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

April 7, 2020

Michael A. Ceballos
Director
Wyoming Department of Health
6101 Yellowstone Road, Suite 210
Cheyenne, WY 82002

Dear Mr. Ceballos:

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. As relevant here, 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 the 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) has approved Wyoming's request for an extension of the Wyoming "Pregnant by Choice" section 1115 demonstration (Project Number: 11-W-00238/8) (the "demonstration"), in accordance with section 1115(a) of the Act. This approval is effective as of the date of this letter through December 31, 2027.

Objectives of the Medicaid Program

Under section 1901 of the Act, the Medicaid program provides federal funding to participating states "[f]or the purpose of enabling 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."

As this statutory text makes clear, a basic objective of Medicaid is to enable states to "furnish…medical assistance" to certain vulnerable populations (i.e., payment for certain healthcare services defined at section 1905 of the Act, the services themselves, or both). By paying these costs, the Medicaid program helps vulnerable populations afford the medical care and services they need to attain and maintain health and well-being. In addition, the Medicaid program is supposed to enable states to furnish rehabilitation and other services to vulnerable populations to help them "attain or retain capability for independence or self-care," per section 1901 of the Act.

We are committed to supporting states that seek to test policies that are likely to improve beneficiary health because we believe that promoting independence and improving health outcomes is in the best interests of the beneficiary and advances the fundamental objectives of the Medicaid program. Healthier, more engaged beneficiaries may also consume fewer medical services and have a lower risk profile, making the program more sustainable. Policies designed to improve beneficiary health that lower program costs make it more practicable for states to make improvements and investments in their Medicaid program and ensure the program's sustainability so it is available to those who need it most. In so doing, these policies can promote the objectives of the Medicaid statute.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration projects are likely to promote the objectives of the Medicaid statute, including through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, information technology (IT) systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

In its consideration of Wyoming's extension proposal, CMS considered whether the demonstration was likely to assist in improving health outcomes and better enable Wyoming, "as far as practicable under the conditions in" the state, to furnish medical assistance, per section 1901 of the Act. CMS has determined this extension is likely to promote these Medicaid objectives, and the expenditure authorities sought are necessary and appropriate to carry out the demonstration. For the following reasons, the Secretary has determined that the Wyoming "Pregnant by Choice" section 1115 demonstration, as presented, is likely to assist in promoting the objectives of the Medicaid program by: 1) increasing access to family planning state plan services; 2) increasing child spacing intervals through effective contraceptive use; and, 3) reducing Medicaid costs by reducing the number of unintended pregnancies by women who otherwise would be eligible for Medicaid pregnancy-related services.

Extent and Scope of the Demonstration Extension

The Wyoming "Pregnant by Choice" section 1115 demonstration extension approval will authorize the state to provide family planning services to women ages 19 through 44 with family

incomes at or below 159 percent of the federal poverty level (FPL) who lose pregnancy-related Medicaid coverage through the Wyoming Medicaid Pregnant Women Program.

Consideration of Public Comments

Wyoming's state public comment period produced no comments. The state held its public notice and comment period from May 15, 2019 through June 14, 2019. The state did not have anyone attend its two public hearings nor did anyone submit comments on the proposed extension application. The state also did not receive any comments or request for consultation from its federally-recognized tribes.

CMS held its federal public notice and comment period from August 9, 2019 through September 8, 2019 and received one comment from the American College of Obstetricians and Gynecologists (ACOG). ACOG expressed support for the proposed extension of the demonstration as well as proposed approaches Wyoming could consider to expand the scope of the Medicaid family planning benefit in the state. ACOG encouraged CMS to work with the state to submit a state plan amendment to permanently adopt an extended Medicaid family planning program in Wyoming and recommended that CMS work with the state to broaden the scope of their section 1115 demonstration family planning program.

CMS appreciates ACOG's expressed support for the expansion of family planning services in Wyoming. States, as the administrators of the Medicaid program, are in the best position to assess the unique needs of their Medicaid program and Medicaid-eligible populations and advance reforms that result in better health outcomes. States have discretion to adopt the optional state plan family planning eligibility group pursuant to section 1902(a)(10)(A)(ii)(XXI) of the Act or utilize longstanding section 1115 authority to provide family planning services. As we indicate above, states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations. CMS supports Wyoming's approach to expanding the provision of family planning services in the state and is committed to working with the state should it decide to pursue a further expansion of the family planning program.

