TEXAS
Health and Human Services

Cecile Erwin Young
Executive Commissioner

December 8, 2020

Lorraine Nawara
Centers for Medicare and Medicaid Services
Center for Medicaid, and CHIP Services
Division of State Demonstrations and Waivers
7500 Security Boulevard
Mail Stop S2-25-26
Baltimore, MD 21244-1850

Dear Ms. Nawara:

The Texas Health and Human Services Commission (HHSC) is requesting to amend the Healthy Texas Women waiver (11 -W-00326/6), a Medicaid waiver program operating under the authority of Section 1115 of the Social Security Act. The current waiver is approved through December 31, 2024.

This amendment is being requested to comply with Texas Health and Safety Code, Section 32.102, as added by Senate Bill (S.B.) 750, 86th Legislature, Regular Session, 2019. Section 32.102 requires HHSC to evaluate postpartum care services provided to women enrolled in the HTW program after the first 60 days of the postpartum period and, based on the evaluation, develop enhanced, cost-effective, and limited postpartum care services for women enrolled in the program. HHSC launched the enhanced postpartum care services package, called HTW Plus, for eligible women enrolled in HTW on September 1, 2020 using state general revenue funds.

S.B. 750 directs HHSC to seek an amendment to the Section 1115 Demonstration Waiver to obtain CMS approval to draw down federal funds for the postpartum care services.

The postpartum care services will focus on treating major health conditions recognized as contributing to maternal morbidity and mortality in Texas. A description of the health conditions and the services offered to treat them are as follows:

Postpartum depression and other mental health conditions
individual, family and group psychotherapy services;

peer specialist services;
Cardiovascular and coronary conditions
cardiovascular evaluation imaging and laboratory studies;
blood pressure monitoring;
anticoagulant, antiplatelet, and antihypertensive medications;
Substance use disorders
screening, brief intervention, and referral for treatment;
outpatient substance use counseling;
smoking cessation services;
medication-assisted treatment;
peer specialist services
Diabetes
glucose monitoring supplies
Asthma
treatment services.

If approved by CMS, the waiver amendment proposed by HHSC will provide federal matching funds for postpartum care services for women enrolled in HTW Plus, with an effective date of April 1, 2021. Kathi Montalbano, Manager of Policy Development Support, is the lead staff on this matter and can be contacted by telephone at (512) 771-3503.

Sincerely,

stephanie stephens

Digitally signed by stephanie stephens
Date: 2020.12.08 10:51:45 -06'00'

Stephanie Stephens
State Medicaid Director

Healthy Texas Women 1115 waiver
Number: 11 -W-00326/6
Demonstration Period: January 22, 2020 through December 31, 2024 Amendment Request: HTW Plus Postpartum Services
Submitted: December 8, 2020

III. General Program Requirements

STC 7 Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanations must include a summary of any public feedback received and identification of how this feedback was addressed by the state in final amendment request submitted to CMS;

Pursuant to STC 12 Public Notice, Tribal Consultation, and Consultation with Interested Parties, the public notice for public comment about the changes requested in Amendment 1 was published in the Texas Register on October 16, 2020, (see attachment named TX Reg Public Notice). HHSC issued a revised notice on November 6, 2020, based on recent feedback from the Centers for Medicare and Medicaid Services (CMS) about 1115 waiver public notice requirements, applicable for all amendments. The revised PNI provides further clarification around the amendment changes being made. The Texas Register is published weekly and is the journal of state agency rulemaking for Texas. In addition to activities related to rules, the Texas Register publishes various public notices including attorney general opinions, gubernatorial appointments, state agency requests for proposals and other documents, and it is used regularly by stakeholders. HHSC publishes all Medicaid waiver submissions in the Texas Register in addition to many other notices. The publication is available online and in hard copy at the Texas State Library and Archives Commission, the State Law Library, the Legislative Reference Library located in the State Capitol building, and the University of North Texas libraries. All of these sites are located in Austin, except for the University of North Texas, which is located in Denton. Printed copies of the Texas Register are also available through paid subscription; subscribers include cities, counties and public libraries throughout the state. In accordance with the requirements included in STC 12, letters were sent on October 2, 2020, to Tribal Governments requesting comments, questions, or feedback on the amendment by November 2, 2020, (see attached copy of one Tribal letter and read receipts for all Tribal letters sent). HHSC issued a revised tribal notice on November 6, 2020 based on recent feedback from CMS about

1115 public notice requirements, applicable for all amendments. The revised tribal notice provides further clarification around the amendment changes being made and gave the tribal Governments an opportunity to provide comments, questions or feedback on the amendment by December 6, 2020. HHSC received no comments regarding the amendment. HHSC received one question asking for clarification about whether diabetes testing supplies include continuous glucose monitors, and HHSC informed the stakeholder that continuous glucose monitors are not included in the HTW Plus benefit package.

b. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;

The Texas Health and Human Services Commission (HHSC) is requesting to amend the Healthy Texas Women (HTW) demonstration waiver (11 -W-00326/6), a Medicaid waiver program operating under the authority of Section 1115 of the Social Security Act. The current waiver is approved through December 31, 2024.

