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

March 29, 2019

Marie Matthews
Medicaid Director
Department of Public Health and Human Services
111 North Sanders, Room 301
P.O. Box 4210
Helena, Montana 59604-4210

Dear Ms. Matthews:

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.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 Montana's request for an extension of its section 1115 family planning demonstration, entitled "Montana Plan First," (Project Number 11-W-00276/8). 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 family planning services that produce positive health outcomes for individuals. This approval is effective for ten years as of the date of this letter through, December 31, 2028. This ten year approval is contingent upon the state's compliance with the demonstration application and eligibility process requirements described in special term and condition (STC) paragraphs 18 and 19. As noted in the document, CMS reserves the right to withdraw demonstration authority if the state fails to comply with these requirements.

Our approval of this demonstration extension is subject to the enclosed STCs and the limitations specified in the list of expenditure authorities and title XIX requirements made not applicable.

The state may deviate from Medicaid state plan requirements 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 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

Under this demonstration, the state will continue to provide family planning and family planning-related services to women aged 19 through 44, with income up to 211 percent of the Federal Poverty Level (FPL) who are not otherwise eligible for Medicaid, who are losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum period or losing Medicaid or CHIP coverage, or who have private health insurance coverage but meet all other demonstration eligibility criteria.

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 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 Plan First demonstration improves access to family planning services and family planning related services for beneficiaries who otherwise would not have access to these services. Therefore, the

[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.

Secretary has determined that the Montana Plan First 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. Montana received one comment supporting the extension request by stating that federally qualified health centers (FQHCs) around the state have expressed appreciation for the demonstration, and the demonstration fills the family planning needs of women who do not otherwise qualify for Medicaid. CMS received no public comments.

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

Ms. Valisha Andrus
Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: valisha.andrus@cms.hhs.gov

Official communications regarding this demonstration should be sent simultaneously to Ms. Andrus and Mr. Richard Allen, Director, Division of Field Operations West. Mr. Allen's contact information is as follows:

Mr. Richard Allen
Director
Centers for Medicare & Medicaid Services
Division of Field Operations West
1961 Stout Street, Room 08-148
Denver, Colorado 80294
Email: Richard.Allen@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,

/s/

Chris Traylor
Deputy Administrator and Director

cc: Richard Allen, Director, Division of Field Operations West

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11 -W-00 276/8**

TITLE: **Montana Plan First Section 1115 Demonstration**

AWARDEE: **Montana Department of Public Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Montana for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration extension, be regarded as expenditures under the state's Title XIX plan. All requirements of the Medicaid statute will be applicable to such expenditure authorities (including adherence to income and eligibility system verification requirements under section 1137(d) of the Act), except those specified below as not applicable to these expenditure authorities.

The following expenditure authorities and the provisions specified as "not applicable" enable Montana to operate its demonstration effective April 1, 2019 through December 31, 2028, contingent upon Montana's compliance with demonstration special term and condition (STC) 18 and 19.

Effective through December 31, 2028, expenditures for extending Medicaid eligibility for family planning and family planning-related services to women aged 19 through 44, with income up to 211 percent of the Federal Poverty Level (FPL) who are not otherwise eligible for Medicaid, who are losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum period or losing Medicaid or CHIP coverage, or who have private health insurance coverage but meet all other demonstration eligibility criteria.

Demonstration enrollment is capped at 4,000 beneficiaries.

Medicaid Requirements Not Applicable to the Medicaid Expenditure Authorities:

All Medicaid requirements apply, except the following:

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 the demonstration population.

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

To the extent necessary to allow the state to offer the demonstration population a benefit

package consisting only of family planning services and family planning-related services.

3. Retroactive Coverage **Section 1902(a)(34)**

To the extent necessary to enable the state to not provide medical assistance to the demonstration population for any time prior to when an application for the demonstration is made.

4. 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 EPSDT services to the demonstration populations.