Consistent with federal transparency requirements, CMS reviewed all of the public comment materials submitted by the state and received during the federal comment period, and determined that the Wyoming "Pregnant by Choice" section 1115 demonstration as a whole is likely to assist in promoting the objectives of the Medicaid program and the state's extension request should be approved.

Other Information:

CMS also notes that, in the course of reviewing the state's family planning demonstration extension request, we determined that Wyoming's eligibility renewal and electronic notices policies are not in compliance with regulatory requirements at 42 CFR 435.916 and 42 CFR 435.918 respectively. We understand that these compliance issues are not unique to the family planning demonstration. As such, CMS concluded that the demonstration is still likely to continue to promote the objectives of Medicaid and we will work with the state to achieve compliance regarding these requirements separately from the family planning demonstration.

CMS's approval of this section 1115 demonstration extension is subject to the enclosed Special Terms and Conditions (STCs) and expenditure authorities that define the nature, character, and extent of federal involvement in this project. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been specifically listed as not applicable to expenditures under the demonstration.

This approval is also subject to your written acknowledgement of the award and acceptance of the STCs within 30-calendar days of the date of this letter. Please send your written acceptance to your CMS project officer, Mr. Felix Milburn. Mr. Milburn is available to answer any questions concerning your section 1115(a) demonstration. His contact information is as follows:

Mr. Felix Milburn
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-1315
E-mail: Felix.Milburn@cms.hhs.gov

If you have questions regarding this approval, please contact Mrs. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services at (410) 786 9686.

We look forward to continuing to work with you and your staff.

Sincerely,

Calder Lynch
Deputy Administrator and Director

Enclosure

cc: Ford Blunt, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11 -W-00 238/8**

TITLE: **Wyoming Pregnant by Choice Section 1115 Family Planning Demonstration**

AWARDEE: **Wyoming Department of Health**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Wyoming 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 Wyoming to operate its demonstration effective April 7, 2020 through December 31, 2027, unless otherwise stated.

Effective through December 31, 2027, expenditures for extending Medicaid eligibility (subject to an annual redetermination) for family planning services to:

a. Women aged 19 through 44, with incomes up to 159 percent of the Federal Poverty Level (FPL) who are losing Medicaid through the Wyoming Medicaid Pregnant Woman Program.

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.

Centers for Medicare & Medicaid Services
SPECIAL TERMS AND CONDITIONS

NUMBER: 11 -W-00238/8

TITLE: Wyoming "Pregnant by Choice" Section 1115 Family Planning Demonstration

AWARDEE: Wyoming Department of Health

I. PREFACE

The following are the Special Terms and Conditions (STCs) for Wyoming's "Pregnant by Choice" program, a Medicaid section 1115(a) family planning demonstration (hereinafter "demonstration"). The parties to this agreement are the Wyoming Department of Health and the Centers for Medicare & Medicaid Services (CMS). These 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 approved demonstration period specified in these STCs. The STCs are effective April 7, 2020, the date of the CMS approval letter that accompanied these STCs, through December 31, 2027, unless otherwise specified. All previously approved STCs and expenditure authorities are superseded by the STCs set forth below.

The STCs have been arranged into the following subject areas:

II. PROGRAM DESCRIPTION AND HISTORICAL CONTEXT

Demonstration Description

The Wyoming "Pregnant by Choice" family planning demonstration expands the provision of family planning services to women aged 19 through 44, with family income at or below 159 percent of the Federal Poverty Level (FPL), who are losing pregnancy-related coverage provided through the Wyoming Medicaid Pregnant Woman Program. These women must not have health insurance and must not be otherwise eligible for another Medicaid program. The demonstration specifically allows enrollees to receive contraception management services and certain medical diagnosis or treatment services that are provided within the context of a visit for contraception management services.

