#### Family Planning Section 1115 Demonstration Evaluation Design for Georgia's Planning for Healthy Babies (P4HB) Program February 25. 2020

#### 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 in 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, 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) recently 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: <a href="https://medicaid.georgia.gov/planning-healthy-babies-quarterly-reporting-0">https://medicaid.georgia.gov/planning-healthy-babies-quarterly-reporting-0</a>. The original evaluation design was based on a quasi-experimental, pre/post analysis of key outcomes. Below is a short summary of these findings:

- <u>P4HB was associated with the following positive outcomes for Georgia's Medicaid population:</u>
  - o decreased unintended pregnancies;
  - o decreased teen births;
  - o decreased very short (< 6 months) interpregnancy intervals; and
  - o 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 as a result 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:

- Reduce Georgia's Medicaid LBW and VLBW rates among Medicaid insured;
- 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 services for eligible women who have previously delivered a VLBW infant; and
- Increase child spacing intervals through effective contraceptive use.

The evaluation design outlined below includes quantitative data collection and analyses and qualitative analyses of survey data in order to test for 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**

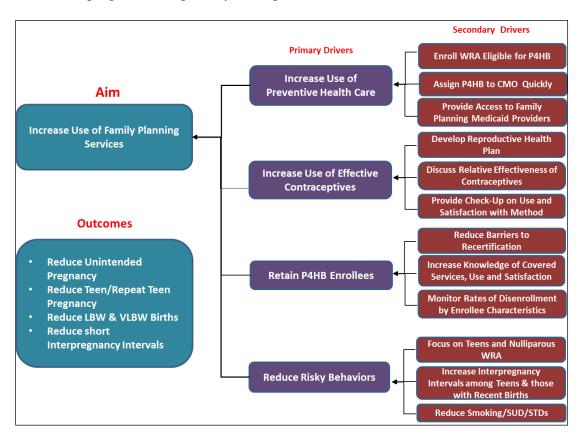
Our approach to the conceptual framework follows that proposed and refined by Andersen [21]. This model asserts that the use of health care services is driven by the predisposing (e.g. age, race/ethnicity, and education level), enabling (e.g. income, insurance) and need (health risks) characteristics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

#### **Family Planning Only Diagram**

The overall aim of the FP only component of P4HB is to increase the use of family planning services among those women eligible and enrolling into this component of the program. In turn, the expected outcomes are to reduce unintended pregnancies especially among teens.



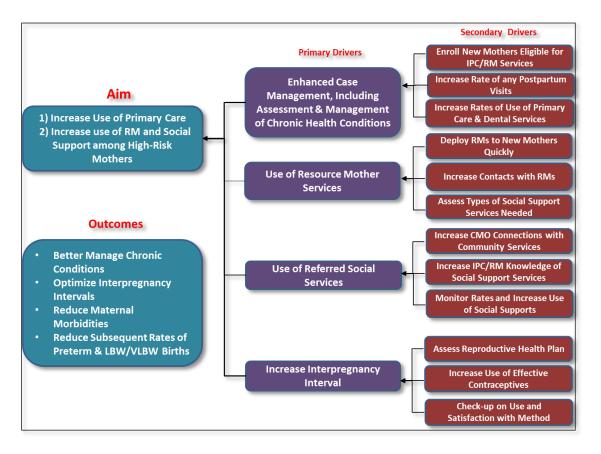
A primary driver is the increased use of preventive services (e.g. STD testing/treatment, family planning visits). Secondary drivers that affect this use is enrollment of a significant portion of eligible women of WRA into P4HB and once enrolled, assignment to one of the four Medicaid CMOs. The CMOs will provide access to a network of providers that accept Medicaid and can provide family planning 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 their use 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 therefor 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**

The overall aims 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 aim 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 outcome would be lower rates of preterm and LBW/VLBW infants among these Medicaid insured women.



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. Secondary drivers that affect the ability of the program to meet its aims 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 and 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. 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 these 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 these are increased the outcomes of lower maternal morbidities in subsequent pregnancies and lower rates of preterm and LBW/VLBW births can be achieved.

#### **B.2** Evaluation Questions and Analysis

In the table that follows we state the core evaluation questions, the hypothesized effects, and the data sources we propose to use to address the research questions in the evaluation of P4HB. We also include a brief description of the analytic approaches for each proposed question. A detailed description of the analytic approaches is included in section D: Methodology. We note that our proposed evaluation goes beyond the basic measures noted by CMS for evaluation of family planning demonstrations and in particular, 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 for comparison of Georgia to other states and the nation on key outcome measures. In each instance we include the: 1) associated evaluation question, 2) hypothesis, 3) data source, and 4) general description of analytic approach in the table below.

