DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-25-26 Baltimore, Maryland 21244-1850



State Demonstrations Group

December 15, 2021

Stephanie Stephens
State Medicaid Director
Texas Health and Human Services Commission
4900 Lamar Boulevard
MC:H100
P.O. Box 13247
Austin, Texas 78751

Dear Ms. Stephens:

The Centers for Medicare & Medicaid Services (CMS) completed its review of Texas's Evaluation Design, which is required by the Special Terms and Conditions (STCs) of the state's section 1115 demonstration "Healthy Texas Women" (Project Number: 11-W-00326/6), effective through December 31, 2024. CMS determined that the Evaluation Design, which was first submitted on May 19, 2020 and subsequently revised on November 4 2021, meets the requirements set forth in the STCs, and therefore, approves the state's Healthy Texas Women Evaluation Design.

CMS added the approved Healthy Texas Women Evaluation Design to the demonstration's STCs as Attachment D. A copy of the STCs, which includes the new attachment, in enclosed with this letter. In accordance with 42 CFR § 431.424, the approved Evaluation Design may now be posted to the state's Medicaid website within thirty days. CMS will also post the approved Evaluation Design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an Interim Evaluation Report, consistent with the approved Evaluation Design, is due to CMS on December 31, 2023. Additionally, if the state is seeking to extend the demonstration, the draft of the Interim Evaluation Report is to be included in the extension application. Likewise, a Summative Evaluation Report, consistent with this approved Evaluation Design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR § 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

Page 2 – Ms. Stephanie Stephens

We appreciate our continued partnership with Texas to evaluate the Healthy Texas Women section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S Digitally signed by Danielle Daly -S Date: 2021.12.15 07:56:03 -05'00' Danielle Daly Director Division of Demonstration Monitoring and Evaluation State Demonstration Group

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

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.

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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

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.

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- 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.

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- **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. <u>Transition and Phase-out Plan Requirements.</u> 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. <u>Transition and Phase-out Plan Approval.</u> 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. <u>Transition and Phase-out Procedures.</u> 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. <u>Enrollment Limitation during Demonstration Phase-Out.</u> 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. <u>Federal Financial Participation (FFP).</u> 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

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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. <u>Application</u>. 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. <u>Reasonable Opportunity Period.</u> 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. <u>Notices</u>. 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. <u>Verifications.</u> 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. <u>Renewals</u>. The state will continue to conduct redeterminations of eligibility once every 12 months.

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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. 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. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) consistent with the guidance set forth in the State Health Official Letter #14-002, issued by CMS on November 7, 2014.
- 23. Primary Care Referrals. Primary care referrals to other social service and health care providers as medically indicated 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. 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. 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. 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. Submission of Post-Approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

- **28.** 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. 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 postaward 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. <u>Evaluation Activities and Interim Findings.</u> 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. 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. 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. 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. 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. 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.** 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. 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. <u>Cost Settlements.</u> 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

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- Manual.
- c. <u>Use of Waiver Forms.</u> 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. 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.** 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. 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.** 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, 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. 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. 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

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- 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. 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. 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. 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

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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. 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. 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. 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. 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. 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. <u>PMPM Cost.</u> 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. <u>Composite Federal Share.</u> 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

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- 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. <u>Structure.</u> 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. <u>Application of the Budget Limit</u>. 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. 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. 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. 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. 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. 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. 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. 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.** 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. 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. 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. 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. 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. 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. 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. 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.

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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.

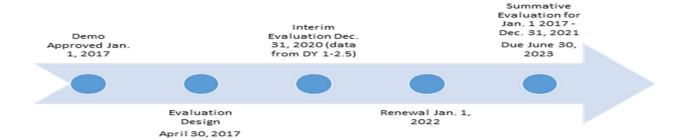
The format for the Evaluation Design is as follows:

- 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.

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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

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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.

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- 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

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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	Compared	Data Sources	Wiethous
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:

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- 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.

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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.

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- **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.

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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:

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- 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?

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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]
	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)
Utilization	Total Number of Beneficiaries Tested for any Sexually Transmitted Disease (See table
Monitoring	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	15-20 years	21-44 years	45 years and	Total Unduplicated		
	and under	old	old	older	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

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

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

Table 4: Contraceptive Utilization by Age Group per Demonstration Year

Effectiveness	Users of Contraceptives

^{**}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.

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

	Femal	e Tests	Total Tests	
Test	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

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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.

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Healthy Texas Women Approval period: January 22, 2020 through December 31, 2024

Attachment D Approved Evaluation Design

Healthy Texas Women Section 1115 Demonstration Waiver Evaluation Design



As Required by Centers for Medicare and Medicaid Services

Texas Health and Human
Services Commission

November 2021

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1. Background

Texas has the fifth highest birth rate in the United States (13.2 births per 1,000 women), with almost 380,000 births in 2018 (Texas Health and Human Services Commission, 2019). Thirty percent of pregnancies in Texas are unintended (Texas Department of State Health Services, 2019), and approximately half of the state's births are paid for by Medicaid (Texas Health and Human Services Commission, 2019). Despite promising trends in several Texas birth indicators over the last decade—including reductions in infant mortality, teen birth rates, and smoking during pregnancy—serious public health challenges remain relating to prepregnancy obesity, maternal diabetes, and maternal hypertension (Kormondy & Archer, 2018; National Center for Health Statistics, 2020). Moreover, Texas continues to report higher than average rates of preterm birth and low birthweight, both of which affect the Medicaid population at a disproportionate rate and carry short- and long-term consequences (Texas Health and Human Services Commission, 2019). Rates of postpartum depression also exceed national averages, with 15.6 percent of Texas women reporting depressive symptoms after the birth of a child in 2017 compared to 12.5 percent nationally (Texas Department of State Health Services, 2020; Centers for Disease Control and Prevention, 2020). Collectively, these trends highlight the important role of the state and its federal partners in supporting family planning, preconception, and interconception health care services.

Overview of Women's Health Programs

Historically, Texas has delivered women's health and family planning services through numerous programs administered by both the Texas Health and Human Services Commission (HHSC) and Texas Department of State Health Services (DSHS). In 2014, the Texas Sunset Advisory Commission reviewed the State's health agencies and recommended Texas women's health care programs be consolidated to improve service and efficiency for clients and providers. In

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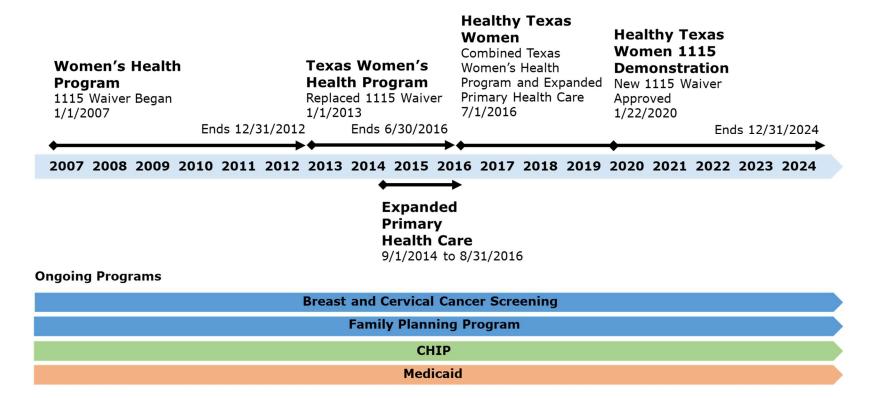
¹ In 2018, the preterm birth rate was 10.8 percent for Texas and 10.0 percent nationally. The rate of low birthweight was 8.5 percent for Texas and 8.3 percent nationally (Texas Health and Human Services Commission, 2019).

response, the Texas Legislature directed HHSC to consolidate the state's women's health services and appropriated an additional \$50 million to the new programs.