5. Prospective Payment for Federally Qualified Health Centers and Rural Health Centers and Rural Health Clinics **Section 1902(a)(15)**

To the extent necessary for the state to establish reimbursement levels to these clinics that will compensate them solely for family planning and family planning related services.

6. Eligibility Procedures **Section 1902(a)(17)**

To the extent necessary to allow the state to not require reporting of changes for income or household size for 12 months, for a person found income-eligible upon application or annual redetermination when determining eligibility for the family planning demonstration.

6. Reasonable Promptness **Section 1902(a)(8)**

To enable the state to utilize an enrollment limit for the demonstration population.

Centers for Medicare & Medicaid Services

SPECIAL TERMS AND CONDITIONS

NUMBER: **11 -W-00 276/8**

TITLE: **Montana Plan First Section 1115 Family Planning Demonstration**

AWARDEE: **Montana Department of Public Health and Human Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Montana family planning section 1115(a) Medicaid demonstration (hereinafter "demonstration"). The parties to this agreement are the Montana Department of Public Health and Human Services and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs are effective April 1, 2019 through December 31, 2028, contingent upon Montana's compliance with demonstration STC 18 and 19. CMS reserves the right to withdraw demonstration authority if the state fails to meet the requirements in STC 18 and 19. All previously approved STCs, waivers, and expenditure authorities are superseded by the STCs set forth below.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility
V. Benefits and Delivery Systems
VI. General Reporting Requirements
VII. Monitoring Calls and Discussions
VIII. General Financial Requirements
IX. Monitoring Budget Neutrality
X. Evaluation

Appendix A: Annual Monitoring Report Template
Appendix B: Evaluation Design Template

II. PROGRAM DESCRIPTION AND HISTORICAL CONTEXT

Demonstration Description

Montana's section 1115 family planning demonstration entitled, "Montana Plan First," has been operating since May 30, 2012. The demonstration extends eligibility for family

planning and family planning related services to women aged 19 through 44, with income up to 211 percent of the Federal Poverty Level (FPL) who are not otherwise eligible for Medicaid, who are losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum period or losing Medicaid or CHIP coverage, or who have private health insurance coverage but meet all other demonstration eligibility criteria. Enrollment in this demonstration is capped at 4,000 individuals.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with applicable federal statutes relating to non-discrimination. 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), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, understanding program rules and notices, in establishing eligibility for an exemption from the community engagement requirement on the basis of disability, meeting and documenting the community engagement requirement, and meeting other program requirements necessary to obtain and maintain benefits.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid programs expressed in 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), must apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid programs that occur during this demonstration approval period, unless the provision being changed is expressly waived. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 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 Statements.**

    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 state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration 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 changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

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

6. **Changes Subject to the Amendment Process** Changes related to eligibility, enrollment, benefits, beneficiary rights, 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 state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7, 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 elements of a viable amendment request as found in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified herein. 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 13. 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 worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall

include 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 detail 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) An up-to-date CHIP allotment worksheet, if necessary ; and

e) The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a 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 a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 Code of Federal Regulations (CFR) 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Transition and Phase-Out.** The state may 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 each public comment received, the state's response to the comment and how the state incorporated the received comment into the revised transition and phase-out plan.

b) Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its transition and 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 eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities, 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 days after CMS approval of the transition and phase-out plan.

d) Transition and Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a demonstration beneficiary 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 eligibility under a different eligibility category.

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

g) Federal Financial Participation (FFP): FFP will 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 beneficiaries' interest or promote the objectives of title XIX. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state 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 authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. **Adequacy of Infrastructure**. The state must 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 Health 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.** No federal 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, 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 shall 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 program – including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary 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 46.101(b)(5).

IV. ELIGIBILITY

16. **Use of Modified Adjusted Gross Income (MAGI) Based Methodologies.** The state must use MAGI income methodology for determination of eligibility for the demonstration, in accordance with 42 CFR 435.603 and elections in the State Plan.