This amendment is being requested to comply with Texas Health and Safety Code, Section 32.102, as added by Senate Bill (S.B.) 750, 86th Legislature, Regular Session, 2019. Section 32.102 requires HHSC to evaluate postpartum care services provided to women enrolled in the HTW program after the first 60 days of the postpartum period and, based on the evaluation, develop enhanced, cost-effective, and limited postpartum care services for women enrolled in the program. HHSC launched the enhanced postpartum care services package, called "HTW Plus," for eligible women enrolled in HTW on September 1, 2020 using state general revenue funds.

S.B. 750 directs HHSC to seek an amendment to the Section 1115 Demonstration Waiver to obtain CMS approval to draw down federal funds for the postpartum care services.

The postpartum care services focus on treating major health conditions recognized as contributing to maternal morbidity and mortality in Texas. A description of the health conditions and the services offered to treat them are as follows: Postpartum depression and other mental health conditions individual, family and group psychotherapy services; peer specialist services;

Cardiovascular and coronary conditions cardiovascular evaluation
imaging and laboratory studies; blood pressure monitoring;
anticoagulant, antiplatelet, and antihypertensive medications;

Substance use disorders screening, brief intervention, and referral
for treatment; outpatient substance use counseling;
smoking cessation services; medication-assisted
treatment; peer specialist services

Diabetes
glucose monitoring supplies

Asthma
treatment services.

Under the current approved HTW waiver, the objectives of Medicaid (Title XIX of the Social Security Act) are promoted by providing coverage of family planning services to low income women who would not otherwise have coverage. The requested amendment helps meet the above federal objective as well as state objectives outlined in the HTW waiver by increasing access to women's health services and improving health outcomes for low income women by providing additional family planning and inter-conception services to eligible women. HTW Plus also provides additional preventive services, such as diabetes testing and postpartum depression treatment services, which positively impact the health and well-being of enrolled women. In addition, these services treat the underlying conditions associated with the key drivers of maternal mortality in Texas. Preventive health services are expected to improve birth outcomes, improve maternal health outcomes, and reduce maternal morbidity and mortality.

The amendment also helps meet the HTW objective to reduce the overall cost of publicly funded health care by providing low-income Texans access to safe, effective services and promoting improved health, wellness, and preventive healthcare.

Women in the HTW Program who were pregnant in the 12 months prior to enrollment are automatically eligible to receive HTW Plus. There is no impact to enrollment from an eligibility perspective. Women who are eligible for HTW Plus are already included in the caseload for Healthy Texas Women. There is not a separate eligibility determination for HTW Plus.

Additionally, there are no cost sharing requirements for women receiving HTW Plus services.

If approved by CMS, the waiver amendment proposed by HHSC will provide federal matching funds for postpartum care services for women enrolled in HTW, with an effective date of April 1, 2021.

c. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment; and

HHSC will also be submitting a budget neutrality amendment due to the impact of HTW Plus services. The anticipated result of implementing HTW Plus is an increased per member per month (PMPM) cost in the HTW program due to the addition of the HTW Plus services, as the original development of the PMPM did not include these additional services.

The budget neutrality amendment estimated the number of HTW Plus utilizers based primarily on the number of women receiving Medicaid for pregnant women who have auto-enrolled into

HTW. HHSC identified Texas Medicaid medical procedure codes and drugs available as part of the HTW Plus service array and analyzed utilization levels in the Medicaid for pregnant women population. Utilization rates for these HTW Plus services have been estimated based on SFY19 utilization data of Medicaid for pregnant women. Psychotherapy services assume higher utilization to account for potential demand due to postpartum depression.

Please also refer to the attached budget neutrality workbook.

d. The state must provide updates to existing demonstration reporting, 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.

Texas Health and Safety Code, Section 32.102, requires HHSC to develop enhanced, cost-effective, and limited postpartum care services for women enrolled in the Healthy Texas Women (HTW) Program. The postpartum care services ("HTW Plus") treat major health conditions recognized as contributing to maternal morbidity and mortality in Texas. Women in the HTW Program who were pregnant in the 12 months prior to enrollment are automatically eligible to receive HTW Plus. Texas began providing HTW Plus to women in the HTW Program on September 1, 2020 using general revenue funds. HHSC is seeking an amendment to the Section 1115 Demonstration Waiver to provide HTW Plus under the waiver starting April 1, 2021.

