birth if they responded that they were: 1) *unsure what they wanted;* or 2) *were not trying to get pregnant*. With this measure, we will test models excluding mothers who were unsure what they wanted. We with then test models based on whether a mother was trying to get pregnant based on the following question: *When you got pregnant with your new baby, were you trying to get pregnant?*

We previously used data from 2008 through 2013 and used a difference-in-difference method to estimate the effects of P4HB on these outcomes. With this method, changes in the outcomes from the control group are subtracted from those of the treatment group, controlling for any group-specific and time-specific effects that may have altered the outcomes during the study years. We used logistic analysis and controlled for mother's age, race/ethnicity, number of stressors, if the mother drank alcohol three months before her pregnancy, if the mother smoked three months before her pregnancy, number of previous live births, and number of terminations. All regression models included state and year fixed effects and adjusted standard errors for clustering at the state/year level.

In prior analysis of the 2008-2013 data we used a treatment group of mothers in Georgia that were uninsured pre-pregnancy but insured with Medicaid at delivery and the control group includes these women in the control states (Arkansas, Oklahoma, and Maryland). The Georgia PRAMS data were not available to the outside evaluator for years 2014-2017; weighted data are now available for 2018 and more current years from the CDC. We will obtain these data by appending an existing DUA for Georgia and comparison states to assess whether the decrease in unintended pregnancies after the implementation of P4HB continued through the more current period.

**RQ5: Is the P4HB program providing the IPC services to IPC and RM only women as originally envisioned?**

Data and Analysis: The primary data sources will be the administrative data on Medicaid enrollment and claims as well as a file newly available to the outside evaluator that includes the encrypted Medicaid ID for individual P4HB members who received RM services. After 2016 this file contained individual data on the number and nature of RM contacts, referrals and use of social support services by each woman. Once it is linked to the Medicaid claims/enrollment data we will complete analysis of the 1) use of any services, 2) medically appropriate services and 3) receipt of RM services and referrals.

Total numbers of users and rates of use of non-family planning related covered services (including primary care, dental, and substance use treatment), receipt of covered primary and preventive care among all enrollees and medically appropriate preventive and disease management among IPC/RM enrollees will be estimated for each demonstration year. Service receipt will include an assessment of enrollees' receipt of clinically-indicated screening and follow-up services based on evidence of diagnoses of chronic health conditions (e.g., diabetes, hypertension, substance use disorder) and/or diagnoses of complications of pregnancy (e.g., gestational diabetes, gestational hypertension) in the index pregnancy.

We will provide descriptive statistics (frequencies and percentages) of the total number and type of clinical services utilized for women in the IPC and RM only components overall and according to their chronic health condition/pregnancy complication status. We will use Chi-square or T-test of differences across 1) the four CMOs, 2) racial/ethnic and 3) age groups of women within IPC and RM only components.

Total numbers and rates of use of RM services, including referrals to social support services.

- **Survey Data and Methods**

The key research question that needs to be addressed with survey data is shown below.

**RQ6: Are beneficiaries sufficiently aware of services covered and available providers? Does this result in high levels of satisfaction with the P4HB program?**

**Data:** The evaluation design assumes the CMOs will continue to contract with the previous survey firm to implement a survey aimed at P4HB beneficiaries. The member survey has now been revised and is included in Appendix A. As written, it consists of five composite areas with yes/no responses to approximately 30 statements. There is also one open-ended free-text question for survey respondents to enter their recommendations for how to improve P4HB. The messaging to P4HB members about the first survey will occur July-September 2021. DCH and the CMOs will work collaboratively to determine effective and timely communication to members prior to the actual launch. The survey will be launched October 2021 and every October thereafter. Survey results will be submitted to DCH by the CMOs in December of each year to be summarized in the annual reports due to CMS in March of the following year.

As the outside evaluator we support a sampling design based on 80% power to detect changes over time in the answers to questions related to enrollee access to contraceptives, availability of providers and indicators of satisfaction. We estimate that a sample of approximately 1,500 FP only members will allow detection of a 5 percentage point *increase* in 'started using birth control' and 'able to get preventive care (such as Pap smears) and family planning counseling' with 80% power. This same sample size will allow detection of a 2.5 percentage point *decrease* in 'cannot find a doctor or nurse willing to take P4HB clients' and a 1.5 percentage point *decrease* in 'my P4HB doctor or nurse will not prescribe the birth control method I want'.