17. **Eligibility Requirements.** Family planning and family planning related services are provided to women aged 19 through 44, with income up to 211 percent of the FPL who are not otherwise eligible for Medicaid, who are losing Medicaid pregnancy coverage at the conclusion of 60 days postpartum period or losing Medicaid or CHIP coverage, or who have private health insurance coverage but meet all other demonstration eligibility criteria, provided the individual is redetermined eligible for the program on an annual basis.

The state will provide 12 months of continuous eligibility, and not require reporting of changes in income or household size for this 12-month period, for an individual found to be eligible for this demonstration upon initial application or annual redetermination.

Enrollment in this demonstration is capped at 4,000 individuals.

18. **Eligibility Determination Process.** Application and enrollment processes for this demonstration must comply with section 1943 of the Act and implementing regulations at 42 CFR part 435. Transition to full compliance must be completed no later than March 31, 2022.

    a) Mitigation Work Plan and Timeline. The state must submit for CMS review and approval a work plan describing the changes the state will make to its demonstration application and enrollment processes that meet the intent of section 1943 of the Act and regulations at 42 CFR part 435 (referred to herein as mitigations) and the timeline for implementing the mitigations. The work plan must be submitted to CMS by a date mutually agreed to by CMS and the state. The state must implement all mitigations no later than 90 days after a date mutually agreed to by CMS and the state through the mitigation work plan review and approval. The mitigation work plan must address each of the following areas:
        i) Application
        ii) Notices
        iii) Redetermination
        iv) Verification, and
        v) Coordination with other Insurance Affordability Programs.

    b) Systems coordination and full compliance with section 1943 and implementing regulations at 42 CFR part 435. The state must achieve compliance with section 1943 of the Act and implementing regulations at 42 CFR part 435. The state must specifically address the following issues: coordination between the family planning program and the full benefit Medicaid program application processes such that individuals can file a single application to be considered for all bases of eligibility; integrating family planning eligibility into the state's Medicaid eligibility hierarchy; redetermining a beneficiary's Medicaid eligibility on all bases of eligibility and without re-application; and conducting verification in accordance with 42 CFR 435.916. The state must be in full compliance with applicable statute and regulations no later than March 31, 2022.
        i) *Documentation*. The state must notify CMS in writing when it achieves full compliance with applicable statute and regulations. This notification must include documentation to demonstrate the state's compliance.
        ii) *CMS Review*. Upon receipt of the documentation in STC 18(b)(i), CMS will review the information and work with the state to verify compliance with applicable statute and regulations.

    A delay in implementing the processes necessary to align with section 1943 of the Act (and implementing federal regulations at 42 CFR part 435) may subject the state to the penalty described in STC 10.

19. **Demonstration Disenrollment.** If a woman becomes pregnant while enrolled in the demonstration, she may be determined eligible for Medicaid under the state plan. The state must not submit claims under the demonstration for any woman who is found to be eligible under the Medicaid state plan. In addition, women who receive a sterilization procedure and complete all necessary follow-up procedures will be disenrolled from the demonstration. Prior to the integration process described in STC 18, beneficiaries disenrolled from the demonstration due to sterilization must be provided information on how to apply for comprehensive coverage; after the integration process described in STC 18, the state must conduct a full redetermination in accordance with 42 CFR 435.916 prior to termination.

V. BENEFITS AND DELIVERY SYSTEMS

20. **Family Planning Benefits.** Family planning services and supplies described in section 1905(a)(4)(C) and are limited to those services and supplies whose primary purpose is family planning and which are provided in a family planning setting. As the Montana Plan First family Planning Demonstration is limited to a specific category of benefits to treat specific medical conditions, the demonstration is not recognized as Minimum Essential Coverage (MEC) consistent with the guidance set forth in the State Health Official Letter #14-002, issued by CMS on November 7, 2014. Family planning services and supplies are reimbursable at the 90 percent matching rate, including:
    a) 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 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.

