

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-26-12
Baltimore, Maryland 21244-1850



AUG 29 2019

Lynette Rhodes
Executive Director
Medical Assistance Plans
State of Georgia, Department of Community Health
2 Peachtree Street, NW, Suite 36450
Atlanta, GA 30303

Dear Ms. Rhodes:

Under Section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not “stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients.” S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.A.N. 1943, 1961. Section 1115 of the Act allows the Secretary to waive compliance with the Medicaid program requirements of section 1902 of the Act, to the extent and for the period he finds necessary to carry out such demonstration project. In addition, section 1115 of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Georgia’s request for an extension of its section 1115 family planning demonstration, entitled “Planning for Healthy Babies” (P4HB), Project Number 11-W-00249/4. Approval of this extension is granted under the authority of section 1115(a) of the Social Security Act and is based on the determination that the expenditure authority granted therein is likely to assist with promoting the objectives of title XIX of the Act by improving access to high-quality, person-centered family planning services that produce positive health outcomes for individuals. The demonstration also promotes positive health outcomes by providing a targeted benefit package to otherwise uninsured women that have delivered very low birth weight babies (VLBW), called Interpregnancy Care (IPC), that includes physical and behavioral health services, case management and outreach services. This approval is effective as of the date of this letter through December 31, 2029.

Our approval of this demonstration extension is subject to the enclosed Special Terms and Conditions (STCs) and the limitations specified in the list of expenditure authorities and title XIX

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only to the extent those requirements have been specifically listed as granted expenditure authority or title XIX requirements not applicable. All requirements of the Medicaid program as expressed in law, regulation, and policy statement not expressly identified as not applicable in this letter, shall apply to this demonstration.

CMS approval of this demonstration is also conditioned on continued compliance with the enclosed set of STCs that define the nature, character, and extent of anticipated Federal involvement in the project. The award is subject to your written acknowledgement of the award and acceptance of the STCs within 30 days of the date of this letter.

Extent and Scope of the Demonstration

Georgia's section 1115 family planning demonstration, entitled "Planning for Healthy Babies (P4HB)," has been operating since January 1, 2011. The demonstration has three components. The first component is the family planning program, which extends eligibility for family planning and family planning related services to uninsured women ages 18 through 44, with income up to and including 211 percent of the Federal Poverty Level (FPL) who are not otherwise eligible for Medicaid or the Children's Health Insurance Program (CHIP), women who are losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum period or losing other Medicaid or CHIP coverage.

The second component, entitled IPC, offers a limited benefit package to uninsured women ages 18 through 44, within three years of delivery of a VLBW baby (less than 1,500 grams or 3 pounds, 5 ounces), who have income up to and including 211 percent of the FPL, and who are not otherwise eligible for Medicaid or CHIP.

The third component under the demonstration is the provision of Resource Mother (RM) Outreach services to women ages 18 through 44, within three years of delivery of a VLBW baby, who are eligible for Medicaid under the Georgia Medicaid State plan, and who have income at or below 211 percent of the FPL.

Beneficiaries eligible for the P4HB demonstration receive services in a managed care delivery system operated by Care Management Organizations (CMOs).

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations.

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries' financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may "result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing." Act § 1115(d)(1). But in the long term, they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

Section 1115 demonstration projects also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better "enabling each [s]tate, as far as practicable under the conditions in such [s]tate" to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility may decrease the number of individuals who need financial assistance, including medical assistance, from the state. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.¹ By the same token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their Medicaid programs

¹ States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state's program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population (ACA expansion population) that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of the ACA expansion population became optional as a result of the Supreme Court's decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they "have flexibility to start or stop the expansion." CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure authority under section 1115(a)(2) of the Act. For example, recently, many states have been relying on this authority to expand the scope of services they offer to address SUD beyond what the statute explicitly authorizes.

and to provide more medical services to more Medicaid beneficiaries. Accordingly, such demonstration projects advance the objectives of the Medicaid program.

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstration is likely to assist with promoting the objectives of Medicaid. This extension of the P4HB demonstration improves access to family planning services and family planning-related services for beneficiaries who otherwise would not have access to these services. This demonstration extension further improves access to a limited benefits package to mothers of VLBW babies for beneficiaries who would otherwise not have access to these services to improve health outcomes, reduce the number of low birth weight (LBW) and VLBW births in the state, and promotes Georgia Medicaid's sustainability for beneficiaries over the long term by reducing costs associated with unintended pregnancies and VLBW births. Finally, the demonstration also includes the provision of additional RM outreach services to mothers who are eligible for Medicaid as a parent or caretaker relative or in an ABD group who deliver a VLBW baby, aiming to improve health outcomes for these mothers as well.