Evaluation Component	Evaluation Question	Evaluation Hypotheses	Measure (to be reported for each Demonstration Year)	Recommende d Data Source	Analytic Approach
	n Goal: Ensure acc ot otherwise eligible		tion of family planning and/or family plann	ning-related servio	ces for
Process	How did beneficiaries utilize covered health services?	Enrollees will utilize family planning services and/or family planning related services at desired rates.	Number and percentage of family planning only and IPC/RM enrollees who had a family planning and/or family planning related service encounter.	Enrollment and Encounter data linked to vital records); Behavioral Risk Factor Surveillance System (BRFSS)	Descriptive statistics (frequencies and percentages); Chi-square or T-test of differences across CMO, racial/ethnic and age groups. Multivariate analysis of the (BRFSS) data for Georgia and comparison states. Descriptive statistics (frequencies and percentages); Chi-square or T-test of differences across CMO, racial/ethnic and age groups.
			Number of family planning services utilized/total number of beneficiaries		
			Number of female beneficiaries who utilized any contraceptive method in each year of the demonstration /total number of female beneficiaries		
			Number of female beneficiaries who utilized 1) any family planning services or 2) any contraceptive method in each year of the demonstration/ total number of female beneficiaries; users of contraceptive methods will be categorized by WHO tier of effectiveness; use of Tier 1 (LARCs and sterilization) will be measured		
			Number and percent of female family planning only enrollees who received guideline concordant screening services (e.g. age-appropriate STI screening and treatment, cervical cancer screening, vaccinations)/total number of female beneficiaries.		
	Do beneficiarieswmaintaincoverage long-coverage long-oterm (12 months1or more)?end	Beneficiaries will maintain coverage for one or more 12-month enrollment period.	Number (and percent of total enrolled) of family planning only and IPC/RM enrollees who completed one period of 12- month enrollment/total number of beneficiaries		
			Number (and percent of total enrolled) of family planning only and IPC/RM enrollees who re-enrolled for at least their second period of coverage/total number of beneficiaries		
	How do sociodemograph ic, county and economic factors affect	Age, race/ethnicity and parity as well as employment levels and	Change in probability of disenrollment by waiver year.	Enrollment data supplemented by Area	Logistic or hazard rate models.

Evaluation Component	Evaluation Question	Evaluation Hypotheses	Measure (to be reported for each Demonstration Year)	Recommende d Data Source	Analytic Approach
	probability of disenrollment?	urban location affect the probability of disenrollment.		Resource File (ARF) and American Community Survey (ACS) data.	
			h outcomes for the target populations (Fami lanning-related services OR interpregnancy		
	Does the demonstration improve health outcomes by		Number of pregnancies that occurred with an interpregnancy interval of 18 months or longer/ total number of subsequent pregnancies among IPC/RM beneficiaries.	Enrollment and Encounter data linked to vital records).	Descriptive statistics (proportions) and significance testing (chi- squared of the proportions). Regression analysis using RSM women who delivered an infant on Medicaid and enrolled in P4HB compared to those not enrolling (controls wil include age, race/ethnicit y, months enrolled, education, parity, rural/urban location).
	increasing interpregnancy intervals?	Health outcomes among beneficiaries will improve. Health outcomes will improve among Medicaid women eligible for and participating in P4HB. Management of chronic conditions among IPC/RM only beneficiaries will improve their health.	Rate of severe maternal morbidity among all Medicaid pregnancies and among women ever participating in P4HB.		
Outcome/ Impact Does the demonstration improve health outcomes by increasing birth	Notewill improve.Does the demonstration improve health outcomes by reducing severe maternal morbidities in any subsequent pregnancies?Health outcomes will improve among Medicaid women eligible for and participating in P4HB.Does the demonstration improve health outcomes by reducing severe maternal morbidities in any subsequentMealth outcomes in and participating in P4HB.Does the demonstration improve health outcomes by increasing birth outcomes in any subsequentManagement of chronic conditions among IPC/RM only beneficiaries will improve their health.		Rate of severe maternal morbidity among subsequent pregnancies to IPC/RM only beneficiaries.		
			Receipt of medically appropriate preventive and disease management services post-partum among IPC/RM women with diagnoses of chronic conditions known to impact reproductive health and pregnancy outcomes (e.g. diabetes, hypertension, depression).		
			Rate of severe maternal morbidity among subsequent pregnancies to IPC/RM enrollees with evidence of complications of pregnancy and/or chronic health conditions known to impact women's health and/or subsequent pregnancy		
			outcomes (e.g., gestational hypertension, gestational diabetes, chronic hypertension, chronic diabetes, depression, substance use disorders), stratified according to receipt of recommended clinical screenings and follow-up management of these conditions.		
		in P4HB increases probability that future births have	Rate of healthy birth outcomes (e.g., full term, normal birth weight infants) among all Medicaid pregnancies and among women ever participating in P4HB		Comparison group for IPC/RM enrollees will be women who
		Rate of healthy birth outcomes (e.g., full term, normal birth weight infants) will increase among family planning only enrollees who participate vs. who do not participate in covered services.		delivered a VLBW infant but di not enroll in P4HB.	
			Rate of healthy birth outcomes (e.g., full term, normal birth weight infants) will		Using the long-ID in