The HTW 1115 evaluation design submitted to CMS on May 19, 2020 included 4 evaluation questions and 7 hypotheses. No evaluation questions, hypotheses, or measures are directly related to HTW Plus. However, given the overlap between the goals of the HTW 1115 Demonstration and HTW Plus, the addition of HTW Plus will likely impact a variety of measures included in the HTW 1115 evaluation design. HHSC anticipates HTW Plus may impact the following measures included in the original evaluation design submitted to CMS:

- HTW clients who received an HTW service
- HTW-certified active billing providers
- Network adequacy
- Hypertension medication adherence
- Diabetes medication adherence
- Cholesterol medication adherence
- Antidepressant medication management
- Pregnancy complications
- Adverse birth outcomes
- Severe maternal morbidity
- Per member per month costs

At the time the state was preparing the amendment request, HHSC was also incorporating CMS feedback into the HTW 1115 evaluation design. HHSC incorporated the following adjustments to existing measures in the HTW 1115 evaluation design which may be

impacted by HTW Plus:

- Measures using a one-group pretest-posttest design originally directed the evaluator to explore changes in measures before and after the HTW 1115 Demonstration. For measures impacted by HTW Plus, HHSC revised the post-Demonstration time frame to also explore changes in measures following HTW Plus implementation, as feasible.
    - HHSC adjusted Measure 1.1.6 (network adequacy) from a one-group pretest-posttest design to a one-group posttest only design due to challenges obtaining pre-Demonstration data. HHSC revised the post-Demonstration time frame for Measure 1.1.6 to explore changes following HTW Plus implementation, as feasible.
- Measures using a nonequivalent comparison group pretest-posttest design originally directed the evaluator to explore differences in measures between two groups over time: women with Medicaid-paid births who were previously enrolled in HTW and women with Medicaid-paid births who were not previously enrolled in HTW. The evaluation design included subgroup analyses to further examine differences by demographic subgroup where feasible (i.e. by race/ethnicity or age). HHSC added HTW Plus to the subgroup analyses to explore whether differences between the two groups are affected by utilization of HTW Plus postpartum services.
- HHSC increased per member per month costs to incorporate costs associated with HTW Plus postpartum services.

A summary of expected impacts to measures in the original evaluation design, as well as corresponding adjustments, are presented in Table 1.

HHSC incorporated similar adjustments to account for HTW Plus in any new hypotheses or measures added to the revised HTW evaluation design in response to CMS feedback, where applicable. Finally, HHSC added a new hypothesis (Hypothesis 2.4.) directly addressing HTW Plus under the following evaluation question: *Did the HTW Demonstration increase utilization of family planning, family planning-related, and preconception care services?* The new hypothesis tests whether HTW Plus increased utilization of specific postpartum care services, and includes the following three measures:

- HTW clients eligible for HTW Plus
- HTW clients utilizing any HTW Plus postpartum services
- Frequency of utilization of HTW Plus postpartum services

Additional details and technical specifications will be provided in the revised HTW 1115 evaluation design due to CMS on December 9, 2020. HHSC is not proposing changes to the oversight, monitoring, and measurement of the provisions.

Table 1. Summary of HTW Plus Amendment Impact on Original Evaluation Measures

Measures Included in Original Submission (May 2020)	Expected Impact of Amendment	Predicted Impact and Evaluation Adjustment
Evaluation Question 1. Did the HTW Demonstration increase access to family planning, family planning-related, and preconception care services for low-income women in Texas?		
1.1.1 HTW clients	None	HTW Plus does not impact HTW Demonstration enrollment
1.1.2 HTW client member months[1]	None	HTW Plus does not impact HTW Demonstration enrollment
1.1.3 HTW clients who received an HTW service	Significant	HTW Plus introduces a new service package, which may increase HTW clients receiving an HTW service **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
1.1.4 Eligible population enrolled in HTW[1]	None	HTW Plus does not impact HTW enrollment
1.1.5 HTW-certified active providers	Significant	HTW Plus introduces a new service package, which may increase active billing providers **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
1.1.6 Network adequacy	Significant	HTW Plus introduces a new service package, which may introduce new HTW providers and provider types, which may influence network adequacy reports **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
Evaluation Question 2. Did the HTW Demonstration increase utilization of family planning, family planning-related, and preconception care services?		
2.1.1 Provision of most effective or moderately effective contraceptive methods	None	HTW Plus services do not include moderately effective contraceptive methods
2.1.2 Long-acting reversible contraceptive use	None	HTW Plus services do not include long-acting reversible contraceptive
2.1.3 Tests for any sexually transmitted infection/disease	None	HTW Plus services do not include tests for any sexually transmitted infection/disease
2.2.1 HTW clients utilizing	None	HTW Plus services are do not include