Historical Context

The Wyoming Pregnant by Choice demonstration was initially approved for a 5-year period on September 8, 2008 and implemented by the state on January 1, 2009. The demonstration has been temporarily extended since December 31, 2014 to permit the state to determine how it wished to proceed with the extension of the program. On August 5, 2019, the Wyoming Department of Health submitted a request to extend the demonstration for a 5-year period with no changes. CMS is providing a 10-year extension of the demonstration, starting from the date the demonstration was originally set to expire, given the positive program outcomes the state has demonstrated as summarized below.

Since initial implementation, the overall goals of this demonstration are to reduce the incidence of closely spaced pregnancies and decrease the number of unintended pregnancies, thereby achieving cost savings and reducing health risks to women and children in the state. The latest program outcomes reported by the state show that the proportion of demonstration enrollees accessing Medicaid-family planning services has increased almost every year of the demonstration, with only one demonstration year showing a slight decline. As well as, the most recent Pregnancy Risk Assessment Monitoring System (PRAMS) data available in the state shows that the overall rate of unintended pregnancies in Wyoming decreased from 44.4 percent to 36.1 percent from 2007 to 2011.

The demonstration is expected to continue to progress these outcomes and promote the objectives of title XIX by:

- Increasing access to family planning services;
- Increasing child spacing intervals through effective contraceptive use;
- Reducing the number of unintended pregnancies in Wyoming; and
- Reducing Medicaid costs by reducing the number of unintended pregnancies by women who otherwise would be eligible for Medicaid pregnancy-related services.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, 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).

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the expenditure authority document (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, court order, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is 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 pursuant to STC 6. 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 of Changes in Federal Law, Regulation, and Policy on the Demonstration.**

    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 modified budget neutrality agreement will be effective upon the implementation of the change. Further, the state reserves the right to seek an amendment to the demonstration (as per STC 6) 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. **Changes Subject to the Amendment Process.** Changes related to demonstration features such as eligibility, enrollment, benefits, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements in these STCs 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 Social Security Act (the Act). The state must not implement changes to these demonstration elements without prior approval by CMS. Amendments to the demonstration

are not retroactive and FFP will not be available for 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.

6. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval 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 specified in this STC and submission of required deliverables specified in these STCs in accordance with the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

   a) *Demonstration Amendment Summary and Objectives.* The state must provide a detailed description of the amendment, including what the state intends to demonstrate via this amendment as well as the impact on beneficiaries, with sufficient supporting documentation, the objective of the change and desired outcomes including a conforming title XIX and/or title XXI state plan amendment, if necessary;

   b) *Budget Neutrality Worksheet.* The state must provide a data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality expenditure limit;

   c) *Waiver and Expenditure Authorities*. The state must provide a list of waivers and expenditure authorities that are being requested or terminated, along with the programmatic description of why these waivers and expenditure authorities are being requested for the amendment;

   d) *Evaluation*. 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; and;

   e) *Public Notice.* The state must provide 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.

7. **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 8.

8. **Demonstration Transition and Phase-Out.** The state may suspend or terminate this demonstration, in whole or in part, at any time prior to the date of expiration, 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 its 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 13. 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 considered the comments received when developing the revised transition and phase-out plan.

   b) Transition and Phase-out Plan Requirements: The state must minimally include in its phase-out plan the following: i) the process by which it will notify affected beneficiaries; the content of said beneficiary notices (including information on the beneficiary's appeal rights); ii) the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries; iii) the process by which the state will ensure ongoing coverage for eligible individuals; and, iv) any community outreach activities the state will undertake to notify affected beneficiaries (including any 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 the 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 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 appeal and hearing rights are afforded to demonstration beneficiaries as outlined in 42 CFR part 431 subpart E, including 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 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 Commonwealth 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 per 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. The limitation on enrollment into the demonstration does not impact the state's obligation to determine Medicaid or CHIP eligibility in accordance with the approved Medicaid or CHIP state plans.

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

9. **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 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 authorities, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration, in whole or in part, at any time before the date of expiration, whenever it determines following a hearing that the state has materially failed to comply with the terms of the project. CMS will promptly notify the State in writing of the determination and the reasons for the suspension or termination, together with the effective date.