Evaluation Component	Ensive Evaluation Evaluation Question	Evaluation Hypotheses	Measure (to be reported for each Demonstration Year)	Recommende d Data Source	Analytic Approach
			increase among subsequent pregnancies to IPC/RM enrollees who participate vs. who do not participate in covered services. Probability of a subsequent birth among women ever participating in P4HB being on Medicaid vs. private coverage.		the linked vital records/Medi caid files and logistic regression analysis of the probability it will be Private or Medicaid financed.
Demonstratio	n Goal: Reduce the	e number of unin	tended pregnancies in Georgia.		
SPECIFY DETAILS					
Outcome Impact	Did the implementation of P4HB reduce the number of unintended pregnancies among the target population?	The probability of an unintended pregnancy ending in a live birth in Georgia has remained lower than in comparison states that did not expand Medicaid.	Probability of unintended pregnancy ending in a live birth as reported on the PRAMS survey 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 Pregnancy Risk Assessment Monitoring System (PRAMS) data on unintended pregnancies.
Demonstratio	n Goal: Reduce the	1	d VLBW among Medicaid births.	I	I
Outcome Impact	Is P4HB associated with a reduction in the rates of VLBW and LBW among Medicaid live births?	Enrollees in P4HB have lower probabilities of LBW/VLBW in any birth following their enrollment in P4HB.	Number of normal birth weight/LBW/VLBW babies born to women ever enrolled in P4HB over past 18 months /total number of babies born to women ever enrolled in P4HB over past 18 months. Number of normal birth weight/LBW/VLBW babies born to Medicaid insured women in Georgia/total number of babies born to Medicaid insured women in Georgia.	Linked Medicaid claims/vital records data.	Tests for differences in the probability of VLBW or LBW birth among P4HB enrollees using versus those not using, P4HB services.
		Trends in normal/LBW/			Tests for significant

Evaluation Component	Evaluation Question	Evaluation Hypotheses	Measure (to be reported for each Demonstration Year)	Recommende d Data Source	Analytic Approach
	Are rates of normal/LBW/V LBW among Medicaid insured women in Georgia better than in other parts of the country and specifically, in the Southeast?	VLBW will compare favorably in comparison to national and regional trends.	Number of normal birth weight/LBW/VLBW babies born to Medicaid insured women in Georgia/total number of babies born to Medicaid insured women in Georgia compared to this percentage in all other states and all other states in the Southeast region.	NCHS, CDC Wonder systems on national and regional rates of VLBW and LBW among Medicaid paid births.	differences in the rates and changes in rates for Georgia Medicaid compared to national and regional trends 2019- 2028. Separate trending and testing for racial ethnic
Demonstratio	n Goal: Provide ac	ccess to IPC servi	ces for eligible women who have previously	delivered a VLB	groups. W baby
	Did women in IPC and RM only components of P4HB receive adequate RM services? Did IPC and RM only women obtain social support services?		Number and percentage of IPC and RM enrollees who utilized any non-family planning related covered services (including primary care, dental and substance use treatment covered services) in each year. Number of non-family planning related covered services utilized/total number of beneficiaries Receipt of medically appropriate preventive and disease management services postpartum among IPC/RM women with diagnoses of chronic conditions known to impact reproductive health and pregnancy outcomes (e.g. diabetes, hypertension, depression, substance use disorders). Number and percent of IPC/RM enrollees with evidence of complications of pregnancy and/or chronic health conditions known to impact women's health and/or subsequent pregnancy outcomes (e.g., gestational hypertension, gestational diabetes, chronic hypertension, chronic diabetes, depression, substance use disorders) who receive recommended	Enrollment and Encounter data linked to vital records);	Descriptive statistics (frequencies and percentages): Chi-square or T-test of differences across CMO, racial/ethnic and age groups.
			management of these conditions. Data on receipt of RM services including referrals to social support services and utilization of social support services.		