family planning-related services[1]		family planning related services outlined in STCs
2.2.2 Frequency of family planning-related services [1]	None	HTW Plus services do not include family planning-related services outlined in STCs
2.3.1 Cervical cancer screenings	None	HTW Plus services do not include cervical cancer screening
2.3.1 Breast cancer screenings[1]	None	HTW Plus services do not include breast cancer screenings
Evaluation Question 3. Did the HTW Demonstration improve women's health and pregnancy outcomes?		
3.1.1 Hypertension medication adherence	Significant	HTW Plus introduces a new service package that includes new tests, supplies, and medications which may support medication adherence **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
3.1.2 Diabetes medication adherence	Significant	HTW Plus introduces a new service package that includes new tests, supplies, and medications which may support medication adherence **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
3.1.3 Cholesterol medication adherence	Significant	HTW Plus introduces a new service package that includes new tests, supplies, and medications which may support medication adherence **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
3.1.4 Antidepressant medication management	Significant	HTW Plus introduces a new service package that includes psychotherapy services which may support medication adherence **Adjustment**: Directed evaluator to explore changes following HTW Plus implementation
3.2.1 Unintended pregnancies	None	HTW Plus services are not expected to impact unintended pregnancies
3.2.2 Birth spacing	None	HTW Plus services are not expected to impact birth spacing
3.2.3 Pregnancy complications (Gestational diabetes, preeclampsia)	Significant	HTW Plus introduces a new service package that treats major health conditions recognized as contributing

		to maternal morbidity and mortality in Texas which may reduce pregnancy complications **Adjustment**: Directed evaluator to add HTW Plus to the subgroup analyses
3.2.4 Adverse birth outcomes (Low birth weight, preterm birth)	Significant	HTW Plus introduces a new service package that treats major health conditions recognized as contributing to maternal morbidity and mortality in Texas which may reduce adverse birth outcomes **Adjustment**: Directed evaluator to add HTW Plus to the subgroup analyses
3.2.5 Severe maternal morbidity	Significant	HTW Plus introduces a new service package that treats major health conditions recognized as contributing to maternal morbidity and mortality in Texas which may reduce severe maternal morbidity **Adjustment**: Directed evaluator to add HTW Plus to the subgroup analyses
Evaluation Question 4. Did the HTW Demonstration effectively use public funds to provide women's health care in Texas?		
4.1.1 Per member per month costs	Significant	HTW Plus introduces a new service package which will increase annual cost expenditures **Adjustment**: Per member per month annual cost expenditure limits increased; directed evaluator to explore changes following HTW Plus implementation

[1] CMS approved the removal these measures from the HTW evaluation design on October 30, 2020 and November 13, 2020. HHSC will not include these measures in the revised submission of the HTW evaluation design due to CMS on December 9, 2020.

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 11 -W-00326/6

TITLE: Healthy Texas Women

AWARDEE: Texas Health and Human Services Commission

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Texas for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 22, 2020 through December 31, 2024, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

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

1. **Healthy Texas Women.** Effective through December 31, 2024, expenditures for extending Medicaid eligibility for family planning services, family planning-related services and other preconception women's health services to women who are otherwise ineligible for Medicaid or the Children's Health Insurance Program (CHIP), ages 18 through 44 with income at or below 200 percent of the Federal Poverty Level (FPL), including women who are losing Medicaid pregnancy coverage at the conclusion of the 60-day postpartum coverage period.

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, family planning-related services, and other

preconception women's health services.

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

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

4. Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) **Section 1902(a)(43)(A)**

To the extent necessary to enable the state to not furnish or arrange for EPSDT services to the demonstration populations.

5. Freedom of Choice **Section 1902(a)(23)**

To the extent necessary to enable the state to limit freedom of choice of provider in accordance with state law as described in the STCs.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11 -W-00326/6

TITLE: Healthy Texas Women

AWARDEE: Texas Health and Human Services Commission

I. PREFACE

The following are the Special Terms and Conditions (STC) for the "Healthy Texas Women" section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable the Texas Health and Human Services Commission (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted the state expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to this demonstration. The Healthy Texas Women demonstration will be statewide and is approved for a five year period, from January 22, 2020 through December 31, 2024 (contingent upon the state's compliance with demonstration STC 17).

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility
V. Benefits
VI. General Reporting Requirements
VII. General Financial Requirements
VIII. Monitoring Budget Neutrality
IX. Evaluation of the Demonstration

Additional attachments have been included to provide supplementary information and guidance for specific STCs:

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Evaluation Report
Attachment C: Annual Monitoring Report Template
Attachment D: Evaluation Design (reserved)
Attachment E: Implementation Plan (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Healthy Texas Women demonstration expands the provision of family planning services,

family planning-related services and other preconception women's health services to women ages 18 through 44 with family income at or below 200 percent of the FPL who are not otherwise eligible for Medicaid or CHIP, or enrolled in other creditable health insurance coverage that provides family planning services.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, to ensure they understand program rules and notices, as well as meeting other program requirements necessary to obtain and maintain benefits.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program, expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon the issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet as necessary, to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

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

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

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
    a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanations must include a summary of any public feedback received and identification of how this feedback was addressed by the state in final amendment request submitted to CMS;
    b. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;
    c. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment; and
    d. The state must provide updates to existing demonstration reporting, quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request 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 Code of Federal Regulations (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 transition and phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements:
    a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the received comment into the revised transition and phase-out plan.
    b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan, the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities , including community resources that are available.
    c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 days after CMS approval of the transition and phase-out plan.
    d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a demonstration beneficiary requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category.
    e. Exemption from Public Notice Procedures, 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
    f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the

demonstration, enrollment of new individuals into the demonstration must be suspended.

g. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. **Withdrawal of Expenditure Authority.** CMS reserves the right to withdraw 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 must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

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

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

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

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

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

entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program – including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Requirements.** Family planning, family planning-related, and other preconception women's health services are provided to eligible individuals with income at or below 200 percent of the FPL.