11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge the CMS finding that the state materially failed to comply with the terms of this agreement.

12. **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 to the extent they apply; and reporting on financial and other demonstration components.

13. **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 an application.

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.

In states with Federally-recognized Indian tribes, Indian health programs, and/or Urban Indian health organizations, the state is required to 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 6 or extension, are proposed by the state.

14. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including administrative and medical assistance expenditures, will be available until the effective date identified in the CMS demonstration approval letter.

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(d)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility for the Demonstration.** Family planning services are provided to eligible individuals as defined below, provided the individual is redetermined eligible for the program on an annual basis in alignment with the requirements of section 1943 of the Act.

    Eligibility criteria for the demonstration is as follows:

    (1) Are transitioning from the Wyoming Medicaid Pregnant Women program;
    (2) Are between the ages of 19 and 44;
    (3) Are not eligible for another Medicaid program;
    (4) Do not have health insurance (i.e., must not be eligible for other insurance that provides family planning services);
    (5) Have not had a medical procedure to prevent pregnancy;
    (6) Have a family income at or below 159 percent of the Federal Poverty Level (FPL);
    (7) Are U.S. citizens or qualified immigrants;
    (8) Are residents of Wyoming; and,

(9) Are not pregnant.

17. **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 this 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 subsequently be disenrolled from this demonstration.

18. **Eligibility Determination Process.** Eligibility and enrollment processes for this demonstration must comply with section 1943 of the Act and implementing federal regulations at 42 CFR part 435. The state must ensure that any changes made to the state's Medicaid eligibility and enrollment processes to ensure compliance with section 1943 of the Act and implementing regulations at 42 CFR part 435 are implemented for the demonstration and its population concurrently with the implementation for the state plan. A delay in implementing any such changes for the demonstration may subject the state to the penalty described in STC 10.

V. BENEFITS AND DELIVERY SYSTEMS

19. **Family Planning Benefits.** Individuals eligible under this demonstration will receive family planning services and supplies as described in section 1905(a)(4)(C) of the Act, which are reimbursable at the 90 percent federal matching rate. The specific family planning services provided under this demonstration are as follows:

    a) Approved methods of contraception;

    b) Sexually transmitted infection (STI)/sexually transmitted disease (STD) testing, Pap smears and pelvic exams;
        - Note: 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;

20. **Minimum Essential Coverage (MEC).** The Wyoming family planning demonstration is limited to the provision of services as described in STC 19. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) as indicated by

CMS in its February 12, 2016 correspondence from Vikki Wachino to Teri Green, State Medicaid Agent, regarding the designation of MEC for the state's section 1115 demonstration.

21. **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.

22. **Delivery of Services.** Enrollees will receive family planning demonstration services on a fee-for-service (FFS) basis. Beneficiary freedom of choice of which provider to see for family planning services shall not be restricted.

VI. GENERAL REPORTING REQUIREMENTS

23. **Deferral of Payment 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 and analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverables(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 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 the state's 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.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, the 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.

24. **General Financial Requirements.** The state must comply with all general financial requirements under title XIX and as set forth in section VII.

25. **Reporting Requirements Relating to Budget Neutrality.** The state must comply with all reporting requirements for monitoring budget neutrality as set forth in section VIII.

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 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, Transformed Medicaid Statistical Information System (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 Calls**. CMS will convene biannual conference calls with the state in addition to ad hoc communications, as needed. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Areas to be addressed

include, but are not limited to, health care delivery, enrollment, cost-sharing, quality of care, access, the benefit package, audits, lawsuits, financial reporting and budget neutrality issues, progress on evaluation, legislative developments, and any demonstration amendments the state is considering submitting. CMS shall provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration. The state and CMS shall jointly develop the agenda for the calls.