Evaluation Component	Evaluation Question	Evaluation Hypotheses	Measure (to be reported for each Demonstration Year)	Recommende d Data Source	Analytic Approach
	onstration Goal: M ved through P4HB		aware of covered services, available provid	lers and assure sa	tisfaction with
	Are beneficiaries satisfied with services?	Beneficiaries will largely be satisfied with services received.	Percentage of survey respondents reporting satisfaction with their usual source of care for primary/preventive care, receipt of primary/preventive and family planning services, contraceptives, choice of contraceptive, and out-of-pocket costs.		
	Are beneficiaries knowledgeable of covered services and how to access them?	Beneficiaries are confused about services covered and this affects satisfaction.	Percentage of survey respondents able to answer sample questions about the services they are eligible for and the providers they can use under P4HB. Percentage of survey respondents able to answer sample questions about the P4HB provider network?		Client Surveys of a representativ e comparison
			Descriptive information regarding P4HB enrollees' ideas for enhancement.		sample of women ages
	Are enrollees knowledgeable of the provider network available to them? Have ideas for enhancement?	Beneficiaries are not aware of the providers who accept P4HB and can serve them through the program.	Descriptive information regarding P4HB enrollees' satisfaction with services. Includes FP only and IPC enrollees.	Yearly CMO contracted Client Surveys following sample design developed by Evaluation Contractor.	18-44 in Medicaid/C HIP and clients in the FP only component of P4HB. Client survey of a sample of IPC/RM only
	What do beneficiaries recognize as facilitators or barriers to their accessing and utilization of covered services?	Beneficiaries identify certain facilitators to the utilization of covered services, as being able to utilize a broad range of contraception and other limitations on the scope of FP services.	Descriptive information regarding facilitators and barriers to P4HB enrollee utilization and access to covered services.		component enrollees and a comparison sample of LIM and RSM women with VLBW or LBW infants.
	Do those who did not re-enroll not value the program or	Family planning only beneficiaries disenroll	Percent of women contacted who had disenrolled from P4HB and if so,		

Evaluation	Evaluation	Evaluation	Measure (to be reported for each	Recommende	Analytic
Component	Question	Hypotheses	Demonstration Year)	d Data Source	Approach
	were there barriers to utilization or re- enrollment that were too high?	because of barriers to recertification, lack of access to providers or dissatisfaction with the program.	descriptive information about the reasons for disenrollment.		

#### C. Methodology

1. <u>Evaluation design</u>: 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. <u>Data Collection and Sources</u>: The data used in the proposed evaluation will include data collected both retrospectively and prospectively.

<u>Administrative Data</u>. The majority 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 Community 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.

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.

<u>Survey Data.</u> In the proposed evaluation, survey data will continue to be collected through a vendor chosen by the CMOs serving Medicaid and P4HB enrollees. The evaluation design assumes the CMOs will continued to contract with a survey firm to implement a survey on P4HB beneficiaries.

The survey sampling design will be led by the outside evaluator for the CMOs and the survey firm with which they contract. The survey will be broadened to include women of reproductive age (ages 18-44 to be comparable to P4HB) enrolled in non-P4HB eligibility categories within Medicaid. They will serve as a comparison group for enrollees in the family planning only component of P4HB. The evaluator will work with the survey firm to assess their methods to achieve desirable response rates from this broad group of women and to survey women who disenrolled from P4HB family planning only component. A separate effort will be made to assure that the survey firm reaches desirable response rates from IPC and RM only current and post enrollees.

To obtain some qualitative information about P4HB beneficiaries the survey should include some openended questions. For example, we want the beneficiaries to be asked about "recommendations for improvement." These types of questions have not been used in the survey prior to this so it is uncertain if the firm contracted by the CMOs will be able to incorporate such questions. We discuss this further under Methodological Limitations.