21. **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 Federal Medical Assistance Percentage (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. Examples of family planning-related services and supplies include:
    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/STDs, except for HIV/AIDS and hepatitis, follow-up visit/encounter for the treatment/drugs and subsequent follow-up visits to rescreen for

STIs/STDs based on the Centers for Disease Control and Prevention guidelines may be covered.

c) Drugs/treatment 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 also 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.

22. **Minimum Essential Coverage (MEC)**. The Montana Plan First demonstration is limited to the provision of services as described in STCs 19 and 20. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) consistent with the guidance set forth in the State Health Official Letter #14-002, issued by CMS on November 7, 2014.

23. **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 not covered for enrollees of this demonstration. The state must facilitate access to primary care services for participants, and must assure CMS that written materials concerning access to primary care services are distributed to demonstration participants. The written materials must explain to the participants how they can access primary care services.

24. **Delivery of Services.** Beneficiaries receive family planning services through this demonstration on a fee for service (FFS) basis. Beneficiary freedom of choice of which provider to see for family planning services shall not be restricted

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VI. GENERAL REPORTING REQUIREMENTS

25. **Deferral for Failure to Submit Timely Demonstration Deliverables**. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $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 singularly 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 demonstration. 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 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 submission 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 as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
c) If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets 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 for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

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.

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

27. **Compliance with Federal System Updates**. As federal systems continue to evolve and incorporate additional 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.

28. **Monitoring Reports**. The state must submit one (1) Annual Report each DY. The 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 to be provided by CMS, which will be organized by milestones. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.

a) Operational Updates. 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; 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. 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 required 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. Administrative costs for this demonstration should be reported separately on the CMS-64.
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.

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

30. **Close-out Report**. Within 120 days after the expiration of the demonstration, the state must submit a draft Close-out Report to CMS for comments.
    a) The draft 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 30 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 penalties described in STC 24.

VII. MONITORING CALLS AND DISCUSSIONS

31. **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, 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.

32. **Post Award Forum**. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall 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 quarter in which the forum was held, as well as in its compiled Annual Report.

VIII. GENERAL FINANCIAL REQUIREMENTS

This project is approved for title XIX expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

33. **Annual Expenditure Reports.** The state must provide annual expenditure reports to report total expenditures for services provided under this Medicaid section 1115(a) demonstration following routine CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. CMS must provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined cost limits specified in STC 44.

34. **Reporting Expenditures Subject to the Title XIX Budget Neutrality Agreement.** The following describes the reporting of expenditures subject to the budget neutrality limit:
    a) Tracking Expenditures. In order to track expenditures under this demonstration, Montana must report demonstration expenditures through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES); following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of Title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver

and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made.

b) Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded 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 on lines 9 or 10C as instructed in the State Medicaid Manual.

c) Use of Waiver Forms. The state must report demonstration expenditures on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver each quarter to report Title XIX expenditures for demonstration services.

35. **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must 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.

36. **Claiming Period.** All claims for expenditures subject to the budget neutrality agreement (including any cost settlements) must be made within two 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 years after the conclusion or termination of the demonstration. During the latter two-year period, the state must 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.

37. **Reporting Member Months.** The following describes the reporting of member months for the demonstration:
    a. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the monitoring reports as required under STC 28, the actual number of eligible member months for all demonstration enrollees. The state must submit a statement accompanying the annual reports, certifying the accuracy of this information.
    b. 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 to the total, for a total of four eligible member months.

38. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must 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 30 days after the end of each quarter, the state

must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the 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.

39. **Extent of Federal Financial Participation (FFP) for the Demonstration.** CMS shall provide FFP for family planning and family planning-related services and supplies at the applicable federal matching rates described in STC 19 and 20, subject to the limits and processes described below:
    a) For family planning services, 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.
    b) Allowable family planning expenditures eligible for reimbursement at the enhanced family planning match rate, as described in STC 19, should be entered in Column (D) on the Forms CMS-64.9 Waiver.
    c) Allowable family planning-related expenditures eligible for reimbursement at the FMAP rate, as described in STC 20, should be entered in Column (B) on the Forms CMS-64.9 Waiver.
    d) 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.
    e) Pursuant to 42 CFR 433.15(b)(2), FFP is available at the 90 percent administrative match rate for administrative activities associated with administering the family planning services provided under the demonstration including the offering, arranging, and furnishing of family planning services. These costs must be allocated in accordance with OMB Circular A-87 cost allocation requirements. The processing of claims is reimbursable at the 50 percent administrative match rate.