29. **Annual Monitoring Report**. No later than 90-days following the end of each demonstration year (i.e., by March 31), the state must submit an "Annual Monitoring Report" that represents the status of the demonstration's various operational areas and any state analysis of program data collected for the demonstration year. The Annual Monitoring Report will include all elements required by 42 CFR 431.428 and as listed below, 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 state must submit the Annual Monitoring Report through CMS' designated system using the framework incorporated in these STCs as "Appendix A," which is subject to change as monitoring systems are developed and/or evolve, and will be provided in a structured manner that supports federal tracking and analysis. Each Annual Monitoring Report must minimally include the following:

    a) Operational Updates – Per CFR 431.428, the Annual Monitoring Report 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; description of the last annual public forum held, and a summary of any program integrity and related audit activities for the demonstration. The Annual Monitoring Report should also include a summary of all public comments received through the post-award public forum required per 42 CFR §431.420(c) regarding the progress of the demonstration.

    b) Performance Metrics – Per 42 CFR 431.428, the Annual Monitoring Report 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) and grievances and appeals. The required monitoring and performance metrics will include number of enrollees, beneficiaries with claims (including follow-up claims), contraceptive utilization, beneficiaries tested for sexually transmitted diseases, beneficiaries who obtained a cervical cancer screening, and beneficiaries who received a pelvic and/or clinical breast exam. The required monitoring and performance metrics must be included in writing in the Annual Monitoring Report, 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 Annual Monitoring Report must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with

every Annual Monitoring Report the meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including a total annual member month count for the demonstration population, total annual expenditures for the demonstration population, and the resulting "per member, per month" calculation. The Annual Monitoring Report must also include the submission of corrected budget neutrality data upon request.

d) Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Annual Monitoring Reports must document any results of the demonstration to date per the CMS approved 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.

30. **Program Integrity**. The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration. The state must confirm its process for ensuring there is no duplication of federal funding in each Annual Monitoring Report as specified in STC 29(a).

31. **Draft and final 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 23.

VII. 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.

32. **Quarterly Expenditure Reports.** The state must provide quarterly 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.

33. **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, the state must report demonstration expenditures through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES). 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 and the two digit project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made (e.g., For reporting expenditures with dates of services made in demonstration year 12 (i.e., 1/1/2020 – 12/31/2020), the state would use "12" as the project number extension).

    b) 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. The state will continue to use the waiver name "Family Planning" to report expenditures in the MBES/CBES and in the budget neutrality workbooks required to be submitted with the Annual Monitoring Report per STC 29.

    c) 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.

34. **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must separately track and report administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on Form CMS-64.10 using the waiver name "Family Planning."

35. **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.

36. **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 Annual Monitoring Report required per STC 29, the actual number of eligible member months for all demonstration enrollees. The state must submit

a statement accompanying the Annual Monitoring Report 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 month contributes three eligible member months to the total. Two individuals who are each eligible for two months, each contribute two eligible member months, for a total of four eligible member months.

37. **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 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. If applicable, subject to the payment deferral process set out in STC 23, 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.

38. **Extent of Federal Financial Participation (FFP) for the Demonstration.** CMS shall provide FFP for the family planning services as described in STC 19, at the applicable federal matching rate, subject to the limits and processes described below:

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.

Allowable family planning expenditures eligible for reimbursement at the enhanced family planning match rate of 90 percent, as described in STC 19, should be entered in Column (D) on the CMS-64.9 Waiver Form.

b) 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.

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 provided by eligible Medicaid providers.

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.

39. **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 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 timeframes 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.

40. **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.

VIII. MONITORING BUDGET NEUTRALITY

The following is the method by which budget neutrality will be monitored for the Wyoming "Pregnant by Choice" family planning section 1115(a) Medicaid demonstration.

41. **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.

42. **Budget Neutrality Annual Expenditure Limits.** For each demonstration year (reflected as "DY" in the below table), an annual budget limit will be calculated for the demonstration. For the purposes of this demonstration, the state's demonstration cycle is based on calendar year (reflected as "CY" in the below table) January 1 to December 31.

    PMPM Cost. The following table provides the "per member/per month" (PMPM) (total computable) cost ceiling for each demonstration year represented in this demonstration approval period. The PMPM cost ceilings were constructed based on the state's historical expenditures for demonstration year 10 (i.e., January 1, 2018 – December 31, 2018) and increased by a 4.6 percent rate of growth; which is the trend rate included in the President's Medicaid Budget for federal fiscal year 2020 for the same period of time as demonstration year 12 through demonstration year 19 as outlined below.

