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

**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:

FP Comprehensive Evaluation Design

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

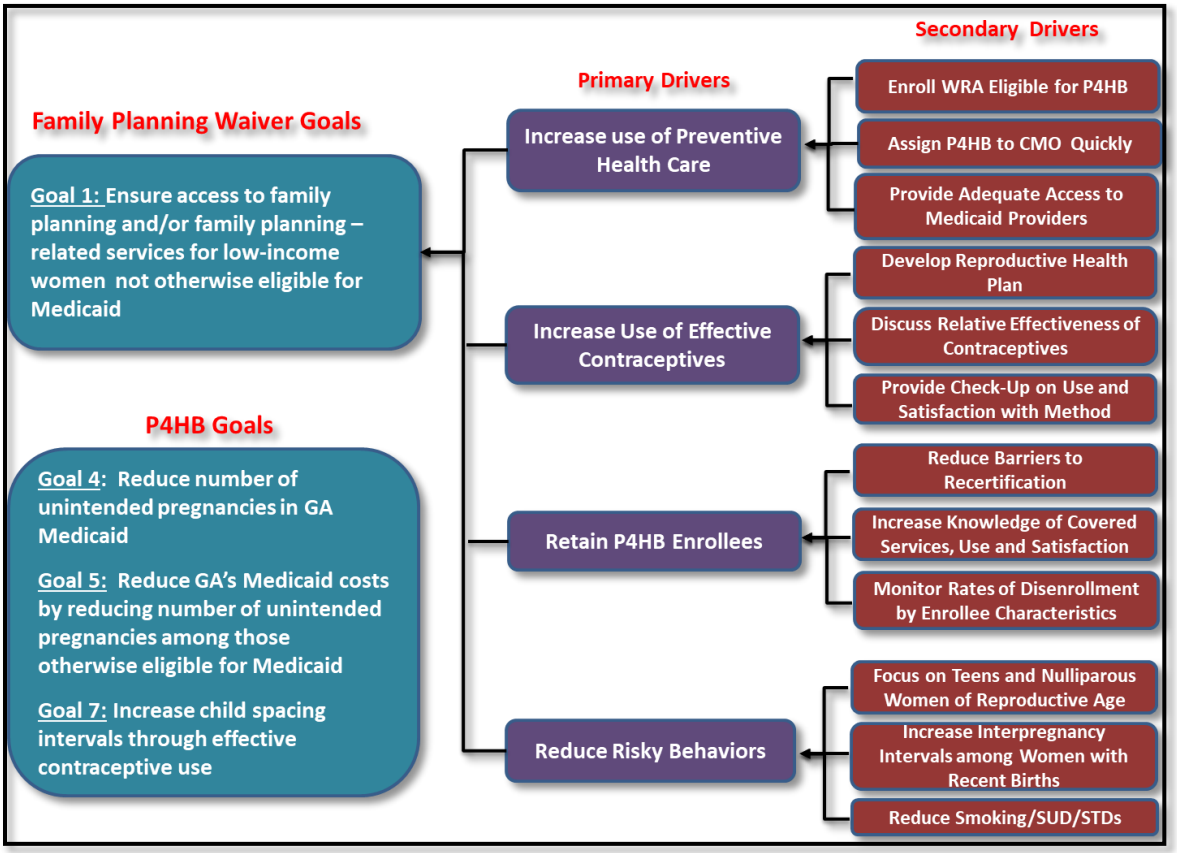
Our approach to the conceptual framework follows that proposed and refined by Andersen [21]. This model asserts that the use of health care services is driven by the predisposing (e.g., age, race/ethnicity, and education level), enabling (e.g. income, insurance) and need (health risks) characteristics 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.

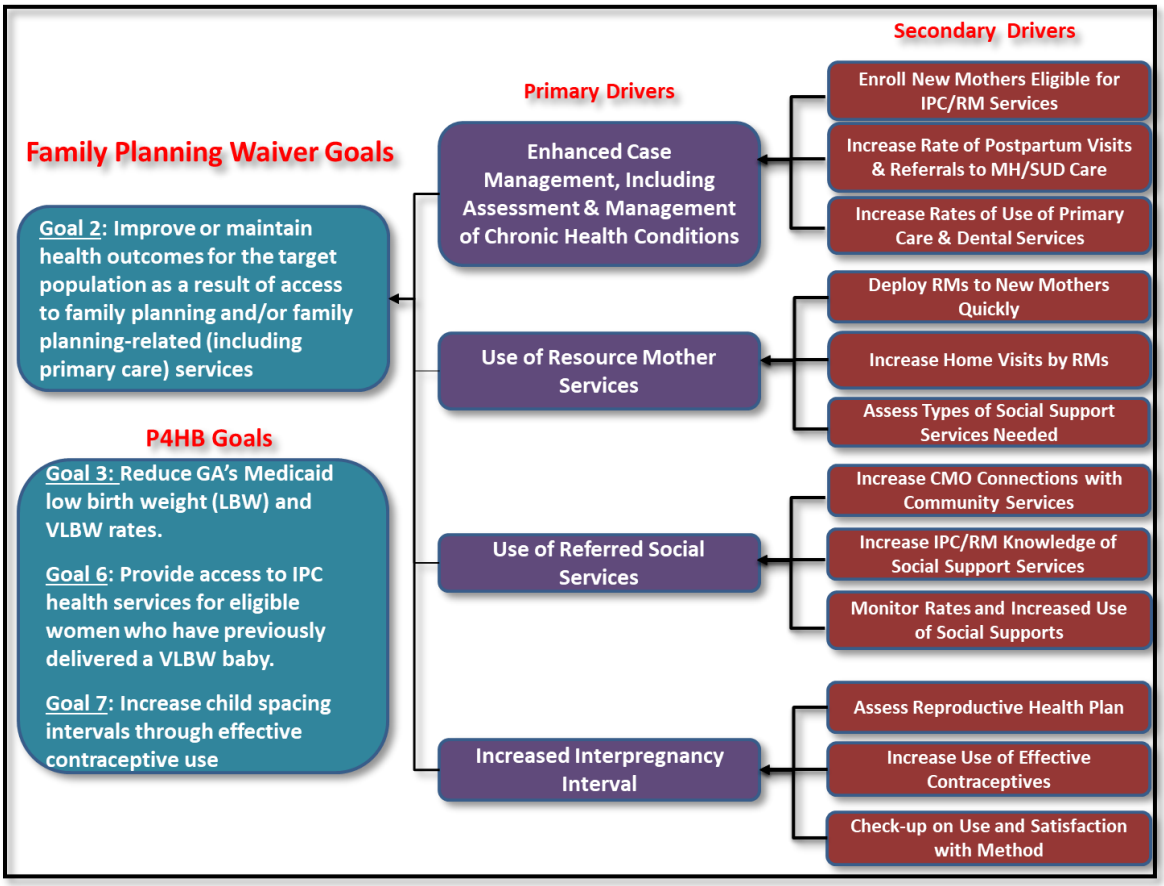
A primary driver to achieving the aim of increased use of family planning services among P4HB enrollees is their retention in the program as long as they are eligible. Recertification of eligibility can create barriers to retention and in turn, disrupt their use of effective family planning services. 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 |

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| | | 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?** | | | | |

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| 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 |

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| **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'.

FP Comprehensive Evaluation Design

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…. |