Evaluation data to date shows that VLBW rates improved in Georgia relative to comparison states, but the rate of low birth weight births (inclusive of VLBW) did not. The state's evaluation data also demonstrates that once women are enrolled either in the family planning or IPC component of the demonstration, they are less likely to have unintended pregnancies and deliveries than comparison groups of other Georgia Medicaid beneficiaries followed over the same time period. As a part of this demonstration, CMS has updated the monitoring and evaluation sections of the STCs to align the P4HB demonstration with CMS's current policy around monitoring and evaluation of section 1115 demonstrations that will better aid the state in measuring and tracking the demonstration's impact on mothers who deliver VLBW babies. A new evaluation design is required post-approval, and must be approved by CMS.

Therefore, the Secretary has determined that the Georgia P4HB section 1115 demonstration is likely to assist in promoting the objectives of the Medicaid program.

Consideration of Public Comments

Consistent with federal transparency requirements, CMS considers all public comments received during both the state and federal public comment periods when evaluating whether the demonstration project as a whole will likely assist in promoting the objectives of Medicaid. CMS and Georgia received a number of public comments about the demonstration during the respective public comment periods, which were supportive of the extension request for the demonstration.

The state received three written comments in the state public comment period. All commenters expressed support and appreciation for the state's creation, implementation, and ongoing

improvement of the demonstration project, including recent steady and substantial increases in enrollment and utilization of services, and positive evaluation results regarding pregnancy prevention and birth spacing to date. Two commenters recommended that the state expand IPC eligibility to include women who have also had a low birth weight (LBW) baby (under 2500 grams, or 5.5 lbs), in addition to women who have delivered a VLBW baby, and all commenters asked whether Georgia had considered expanding the IPC component of the demonstration to provide expanded IPC benefits to all demonstration enrollees, including those currently in the family planning only component of the demonstration. All three commenters also asked the state to consider increasing access to treatment for SUD and/or mental illness by expanding the service package that is currently offered to IPC enrollees, and by offering SUD treatment services to all demonstration enrollees. One commenter noted that women of color are disproportionately affected by mental health issues and post-partum depression, and requested that the state increase access to mental health services in the IPC benefit package in order to respond to this disparity. Finally, one commenter asked the state to consider offering medical transportation services to all enrollees, including enrollees in the family planning only component.

In response to all comments regarding the expansion of eligibility, benefits, and services, Georgia responded that the state acknowledges that a holistic or comprehensive benefits approach may be most optimal for enrollee's and the state's desired outcomes, but budget pressures preclude Georgia from expanding benefits or eligibility at this time. One commenter requested that Georgia survey providers, both accepting and not accepting P4HB, to identify potential barriers to reimbursement and network participation. The commenter further recommended that if this work is already occurring, to include results in the quarterly and annual reports. Finally, the commenter asked if there is an assigned workgroup that works to implement solutions to barriers identified in the surveys or provider feedback, and if there is not, if the state would be open to beginning that work. Georgia responded that at this time, bi-annual surveys are conducted for providers that are in the managed care network, and results of the surveys are included in quarterly reports sent by the state's CMOs to the state. Then, CMOs are able to capture survey information and make changes to their P4HB implementation plan. Because Georgia contracts administration and care management of P4HB members to the CMOs, the state does not have a mechanism to capture feedback on the program from out of network providers. The commenter also asked if Georgia will prioritize education on long-acting reversible contraceptives (LARC) for P4HB enrollees and providers. The state responded that CMOs prioritize provider and beneficiary education on LARCs according to their medical directors and feedback from provider and member surveys. Finally, the commenter noted that as the new enrollment platform for P4HB is integrated into the state's IES, individuals are only able to enroll online between 8 AM and 4 PM, and requested that Georgia extend these enrollment hours, and that federally qualified health centers (FQHCs) have access to the state's Medical Assistance Partner Portal. Georgia responded that while these two enrollment-related issues are outside the scope of this demonstration application, the state will work to consider this request.

The federal public comment period began January 8, 2019 and ended February 27, 2019. CMS received five comments on this demonstration extension during the federal public comment period. The first commenter recommended presumptive eligibility be implemented as a strategy to increase the number of women enrolled in the program. Presumptive eligibility is at state

option and is not offered by Georgia under the State Plan. We also note that Georgia has made several enhancements and upgrades to its eligibility systems and processes in recent years, including the implementation of a new Integrated Eligibility System (IES), which has already resulted in increased enrollment in the demonstration.