40. **Sources of Non-Federal Share.** The state must certify that matching the non-federal share of funds for the 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) CMS shall 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) Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

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

a) Units of government, including governmentally operated health care providers, may certify that state 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 Title XIX (or under section 1115 authority) 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 payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. 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 to the extent that such funds are derived from state or local tax revenues 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. Under all circumstances, health care providers must retain 100 percent of the claimed expenditure. Moreover, no pre-arranged agreements (contractual or otherwise) exist between health care providers and state and/or local government to return and/or redirect 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.

IX. MONITORING BUDGET NEUTRALITY

42. **Limit on Title XIX Funding.** The state shall be subject to a limit on the amount of federal Title XIX funding it may receive on selected Medicaid expenditures during the period of approval of the demonstration. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to budget neutrality expenditure limit shall be reported by the state using the procedures described in STC 33.

43. **Risk.** Montana shall be at risk for the per capita cost (as determined by the method described below in this section) for the Medicaid family planning enrollees, but not for the number of demonstration enrollees. By providing FFP for enrollees in this eligibility group, Montana shall not be at risk of changing economic conditions that impact enrollment levels. However, by placing Montana at risk for the per capita costs for enrollees in the demonstration, CMS assures that federal demonstration expenditures do not exceed the level of expenditures that would have occurred had there been no demonstration.

44. **Budget Neutrality Annual Expenditure Limits.** For each DY, an annual budget limit will be calculated for the demonstration. For the purposes of this demonstration, the DY is based off the calendar year (CY) of January 1 to December 31. The budget limit is calculated as the projected per member/per month (PMPM) cost times the actual number of member months for the demonstration multiplied by the Composite Federal Share.

    PMPM Cost. The following table gives the PMPM (Total Computable) costs for the calculation described above by DY. The PMPM cost was constructed based on state expenditures for DY 6 and increased by the rate of growth included in the President's federal fiscal year 2015 budget for DYs 10 through 14 as outlined below.

	Trend Rate	**DY 8 (CY19)**	**DY 9 (CY20)**	**DY 10 (CY21)**	**DY 11 (CY22)**	**DY 12 (CY23)**
Demonstration PMPM	4.7 %	$14.80	$15.50	$16.22	$16.99	$17.78

DY 13 (CY24)	**DY 14 (CY25)**	**DY 15 (CY26)**	**DY 16 (CY27)**	**DY 17 (CY28)**
$18.62	$19.50	$20.41	$21.37	$22.38

a) Composite 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 on the forms listed in STC 33 above, by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the approval period (see STCs 8 and 9), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable Composite Federal Share may be used.

b) Structure. The demonstration is structured as a "pass-through" or "hypothetical" population. Therefore, the state may not derive savings from the demonstration.

c) Application of the Budget Limit. The budget limit calculated above will apply to demonstration expenditures, as reported by the state on the CMS-64 forms. If at the end of the demonstration period, the costs of the demonstration services exceed the budget limit, the excess federal funds will be returned to CMS.

45. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.