The evaluator will analyze the weighted survey data for reporting in semi-annual reports to CMS.

<u>Publicly Available Data</u>. 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) and the CDC Wonder system linked to National Center for Health Statistics (NCHS) data.

- 3. <u>Data Analysis Strategy:</u> Describe the analytic methods that will be utilized to answer the evaluation questions identified in the above table. If the design is mixed-methods (collecting both quantitative and qualitative), the state should explain how the evaluation team plans to integrate the findings from both types of assessments.
  - Quantitative Methods: For each of the process and outcome related evaluation questions, we describe the statistical and analytical methods that will be employed to assess 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?

<u>Data and Analysis</u>: 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 service receipt 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 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. The main analysis will use states that have not expanded Medicaid or changed their family planning programs significantly over the years studied as comparison states to Georgia.

# **RQ2:** Do P4HB enrollees maintain coverage for 12 months or longer? What factors affect their 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 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).

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 above as well as measures such as; 1) parity; 2) evidence of chronic conditions and 3) use of any services postpartum.

# **RQ3:** Do health outcomes (lower maternal morbidities, optimum interpregnancy intervals, better birth outcomes in future deliveries) among beneficiaries improve? Among beneficiaries actually using services?

<u>Data and Analysis</u>: The primary data source will be the administrative data on Medicaid enrollment and claims.

When analyzing the effect of the *family planning only* component, for example, we will use multivariate logistic regression to assess the difference in the probability of conceiving within 6, 12 or 18 months after enrollment for those using any family planning service compared to those you do not. We will use multivariate logistic regression to assess the difference in this probability. A generic logistic equation for this type of analysis is shown below:

$$y_{it} = \alpha + \beta^1 Part_i + \beta^2 Demographics_i + \beta^3 \tau_i + \varepsilon_{it}$$

Where  $y_{it}$  represents one of our outcome measures for the i<sup>th</sup> woman at time of outcome t (e.g. repeat pregnancy in 12, 18 months). The variable  $Part_i$  is a 0/1 indicator for participation by the i<sup>th</sup> woman in the family planning only or other component of P4HB. Since the great majority of RSM women who delivered an infant on Georgia Medicaid will be eligible for the P4HB *family planning only* component we will use those enrolling as a 'treatment' group and those not enrolling as a 'control' group ( $Part_i=0$ ). The demographics will include age, race/ethnicity, month/year of index birth, parity and characteristics (employment, percent uninsured, poverty, etc.) Separate analysis will be completed on those enrolling and using services ('treatment') versus those enrolling and not using P4HB services ('control') under the family planning only component. Since the data are linked to vital records we can test models with a fuller set of demographic and clinical determinants (education, parity, clinical risk factors) but the samples will be smaller given a linkage rate of ~90-95%. The variable  $\tau_i$  measures the number of months enrolled in Medicaid over the 12 or 18 month follow-up.

We will also use multivariate regression analysis of the probability of conceiving within 6, 12 or 18 months *IPC and RM only* components of P4HB. Since these groups 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. These women are at increased risk of repeat pregnancies at short interpregnancy intervals and subsequent poor outcomes and hence, the dependent variables will include the probability of: 1) short (< 6 months) and suboptimum (< 18 months) interpregnancy intervals; 2) severe maternal morbidities in a subsequent pregnancy (defined according to the presence of any one of 21 indicators and corresponding ICD codes <a href="https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/severe-morbidity-ICD.htm">https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/severe-morbidity-ICD.htm</a> used to identify delivery hospitalizations with SMM in the claims data); 3) adverse birth outcomes (including births that are preterm [less than 37 weeks of gestation] and/or low birth weight [less than 2500 grams]) in a subsequent delivery.

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 include: 1) age; 2) race/ethnicity; 3) parity; 4) month of index birth; 5) months enrolled in respective programs; 6) CMO and county characteristics (employment, percent uninsured, poverty, etc.). If we find a sufficient sample of women in LIM with a VLBW infant prior to P4HB we will test a Pre/Post P4HB indicator *Post* = 1 and interact this with *Part<sub>i</sub>*. This 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.

# **RQ4:** Was P4HB associated with a reduction in unintended pregnancies among Medicaid insured women at delivery?

<u>Data and Analysis</u>: 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 wasn't 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 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?

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 from CDC. We will obtain these data by appending an existing DUA for Georgia and comparison states in order to assess whether the decrease in unintended pregnancies after the implementation of P4HB continued through the more current period.