Another commenter expressed concern that the demonstration's focus on infant outcomes and the eligibility requirements for this demonstration do not adequately address health concerns for women in Georgia; specifically, for other vulnerable low-income women experiencing adverse birth outcomes, including women who have experienced a severe maternal morbidity. The commenter recommends that eligibility for IPC services be broadened, maternal health outcome metrics be added to the demonstration in order to more closely monitor the impact of the demonstration on mothers' health, identify a plan to improve enrollment, retention, and utilization of services, particularly IPC services, and to implement the demonstration for a period of five years, rather than ten years, to allow for greater monitoring and evaluation of the demonstration. Georgia has requested the extension of this demonstration without programmatic changes in order to continue to focus the state's limited resources on the goals identified as a part of this extension of the demonstration. As we described above, CMS has updated the monitoring and evaluation sections of the STCs to align the P4HB demonstration with CMS's current policy around monitoring and evaluation of section 1115 demonstrations that will better aid the state in measuring and tracking the demonstration's impact on mothers who deliver VLBW babies. A new evaluation design is required post-approval, and must be approved by CMS. The demonstration as a whole must be evaluated, including the IPC component of the demonstration. A ten year approval of this demonstration will allow the state and CMS more time to track and evaluate health outcomes for women enrolled in the IPC and RM components of the demonstration, and to isolate the demonstration's effects on its identified goals.

The commenter also raised that enrollment and utilization of services under the demonstration has been lower than anticipated by the state. We note again that Georgia has made several enhancements and upgrades to its eligibility systems and processes in recent years, which has already resulted in increased enrollment in the demonstration. We acknowledge that the state experienced significant fluctuations in demonstration enrollment between 2011 and 2016. The demonstration's evaluation attributes this to ending P4HB's "auto-enrollment" process, in which women who were losing coverage at the end of the sixty day post-partum coverage period were automatically enrolled in the demonstration. The state decided to end this process in 2014 because the state's evaluation data showed that beneficiaries who were auto-enrolled in the demonstration after losing pregnancy-related coverage were unaware of their benefits, and as a result, utilization of services was very low, including utilization of birth control. Currently, a woman losing pregnancy-related coverage at the conclusion of the sixty day post-partum period must apply for the demonstration. The state sends pregnant beneficiaries a letter in the eight month of pregnancy that explains P4HB and invites the beneficiary to apply. Georgia has made several enhancements and upgrades to its eligibility systems and processes in recent years, including the implementation of a new Integrated Eligibility System (IES) in 2017. When individuals apply for coverage through the new IES, all applicants are screened for P4HB and any other coverage program available in the state during the eligibility determination process. As a result, family planning enrollment has tripled between 2017 and 2018. The state has seen a similar result in enrollment in the IPC component of the demonstration, with a 23 percent

projected increase between 2017 and 2018. The state's budget neutrality projections for this amendment show a projected continued growth in enrollment under the demonstration. The state also plans to increase awareness and engagement with targeted outreach to eligible women and communities.

Other commenters expressed general support for the demonstration and its goals in support of the state's extension application. We appreciate those comments and the support for the P4HB demonstration.

Your project officer for this demonstration is Wanda Boone-Massey. She is available to answer any questions concerning your section 1115 demonstration and this extension. Ms. Boone-Massey's contact information is:

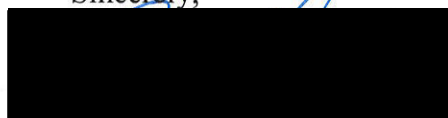
Ms. Wanda Boone-Massey
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: wanda.boone-massey@cms.hhs.gov

Official communications regarding this demonstration should be sent simultaneously to Ms. Boone-Massey and to Trina Roberts, Deputy Director, Division of Field Operations South. Her contact information is as follows:

Trina Roberts, MSN, RN
Deputy Director
Division of Medicaid Field Operations South
Center for Medicaid and CHIP Services
61 Forsyth St., S.W., Suite 4T20
Atlanta, GA 30303-8909
Email: Shantrina.Roberts@cms.hhs.gov

If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, at (410) 786-9686.

Sincerely,



Calder Lynch
Acting Director

cc: Trina Roberts, Deputy Director, Division of Field Operations South

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

NUMBER: 11-W-00249/4

TITLE: Georgia Planning for Healthy Babies (P4HB)

AWARDEE: Georgia Department of Community Health

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

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

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

- 1. Demonstration Population 1:** Expenditures for extending family planning and family planning-related services provided to uninsured women who are otherwise ineligible for Medicaid or the Children’s Health Insurance Program (CHIP), ages 18 through 44, who have family income at or below 200 percent of the federal poverty level (FPL), including women who are losing Medicaid pregnancy coverage at the conclusion of the 60 day postpartum coverage period.
- 2. Demonstration Population 2:** Expenditures for extending family planning, family planning-related, and interpregnancy care (IPC) services to women, ages 18 through 44, within three years of delivery of a very low birth weight (VLBW) baby (less than 1,500 grams or 3 pounds, 5 ounces), with income at or below 200 percent of the FPL, and who are not otherwise eligible for Medicaid or CHIP. Beneficiaries will be eligible for IPC services for two (2) calendar years after the date of enrollment. Additional deliveries of subsequent VLBW babies will grant an additional two-year enrollment period to otherwise eligible beneficiaries.