    The budget limit for each demonstration year will be calculated using the below per PMPM cost multiplied by the actual number of member months (as calculated in accordance with STC 36) and the Composite Federal Share.

Current Year (CY)	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026	CY2027
Demonstration Year (DY)	DY12	DY13	DY14	DY15	DY16	DY17	DY18	DY19
Per Member Per Month (PMPM) Costs	$11.56	$12.10	$12.65	$13.23	$13.84	$14.48	$15.15	$15.84

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 10), 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) Risk. Wyoming shall be at risk for the per capita cost (as determined by the method described below in this section) for demonstration enrollees, but not for the number of demonstration enrollees. By providing FFP for eligible enrollees, Wyoming shall not be at risk of changing economic conditions that impact enrollment levels. However, by placing Wyoming 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.

d) 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. If the costs of the demonstration services do not exceed the budget limit, the state may not derive or utilize any such savings as indicated in 42.b above.

43. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with the MBES/CBES Schedule C Report that reflects the state's certified actual recorded demonstration expenditures or for 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.

44. **Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality over the life of this demonstration extension approval period. No later than 90-days after the end of each demonstration year, the state will calculate and report to CMS an annual cumulative expenditure target for the completed year as part of the Annual Monitoring Report described in STC 29. This amount will be compared with the actual cumulative amount the state has claimed for FFP through the completed year. If the cumulative spending exceeds the cumulative target by more than the indicated percentage, the state will submit a corrective action plan to CMS for approval. The state will subsequently implement the approval plan.

Year	Cumulative Target Expenditures	Percentage
CY 2020	DY 12 budget limit amount	+1.75 percent
CY 2021	DY 12 through DY 13 combined budget limit amount	+1.50 percent

CY 2022	DY 12 through DY 14 combined budget limit amount	+1.25 percent
CY 2023	DY 12 through DY 15 combined budget limit amount	+1.00 percent
CY 2024	DY 12 through DY 16 combined budget limit amount	+0.75 percent
CY 2025	DY 12 through DY 17 combined budget limit amount	+0.50 percent
CY 2026	DY 12 through DY 18 combined budget limit amount	+0.25 percent
CY 2027	DY 12 through DY 19 combined budget limit amount	+0.00 percent

45. **Exceeding Budget Neutrality**. 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 includes submitting a corrective action plan or 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.

    If at the end of the demonstration approval period, the cumulative 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 budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

IX. EVALUATION

46. **Draft Evaluation Design.** The Draft Evaluation Design must be developed in accordance with the Evaluation Design Framework incorporated in these STCs as "Appendix B" and submitted by the state, for CMS comment and approval, by no later than 120 days after the effective date of these STCs. The Draft Evaluation Design must minimally include the plan for rigorous evaluation on unintended pregnancy rates within the demonstration, the number and percentage of individuals served under this demonstration, and family planning service utilization. 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 an independent party in the development of the Draft Evaluation Design.

47. **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.

48. **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 D" 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 29, 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.

49. **Evaluation Questions and Hypotheses.** Consistent with CMS' guidance entitled, "Developing the Evaluation Design" (see Appendix B) and "Preparing the Evaluation Report" (see Appendix C), 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' 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).

50. **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 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 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) The state must provide a draft Interim Evaluation Report for the corresponding years, no longer than one year after completion of the measurement period, as described in subpart "i." and "ii" below. The state must submit a final Interim Evaluation Report for each measurement period sixty calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the final Interim Evaluation Report for this period on the state's website.

        i. A draft Interim Evaluation Report for the period from January 2019 through December 2022 will be due no later than December 31, 2023.
        ii. A draft Interim Evaluation Report for the period from January 2023 through December 2025 will be due no later than December 31 2026, with reference to analysis of the previous interim evaluation report.

    d) If the state is seeking to extend the demonstration, the last draft Interim Evaluation report, as noted in c(ii) above, is due when the application for extension is submitted. If the state is proposing changes to the demonstration in its application for extension, the research

questions and hypotheses, and how the evaluation design was adapted, should be included in the Interim Evaluation Report.

e) If the state is not requesting a demonstration extension, the last draft Interim Evaluation report, as noted in c(ii) above, is due one year prior to the end of the demonstration. For demonstration phase-out prior to the expiration of this demonstration 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.

f) The Interim Evaluation Reports must comply with CMS' guidance entitled, "Preparing the Evaluation Report" (see Appendix C).