On July 1, 2016, HHSC launched a state-funded program called Healthy Texas Women (HTW) to combine the services of programs providing family planning and primary care services to low-income women ages 15-44. HTW merged the Texas Women's Health Program (TWHP) administered by HHSC and the Expanded Primary Health Care (EPHC) program administered by DSHS. Two other HHSC programs—the Breast and Cervical Cancer Services (BCCS) program and Family Planning Program (FPP)—continue to provide screening and/or family planning services to low-income women [Figure 1]. The Children's Health Insurance Program (CHIP) and Medicaid also provide services to low-income women, but women enrolled in either of these programs are not eligible for HTW.

Prior to the launch of HTW, women could be enrolled in multiple family planning/women's health programs depending on need and eligibility. On July 1, 2016, eligibility guidelines were revised to automatically enroll women eligible for multiple programs into the most comprehensive program for which they qualify. For example, individuals who meet eligibility criteria for HTW, BCCS, and FPP would be enrolled in HTW as it offers services not available in the other programs, such as immunizations, and preventative and treatment services for conditions related to family planning.

Figure 1. Women's Health Programs in Texas, 2007 to present



Healthy Texas Women

The goal of HTW is to increase access to women's health and family planning services to avert unintended pregnancies, positively affect the outcome of future pregnancies, and positively impact the health and well-being of women and their families. Since its launch in 2016, HTW client enrollment has increased by 219 percent to an average monthly caseload of 279,671 unduplicated clients in state fiscal year 2019 (Texas Health and Human Services Commission, 2020).

The number of active billing providers has also expanded in recent years, with 3,057 unique providers receiving reimbursement for HTW program services in state fiscal year 2019 (Texas Health and Human Services Commission, 2020). The available provider network, however, is considerably larger since any HTW certified Medicaid provider who provides a covered service to an HTW enrolled woman may bill HTW on a fee-for-service (FFS) basis. In state fiscal year 2018, HTW clients could receive covered services from a network of approximately 33,876 HTW certified providers.²

Utilization of family planning services under the HTW program is associated with significant savings to state and federal budgets. In state fiscal year 2019 alone, participation in the HTW program resulted in an estimated 15,302 averted births, generating a net savings of \$13.0 million to the state and \$152.2 million in Medicaid federal funds (Texas Health and Human Services Commission, 2020).

4

² Provider count defined as unique full National Provider Identifier (NPI)-Texas Provider Identifier (TPI) combinations certified to provide HTW services (Unpublished statistical file).

Program Eligibility and Enrollment

The eligibility criteria for the state-funded HTW program operating prior to the Demonstration were as follows [1 Texas Administrative Code (TAC) §382.7]:

- Ages 15 through 44
 - ▶ Minors³ ages 15 through 17 must have a parent or legal guardian apply, renew, and report changes to her case on her behalf;
- U.S. citizen or qualified immigrant;
- Reside in Texas;
- Not pregnant;⁴
- Does not receive benefits through a Medicaid program that provides full benefits, CHIP, or Medicare Part A or B, and does not have any other creditable health coverage;⁵ and
- Net family income at or below 200 percent of the federal poverty level (FPL).

Clients could apply for the state-funded HTW program in any of the following ways:

- On HealthyTexasWomen.org;
- On YourTexasBenefits.com;
- From a local benefits office of HHSC, an HTW provider's office, or any other location that makes HTW applications available;
- By calling 2-1-1; or
- By any other means approved by HHSC.

To prevent gaps in coverage and improve interconception health, eligible women whose Medicaid for Pregnant Women coverage period was ending (last day of the month in which the 60-day postpartum period ends) were automatically enrolled in

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³ "Minor" is defined as a person under 18 years of age who has never been married and never been declared an adult by a court (1 TAC §382.5). The HTW Demonstration is available to women ages 18-44, however Texas will continue to serve women ages 15-17 who meet all other HTW program requirements through non-Medicaid funded programs.

⁴ Clients who became pregnant while enrolled in HTW were no longer eligible for HTW but may have been eligible for Medicaid for Pregnant Women.

⁵ Applicants may not have had creditable health coverage that covered the services HTW provides, except when an applicant affirmed, in a manner satisfactory to HHSC, her belief that a party may have retaliated against her or caused physical or emotional harm if she assisted HHSC (by providing information or by any other means) in pursuing claims against that third party (1 TAC §382.7).

HTW if they were not otherwise eligible for Medicaid, CHIP, Medicare Part A or B, and did not have other creditable health coverage.

Once individuals were determined eligible or transitioned into HTW, they were able to receive HTW services for a continuous 12-month period.

Covered Services

The state-funded HTW program offered a range of services aimed at improving preconception health for women, reducing the number of unintended pregnancies, and positively affecting birth outcomes. Most clients received services by visiting a participating clinic or physician. In addition, some clients requested prescription refills through their provider without an office visit. Covered services provided at no cost to eligible women included:

- Contraceptive services;
- Pregnancy testing and counseling;
- Preconception health screenings (e.g., screening for obesity, hypertension, diabetes, cholesterol, smoking, and mental health);
- Sexually transmitted infection (STI) services;
- Pharmaceutical treatment for the following chronic conditions:
 - Hypertension;
 - Diabetes;
 - High cholesterol;
- Breast and cervical cancer screening and diagnostic services:
 - Radiological procedures including mammograms;
 - Screening and diagnosis of breast cancer;
 - Diagnosis and treatment of cervical dysplasia;
- Immunizations; and
- Screening for and pharmaceutical treatment of postpartum depression

The Demonstration

On June 30, 2017, HHSC requested approval of an 1115 Demonstration Waiver to increase access to, and participation in, the HTW program. The 1115 Demonstration Waiver for the HTW program (HTW Demonstration) is designed to further the goals of Title XIX of the Social Security Act (Medicaid) by increasing and strengthening coverage for low-income women in Texas through the provision of a unique benefit package for women who would not otherwise be eligible for family planning and preventive services under Texas Medicaid. Additionally, the HTW Demonstration is

designed to improve health outcomes for the Medicaid population by providing preconception and interconception care to women who would be eligible for Medicaid coverage if they were pregnant, with the goal of improving birth outcomes and supporting optimal birth spacing.