Demonstration Services 1: Expenditures for extending Resource Mother Outreach services to women, ages 18 through 44, within three years of delivery of a VLBW baby, with income at or below 200 percent of the FPL, who are eligible for Medicaid under the Georgia Medicaid state plan. The Resource Mother Outreach services include but are not limited to, phone or in person

visits to increase the adoption of healthy behaviors, including healthy eating choices and smoking cessation, follow-up visits to make sure the baby receives regular “well-baby” check-ups and immunizations, and referrals to community resources.

Requirements Not Applicable to the Demonstration Expenditures:

1. Methods of Administration: Transportation

Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53

To the extent necessary, to enable the State to not assure transportation to and from providers for Demonstration Population 1.

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

Section

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

3. Amount, Duration, and Scope of Services

Section 1902(a)(10)(B)

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

4. Freedom of Choice

Section 1902(a)(23)

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

5. Retroactive Eligibility

Section 1902(a)(34)

To the extent necessary to enable the State to not provide medical assistance to Demonstration Populations 1 and 2 for any time prior to when an application for the Demonstration is made.

6. Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Section 1902(a)(43)(A)

To the extent necessary to enable the State to not furnish or arrange for all EPSDT services to Demonstration Populations 1 and 2.

CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00249/4

TITLE: Planning for Healthy Babies (P4HB)

AWARDEE: Georgia Department of Community Health

I. PREFACE

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

The STCs have been arranged into the following subject areas:

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

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Evaluation Report
Attachment C: Evaluation Design (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Georgia section 1115(a) family planning demonstration, P4HB, has been operating since January 1, 2011. The demonstration has three components. The first component is the family planning program, which extends eligibility for family planning (FP) and family planning-related services to uninsured women, ages 18 through 44, who have income at or below 200 percent of the FPL, and who are not otherwise eligible for Medicaid or the CHIP, including

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

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

The third component of the demonstration is the provision of Resource Mother Outreach services, as defined at V.28, to women ages 18 through 44, who have income at or below 200 percent of the FPL, who deliver a VLBW baby and who are eligible in the parent or caretaker relative eligibility group or an aged, blind, or disabled eligibility group under the Georgia Medicaid state plan.

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

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

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Laws.** The state must comply with all applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), and the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (ACA).
- 2. Compliance with Medicaid and CHIP Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3. Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the changed provisions being changed is are explicitly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the

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

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

- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in Federal financial participation (FFP) for expenditures made under this demonstration, the states must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality agreement worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the STC changes must take effect on the day such states legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

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

6. Changes Subject to the Amendment Process. Changes related to eligibility, enrollment, benefits, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The states must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a Demonstration amendment based on non-compliance with these STCs, including, but not limited to, failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified therein. Amendment

requests must include, but are not limited to, the following:

- a. An explanation of the public process used by the state consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
- b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
- c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality expenditure limit. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment which isolates (by Eligibility Group) the impact of the amendment;
- d. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and

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

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

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

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

phase-out plan.

- b. Transition and Phase-Out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase Out Plan Approval: The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures: The state must comply with applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, and 431.213. In addition, the state must assure all applicable and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including §§ 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in the October 1, 2010 State Health Official letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- e. Exemption from Public Notice Procedures, 42 CFR 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs

associated with the termination or expiration of the demonstration, including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

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

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

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

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

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

Agency is responsible for the content and oversight of the quality strategies for the demonstration.

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

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

IV. ELIGIBILITY AND ENROLLMENT

17. Eligibility Requirements.

- a. The state must enroll only individuals meeting the following eligibility criteria into the family planning component of the demonstration:
 - Uninsured women, ages 18 through 44, who have family income up to and including 211 percent of the FPL, who are not otherwise eligible for Medicaid or CHIP, including women losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum.
- b. The State must enroll only individuals meeting the following eligibility criteria into the IPC component of the Demonstration:
 - Uninsured women ages 18 through 44, within three years of delivery of a VLBW baby, who have income up to and including 211 percent of the FPL, who are not otherwise eligible for Medicaid or CHIP.
- c. The state will enroll individuals into the Resource Mothers Outreach component of the demonstration who are:
 - Women, ages 18 through 44, who have income at or below 211 percent of the FPL, within three years of delivery of a VLBW baby, and who qualify under Medicaid State plan.

18. Demonstration Enrollment. Pregnant and post-partum women already enrolled in a Georgia Families Care Management Organization (CMO) will have an expedited enrollment into the plan with which they are currently affiliated. These women will be afforded the opportunity to choose a new CMO if desired. The enrollment processes for each component of the Demonstration are described below:

- a. **FP Component.** The state will follow applicable Federal law and regulations for determining eligibility and enrolling those determined eligible into one of the CMOs. Individuals must enroll in a managed care plan to receive family planning and family planning-related services.
- b. **IPC Component.** Women in the IPC component must enroll in a managed care plan to receive Family Planning and IPC services.
- c. **Resource Mothers Outreach.**
 - i. Women ages 18 through 44 who are eligible under the Medicaid state plan and who are eligible for Resource Mothers Outreach services are auto-assigned or passively enrolled into a CMO. The member will have the opportunity to participate in a choice change period immediately after being auto-assigned.
 - ii. Women ages 18 through 44, within three years of delivery of a VLBW baby and who are eligible under the Medicaid State Plan, will receive Resource Mothers Outreach via a CMO. Eligible women will be allowed to choose a CMO through which they will receive only Resource Mothers Outreach services.