    Eligibility in the demonstration is limited to the following individuals who are not currently receiving benefits through or otherwise eligible for Medicaid, CHIP, Medicare Part A or B, and does not have other creditable health insurance coverage: Women ages 18 through 44 who are United States citizens or qualified immigrants, reside in Texas, and who are not currently pregnant. Individuals found income eligible upon application or annual redetermination are not required to report changes for income or household size for 12 months.

17. **Eligibility Determination Process.** No later than 18 months from the date of CMS approval of this demonstration, the state will integrate eligibility, application, verification, and redetermination processes into the eligibility system operated by the state for Medicaid state plan coverage in accordance with section 1943 of the Act. No later than ninety (90) calendar days after approval of the demonstration, the state will submit for CMS review and approval, its timeline with milestones for aligning eligibility and application processes with the requirements of section 1943 of the Act (and implementing federal regulations at 42 CFR part 435) as a part of the Implementation Plan. A delay in implementing the processes necessary to align comply with the requirements of 1943 of the Act (and implementing federal regulations at 42 CFR part 435) may subject the state to the penalty described in STC 26.

    Until integration into the state's Medicaid state plan eligibility system is complete and the state is in compliance with applicable policies and procedures, the state will conduct a targeted application and eligibility determination process that meets the intent of section 1943 of the Act in accordance with the following processes:

    a. Application. The state will make the separate application for Healthy Texas Women available online for download and fax submission, by mail submission, and available at the local county health department for application and submission in person. The state will maintain a prominent location on its Medicaid/Healthy Texas Women

website where the state offices are located for in person application, as well as a list of the Healthy Texas Women provider locations where application and receipt of family planning services can be completed onsite and by phone.

b. Reasonable Opportunity Period. The state will provide a process for verification of non-financial information (e.g., citizenship and immigration status) at initial application for each 12-month period of coverage under the Healthy Texas Women demonstration in alignment with 42 CFR 435.956.

c. Notices. The separate application and beneficiary eligibility determination notices will provide advance notification that eligibility will be for a 12-month period without a requirement to report a change in income or household size.

d. Verifications. The state will continue to use electronic data sources to which it has system capability to verify factors of eligibility. To the extent the state is not able to verify factors of eligibility electronically, the state will accept self-attestation, except for income and citizenship/immigration status. To verify income and citizenship/ immigration status, the state may request applicants provide this information as part of the eligibility determination. However, the state may not make a final determination of ineligibility based on lack of documentation of income and citizenship/qualified immigration status provided by the applicant until the state first utilizes an alternative process (pre or post enrollment) to verify this information through the electronic data sources utilized for Medicaid state plan eligibility.

e. Notification to Applicants of Other Coverage Options.

    i. Women applying through the Healthy Texas Women family planning only application must be provided information about potential eligibility for full-scope Medicaid or CHIP coverage. If individuals indicate they have not applied, but wish to apply for more comprehensive coverage, individuals must be provided facilitated access to or assistance with applying for full-scope Medicaid or CHIP coverage through the single streamlined application process.

    ii. To provide continuity of care, women 18 through 44 years of age whose Medicaid eligibility as a pregnant woman coverage period is ending will be referred to the demonstration if they are not otherwise eligible for full Medicaid benefits and they do not have other creditable health coverage.

    iii. The state will request attestation on the Healthy Texas Women family planning application from applicants that they have been informed about the availability of full-scope Medicaid or CHIP coverage and are making an informed choice to apply for family planning only coverage.

    iv. Pregnant women will be automatically referred for coverage under Medicaid or CHIP.

f. Individuals that apply for full-scope Medicaid or CHIP coverage through Texas' streamlined eligibility system and are determined ineligible for full-scope coverage must be provided information on the written notice about potential eligibility for Healthy Texas Women family planning only coverage and how to apply for such coverage.

g. Renewals. The state will continue to conduct redeterminations of eligibility once every 12 months.

18. **Demonstration Disenrollment.** If a beneficiary becomes pregnant while enrolled in the demonstration, she must be determined eligible for Medicaid under the state plan or CHIP. The state must not submit claims under the demonstration for any woman who is found to be eligible under the Medicaid state plan or CHIP.