On January 22, 2020, the Centers for Medicare and Medicaid Services (CMS) approved Texas's HTW Demonstration for a five-year period from January 22, 2020 to December 31, 2024. The Special Terms and Conditions (STCs) that govern the HTW Demonstration authorize HHSC to waive application of the following Medicaid requirements under the approved waiver:

- **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.
- 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.
- **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.
- 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.
- **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. Specifically, state law requires HHSC to ensure that no money spent for the purpose of HTW is used to perform or promote elective abortions or to contract or affiliate with entities that do so (Texas Human Resources Code §32.024(c-1)).

Demonstration Population

The HTW Demonstration is available to women ages 18 through 44 who meet all other eligibility requirements of the state-funded HTW program. Texas will continue to serve women ages 15 through 17 who meet all other HTW program requirements through non-Medicaid funded programs. Updates to application, verification, and redetermination processes under the HTW Demonstration include required modifications such as the implementation of a reasonable opportunity period and transition to the use of Modified Adjusted Gross Income (MAGI) for income eligibility determinations.

Beneficiaries ages 18-44 receiving services under HTW were automatically transitioned into the HTW Demonstration without a gap in coverage. Similar to the state-funded HTW program, women ages 18 through 44 years of age whose Medicaid for Pregnant Women⁷ coverage period is ending are automatically enrolled in the HTW Demonstration if they are not otherwise eligible for Medicaid benefits, Medicare Part A or B, or CHIP, and they do not have other creditable health coverage.

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⁶ Demonstration eligibility is limited to individuals ages 18 to 44 who are U.S. citizens or qualified immigrants, reside in Texas, are not currently pregnant, and have a net family income at or below 200 percent FPL. In addition, women may not be eligible for or currently receiving benefits under Medicaid, CHIP, or Medicare Part A or B, and may not have other creditable health insurance coverage.

⁷ Refers to the Medicaid eligibility group identified under Section 1902(a)(10)(A)(i)(III) of the Social Security Act.

HHSC projects the following number of individuals will be eligible for the HTW Demonstration during each year of the waiver:

Table 1. Projected Population Eligible for the HTW Demonstration

Calendar Year	Projected Population ¹
2020	689,600
2021	701,100
2022	713,000
2023	725,200
2024	737,600

Notes. ¹ Reflects HHSC Center for Analytics and Decision Support projections based on U.S. Census Bureau, 2015-2018 American Community Survey Samples for Texas; population projections by Texas Demographic Center, Office of the State Demographer at the University of Texas at San Antonio; and, pregnancy statistics from the Texas DSHS Center for Health Statistics. Population projections may be affected by the COVID-19 pandemic due to temporary Medicaid eligibility changes and potential increases in the number of individuals meeting income eligibility requirements as a result of the pandemic's economic impact.

Demonstration Covered Services

The HTW Demonstration provides women's health and family planning services at no cost to eligible women in Texas. HTW Demonstration services were implemented on February 18, 2020. Covered services were initially the same as those provided through the state-funded HTW program.⁸ In December 2020, HHSC submitted an amendment to the HTW 1115 Demonstration waiver to incorporate additional services in accordance with Texas Health and Safety Code, Section 32.102, which requires HHSC to develop an enhanced, cost effective, and limited postpartum care services package for women enrolled in HTW (referred to as HTW Plus).⁹ HTW Demonstration covered services can be categorized into four benefit types outlined in the HTW Demonstration STCs.

⁸ "Covered service" is defined in 1 TAC §382.5 as a medical procedure for which HTW will reimburse an enrolled health care provider. Covered and non-covered services for the statefunded HTW program are listed in 1 TAC §382.15.

⁹ At the time of writing, the state's amendment seeking to incorporate HTW Plus services into the HTW 1115 Demonstration was pending CMS approval. Texas began offering HTW Plus services through general revenue funds starting September 1, 2020. Based on CMS direction, HHSC incorporated the HTW Plus services into the evaluation plan. If CMS does not approve the amendment, adjustments to this evaluation design may be necessary.

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 Social Security Act, including:

- FDA-approved methods of contraception;
- Contraceptive management, patient education, and counseling;
- Pelvic examinations with a family planning diagnosis;
- STI/sexually transmitted disease (STD) testing and treatment services; and
- Drugs, supplies, or devices related to women's health services described above.

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. 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 provided under this Demonstration include:

- Drugs for vaginal infections/disorders, other lower genital tract and genital skin infections/disorders, and urinary tract infections.
- Other medical diagnosis, treatment, and preventive services that are routinely provided pursuant to family planning services in a family planning setting.
- Treatment of major complications arising from a family planning procedure such as:
 - Treatment of a perforated uterus due to an intrauterine device insertion;
 - ➤ Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
 - ▶ Treatment of surgical or anesthesia-related complications during a sterilization procedure.

Preconception Care Services. Individuals eligible under this Demonstration will also receive certain women's health services related to better preconception care and birth outcomes, including:

- Screening and pharmaceutical treatment for cholesterol, diabetes, and high blood pressure;
- Breast and cervical cancer screening and diagnostic services;
- Screening and treatment for postpartum depression;

- Immunizations; and
- Mosquito repellant prescribed by an authorized health professional.

Postpartum Care Services (HTW Plus). HTW clients who have been pregnant in the 12 months prior to enrollment are eligible to receive additional postpartum care services that target the major drivers of maternal mortality in Texas for the duration of their 12-month certification, including:

- Individual, family and group psychotherapy services;
- Peer specialist services;
- Cardiovascular evaluation imaging and laboratory studies;
- Blood pressure monitoring;
- Anticoagulant, antiplatelet, and antihypertensive medications;
- Screening, brief intervention, and referral for treatment for substance use disorders;
- Outpatient substance use disorder counseling;
- Smoking cessation services;
- Medication-assisted treatment for substance use disorders;
- Diabetes monitoring supplies; and
- Asthma treatment services.

Demonstration Providers

The HTW Demonstration operates through a network of independent healthcare providers across the state who offer family planning and women's health services to HTW clients, as well as refer them to secondary providers for service delivery outside their scope of practice.

Primary providers are those who can provide an annual women's health examination and prescribe family planning drugs or devices. Primary providers include, but are not limited to, clinic/group practices, family practices/general practices, physician extenders, and gynecology providers.

Some specialized services, such as psychiatry or limited surgical procedures, may be available to clients with a referral from a primary provider. Specialist providers include, but are not limited to, surgical-related services, radiology, laboratory, and psychiatry providers.

The HTW Demonstration is administered through a FFS delivery model. Under this model, qualified Medicaid providers can provide HTW Demonstration covered services to eligible clients if they meet the following provider eligibility requirements outlined under Title 1 of the Texas Administrative Code §382.17:

- (1) Be enrolled as a Medicaid provider;
- (2) Complete the HTW certification process affirming the HTW provider does not perform or promote elective abortions outside the scope of HTW and is not an affiliate of an entity that performs or promotes elective abortions; and
- (3) Comply with Texas's requirements for all Medicaid providers relating to submission of Medicaid claims, compliance with civil rights, retention of records, and unauthorized charges.