# **RQ5:** Has the rate of LBW and VLBW among Medicaid paid deliveries declined? Are these measures trending with comparable states that have not expanded Medicaid?

<u>Data and Analysis</u>: The primary data source will be the administrative data on Medicaid claims linked to vital records data as well as vital records summary data from NCHS, CDC Wonder system on national and regional rates of VLBW and LBW among Medicaid paid births.

We will use the linked claims-vital records data to calculate the rate of normal birth weight, LBW and VLBW births (restricting to liveborn singleton births) among women ever enrolled in P4HB over the previous 18 months and among Medicaid insured women in Georgia overall. We will test for differences in the probability of a VLBW or LBW birth among P4HB enrollees relative to Georgia Medicaid enrollees and among P4HB enrollees who used services compared to those who did not use services. We will evaluate differences in rates among these groups using T-tests for the overall group and for women grouped according to race/ethnicity. We will also evaluate the rates in a multivariate model that incorporates covariates that control for age, parity, and county characteristics. We will use evaluate trends in rates for the groups of interest over time and test for differences in change in rates over time from 2019 forward through 2029.

We will also employ an external control and compare the calculated rates of normal birth weight, LBW and VLBW births among Medicaid insured women in Georgia to Medicaid insured women in states in the Southeast region that have not (NC, SC, TN, AL, MS) and have expanded Medicaid (AR, LA).

# **RQ6:** 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.

<u>Total</u> 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.

# **RQ7:** Are beneficiaries sufficiently aware of services covered and available providers? Does this result in high levels of satisfaction with the P4HB program?

Data and Analysis: This analysis will be based on weighted survey data from a CMO contracted survey firm.

The survey firm will work with the outside evaluator to obtain a sufficient response rate of P4HB beneficiaries in the family planning only component and a comparison sample of women ages 18-44 in Medicaid/CHIP. An additional sample of IPC/RM only enrollees and a comparison sample of LIM and RSM women with VLBW or LBW infants who never participated in P4HB will be surveyed.

The outside evaluator will conduct descriptive and where possible, multivariate analysis of the weighted data.

• Qualitative Methods:

The evaluation design does not include the collection or analysis of qualitative data beyond the potential addition of open-ended questions to the survey the CMOs will implement.

#### **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 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 files and for analysis of unintended pregnancies using the PRAMS data. The majority 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 the post-period data and we control for characteristics of the treatment (here, those eligible and enrolling) and control/comparison groups. Yet, there are likely unobserved characteristics of these two groups that relate to the decision to enroll and/or participate by using services that could bias the results. Finally, we propose to use several publicly available data sources (e.g. BRFSS, PRAMS, NCHS and CDC Wonder systems) in parts of the analysis. 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 population. For example, the BRFSS provides data on the rate of screening among women of reproductive age in Georgia and comparison states but only allows for the analysis of insured and uninsured study groups; Medicaid insured cannot be identified. To address this limitation, we propose to use uninsured women ages 18-44 as the study population since women in P4HB remain uninsured.

#### 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. While this evaluation design includes suggestions for the survey that could illicit some contextual information, the outside evaluator is not contracting with the survey firm and hence, will be able only to influence the sample design, desired response rates and importantly, cannot assure the inclusion of open-ended questions.

#### **D. Simplified Evaluation Budget**

We present below a simplified budget for one annual period during the renewal period. The line items

included are for the computer programming all databases as described above, analysis of the data for the various reports required in the renewal period and preparation of the series of reports required under the new STCs. A small amount is also included to cover time spent in meetings and phone calls with DCH. We show the hours, hourly rate and total budget amounts for one annual period.

1. COMPUTER PROGRAMMING					
Hours	Hourly Rate	Total			
509.61	\$76.18	\$38,822			
2. ANALYSIS OF THE DATA					
Hours	Hourly Rate	Total			
904.78	\$114.09	\$103,226.00			
<b>3. PREPARATION OF THE RI</b>	EPORTS				
Hours	Hourly Rate	Total			
1268.77	\$98.43	\$124,885.00			
4. OTHER TASKS (Meetings, p	hone calls, etc.)				
Hours	Hourly Rate	Total			
20.80	\$44.52	\$926.00			
TOTAL	\$267,859.00				
	\$24,831.00				
TOTAL BUDGET \$292,690.00					

**E.** 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.

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