V. BENEFITS

19. **Family Planning Benefits.** Beneficiaries 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. FDA-approved methods of contraception;
    b. Contraceptive management, patient education, and counseling;
    c. Pelvic examinations with a family planning diagnosis;
    d. Sexually transmitted infection (STI)/sexually transmitted disease (STD) testing and treatment services; and
    e. Drugs, supplies, or devices related to women's health services described above.

20. **Family Planning-Related Benefits.** Beneficiaries eligible under this demonstration will also receive family planning-related services and supplies defined as those services provided as part of or as follow-up to a family planning visit and are reimbursable at the state's regular Federal Medical Assistance Percentage (FMAP) rate. Such services are provided because a "family planning-related" problem was identified and/or diagnosed during a routine or periodic family planning visit. Examples of family planning-related services and supplies that would be provided under this demonstration include:
    a. Drugs for vaginal infections/disorders, other lower genital tract and genital skin infections/disorders, and urinary tract infections.
    b. Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services in a family planning setting.
    c. Treatment of major complications arising from a family planning procedure such as:
        i. Treatment of a perforated uterus due to an intrauterine device insertion;
        ii. Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
        iii. Treatment of surgical or anesthesia-related complications during a sterilization procedure.

21. **Preconception Care Services.** Individuals eligible under this demonstration will also receive certain women's health services related to better preconception care and birth outcomes. The preconception care services provided under this demonstration are reimbursable at the state's regular FMAP rate and are as follows:
    a. Screening and treatment for cholesterol, diabetes, and high blood pressure;
    b. Breast and cervical cancer screening and diagnostic services;
    c. Screening and treatment for postpartum depression;
    d. Immunizations; and
    e. Mosquito repellant prescribed by an authorized health professional.

22. Postpartum Care Services. Individuals eligible under this demonstration and who have been pregnant in the 12 months prior to enrollment will qualify to receive additional postpartum care services that focus on treating major health conditions recognized as contributing to maternal morbidity and mortality in Texas. The postpartum care services provided under this demonstration are reimbursable at the state's regular FMAP rate and are as follows:

a. individual, family and group psychotherapy services;
b. peer specialist services;
c. cardiovascular evaluation imaging and laboratory studies;
d. blood pressure monitoring;
e. anticoagulant, antiplatelet, and antihypertensive medications;
f. screening, brief intervention, and referral for treatment (SBIRT) for substance use disorder;
g. outpatient substance use counseling;
h. smoking cessation services;
i. medication-assisted treatment (MAT);
j. diabetes monitoring supplies; and
k. asthma treatment services.

~~22.~~23. **Minimum Essential Coverage (MEC).** The Healthy Texas Women family planning demonstration is limited to the provision of services as described in STCs 19, 20, ~~and~~ 21, and 22. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) consistent with the guidance set forth in the State Health Official Letter #14-002, issued by CMS on November 7, 2014.

~~23.~~24. **Primary Care Referrals.** Primary care referrals to other social service and health care providers as medically indicated will be provided; however, the costs of those primary care services are not covered for beneficiaries of this demonstration. The state must facilitate access to primary care services for beneficiaries and must assure CMS that written materials concerning access to primary care services are distributed to demonstration beneficiaries. The written materials must explain to beneficiaries how they can access primary care services.

~~24.~~25. **Delivery of Services.** Enrollees will receive family planning demonstration services on a fee-for-service (FFS) basis. Qualified Healthy Texas Women providers eligible for participation in this demonstration are those that do not perform or promote elective abortions nor affiliate with entities that perform or promote elective abortions.

~~25.~~26. **Demonstration Access and Operational Information.** To ensure sufficient ongoing beneficiary coverage and access to services, the state will outline specific operational information in the Implementation Plan. The state must submit a draft Implementation Plan to CMS no later than ninety (90) calendar days after approval of the demonstration for CMS review and comment. The state must submit a revised Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The Implementation Plan must cover at least the key policies being tested under this demonstration. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs as Attachment E. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines

for meeting milestones associated with these key policies. Other information in the Implementation Plan should include but is not limited to ensuring: network adequacy including procedures for provider qualification; access to care; beneficiary communication strategies including outreach and education; maintenance of and beneficiary access to provider directories; and complaints and grievances. The plan should describe the strategy for monitoring health outcomes, including but not limited to a data-driven process for reviewing access to care and addressing: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers; changes in beneficiary service utilization; the characteristics of the beneficiary population; and actual or estimated levels of provider payment available from other payers. With the implementation of the Affordable Care Act's requirement to transition to the use of Modified Adjusted Gross Income (MAGI) for determining Medicaid income eligibility, the state's comparable income limit will be increased to convert existing state income standards to MAGI, effective 18 months from the date of CMS approval of this demonstration.

VI. GENERAL REPORTING REQUIREMENTS

~~26.~~27. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $1,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being 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 as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a

written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

~~27.~~28. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

~~28.~~29. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 reporting and analytics functions, the state will work with CMS to:

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

~~29.~~30. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which will be organized by milestone. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration. In addition, the

Monitoring Report should document program outreach and education activities conducted and an assessment of the effectiveness of these outreach and education activities;

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.

d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

~~30.~~31. **Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial sustained directional change, inconsistent with state targets (such as substantial, sustained trends difficulty accessing services). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

~~31.~~32. **Close out Report**. Within 120 calendar 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 thirty (30) calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 26.