2. Evaluation Questions and Hypotheses

Demonstration Goals

The goals of the HTW Demonstration are to:

- 1. increase access to women's health and family planning services to avert unintended pregnancies, positively affect the outcome of future pregnancies, and positively impact the health and well-being of women and their families;
- 2. increase access to preventive health care, including screening and treatment for hypertension, diabetes, and high cholesterol, to positively impact maternal health and reduce maternal mortality;
- 3. increase access to women's breast and cervical cancer services to promote early cancer detection;
- 4. reduce the overall cost of publicly funded health care (including federally funded health care) by providing low-income Texans access to safe, effective services that are consistent with these goals; and
- 5. implement the state policy to favor childbirth and family planning services that do not include elective abortions or the promotion of elective abortions within the continuum of care or services, and to avoid the direct or indirect use of state funds to promote or support elective abortions.¹⁰

The Evaluation Design includes evaluation questions and hypotheses examining all goals of the HTW Demonstration.

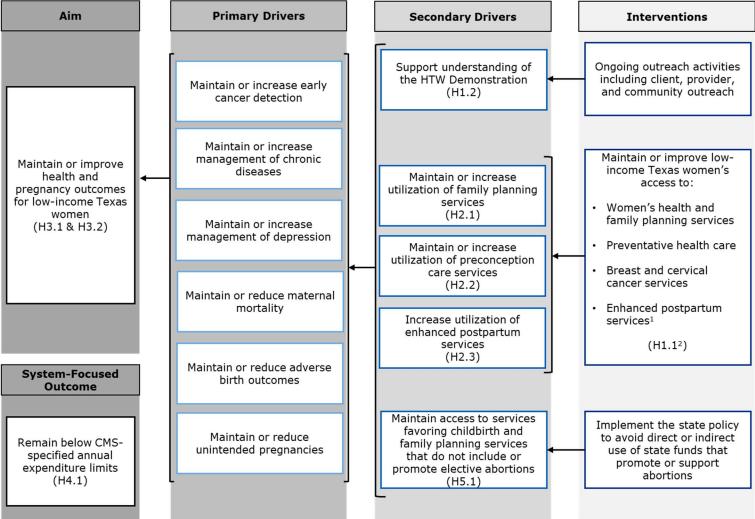
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¹⁰ Texas Human Resources Code §32.024(c-1) directs HHSC to ensure no money spent for the purpose of HTW is used to perform or promote elective abortions or to contract with entities that perform or promote elective abortions or affiliate with entities that perform or promote elective abortions. All HTW providers must certify and attest annually that they do not perform or promote elective abortions or affiliate with individuals or entities that perform or promote elective abortions, as defined in Title 4 of the Texas Health and Safety Code §245.002.

Driver Diagram

The goals of the HTW Demonstration target a variety of client-focused and systemfocused outcomes by providing low-income women in Texas access to women's health, family planning, preventative health care, and breast and cancer care services. Figure 2 depicts the interventions associated with the HTW Demonstration and how they are expected to impact the demonstration's overall goals. Consistent with other CMS Driver Diagrams, the projected causal pathway moves from right to left, beginning with outreach and engagement activities, the provision of services, and implementation of the state policy to avoid direct or indirect use of state funds to support or promote elective abortions. These interventions are expected to motivate utilization of family planning, preconception care, and enhanced postpartum services (secondary drivers). In the next phase, utilization of these services is projected to promote a series of positive health outcomes such as early cancer detection, medication management, and healthy birth outcomes. Positive health outcomes then support the ultimate aim of the HTW Demonstration—to improve health and pregnancy outcomes for low-income women in Texas. A system-focused outcome related to the effective use of public funds to provide women's health care is located outside of the direct causal pathway to signal its broader relationship to the overall efforts of the HTW Demonstration.

Figure 2. HTW Demonstration Driver Diagram



Notes. ¹ Texas began providing enhanced postpartum services using general-revenue funds on September 1, 2019. Inclusion of these services under the HTW Demonstration is pending CMS' approval. ² H1.1-H5.1 refer to the corresponding HTW evaluation hypotheses.

Evaluation Questions and Hypotheses

Five evaluation questions guide this study. The proposed evaluation questions are designed to assess the goals of the HTW Demonstration. Each evaluation question is addressed through a minimum of one corresponding hypothesis that aligns with the interventions, drivers, and outcomes in the HTW Demonstration Driver Diagram [Figure 2]. Subsequent sections operationalize the evaluation hypotheses through a series of measures, study populations, data sources, and analytic methods intended to translate the evaluation questions into quantifiable targets of program performance.

The evaluation questions and hypotheses also promote the objectives of Title XIX by examining how the expansion of family planning and preventative services for low-income women in Texas supports overall health and birth-related outcomes in Texas Medicaid.

Evaluation Question 1. Did the HTW Demonstration increase <u>access</u> to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas?

Hypothesis 1.1. The HTW Demonstration will maintain or increase access to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas.

Hypothesis 1.2. The state's outreach and engagement activities support understanding of the HTW Demonstration.

Evaluation Question 2. Did the HTW Demonstration increase <u>utilization</u> of family planning, preconception care, and postpartum services?¹¹

Hypothesis 2.1. The HTW Demonstration will maintain or increase utilization of family planning services among HTW clients.

¹¹ Evaluation Question 2 does not include family planning-related services. Family planning-related services, while covered per the STCs, are primarily follow-ups to family planning services and are not directly related to the goals of the HTW Demonstration. Additionally, family planning-related services are diverse in scope, making it difficult to combine or interpret measures under this category. CMS approved the exclusion of this service category from Evaluation Question 2 on November 13, 2020.

Hypothesis 2.2. The HTW Demonstration will maintain or increase utilization of preconception care services among HTW clients.

Hypothesis 2.3. The HTW Demonstration will increase utilization of HTW Plus postpartum care services among HTW clients.

Evaluation Question 3. Did the HTW Demonstration improve women's health and pregnancy <u>outcomes</u>?

Hypothesis 3.1. The HTW Demonstration will maintain or improve women's health among HTW clients.

Hypothesis 3.2. The HTW Demonstration will maintain or improve pregnancy outcomes and maternal health among HTW clients.

Evaluation Question 4. Did the HTW Demonstration effectively use <u>public funds</u> to provide women's health care in Texas?

Hypothesis 4.1. The HTW Demonstration will remain at or below the CMS-specified annual expenditures limits.

Evaluation Question 5. How does implementation of the HTW <u>provider eligibility criteria</u> outlined in Goal 5 of the HTW Demonstration affect access to and utilization of women's health and family planning services?

Hypothesis 5.1. The implementation of HTW provider eligibility criteria does not adversely affect access to and utilization of women's health and family planning services.

3. Methodology

The evaluation of the HTW Demonstration (HTW evaluation) is guided by five evaluation questions and ten hypotheses that examine the impact of the HTW Demonstration on access, utilization, health outcomes, and cost, as well as impacts of the HTW provider eligibility criteria. This section summarizes the evaluation design, study populations, and evaluation period for the HTW evaluation as a whole. Subsequent sections provide detailed information for each evaluation question, including the study populations, data sources, analytic methods, evaluation measures, and methodological limitations. Technical specifications for the proposed measures can be found in Appendix E: Detailed Tables.