To implement this design DCH will ask the CMOs to send a full roster of current enrollees with their 1) contact information 2) eligibility (FP only, IPC/RM only) category and 3) member months to the survey firm. The survey firm will randomly sample 4,000 FP only enrollees from each of the three (as of May 1) CMOs for the survey. All IPC/RM only enrollees in the roster need to be contacted with the survey. A response rate of 12% or higher among the FP only enrollees, or approximately 500 of these enrollees per CMO, will meet the 1,500 estimated sample size noted above. The response rate among the IPC/RM only enrollees needs to be as high as possible.

The vendor will use a mail plus phone/text follow-up (of non-respondents) survey method in order to increase the response rates from where they have been historically. The CMOs have been and will continue to be, fully engaged in this survey design process to ensure operational feasibility and standard deployment of the survey.

**Analysis of RQ6:** The evaluator will be able to analyze weighted survey data on questions which can be summarized quantitatively and will report on themes from a content analysis of the open-ended questions for reporting in semi-annual reports to CMS.

- **Qualitative Methods:** The evaluation design does not include the collection or analysis of qualitative data beyond the addition of an open-ended question to the survey the CMOs will implement through their vendor.

- **Covid-19 Impacts.** We will focus on any needed changes to the methods including the definition of comparison groups that will be helpful in completing the analyses as described in the forgoing table and text. Also, as denoted in the guidance from CMS--Implications of COVID-19 for Section 1115 Demonstration Evaluations: Considerations for States and Evaluators, states must document changes to the implementation of the demonstration caused by the pandemic and note the challenges they create for planned evaluation activities as that information becomes available. We anticipate that both enrollment (timing and duration) as well as service utilization by enrollees could be impacted by the pandemic.

  Specifically, while enrollees have been able to remain in P4HB and other categories longer than usual under previous eligibility criteria, utilization of many services usually provided in-person have been curtailed because of delays in accessing services from health care providers and clinics that closed or had limited appointment availability during COVID. As such, we will carefully document the impact of COVID-19 on length of enrollment in the components of P4HB, as well as the potential decline in movement from the RSM eligibility category into P4HB eligibility postpartum related to the COVID -19 extensions, and the utilization of services among enrollees by comparing enrollment and utilization measures during the pandemic to the same measures for the pre-pandemic period. Comparison of the characteristics of newly enrolled P4HB members to the new enrollees in prior periods will be helpful in understanding any changes in the demographic composition of women enrolling in P4HB during COVID-19. Similarly, comparisons of the characteristics of enrolled women who utilize and do not utilize services will be helpful in understanding any disproportionate impact of the pandemic on utilization among enrollees.

  From an evaluation perspective, we anticipate that the biggest challenge will be in accounting for differences in the measurement of service utilization and in particular, contraceptive utilization, during the COVID -19 period in relation to pre- and post-pandemic periods. This is important to several of the proposed analyses that use non-participants (non-users of P4HB services among those enrolled) as a comparison group. To begin to address this, we will document the use of additional procedure codes (e.g. for telehealth services) telemedicine service codes (e.g., POS 02 code to indicate a telemedicine service) to measure total (in person and telemedicine) and telemedicine service utilization by P4HB enrollees during

the March 2020 through December 31 2021 time period as best as possible.

## D. Methodological Limitations

There are several limitations in both the quantitative and qualitative sections of this proposed evaluation design. We address these separately in the following text.

**Quantitative.**

The proposed design uses quantitative analysis of several databases with the emphasis on the linked Medicaid claims/vital records data. Any analysis of claims data has the limitation that we only observe those services for which providers bill Medicaid through their CMO and are paid for while the woman is enrolled in Medicaid/CHIP and inclusive of the P4HB program. Yet, being able to observe women moving in and out of pregnancy/delivery or in and out of Medicaid coverage provides significant power to the types of analyses proposed here. In the original evaluation design the outside evaluator used a quasi-experimental pre/post design in the analysis of the Medicaid/claims and PRAMS data. Given the maturity of the P4HB program this evaluation design only uses this type of more rigorous analysis for selected outcomes (e.g. severe maternal morbidities) using Medicaid administrative files and for analysis of unintended pregnancies, using the PRAMS data. Most of the analysis proposed here will use a control/comparison group of women to increase the rigor of the analysis. For example, we propose to use women eligible for P4HB but not enrolling as a control/comparison group in several parts of the analysis.