~~32.~~33. **Monitoring Calls**. CMS will convene periodic conference calls with the state.
a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The state and CMS will jointly develop the agenda for the calls.

~~33.~~34. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

VII. GENERAL FINANICAL REQUIREMENTS

~~34.~~35. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval periods designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

~~35.~~36. **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 50.

~~36.~~37. **Reporting Expenditures Subject to 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, Texas must report demonstration expenditures through the Medicaid and CHIP

Budget and Expenditure System (MBES/CBES); following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of Title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made.

b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any other cost settlements not attributable to this demonstration, the adjustments should be reported on lines 9 or 10C as instructed in the State Medicaid Manual.

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

~~37.~~38. **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the Forms CMS-64.10.

~~38.~~39. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made 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 will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

~~39.~~40. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state shall submit Form CMS64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the

State.

~~40.~~41. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP for family planning, family planning related, and other preconception women's health services at the applicable federal matching rates as described in STCs 19, 20, ~~and~~ 21, and 22 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), 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 diagnosis or indicator 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.

~~41.~~42. **Sources of Non-Federal Share**. The state must certify that its match for non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. The state acknowledges that CMS has the authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

~~42.~~43. **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 monies have been expended as the non-federal share of

funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments related to taxes, including health care provider-related taxes, fees business relationship 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.

~~43.~~44. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

~~44.~~45. **Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculation, and other purposes related to monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

Table 1: Master MEG Chart					
MEG	**To Which BN Test Does This Apply?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**

Healthy Texas Women	Hypothetical	X		X	Detailed in STC 16

~~45.~~46. **Reporting Expenditures and Member Months.** The following describes the reporting of member months for the demonstration:

a. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the monitoring reports as required under STC 29, the actual number of eligible member months for all demonstration enrollees. The state must submit a statement accompanying the annual reports, certifying the accuracy of this information.

b. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months to the total, for a total of four eligible member months. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the monitoring reports as required under STC 28, the actual number of eligible member months for all demonstration enrollees. The state must submit a statement accompanying the annual reports, certifying the accuracy of this information. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months to the total, for a total of four eligible member months.

~~46.~~47. **Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 2: Demonstration Years		
Demonstration Year 1	January 22, 2020 to December 31, 2020	12 months
Demonstration Year 2	January 1, 2021 to December 31, 2021	12 months
Demonstration Year 3	January 1, 2022 to December 31, 2022	12 months
Demonstration Year 4	January 1, 2023 to December 31, 2023	12 months
Demonstration Year 5	January 1, 2024 to December 31, 2024	12 months

~~47.~~48. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustment to the

budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

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

VIII. MONITORING BUDGET NEUTRALITY

~~48.~~49. **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 approved demonstration service expenditures incurred during the period of demonstration approval. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the approved demonstration period. Actual expenditures subject to budget neutrality expenditure limit shall be reported by the state using the procedures described in STC 36.

~~49.~~50. **Risk.** Texas shall be at risk for the per capita cost (as determined by the method described in this section), but not for the number of demonstration enrollees. By providing FFP for demonstration enrollees, Texas shall not be at risk for changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized has there been no demonstration.

~~50.~~51. **Budget Neutrality Annual Expenditure Limits.** For each demonstration year, an annual budget limit will be calculated for the demonstration. The Healthy Texas Women annual demonstration cycle is January 1 through December 31. The budget limit is calculated as the projected per member/per month (PMPM) cost times the actual number of member months for the demonstration multiplied by the Composite Federal Share.

Table 3: Hypothetical Budget Neutrality Test					
TREND	**DY 1**	**DY 2**	**DY 3**	**DY 4**	**DY 5**
4.6%	$27.13	$28.38	$29.69	$31.06	$32.49

a. PMPM Cost. The following table provides the approved demonstration cost trend (based on the state's historical rate of growth) and the PMPM (total computable) ceiling for each demonstration year.
b. 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 36 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 STC 9), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable Composite Federal Share may be used.
c. Structure. The demonstration's budget neutrality model is structured as a "pass-through" or "hypothetical" expenditure population. Therefore, the state may not derive savings from the demonstration.
d. Application of the Budget Limit. The budget limit calculated above will apply to demonstration expenditures 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.

~~51.~~52. **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 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 approved plan.

Year	Cumulative Target Expenditures	Percentage
DY 1	DY1 budget limit plus:	2.0 percent
DY2	DY1 and DY2 combined budget limit amount plus:	1.5 percent
DY3	DY1 through DY3 combined budget limit amount plus:	1.0 percent
DY4	DY1 through DY4 combined budget limit amount plus:	0.5 percent
DY5	DY1 through DY5 combined budget limit amount plus:	0 percent

~~52.~~53. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 22, 2020 to December 31, 2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget

neutrality test will be based on the time period through the termination date.