46. **Enforcement of Budget Neutrality.** CMS will enforce budget neutrality over the life of the demonstration, rather than annually. However, no later than 6 months after the end of each DY or as soon thereafter as the data are available, the state will calculate annual expenditure targets for the completed year. This amount will be compared with the actual claimed FFP for Medicaid. Using the schedule below as a guide, if the state exceeds these targets, it will submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

Year	Cumulative Target Expenditures	Percentage
DY 8	DY 8 budget limit amount	+2.0 percent
DY 9	DYs 8 and 9 combined budget limit amount	+1.5 percent
DY 10	DYs 8 through 10 combined budget limit amount	+1.0 percent
DY 11	DYs 8 through 11 combined budget limit amount	+0.5 percent
DY 12	DYs 8 through 12 combined budget limit amount	+0 percent
DY 13	DYs 8 through 13 combined budget limit amount	+0 percent
DY 14	DYs 8 through 14 combined budget limit amount	+0 percent
DY 15	DYs 8 through 15 combined budget limit amount	+0 percent
DY 16	DYs 8 through 16 combined budget limit amount	+0 percent
DY 17	DYs 8 through 17 combined budget limit amount	+0 percent

Failure to Meet Budget Neutrality Goals. The state, whenever it determines that the demonstration is not budget neutral or is informed by CMS that the demonstration is not budget neutral, must immediately collaborate with CMS on corrective actions, which must include submitting a corrective action plan to CMS within 21 days of the date the state is informed of the problem. While CMS will pursue corrective actions with the state, CMS will work with the state to set reasonable goals that will ensure that the state is in compliance.

X. EVALUATION

47. **Cooperation with Federal Evaluators.** As required under 42 CFR §431.420(f), the state shall 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 shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall 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 24.

48. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with attachments B of these STCs. The state must submit, for CMS comment and approval,

a draft Evaluation Design with implementation timeline, no later than one hundred twenty (120) calendar days after the effective date of these STCs. 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 state may choose to use the expertise of the independent party in the development of the draft Evaluation Design.

49. **Evaluation Design Approval and Updates**. The state must submit a revised Draft Evaluation Design within 60 days after receipt of CMS' comments. Upon CMS approval of the final Evaluation Design, the document will be included as "Appendix B" to these STCs. Per 42 CFR §431.424(c), the state will publish the approved final Evaluation Design within 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each Annual Monitoring Report as required by STC 27, including any required rapid cycle assessments specified in these STCs. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval.

50. **Evaluation Questions and Hypotheses**. Consistent with attachments B 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 hypothesis. 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'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).

51. **Evaluation Budget**. A budget for 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 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 design is not sufficiently developed, or if the estimates appear to be excessive.

52. **Interim Evaluation Report**. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR §431.412(c)(2)(vi). When submitting an application for extension, the Interim Evaluation Report 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 any 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) If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is

due when the application for extension is submitted. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting an extension of the demonstration, a draft Interim Evaluation Report is due one 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.

d) The state must submit the final Interim Evaluation Report 60 days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
e) The Interim Evaluation Report must comply with CMS' separately provided guidance entitled, "Preparing the Evaluation Report."

53. **Summative Evaluation Report**. The draft Summative Evaluation Report must be developed in accordance with CMS' separately provided guidance entitled, "Preparing the Evaluation Report." The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include information as outlined in the approved evaluation design.
    a) Unless otherwise agreed upon in writing by CMS, the state shall submit the final summative evaluation report within 60 days of receiving comments from CMS on the draft.
    b) The final summative evaluation report must be posted to the state's Medicaid website within 30 days of approval by CMS.

54. **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 also 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 10.

55. **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 state's interim evaluation report, and/or the summative evaluation.

56. **Public Access**. The state shall post the final documents (e.g., monitoring reports, approved evaluation design, interim evaluation report, summative evaluation report, and close-out report) on the state's Medicaid website within 30 days of approval by CMS.

57. **Additional Publications and Presentations.** For a period of 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 other third party directly connected to the demonstration over which the state has control. 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

30 days to review and comment on publications before they are released. CMS may choose to decline to comment 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.