19. Demonstration Disenrollment.

- a. If a woman becomes pregnant while enrolled in the demonstration, she may be determined eligible for Medicaid in the pregnant woman eligibility group in accordance with 42 CFR 435.916.
- b. Women who choose to receive a sterilization procedure and complete all necessary follow-up procedures will be disenrolled from the demonstration.
- c. Women receiving IPC services will be disenrolled from the IPC component of the demonstration and enrolled into the family planning-only component of the demonstration after 2 years of participation. Additional deliveries of subsequent VLBW babies will grant an additional two-year enrollment period in the IPC component of the demonstration to otherwise eligible beneficiaries.
- d. Before disenrollment of any beneficiary eligible under the demonstration is effectuated, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 C.F.R. 435.916(f)(1).

- 20. Redeterminations.** The states must ensure that redeterminations of eligibility for the demonstration are conducted no more frequently than every 12 months in accordance with 42 CFR 435.916(a).
- 21. Primary Care Referral.** The states assure that providers of family planning services will make appropriate referrals to primary care providers, including providers practicing in Federally Qualified Health Centers (FQHCs and Rural Health Centers (RHCs)), as medically indicated. The state also assures that individuals enrolled in this demonstration receive written materials and information about how to access primary care services. The written materials must explain to the participants how they can access primary care services.

V. BENEFITS AND DELIVERY SYSTEMS

- 22. Benefits.** Family planning services and supplies described in section 1905(a)(4)(C) of the Act are reimbursable at the 90 percent matching rate, including:
- a. FDA-approved methods of contraception;
 - b. Sexually transmitted infection (STI)/sexually transmitted disease (STD) testing, Pap smears and pelvic exams. The laboratory tests done during an initial family planning visit for contraception include a Pap smear, screening tests for STIs/STDs, blood count, and a pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program, or provider. Additional laboratory tests may be needed to address a family planning problem or need during an inter-periodic family planning visit for contraception;
 - c. Drugs, supplies, or devices related to women's health services described above that are prescribed by a health care provider who meets the state's provider enrollment requirements, (subject to the national drug rebate program requirements); and,
 - d. Contraceptive management, patient education, and counseling.
- 23. Family Planning-Related Benefits.** Family planning-related services and supplies are defined as those services provided as part of, or as follow-up to, a family planning visit and are reimbursable at the State's regular FMAP rate. Such services are provided because a "family planning-related" problem was identified and/or diagnosed during a routine or periodic family planning visit. The following are examples of family-planning related services:
- a. Colposcopy (and procedures done with/during a colposcopy) or repeat Pap smear performed as a follow-up to an abnormal Pap smear which is done as part of a routine/periodic family planning visit.
 - b. Drugs for the treatment of STIs, except for HIV/AIDS and hepatitis, follow-up visit/encounter for the treatment/drugs and subsequent follow-up visits to rescreen for STIs based on the Centers for Disease Control and Prevention (CDC) guidelines may be covered.

- c. Drugs for vaginal infections/disorders, other lower genital tract and genital skin infections/disorders, and urinary tract infections, where these conditions are identified/diagnosed during a routine/periodic family planning visit. A follow-up visit/encounter for the treatment/ drugs may be covered.
- d. Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services in a family planning setting. An example of a preventive service could be a vaccination to prevent cervical cancer.
- e. Treatment of major complications arising from a family planning procedure such as:
 - i. Treatment of a perforated uterus due to an intrauterine device insertion;
 - ii. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
 - iii. Treatment of surgical or anesthesia-related complications during a sterilization procedure.

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

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

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

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

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

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

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

a. Qualifications and Technical Competencies

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

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

The Resource Mother must meet the Technical Competencies:

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

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

b. Training

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

c. Supervision

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

d. Outreach Case Management Services

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

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

Assist with linking beneficiaries to community resources such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

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

VI. GENERAL REPORTING REQUIREMENTS

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

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state’s anticipated date of submission. Should CMS agree to the state’s request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state’s written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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

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

- a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.

VII. MONITORING

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

- a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be

attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; updates on the state's financing plan and maintenance of effort described in STC 18.b; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

- b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The requiring monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. No later than 6 months after the end of each DY, or as soon thereafter as data are available, the state will calculate and report to CMS annual expenditure targets for the IPC component of the demonstration for the completed year. Administrative costs should be reported separately.
- d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

34. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11.

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

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

- b. The state will present to and participate in a discussion with CMS on the close-out report.
- c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
- d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the close-out report may subject the state to the penalties described in STC 30.

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

- a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
- c. The State and CMS will jointly develop the agenda for the calls.