Use of a control/comparison group adds power to the analysis of outcomes in the post-period data and we control for characteristics of the treatment (here, those eligible and participating by enrolling) and control/comparison groups. Yet, there are very likely unobserved characteristics of these two groups that relate to the decision to enroll and/or participate by using services that results in bias. For example, those choosing to participate and, those choosing to participate and use services are either more risk-adverse or more oriented toward healthy behaviors independent of P4HB. If the latter holds, our findings regarding the effects of P4HB will be biased upward.

Finally, we propose to use publicly available data sources (e.g. BRFSS, PRAMS) in parts of the analysis to proxy those women affected by P4HB. While these data provide valuable information on outcomes in other states that can be used to help evaluate the effects of the P4HB program, there are limitations to our ability to identify study populations that are similar to the P4HB eligible and/or enrolled populations. For example, the BRFSS provides data on the rate of screening among uninsured women under 211% FPL in Georgia and comparison states but does not allow us to restrict the sample to citizens. This means we are not truly identifying the group of women eligible for P4HB. If the comparison states have a significantly different (smaller) percentage of non-citizens, the effect of P4HB will likely be biased downward. Similar survey data were successfully used in an analysis of a family planning waiver on preventive care services. [22]

There are also limitations to identifying the group of Medicaid births affected by P4HB in the PRAMS data. In these data we use births to those uninsured pre-pregnancy but insured with Medicaid at delivery; this serves as a proxy for the group of women only eligible for Medicaid when pregnant. However, if some women who would have been eligible as low-income parents (LIM in Georgia) do not enroll until they are pregnant, they will be included along with those who are only eligible when pregnant. These women are likely a small percentage of those enrolling during pregnancy, but they are lower income and more likely citizens than those only eligible/enrolling when pregnant or at delivery. Yet, the PRAMS data are the only source of data on births resulting from unintended pregnancy by state and over time. They have been successfully used to evaluate family planning waivers[23] using a target population as defined here which should largely reflect the targeted P4HB eligible population.

**Qualitative.**
The survey has historically been limited to quantifiable measures of P4HB enrollees' knowledge of and experiences with the program. Hence, the outside evaluator has not had rich, contextual information to explain the respondents' answers as would be possible if we were to include a full range of qualitative data collection methods in the evaluation. For example, with the prior survey results, we were not able to solicit ideas and recommendations for improving the P4HB program. Qualitative methods, such as focus groups or interviews, would allow for such detailed information that may better inform the continual monitoring and quality improvement efforts needed to evaluate P4HB. This evaluation design includes a revision to the survey instrument to include an open-ended question that could illicit some contextual information. The outside evaluator, as noted earlier, will work with DCH to influence the sample design and the desired response rates.

## E. Milestones for Evaluation Activity

**Milestones.** The proposed research questions and analysis include a series of descriptive and multivariate analyses on previously used as well as new, outcome measures. Since developing and evaluating new measures (e.g. severe maternal morbidities) will take more time than other analysis such as enrollment and birth outcomes they will be presented in later interim reports as detailed in **Table 2** below.

**Table 2. Milestones in Evaluation Activity under STCs for P4HB Renewal Period September 1, 2019 through December 31, 2029**

| Report | Content | Data Sources | Years of Data | Due Date |
|---|---|---|---|---|
| **Summative Evaluation Report for Previous Approval Period** | Results of Quasi-Experimental Analysis of Outcomes pre and post Initial Implementation of P4HB | Administrative Medicaid Claims and Linked Vital Records Data. | January 2011-December 2019 | Completed |
| **2019 Annual Monitoring Report** | Analysis of Enrollment Patterns, Use of Family Planning and Postpartum Services, Repeat Pregnancies and Birth Outcomes | Administrative Medicaid Claims and Linked Vital Records Data. | January 2018-December 2019 | Completed |
| **2022 Draft Interim Evaluation Report (Years 1-2)** | Results of Analysis of Research Questions 1, 2, 4 & 5. Analysis of Enrollee Surveys (RQ6) | Administrative Medicaid Claims and Linked Vital Records Data, BRFSS, PRAMS and Enrollee Surveys | January 2020-December 2021 | December 31, 2022 |
| **2025 Draft Interim Evaluation Report (Years 1-5)** | Updates to Research Questions 1,2 and Research Questions 3a, b &c. Analysis of Enrollee Surveys (RQ6) | Administrative Medicaid Claims and Linked Vital Records Data and Enrollee Surveys | January 2020-December 2024 | December 31, 2025 |
| **2028 Draft Interim Evaluation Report (Years 1-8)** | Updates to Research Questions 1, 2 and 3b and Research Question 5. Analysis of Enrollee Surveys (RQ6) | Administrative Medicaid Claims and Linked Vital Records Data and Enrollee Surveys | January 2020-December 2028 | December 31, 2028 |
| **Summative Evaluation Report for Renewal Period Years 1-10** | Summary of findings from Research Questions 1-6, Budget Neutrality, Biennial Surveys and CMO Reports | Administrative Medicaid Claims and Linked Vital Records Data, BRFSS, PRAMS and Enrollee Surveys | January 2020-December 2029 | July 1, 2031 |