Appendix A
Annual Monitoring Report Template

Purpose and Scope of Annual Monitoring Report:
The state must submit annual progress reports in accordance with the Special Terms and Conditions (STC) and 42 CFR 431.420. The intent of these reports is to present the state's analysis of collected data and the status of the various operational areas, reported by month in the demonstration year. The report should also include a discussion of trends and issues over the year, including progress on addressing any issues affecting access, quality, or costs. Each annual monitoring report must include:

A. Executive Summary
B. Utilization Monitoring
C. Program Outreach and Education
D. Program Integrity
E. Grievances and Appeals
F. Annual Post Award Public Forum
G. Budget neutrality
H. Demonstration evaluation activities and interim findings.

A. Executive Summary

1. Synopsis of the information contained in the report

2. Program Updates, Current Trends or Significant Program Changes

a. Narrative describing the impact of any administrative and operational changes to the demonstration, such as eligibility and enrollment processes, eligibility redetermination processes (including the option to utilize administrative redetermination), systems, health care delivery, benefits, quality of care, anticipated or proposed changes in payment rates, and outreach changes.

b. Narrative on any demonstration changes, such as changes in enrollment, renewal processes service utilization, and provider participation. Discussion of any action plan if applicable.

c. Narrative on the existence of or results of any audits, investigations, or lawsuits that impact the demonstration.

3. Policy Issues and Challenges

a. Narrative of any operational challenges or issues the state has experienced.

b. Narrative of any policy issues the state is considering, including pertinent legislative/budget activity, and potential demonstration amendments.

c. Discussion of any action plans addressing any policy, administrative or budget issues identified, if applicable.

B. Utilization Monitoring

The state will summarize utilization through a review of claims/encounter data for the demonstration population in the subsequent tables. This includes the following:

Table 1. Summary of Utilization Monitoring Measures

Topic	Measure [Reported for each month included in the annual report]
Utilization Monitoring	Unduplicated Number of Enrollees by Quarter (See table 2 below)
	Unduplicated Number of Beneficiaries with any Claim by Age Group, Gender, and Quarter (See table 3 below)
	Contraceptive Utilization by Age Group (See table 4 below)
	Total Number of Beneficiaries Tested for any Sexually Transmitted Disease (See table 5 below)
	Total Number of Female Beneficiaries who Obtained a Cervical Cancer Screening (See table 6 below)
	Total Number of Female Beneficiaries who Received a Clinical Breast Exam (See table 7 below)

Table 2: Unduplicated Number of Enrollees by Quarter

	Number of Female Enrollees by Quarter				
	14 years old and under	15-20 years old	21-44 years old	45 years and older	Total Unduplicated Female Enrollment*
Quarter 1					
Quarter 2					
Quarter 3					
Quarter 4					

*Total column is calculated by summing columns 2-5.

Table 3: Unduplicated Number of Beneficiaries with any Claim by Age Group and Gender per Quarter in the Demonstration Year

	Number of Females Who Utilize Services by Age and Quarter					
	14 years old and under	15-20 years old	21-44 years old	45 years and older	Total Female Users *	Percentage of Total Unduplicated Female Enrollment
Quarter 1						
Quarter 2						
Quarter 3						
Quarter 4						
Total Unduplicated**						

*Total column is calculated by summing columns 2-5.

**Total unduplicated row cannot be calculated by summing quarter 1 – quarter 4. Total unduplicated users must account for users who were counted in multiple quarters, and remove the duplication so that each user is only counted once per demonstration year.

Table 4: Contraceptive Utilization by Age Group per Demonstration Year

Effectiveness	Users of Contraceptives

		14 years old and under	15 – 20 years old	21 – 44 years old	45 years old and older	Total
Most and Moderately Effective*	Numerator					
	Denominator					
Long-acting reversible contraceptive (LARC)*	Numerator					
	Denominator					
Total	Numerator					
	Denominator					

*This measure is calculated as per the Medicaid and CHIP Child and Adult Core Set measure for contraceptive care for all women. Measure specifications can be found at the links below:

- Child Core Set (CCW-CH measure for ages 15-20): https://www.medicaid.gov/license-agreement.html?file=%2Fmedicaid%2Fquality-of-care%2Fdownloads%2Fmedicaid-and-chip-child-core-set-manual.pdf
- Adult Core Set (CCW-AD measure for ages 21-44): https://www.medicaid.gov/license-agreement.html?file=%2Fmedicaid%2Fquality-of-care%2Fdownloads%2Fmedicaid-adult-core-set-manual.pdf

States needing technical assistance in applying the Core Set specifications to their family planning demonstration can send an email to MACqualityTA@cms.hhs.gov.