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

VIII. EVALUATION OF THE DEMONSTRATION

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

maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 30

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

40. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs.

The state must submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than 180 days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

- a. All applicable Evaluation Design guidance. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes of participants in the demonstration; the demonstration's progress on achieving its intended outcomes; and the financial impact of the demonstration.
- b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a draft Evaluation Design.

41. Evaluation Budget. A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations, such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be

excessive.

42. Evaluation Design Approval and Updates. The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Designs, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation process in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

43. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypotheses. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS' Core Set of Health Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by the National Quality Forum (NQF).

44. Interim Evaluation Reports. The State must submit an Interim Evaluation Report for the approved evaluation design for the completed years of the demonstration specified in subparagraph c, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Reports should be posted to the state's website with the application for public comment.

- a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.
- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
- c. The state must provide a draft Interim Evaluation Report for the corresponding years, no longer than one (1) year after completion of the measurement period, as follows. The state must submit a final Interim Evaluation Report for each measurement period sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the documents to the state's website.

- i. An Interim Evaluation Report for demonstration years 10-12 (calendar years 2019-2021) will be due no later than December 31, 2022.
 - ii. An Interim Evaluation Report for demonstration years 13-15 (calendar years 2022-2024) will be due no later than December 31, 2025.
 - iii. An Interim Evaluation Report for demonstration years 16-18 (calendar years 2025-2027) will be due no later than December 31, 2028.
- d. If the state is seeking to renew or extend the demonstration, the last draft Interim Evaluation Report, representing demonstration years 16-18 (calendar years 2025-2027) is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for the demonstration, as noted at subsection c.iii, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- e. All Interim Evaluation Reports must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

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

- f. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
- g. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

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

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

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

49. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any third party directly connected to the demonstration. Prior to release of these reports, articles, or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

IX. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

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

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

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

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

- h. Administrative costs, including those associated with the administration of the demonstration;
- i. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- j. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

53. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-Federal share of funding are subject to CMS approval.

- a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
- b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

54. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration demonstration demonstration demonstration demonstration demonstration expenditures are met:

- a. Units of government, including governmentally operated health care providers, may certify that states or local tax dollars have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for the state share of title XIX payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed

explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally-operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes,, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

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

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

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

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

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (Form CMS-64.9P WAIVER) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any other cost settlements not attributable to this demonstration, the adjustments

should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. Pharmacy Rebates. Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the Forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Semi-Annual and Annual Monitoring Reports described in section VII, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting Table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a

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

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

Table 2: MEG Detail for Expenditure and Member Month Reporting							
MEG (Waiver Name)	Detailed Description	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Family Planning	Family planning and family planning-related services (Expenditure Authority 1)	FP Benefits	Date of service	MAP	Y	1/1/11	12/31/29
IPC Services	See expenditure authority 2	IPC Benefits	Date of service	MAP	Y	1/1/11	12/31/29
Resource Mother Services	See expenditure authority 3	Outreach	Date of service	MAP	Y	1/1/11	12/31/29

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

- a. For procedures or services clearly provided or performed for the primary purpose of family planning (i.e., contraceptive initiation, periodic or inter-periodic contraceptive management, and sterilizations), and which are provided in a family planning setting, FFP will be available at the 90 percent federal matching rate.

Reimbursable procedure codes for office visits, laboratory tests, and certain other procedures must carry a primary diagnosis or a modifier that specifically identifies them as a family planning service. Note: The laboratory tests performed during an initial family planning visit for contraception include a Pap smear, screening tests for STIs, blood counts, and pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program, or provider. Additional laboratory tests may be needed to address a family planning problem or needed during an inter-periodic family planning visit for contraception.

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

- b. In order for family planning-related services to be reimbursed at the FMAP rate they must be defined as those services generally performed as part of, or as follow-up to, a family planning service for contraception. Such services are provided because a “family planning-related” problem was identified/diagnosed during a routine/periodic family planning visit. These expenditures should be entered in Column (B) on the appropriate waiver sheets. Four kinds of family planning related services are recognized:
 - i. A colposcopy (and procedures done with/during a colposcopy) or repeat Pap smear performed as a follow-up to an abnormal Pap smear which is done as part of a routine/periodic family planning visit.
 - ii. Treatment/drugs for STIs, except for HIV/AIDS and hepatitis, where the STIs are identified/diagnosed during a routine/periodic family planning visit. A follow-up visit/encounter for the treatment/drugs may be covered at the applicable Federal matching rate for the State. Subsequent follow-up visits to rescreen for STIs based on the Centers for Disease Control and Prevention guidelines may be covered at the applicable Federal matching rate for the State.
 - iii. Treatment/drugs for vaginal infections/disorders, other lower genital tract and genital skin infections/disorders, and urinary tract infections, where these conditions are identified/diagnosed during a routine/periodic family planning visit. A follow-up visit/encounter for the treatment/drugs may be covered at the applicable Federal matching rate for the State.
 - iv. Treatment of major complications such as:
 - 1. Treatment of a perforated uterus due to an intrauterine device insertion;

2. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
 3. Treatment of surgical or anesthesia-related complications during a sterilization procedure.
- c. FFP will not be available for the costs of any services, items, or procedures that do not meet the requirements specified above, even if family planning clinics or providers provide them. For example, in the instance of testing for STIs as part of a family planning visit, FFP will be available at the 90 percent Federal matching rate. The match rate for the subsequent treatment would be paid at the applicable Federal matching rate for the State. For testing or treatment not associated with a family planning visit, no FFP will be available.
- d. CMS will provide FFP at the appropriate 50 percent administrative match rate for general administration costs, such as, but not limited to, claims processing, eligibility assistance and determinations, outreach, program development, evaluation, and program monitoring and reporting.

59. Extent of FFP for IPC Services. CMS shall provide FFP for services described in STC 26 for women enrolled in the IPC component of the Demonstration at the state's regular federal matching rate.

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

Table 3: Demonstration Years		
DY 9	January 1, 2019 to December 31, 2019	12 months
DY 1	January 1, 2020 to December 31, 2020	12 months
DY 2	January 1, 2021 to December 31, 2021	12 months
DY 3	January 1, 2022 to December 31, 2022	12 months
DY 4	January 1, 2023 to December 31, 2023	12 months
DY 5	January 1, 2024 to December 31, 2024	12 months
DY 6	January 1, 2025 to December 31, 2025	12 months
DY 7	January 1, 2026 to December 31, 2026	12 months
DY 8	January 1, 2027 to December 31, 2027	12 months

DY 9	January 1, 2028 to December 31, 2028	12 months
DY 10	January 1, 2029 to December 31, 2029	

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

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

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

- k. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- l. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified

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

budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

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

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

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

- n. Georgia shall be at risk for the per capita cost (as determined by the method described below in this section) for Medicaid eligible in the "Family Planning" eligibility group, but not for the number of demonstration eligibles in this group.
- o. Georgia shall be at risk for both per capita costs and enrollment for the IPC Services group.

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

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

- p. The aggregate financial cap for the IPC component is determined by applying state historical enrollment and cost trend rates to obtain annual budget limits for demonstration years ten (10) through twenty (20). The budget neutrality limit is determined using a births averted model, under which demonstration expenditures for the IPC MEG are not to exceed the total cost of pregnant women and infants under one (1) year of age absent the births averted by the demonstration, summed.
- q. The budget neutrality limit for the IPC component will be for the total computable cost of \$28,087,172,280, for the life of the demonstration, which is the sum of the ten (10) annual components shown in Tables 4 and 5 below. If the state chooses to operate the demonstration for fewer than ten (10) years, then the budget neutrality limit will be reduced on a pro rata basis to reflect the shortened approval period, and budget neutrality will be assessed based on the shortened period.

<u>Table 4: Main Budget Neutrality Test, IPC Services, DYs 9--13</u>

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

MEG Used to Calculate the Limit	PC or Agg ⁵	WOW Only, WW Only, or Both	Enrollment Trend Rate	Cost Trend Rate	DY 5 CY 2024	DY 6/ CY 2025	DY 7/ CY 2026	DY 8/ CY 2027	DY 9/ CY 2028	DY 10/ CY 2029
Pregnant Women	Agg Annual Limit	Both	8.70%	0.0%	\$1,337,376,883	\$1,453,728,672	\$1,580,203,066	\$1,717,680,733	\$1,867,118,957	\$1,867,118,957.05

³ PC = Per Capita, Agg = Aggregate

⁴ The aggregate budget neutrality model outlined in these STCs is effective as of the date of approval of the demonstration's extension, June 25, 2019.

⁵ PC = Per Capita, Agg = Aggregate

Infants 0-1	Agg Annual Limit	Both	2.0%	1.60%	\$1,173, 064,589	\$1,215, 670,295	\$1,259,8 23,440	\$1,305, 580,227	\$1,352,9 98,901	\$1,352 ,998,9 00.99
Total	Agg Annual Limit	Both	N/A	N/A	\$2,510, 441,472	\$2,669, 398,967	\$2,840,0 26,506	\$3,023, 260,960	\$3,220,1 17,858	\$3,220 ,117,8 58

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

69. Hypothetical Budget Neutrality: Family Planning and Resource Mothers

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

Table 6: Hypothetical Budget Neutrality Tests 1 and 2, DYs 10-14									
MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 9/CY 2019	DY 1/CY 2020	DY 2/CY 2021	DY 3/CY 2022	DY 4/CY 2023
Family Planning	PC	Both	2018	2.7%	\$31.80	\$32.66	\$33.54	\$34.45	\$35.38