Data, analytic methods, and reporting will meet the traditional standards of scientific and academic rigor, as appropriate and feasible for each aspect of the HTW evaluation, including evaluation design, data collection, analysis, and reporting. The HTW evaluation will rely on secondary data from HHS sources and primary data collection developed by the external evaluator. The respective limitations of these sources are reported accordingly. Methods outlined here reflect the analytic strategies deemed most appropriate; however, the external evaluator may revise specific methods as they assess key data sources for completeness, relevance, and quality required for the proposed analyses. Necessary revisions to the data and analytic methods outlined in HTW Evaluation will be relayed to CMS in Quarterly Monitoring Reports for the HTW Demonstration and, if deemed necessary by CMS, submitted through a revised Evaluation Design to CMS for approval.

Evaluation Design

A general challenge to the evaluation of the HTW Demonstration is the similarity of its predecessor program. Texas has offered women's health services through a series of programs for more than a decade; while the HTW Demonstration seeks to expand access to these services, it does not substantively change them or the populations receiving them. Accordingly, the HTW Demonstration meets the description of a "long-standing, non-complex, [or] unchanged," program, as specified in Attachment A of the STCs (see "Special Methodological Considerations"). The proposed evaluation design attempts to capture changes resulting from the HTW Demonstration, but observed changes are likely to be modest given the similarity of the counterfactual condition.

In view of these challenges, the HTW evaluation relies on three quasi-experimental designs: a one-group pretest-posttest design, a one-group posttest only design, and a nonequivalent comparison group pretest-posttest design. Most measures are evaluated using a one-group pretest-posttest design due to the longstanding nature of the HTW program. A subset of measures does not have pre-Demonstration data available and will rely on a one-group posttest only design, and several measures under Hypothesis 3.2 are evaluated using a nonequivalent comparison group pretest-posttest design. No evaluation measures use all three designs.

- One-Group Pretest-Posttest Design: This evaluation design relies on repeated observations of HTW clients to monitor changes in the intervention group before and after the HTW Demonstration. Due to the long-standing nature of the HTW program, the pre-HTW Demonstration period is functionally similar to the post-HTW Demonstration period. As a result, advanced techniques for examining changes over time, such as interrupted time series analysis, are not appropriate because changes in the level or slope of outcome measures cannot be directly attributed to programmatic changes associated with the HTW Demonstration. Measures evaluated through a one-group pretest-post-test design will be implemented using descriptive trend analysis (DTA). To strengthen DTA, the evaluation will also leverage benchmarks and subgroup analyses where feasible to help substantiate and contextualize observed trends.
- One-Group Posttest Only Design: This evaluation design relies on measuring outcomes among HTW clients in the post-Demonstration period only. Of the three designs in this evaluation, the one-group posttest only design is most vulnerable to threats to validity and is used only in cases where pre-Demonstration and comparison group data are unavailable. One measure under Hypothesis 1.1 (network adequacy) and hypotheses that use primary data collection (Hypothesis 1.2 and 5.1) are evaluated using a one-group posttest only design. Primary data collection measures evaluated through a one-group posttest only design will be implemented using descriptive statistics and qualitative analysis, where applicable. Network adequacy measures will be examined in the post-Demonstration period through DTA due to the availability of quarterly or annual reports.

 Benchmark and subgroup analyses will be leveraged where feasible to support interpretation of findings.

• Nonequivalent Comparison Group Pretest-Posttest Design: For measures evaluated using a nonequivalent comparison group pretest-posttest design, differences between Medicaid deliveries to women previously enrolled in HTW and Medicaid deliveries to women not previously enrolled in HTW will be compared before and after the HTW Demonstration. The nonequivalent comparison group pretest-posttest design will be implemented using difference-in differences (DID) estimation. DID mimics an experimental study by estimating the effect of an intervention by comparing changes in outcome measures over time for an intervention and comparison group. DID mitigates threats to validity from selection bias and history by accounting for statistical biases in the post-period that could be the result of pre-existing differences between the groups or general trending due to other causes. Measures evaluated using a nonequivalent comparison group pretest-posttest design will also leverage benchmarks and subgroup analyses where feasible.

Subsequent sections provide additional information on the study populations, evaluation periods, and analytic methods for each design.

Study Populations

The target population for the HTW evaluation includes all clients enrolled in the HTW Demonstration; no additional inclusion or exclusion criteria are applied. The target population is conceptually consistent with an intent-to-treat framework in which all women transitioned to or self-enrolled in the HTW Demonstration are considered part of the intervention group, regardless of whether they actively chose to receive services. The HTW evaluation utilizes data from clients enrolled in HTW before the HTW Demonstration as a historical reference group, except for clients 15 to 17 years old, to match the age range of clients in the HTW Demonstration.¹²

The HTW evaluation includes client-, provider-, and system-level analyses. For most measures, population-level data (rather than a sample) will be used to assess processes and outcomes. These data are available at the individual level for both clients and providers, which are the primary units of analyses. Measures relating to clients and providers may be stratified into key demographic subgroups such as age, race/ethnicity, region, or provider type, where applicable.

¹² Texas serves women ages 15 through 17 who meet all other HTW program requirements through non-Medicaid funded programs.

In addition to population-level client and provider data, the evaluation will draw on survey data from the Centers for Disease Control and Prevention's Pregnancy Risk Assessment Monitoring System (PRAMS) survey, which is representative at the state level. These data are used to estimate the population of women in Texas who have recently given birth. Survey subgroup analysis will note the appropriate implications for representativeness and cite confidence intervals where applicable.

Potential Comparison Groups

Because the HTW Demonstration is available statewide and clients are placed in the most comprehensive program for which they are eligible, there are no truly comparable clients in other HHSC programs. However, in keeping with the rigor of the proposed evaluation design, HHSC assessed the viability of two non-HTW comparison groups: 1) the Family Planning Program (FPP), and 2) Medicaid managed care (MMC). FPP is a primarily state general revenue-funded program that provides family planning services to women and men below the age of 64 who live in Texas and have a family income at or below 250 percent of the FPL. MMC includes a potential comparison group of non-pregnant women in STAR or STAR+PLUS managed care plans between the ages of 18 and 44 who have received a family planning-related service. Though the HTW benefit package is largely covered in both comparison programs, differing eligibility requirements, program structures, and funding mechanisms present significant problems for comparative analysis. Due to substantial validity issues arising from these differences—as well as technical issues related to client identification and selection bias—no viable comparison group exists for the HTW evaluation as a whole. For a detailed assessment of each potential comparison group, see Appendix C.

Medicaid-Paid Deliveries

Although there is no viable comparison group for the HTW evaluation overall, information from Medicaid-paid deliveries will be used as a comparison for pregnancy-related measures in the DID study design (Hypothesis 3.2). HHSC estimates that approximately 5-7 percent of Medicaid-paid deliveries in a given year (i.e., 11,000-15,400) are to women who were enrolled in HTW during the previous year. Researchers will identify a random sample of Medicaid-paid deliveries among women not enrolled in HTW during the prior year to serve as a comparison group for pregnancy-related measures. If feasible, women in the Medicaid-paid deliveries comparison group will be matched to women in the intervention group using propensity score matching (PSM) based on observable population characteristics such as age, race/ethnicity, and/or state region. Matching

allows for a comparison between two groups of mothers that are characteristically similar, except for access to HTW services prior to pregnancy.