The first major milestones were the submission of the summative evaluation and annual monitoring reports for the previous approval period for P4HB (January1, 2011 – August 31, 2019). The summative report reflected the original evaluation design which was quasi-experimental in nature and included data from 2008, prior to the implementation of P4HB through December 31, 2019. The annual monitoring report included analysis of enrollment patterns, use of services and outcomes during the January - December 2019 period.

Major milestones during the renewal period include three interim reports in 2022, 2025 and 2028 as noted. The first in 2022, will report on the analysis of research questions 1, 2, 4 and 5. These analyses will use administrative data for years 2020 and 2021 as well as secondary data from the BRFSS and PRAMS for the years noted earlier. Results from the enrollee survey in 2021 will also be included.

The 2025 interim report will include updates where possible (e.g. PRAMS data), to results from research questions in the 2022 interim report. The BRFSS analysis will not be updated. The analysis in this report will focus on results of the three components of research question 3. These analyses are multivariate in nature and will use data on outcomes through December 2024. Results from the annual enrollee surveys will also be included. This will include tests on significant changes in enrollees' awareness of covered services, available providers, and satisfaction with the program from the annual 2021 through 2023 surveys.

The 2028 interim report will include updates where possible, to prior results from research questions in the 2022 and 2025 interim reports. It will include analysis of research question 5 using the newly available files on RM visits, referral and use of social support services in the community. Once linked to the administrative data on use of health care services and maternal health/outcomes this analysis will shed important information on how well this unique component of P4HB is being implemented and in turn, how it affects women's health. These analyses involve new linking and analytic processes and will use data on outcomes through December 2027. Results from the enrollee surveys through 2025 will be included in this interim report. This will add to our understanding of significant changes 2021-2025 in enrollees' awareness of covered services, available providers, and satisfaction with P4HB.

The summative report for the full renewal period, due 18 months after the end of the renewal period, will use data through December 2029. This report will provide a summary of findings from all six research questions, the annual enrollee surveys and CMO reports previously summarized in the semi-annual and annual reports.

**F. Independent Contractor:** The state plans to continue to use Emory University, Rollins School of Public Health (RSPH) as the outside evaluator in this renewal period. This entity has been the evaluator since the initiation of P4HB and hence, can seamlessly continue the evaluation work under an existing data use agreement with the Department of Community Health (DCH) and the Department of Public Health (DPH) in Georgia. Their simplified budget for each annual period from 2021 through 2031 is shown below in **Table 3.** The summative report for the full ten-year renewal period is due 18 months after the end of this period in December 2029 and hence, falls in 2031. Budget is included for the last six months of 2031 for the evaluator to help with report documentation, reports to the legislator, final Issue Briefs, etc. The major budget categories shown in the budget are: 1) Data Cleaning and Programming; 2) Survey 3) Analysis & Report Preparation; 4) Project Management.