~~53.~~54. **Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold level in the tables below as a guide for determining when corrective action is required.

IX. EVALUATION OF THE DEMONSTRATION

~~54.~~55. **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; providing data and analytic files to CMS; 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 that collect, produce or maintain data and files for the demonstration, that they make 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 26.

~~55.~~56. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

~~56.~~57. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with CMS guidance, including but not limited to attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred twenty (120) calendar days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the draft Evaluation Design.

~~57.~~58. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each

of the Monitoring Reports. 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.

~~58.~~59. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Hypotheses should include, but are not limited to, testing the effects of the demonstration on sustainability, and access to women's health, family planning, and preventative care services. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

~~59.~~60. **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.

~~60.~~61. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

e. The Interim Evaluation Report must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

~~61.~~62. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

~~62.~~63. **Corrective Action Plan Related to Evaluation**. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increases difficulty accessing services). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

~~63.~~64. **State Presentations for CMS**. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

~~64.~~65. **Public Access**. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.

~~65.~~66. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any 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 ten (10) business 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.

Attachment A
Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform 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

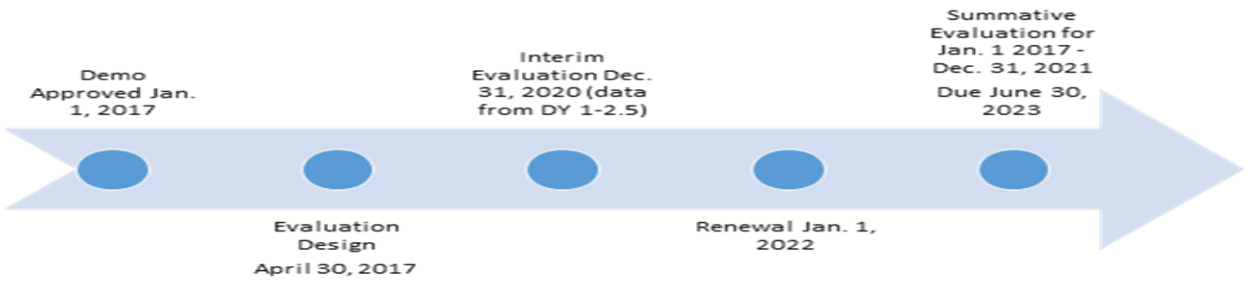
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

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

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
   a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
   b. Qualitative analysis methods may be used, and must be described in detail.

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

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

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

Attachment B
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 Attachment 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.

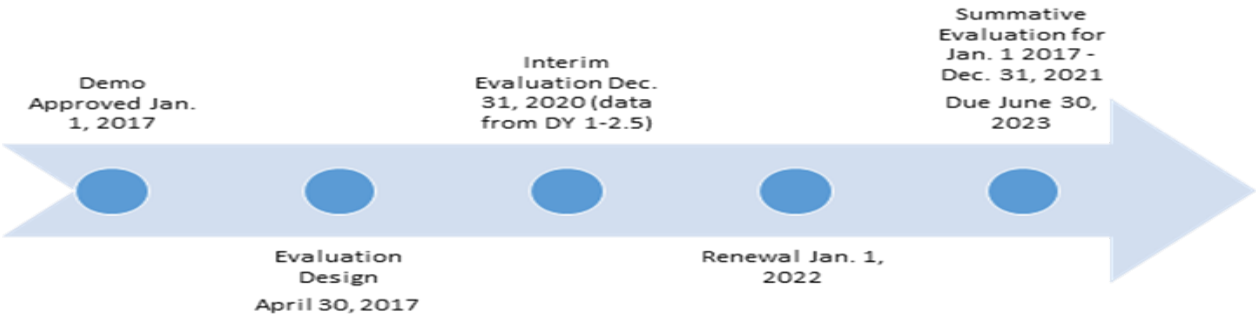
The format for the Interim and Summative Evaluation reports is as follows:

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:

i. 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.

ii. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

iii. 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;

iv. 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.

v. 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?

Attachment C
Annual Monitoring Report Template

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

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

A. Executive Summary

1. Synopsis of the information contained in the report

2. Program Updates, Current Trends or Significant Program Changes

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

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

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

3. Policy Issues and Challenges

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

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

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

B. Utilization Monitoring

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

Table 1. Summary of Utilization Monitoring Measures

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

Table 2: Unduplicated Number of Enrollees by Quarter

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

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

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

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

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

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

Table 4: Contraceptive Utilization by Age Group per Demonstration Year

Effectiveness	Users of Contraceptives

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

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

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

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

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

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

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

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

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

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

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

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

Table 7: Breast Cancer Screening

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

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

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

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.

Attachment D (reserved)
Approved Evaluation Design

Attachment E (reserved)
Implementation Plan