Evaluation Period

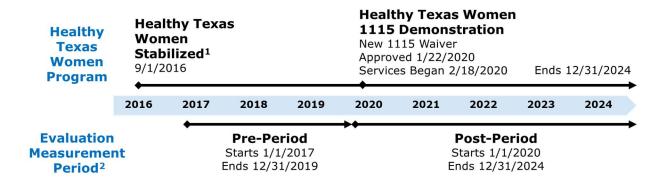
The study period for the HTW evaluation is January 1, 2017 to December 31, 2024 [Figure 3]. This timeframe corresponds to an approximate three-year period before the HTW Demonstration, and a five-year period under the HTW Demonstration. The pre-Demonstration period for the HTW evaluation refers to the period after which the state-funded HTW program consolidated services previously provided by TWHP and EPHC, and ensures the population, services, and data sources are comparable for the pre- and post-Demonstration periods. Though the HTW Demonstration was approved on January 22, 2020, to ensure consistency in metrics and analysis, the post-Demonstration measurement period begins on January 1, 2020 and continues to the end of the approval period on December 31, 2024. CMS has provided guidance stating that the interim and summative evaluation reports should frame the evaluation in alignment with the HTW Demonstration approval period, but for purposes of measurement and analysis may treat the post-Demonstration period as beginning on January 1, 2020.

At this time, the post-period is expected to include the final year of the HTW Demonstration. However, HHSC may truncate the post-period to ensure all submitted claims are complete and the external evaluator has adequate time to complete data analyses for the final report due June 30, 2026.

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¹³ The HTW Demonstration DYs follow a calendar year schedule. The HTW Demonstration was approved on 1/22/2020 and HTW Demonstration services began on 2/18/2020. Because HTW services did not substantially change with implementation of the HTW Demonstration, and to ensure consistent calculation of pre- and post-Demonstration metrics, the post-Demonstration measurement period is adjusted to begin on 1/1/2020. Measures calculated for DY1 will include approximately three weeks of the state-funded HTW program before the HTW Demonstration was approved.

Figure 3. HTW Evaluation Period



Notes. ¹ The state-funded Healthy Texas Women program began on 7/1/2016, but the EPHC program continued to operate for two additional months, ending 8/31/2016. The program environment for women's health services in Texas has been stable since 9/1/2016. ² The HTW Demonstration period is from 1/22/2020 to 12/31/2024. However, the HTW evaluation measurement post-period begins on 1/1/2020 to ensure consistent calculation of metrics in pre- and post-periods.

Some measures under Hypothesis 3.2 use a truncated portion of the study period due to operationalization constraints or source-specific data lags. Study period time frames for individual measures can be found in Appendix E: Detailed Tables.

Access, Utilization, and Health Outcomes

This section details the methods for eight evaluation hypotheses related to access, utilization, and health outcomes. These three domains constitute the bulk of the evaluation and are addressed collectively because, while specific measures vary, the study populations, data sources, and analytic methods are similar. Cost and provider eligibility criteria domains are addressed in subsequent sections. Table 2 reviews the hypotheses for each domain in this section.

Table 2. Evaluation Hypotheses for Access, Utilization, and Health Outcomes

Domain	Hypothesis
Access	Hypothesis 1.1. The HTW Demonstration will maintain or increase access to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas. Hypothesis 1.2. The state's outreach and engagement activities
	support understanding of the HTW Demonstration.
Utilization	Hypothesis 2.1. The HTW Demonstration will maintain or increase utilization of family planning services among HTW clients. Hypothesis 2.2. The HTW Demonstration will maintain or increase utilization of preconception care services among HTW clients. Hypothesis 2.3. The HTW Demonstration will increase utilization of HTW Plus postpartum care services among HTW clients.
Health Outcomes	Hypothesis 3.1. The HTW Demonstration will maintain or improve women's health among HTW clients. Hypothesis 3.2. The HTW Demonstration will maintain or improve pregnancy outcomes and maternal health among HTW clients.

Study Populations

The primary study population for measures related to access, utilization, and health outcomes is women enrolled in the HTW Demonstration. However, several other populations will also be examined to help contextualize access and health outcome measures. Table 3 presents the definitions and approximate population sizes for the various study populations under consideration.

Table 3. Study Populations

Study Population	Definition	N
HTW clients ¹	Eligible women enrolled in HTW.	244,153
HTW clients eligible for HTW Plus ²	Eligible women enrolled in HTW who have been pregnant in previous 12 months. ³	93,333
HTW active billing providers ⁴	Texas Medicaid providers with HTW paid claims.	3,085
Medicaid-paid deliveries ⁵	Women who gave birth while enrolled in or receiving Texas Medicaid.	212,235

Note. ¹ Reflects average monthly unduplicated clients in state fiscal year (SFY) 2018. ² Reflects estimated average monthly HTW Plus caseload during SFY 2021. ³ Pregnancies do not have to result in a live birth for women to be eligible for HTW Plus. ⁴ Reflects unique full NPI-TPI combinations with HTW paid claims in SFY18. ⁵ Reflects unduplicated Medicaid clients with a delivery in SFY16.

Data Sources

The HTW evaluation will leverage several administrative data sources collected by HHSC for reporting and payment purposes to assess the impact of the HTW Demonstration. In addition, external data will be used to estimate rates of unintended pregnancy. Primary data collection by the external evaluator will also be used to explore client and provider perspectives related to the HTW Demonstration.

HHSC Data Sources

- Client-level enrollment files. The client-level enrollment files contain
 information about clients' age, race/ethnicity, county, and the number of
 months the client has been enrolled in HTW. Enrollment data for the HTW
 evaluation will come primarily from an HHSC Structured Query Language
 (SQL) database that is refreshed every April with an eight-month lag, such
 that on April 1 the data would include cumulative enrollment data through
 August 31 of the previous year.
- Delivery Supplemental Payment (DSP) data. DSP data contain supplemental delivery encounter information for clients enrolled in MMC programs. The DSP system is maintained by HHSC with a one-month lag, and may serve as an additional source in the identification of Medicaid-paid deliveries.
- **Medicaid FFS claims data.** FFS claims data contain information on client diagnoses and procedures provided under the FFS delivery model, including Current Procedural Terminology (CPT) codes; International Classification of

Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes; provider identification numbers (National Provider Identifier (NPI), Texas Provider Identifier (TPI)); and other information necessary to calculate individual-level measures. Medicaid claims data have been processed by Texas Medicaid & Healthcare Partnership (TMHP) since January 1, 2004. TMHP is the claims administrator and data warehouse for Texas Medicaid data, and performs internal edits for data quality and completeness as part of the claims adjudication process. FFS claims data for the HTW evaluation will come primarily from an HHSC SQL database that is sourced from TMHP and refreshed every April with an 8-month lag, such that on April 1 the data would include cumulative claims through August 31 of the previous year.