**Table 3. Annual Direct Costs for Evaluator Staff by Budget Categories and Calendar Year**

| Budget Categories | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Data Cleaning and Programming | $65,793 | $68,560 | $80,069 | $74,446 | $77,917 | $81,383 | $84,422 | $85,347 | $90,810 | $94,222 | $104,658 |
| Survey | $19,577 | $12,540 | $21,255 | $13,617 | $23,081 | $14,976 | $24,704 | $24,462 | $26,164 | $26,456 | $27,568 |
| Analysis and Report Preparation | $155,664 | $197,661 | $169,030 | $193,654 | $216,810 | $202,875 | $202,204 | $231,764 | $215,093 | $223,322 | $225,982 |
| Project Management | $14,042 | $14,632 | $15,246 | $15,888 | $16,898 | $17,609 | $18,348 | $17,139 | $19,518 | $20,338 | $21,152 |
| **Total Direct Costs** | **$255,076** | **$293,393** | **$285,600** | **$297,605** | **$334,706** | **$316,843** | **$329,678** | **$358,712** | **$351,585** | **$364,338** | **$379,360** |

**Data Cleaning and Programming:** External evaluator activities for this task include receipt of multiple files of administrative data on enrollment, claims/encounters, drug files, provider files and multiple state-generated reports on enrollment. In addition, quarterly reports from the CMOs are received as well as financial reports on capitated payments to P4HB CMOs. Along with the administrative data, a crosswalk is received that allows the evaluator to link Medicaid mother/baby records to vital records. Vital records include all live birth and stillborn records. These various files are used for the reports required in the renewal period, preparation of the series of reports required under the new STCs and for the variables used in the analysis addressing research questions 1-5. An average of 866 hours annually for this task are estimated across all ten years and an average 833 hours in 2022, 2025 and 2028 are estimated when interim reports are due.

**Survey**: The state will direct the CMOs to implement enrollee surveys on an annual basis as noted earlier. The evaluation budget includes staff time to assist DCH in evaluating the sampling design and implementation of the survey through the firm hired by the CMOs. Staff time is also included for the analysis of weighted survey data and 'themes' obtained from open-ended questions. An average of 289 hours annually for this task are estimated across all ten years but an average 276 hours in 2022, 2025 and 2028 are estimated when interim reports are due.

**Analysis and Report Preparation:** A large amount of staff time is devoted to the development of analytic files to be used in statistical and regression-based analyses. Developing and cross-checking definitions of variables used for process and outcome measures included in the reporting process requires significant staff time especially for the proposed multivariate analyses. More staff time has been budgeted for those years in which Interim reports are due [2022, 2025 and 2028]. An average of 1496 hours annually for this task are estimated across all ten years but an average 1793 hours in 2022, 2025 and 2028 are estimated when interim reports are due.

**Project Management:** The budget also includes 104 hours annually for the overall management of the evaluation and reporting process. Management tasks will largely include meetings, phone calls and other tasks to assure coordination of efforts to complete analysis and produce the scheduled reports in a timely manner.

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## Appendix A. Revised Member Survey

| | Revised Member Survey - DRAFT 2021 |
|---|---|
| 1 | **Before enrolling in P4HB®, had trouble getting…** |
| | Birth control or family planning services |
| | Pregnancy testing |
| | Testing or treatment for sexually- transmitted infections |
| | Primary care (such as routine check-up, care for an illness) |
| | Other |
| 2 | **Major changes since enrolling in P4HB…** |
| | I am going to a different doctor or nurse for family planning services or birth |
| | I am going to a different doctor or nurse for primary care |
| | I have started using a birth control |
| | I have changed the birth control method I use |
| | I have more choices of birth control methods |
| | I do not have to use my own money for family planning services or birth control |
| | I am able to get preventive care (such as Pap smears) and family planning counseling |
| | I am able to get care for illnesses |
| | I am able to get medicines for illnesses when I need them |
| | Other |
| 3 | **Problems Under P4HB Program…** |
| | I cannot get the family planning services I want |
| | I cannot get referrals or follow-up for care I need |
| | I cannot find a doctor or nurse willing to take P4HB clients |
| | I don't want to leave my current doctor or nurse |
| | I have to wait too long to get services |
| | I do not have transportation |
| | I cannot get to the doctor or nurse when they are open |
| | My P4HB doctor or nurse will not prescribe the birth control method I want to use |
| | Other |
| 4 | **During your last visit did Dr/Nurse ask you about any of the following?** |
| | Your thoughts or plans about having or not having children in the future |
| | Your thoughts or plans about timing or spacing pregnancies |
| | Your sexual practices |
| | Whether you use birth control to prevent or space pregnancies |
| | Whether you use male or female condoms to prevent STIs |
| | Your life plans or goals |
| 5 | **How did you learn about P4HB?** |
| | Health Department |
| | Provider's Office |
| | CMO P4HB letter |
| | Flyer / Advertisement |
| 6 | **How can we improve the P4HB program?** |
| | Free text response…. |