Table 5: Number Beneficiaries Tested for any STD by Demonstration Year

Test	**Female Tests**		**Total Tests**	
	Number	Percent of Total	Number	Percent of Total
Unduplicated number of beneficiaries who obtained an STD test				

Table 6: Total Number of Female Beneficiaries who obtained a Cervical Cancer Screening

Screening Activity	**Numerator***	**Denominator***	Percent
Unduplicated number of female beneficiaries who obtained a cervical cancer screening*			

*This measure is calculated as per the Medicaid and CHIP Adult Core Set measure for cervical cancer screening and is defined as women ages 21 to 64 who had cervical cytology (Pap test) performed every 3 years or women ages 30 to 64

who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.

Measure specifications can be found at: https://www.medicaid.gov/license-agreement.html?file=%2Fmedicaid%2Fquality-of-care%2Fdownloads%2Fmedicaid-adult-core-set-manual.pdf

States needing technical assistance in applying the Core Set specifications to their family planning demonstration can send an email to MACqualityTA@cms.hhs.gov.

Table 7: Breast Cancer Screening

Screening Activity	Numerator*	Denominator*	Percent
Unduplicated number of female beneficiaries who received a Breast Cancer Screening*			

*This measure is calculated as per the Medicaid and CHIP Adult Core Set measure for breast cancer screening and is defined as the percentage of women ages 50 to 74 who had a mammogram to screen for breast cancer and is reported for two age groups (as applicable): ages 50 to 64 and ages 65 to 74.

Measure specifications can be found at: https://www.medicaid.gov/license-agreement.html?file=%2Fmedicaid%2Fquality-of-care%2Fdownloads%2Fmedicaid-adult-core-set-manual.pdf

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C. Program Outreach and Education

1. General Outreach and Awareness
   - **a.** Provide information on the public outreach and education activities conducted this demonstration year; and,
   - **b.** Provide a brief assessment on the effectiveness of these outreach and education activities.

2. Target Outreach Campaign(s) (if applicable)
   - **a.** Provide a narrative on the populations targeted for outreach and education campaigns and reasons for targeting; and,
   - **b.** Provide a brief assessment on the effectiveness of these targeted outreach and education activities.

D. Program Integrity

Provide a summary of program integrity and related audit activities for the demonstration, including an analysis of point-of-service eligibility procedures.

E. Grievances and Appeals

Provide a narrative of grievances and appeals made by beneficiaries, providers, or the

public, by type and highlighting any patterns. Describe actions being taken to address any significant issues evidenced by patterns of appeals.

F. Annual Post Award Public Forum

Provide a summary of the annual post award public forum conducted by the state as required by 42 CFR §431.420(c) that includes a report of any issues raised by the public and how the state is considering such comments in its continued operation of the demonstration.

G. Budget Neutrality

1. Please complete the budget neutrality workbook.
2. Discuss any variance noted to the estimated budget, including reasons for variance in enrollment and/or in total costs, and/or in per enrollee costs. Describe any plans to mitigate any overages in budget neutrality by the end of the demonstration period.

H. Demonstration Evaluation Activities and Interim Findings

Please provide a summary of the progress of evaluation activities, including key milestones accomplished. Include:

1. Status of progress against timelines outlined in the approved Evaluation Design.
2. Any challenges encountered and how they are being addressed.
3. Status of any evaluation staff recruitment or any RFPs or contracts for evaluation contractual services (if applicable).
4. Description of any interim findings or reports, as they become available. Provide any evaluation reports developed as an attachment to this document. Also discuss any policy or program recommendations based on the evaluation findings.