- Medicaid Managed Care (MMC) encounter data. MMC encounter data
 contain information on client diagnoses and procedures provided under the
 MMC delivery model, including the relevant CPT codes, ICD-10-CM codes,
 NPIs, TPIs, and other information needed to calculate individual-level
 measures. Like FFS claims, MMC encounters are housed by TMHP and subject
 to an approximate eight-month lag.
- **Network adequacy reports.** HHSC developed a methodology for assessing network adequacy annually for the HTW Demonstration based on standards used in the Texas STAR MMC program. The initial methodology for Demonstration Year (DY) 1 relies on distance standards for active HTW Primary Care Providers (PCPs) and all HTW-enrolled pharmacies. The standards vary across MMC service areas¹⁴ and county type (metro, micro, or rural). At the time of writing, HHSC was working to establish performance standards for DYs 2-5. Performance standards will set a minimum percentage of HTW beneficiaries who live within the specified distance standards for active HTW PCPs and all HTW-enrolled pharmacies. Reports will be shared with the external evaluator as they become available. Specific information in network adequacy reports include the number HTW clients, the distance standards for active HTW PCPs and all HTW-enrolled pharmacies, the percentage of HTW clients meeting prescribed distance standards, and performance standards (starting in DY2). Network adequacy reports include findings for the state as a whole and for each of the MMC services areas broken down by county type.

¹⁴ A map of MMC service areas in Texas is available via: https://www.hhs.texas.gov/sites/default/files/documents/services/health/medicaid-chip/programs/managed-care-service-areas-map.pdf

- **Pharmacy claims data.** Client-level pharmacy claims contain information about filled prescriptions, including the drug name, dose, date filled, number of days prescribed, and refill information. Pharmacy data for the HTW evaluation will be drawn from an HHSC SQL database that is refreshed every April with an eight-month lag, such that on April 1 the data would include cumulative pharmacy claims through August 31 of the previous year.
- Provider-level enrollment files. Provider-level enrollment files contain information on NPI, TPI, provider location, provider type, provider specialty, and other information relevant to assessing network adequacy. Provider data will be sourced from TMHP and an HHSC SQL database, and are subject to an approximate one-month lag.
- Vital statistics. Vital statistics are maintained by DSHS and include a
 variety of vital records for the state of Texas, including birth records. A birth
 record is a vital document that records a person's birth and includes
 information related to the birth, the mother and her pregnancy history, the
 father, and the newborn. Birth records may serve as an additional source in
 the identification of Medicaid-paid deliveries.

External Data Sources

- Pregnancy Risk Assessment Monitoring System. PRAMS is an annual survey developed by the Centers for Disease Control and Prevention and conducted in 47 states, including Texas. The Texas PRAMS is administered by DSHS to a systematic stratified sample of Texas residents who gave birth to a live infant (n≈3,300 annually). Source data are derived from state birth certificates. The PRAMS survey and associated birth certificate data include measures related to pregnancy intention and insurance coverage (e.g., Medicaid-paid deliveries). PRAMS data include a two-year time lag from the birth year and are representative at the state and regional levels.
- Benchmark data. The evaluation leverages ongoing reporting of state and national benchmarks. Importantly, benchmarks at the state or national level may not be representative of HTW clients and may not be available at the subgroup level (e.g. by race/ethnicity or age) or at the same time intervals as the HTW Demonstration. The sources below may be used to develop evaluation-specific benchmarks, where applicable.
 - ▶ Behavioral Risk Factor Surveillance System (BRFSS) Public Use Data Files
 - National Health Interview Survey (NHIS) Public Use Data Files
 - ▶ Texas Hospital Inpatient Discharge (THID) Public Use Data Files

Primary Data Collection

The perspectives of HTW clients and providers offer valuable insight about the HTW Demonstration not otherwise available through administrative or publicly-available data sets. Primary data collection will assess client and provider perspectives on the HTW Demonstration, including eligibility requirements, covered services, how to access services, and communication channels. 15 The external evaluator will determine the most appropriate primary data collection approach and develop corresponding instruments and/or guides. To the extent possible, the external evaluator will model questions after existing and previously-validated tools, such as the Consumer Assessment of Health Care Providers and Systems (CAHPS), the Biennial Health Insurance Survey, or the National Electronic Health Records Survey, as applicable. The external evaluator should also incorporate Mathematica's best practices for designing and administering beneficiary surveys specific to 1115 demonstration evaluations (Matulewicz, Bradley, & Wagner, 2019). If feasible, the external evaluator should make efforts to assure primary data collection activities target women of different race/ethnicities and geographic regions to ensure different perspectives are represented in the evaluation. Additional details on the requirements for primary data collection, including possible methods, sampling strategy, data analysis, and timing of primary data collection activities, can be found in Appendix D: Primary Data Collection Protocol.

Evaluation Measures

A series of measures has been identified to operationalize hypotheses related to access, utilization, and health outcomes. Table 4 provides an overview of the proposed measures, study populations, data sources, and analytic methods by evaluation hypothesis. Specific details regarding each of the proposed measures can be found in Appendix E: Detailed Tables.

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¹⁵ Primary data collection is also the primary data source for Evaluation Question 5 related to HTW provider eligibility criteria. The external evaluator may combine primary data collection efforts into a comprehensive approach, if feasible.

Table 4. HTW Evaluation Measures – Hypotheses 1-3

Evaluation Hypothesis	Measures	Study Population	Data Sources or Data Collection Methods	Analytic Methods			
related, preconcept	Evaluation Question 1: Did the HTW Demonstration increase <u>access</u> to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas?						
1.1 The HTW Demonstration will maintain or increase access to family planning, family planning-related, preconception care, and postpartum services for low- income women in Texas.	1.1.1 HTW clients 1.1.2 HTW clients who received an HTW service 1.1.3 HTW active billing providers 1.1.4 Network adequacy	 HTW clients HTW active billing providers HTW active billing providers HTW clients 	 Client-level enrollment files FFS claims data Network adequacy reports Pharmacy claims data 	 Descriptive statistics Descriptive trend analysis Subgroup analysis, where applicable 			
1.2 The state's outreach and engagement activities support understanding of the HTW Demonstration.	1.2.1 Motivating factors for HTW enrollment and renewal 1.2.2 Understanding of eligibility requirements 1.2.3 Understanding of HTW benefits 1.2.4 Awareness of how to obtain services 1.2.5 Effectiveness of outreach channels 1.2.6 Effectiveness of HTW Demonstration resources	HTW clients HTW active billing providers	Primary data collection	 Descriptive statistics Thematic content analysis, where applicable Subgroup analysis, where applicable 			