Resource Mothers	PC	Both	2018	4.6%	\$206.42	\$215.92	\$225.85	\$236.24	\$247.11
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Table 7: Hypothetical Budget Neutrality Test, DYs 15-20

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR <i>[define]</i>	TREND	DY 5CY 2024	DY 6/CY 2025	DY 7/CY 2026	DY 8/CY 2027	DY 9/CY 2028	DY 19/CY 2029
Family Planning	PC	Both	2018	2.7%	\$36.34	\$37.32	\$38.33	\$39.36	\$40.42	\$41.51
Resource Mothers	PC	Both	2018	4.6%	\$258.48	\$270.37	\$282.81	\$295.82	\$309.43	\$323.66

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

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

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

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

Main Budget Neutrality Test

Table 9: Main Budget Neutrality Test Mid-Course Correction Calculations for IPC & RM Components		
	Cumulative Target Definition	Percentage
DY 9	Cumulative budget neutrality limit plus:	2.0 percent
DY 9 through DY 1	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.0 percent
DY 2 through DY 3	Cumulative budget neutrality limit plus:	0.5 percent
DY 3 through DY 10	Cumulative budget neutrality limit plus:	0.0 percent

Hypothetical Budget Neutrality Test

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations for FP Only		
	Cumulative Target Definition	Percentage
DY 9	Cumulative budget neutrality limit plus:	2.0 percent
DY 9 through DY 91	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.0 percent
DY 2 through DY 3	Cumulative budget neutrality limit plus:	0.5 percent
DY 3 through DY 10	Cumulative budget neutrality limit	0.0 percent

ATTACHMENT A

Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

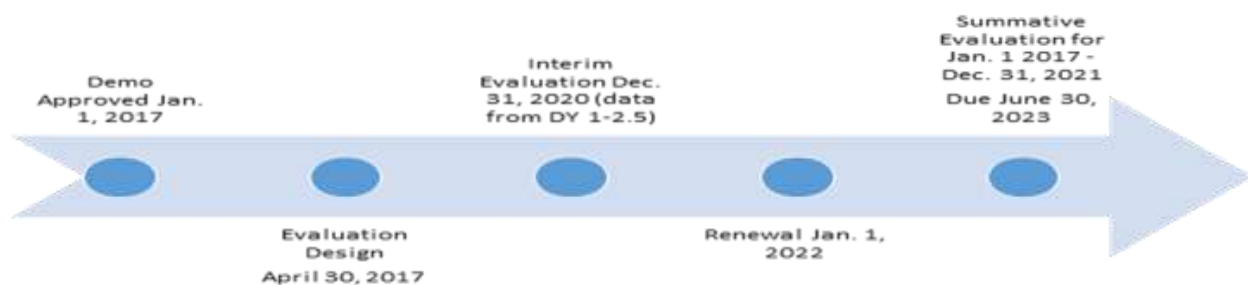
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

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



Required Core Components of All Evaluation Designs

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

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of the depicted information.

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

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

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

- 1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: <https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
- 3) Identify the state's hypotheses about the outcomes of the demonstration:
- 4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
- 5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

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

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic

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rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.
- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
 - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

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must be reviewed with CMS for approval before implementation).

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
 - a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
 - b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
 - c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
 - d. The application of sensitivity analyses, as appropriate, should be considered.
- 7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

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

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

E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Guidance

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

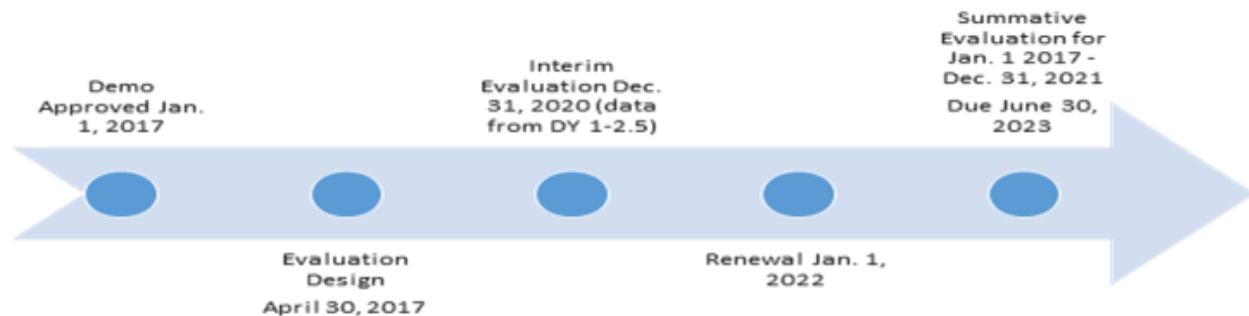
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Preparing the Interim and Summative Evaluation Reports

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

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

Submission Timelines

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



Required Core Components of Interim and Summative Evaluation Reports

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

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
 - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
 - 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
 - 2) Identify the state's hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

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

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

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

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

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

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

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

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

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

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- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
 - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives

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

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

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

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

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