51. **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.

52. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the complete demonstration approval period represented by these STCs within 18-months of the end of the approval period. The draft Summative Evaluation Report must be developed in accordance with CMS' guidance entitled, "Preparing the Evaluation Report" (see Appendix C). The Summative Evaluation Report must include information as outlined in the approved evaluation design.

    i. 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.
    ii. The final summative evaluation report must be posted to the state's Medicaid website within 30 days of approval by CMS.

53. **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.

54. **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.

55. **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 these STCs 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

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

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.

Appendix B: 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 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 need rigorous quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

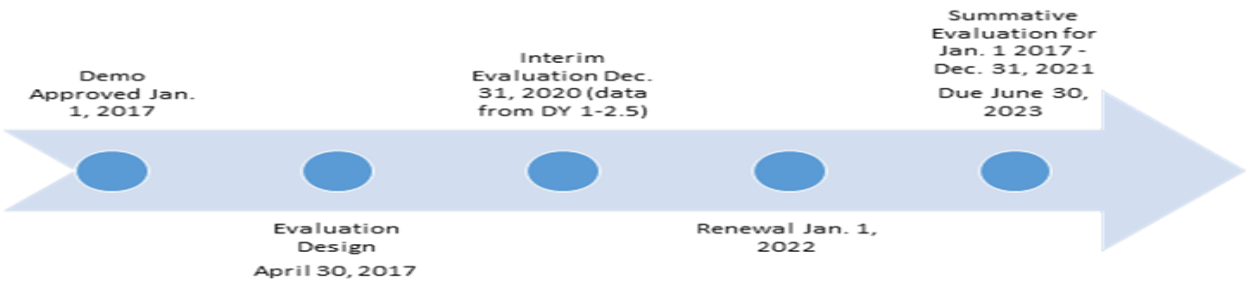
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations; and
E. 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 30 days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

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

3) Identify the state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

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

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

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

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

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

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

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

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -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.

E. Special Methodological Considerations- CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

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.

F. 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 a "No Conflict of Interest" statement 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.

Appendix C: Preparing the Evaluation Report

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 need 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. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. 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. 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 Attachment

Title XIX of 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 appendix is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

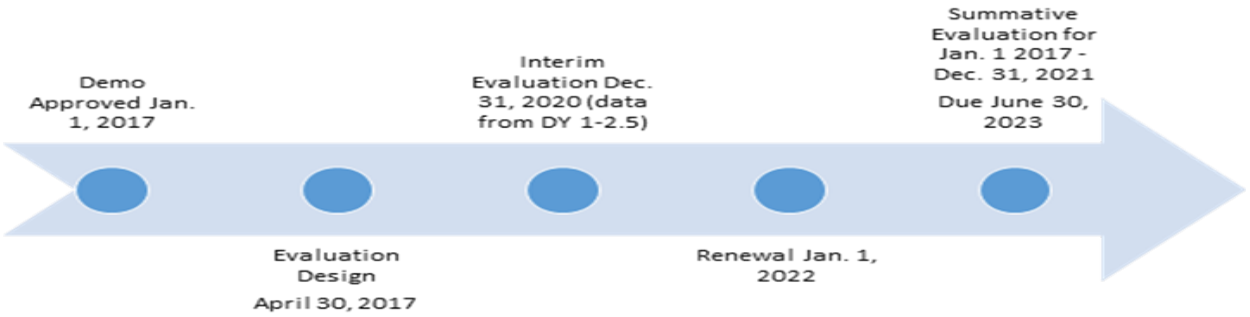
The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;

D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

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



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 Attachment) 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; and,
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.

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

F. 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.

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

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

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

H. 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.

I. 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?

Appendix D: Demonstration Evaluation Plan (*Reserved for CMS Approval*)