Evaluation Hypothesis	Measures		Study Population	Data Sources or Data Collection Methods	Analytic Methods
Evaluation Question care, and postpartu	n 2: Did the HTW Demonstration m services?		n increase <u>utiliza</u>	tion of family planning	g, preconception
2.1 The HTW Demonstration will maintain or increase utilization of family planning services among HTW clients.	2.1.1 Provision of most effective or moderately effective contraceptive methods 2.1.2 Long-acting reversible contraceptive use 2.1.3 Tests for any sexually transmitted infection/disease	will rease nily es 2.1.2 ents.	HTW clients	 Client-level enrollment files DSP data, if applicable FFS claims data MMC encounter data Pharmacy claims data Vital statistics, if applicable 	 Descriptive statistics Descriptive trend analysis Subgroup analysis, where applicable
2.2 The HTW Demonstration will maintain or increase utilization of preconception care services among HTW clients. ¹⁶	2.2.1 Compliance with cervical cancer screening recommendations	will rease are	HTW clients	 Client-level enrollment files FFS claims data MMC encounter data 	 Descriptive statistics Descriptive trend analysis Subgroup analysis, where applicable

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¹⁶ Hypothesis 2.2 does not include a breast cancer screening measure. Though increasing access to women's breast and cervical cancer services is listed as a goal of the HTW Demonstration, the U.S. Preventative Services Task Force only recommends breast cancer screenings for women ages 50-74 unless there are prior risk factors. Similarly, most validated breast cancer screening measures, including the measure in the 2020 CMS Adult Core Measure Technical Specifications and Resource Manual, are only applicable to women ages 50-74. The HTW Demonstration is only available to women ages 18-44; as a result, most validated breast cancer screening measures are not applicable to HTW clients. CMS approved the exclusion of a breast cancer screening measure on November 13, 2020.

Evaluation Hypothesis		Measures		Study Population		Data Sources or Data Collection Methods		Analytic Methods
2.3 The HTW Demonstration will increase utilization of HTW Plus postpartum care		HTW clients eligible for HTW Plus HTW clients utilizing any HTW Plus postpartum services			•	Client-level enrollment files FFS claims data Pharmacy claims		
services among HTW clients.		Frequency of utilization of HTW Plus postpartum services						
		I the HTW Demonstratio	n ir		n's		ncy	
3.1 The HTW Demonstration will maintain or improve women's health among HTW clients.	3.1.2	Hypertension medication adherence Diabetes medication adherence Cholesterol medication adherence Antidepressant	•	HTW clients	•	Client-level enrollment files FFS claims data MMC encounter data Pharmacy claims data	•	Descriptive statistics Descriptive trend analysis Subgroup analysis, where applicable
		medication management						
3.2 The HTW Demonstration will maintain or improve maternal health and pregnancy outcomes among HTW clients.	3.2.1	Unintended pregnancies	•	Texas residents with a recent live birth	•	PRAMS	•	Descriptive statistics Descriptive trend analysis Subgroup analysis, where applicable
	3.2.1 3.2.2	Pregnancy complications (Gestational diabetes, preeclampsia)	•	HTW clients Medicaid-paid deliveries	•	Client-level enrollment files DSP data, if applicable FFS claims data	•	Descriptive statistics Difference-in-differences estimation
	3.2.4	Adverse birth outcomes (Low birth weight, preterm birth) Severe maternal morbidity			•	MMC encounter data Vital statistics, if applicable	•	Subgroup analysis, where applicable

Analytic Methods

Access, utilization, and health outcomes will be evaluated using a series of quantitative and qualitative methods. This section describes the proposed analytic strategies for examining the measures presented in Table 4. All analytic methods will incorporate subgroup analyses and benchmarks, as applicable, to strengthen the validity of observed outcomes.

Descriptive Statistics

All evaluation measures except open-ended primary data collection questions may be examined through a variety of descriptive and inferential statistics. Descriptive statistics include estimates of central tendency and dispersion. Potential inferential analyses include bivariate statistics, parametric tests (e.g., paired or unpaired t-tests), and non-parametric tests (e.g., McNemar's test, Wilcoxon signed-rank test). The external evaluator will select the appropriate statistical test depending on whether the measure is categorical or continuous, and whether the data meet the assumptions of parametric tests (e.g., normality, independence).

Descriptive Trend Analysis

HTW is a long-standing program within the state of Texas, which precludes the availability of a pre-Demonstration period free of the relevant intervention, a necessary assumption for conducting preferred time-series designs such as interrupted time series. DTA is an alternative approach to time-series analysis for programs that do not have substantial programmatic changes or appropriate comparison groups. DTA plots and analyzes time-series data calculated at equally spaced intervals to explain patterns in selected measures over time. DTA typically focuses on identification and quantification of a trend through the use of correlation coefficients and ordinary least squares regression. The primary intervention point for DTA will be the evaluation post-period (January 1, 2020), however the external evaluator should attempt to account for or provide context for confounding environmental and historical factors, as necessary. DTA will be used for all measures with pre- and post-Demonstration data available, except several measures under Hypothesis 3.2 which will leverage DID due to availability of a comparison group. DTA will also be used for one measure under Hypothesis 1.1 (network adequacy) with post-Demonstration data only.

Unintended Pregnancies

Hypothesis 3.2 includes a measure of unintended pregnancies (3.2.1) derived from the PRAMS survey. The PRAMS survey is administered to a statewide sample of Texas women with a recent live birth and is not specific to HTW clients. Approximately half of the births in the PRAMS sample are paid by Medicaid. Like most evaluation measures, DTA will be used to examine changes in the unintended pregnancy rate among women with Medicaid-paid births. Given the availability of longitudinal data, the external evaluator may also generate a comparative time series to help determine whether movement in rate of unintended pregnancies is specific to the Medicaid population or the result of broader trends, if feasible. Potential comparison groups include private insurance deliveries (Texas PRAMS), all non-Medicaid deliveries (Texas PRAMS), or Medicaid deliveries in other states (Comparison State PRAMS).

Difference-in-Differences Estimation

All measures under Hypothesis 3.2, except 3.2.1, will rely on DID analysis. DID mimics an experimental study by examining the average change in individual-level outcomes for intervention and comparison group clients over time, and helps to mitigate selection concerns that might exist with a single cross-sectional comparison between groups.¹⁷ The regression equation for a simple DID model is:

$$Y_{ist} = \beta_0 + \beta_1(HTW group_s) + \beta_2(time_t) + \beta_3(HTW group_s * time_t) + \varepsilon_{ist}$$

Where Y is the outcome measure; β_0 reflects the level of the measure when treatment group and time specifications are set to zero; β_1 estimates main effect of the dummy-coded treatment group; β_2 estimates the main effect of the dummy-coded time variable; β_3 estimates the interaction effect between the treatment group and time (i.e., the treatment effect); and ε is an error term. Additional covariates may be added to determine the effect of certain provider or client characteristics.

¹⁷ If selection bias between the intervention and comparison groups is not consistent over time, bias may be introduced into the DID model. To help account for potential selection threats, the evaluator may choose to employ balancing techniques such as PSM prior to conducting DID analyses. Implementing PSM during the sample identification phase may help reduce potential bias originating from differences in observed characteristics between the intervention and comparison groups.

The traditional DID model relies on linear regression, which assumes a linear relationship between normally distributed independent and dependent variables. Several measures under Hypothesis 3.2 are based on dichotomous variables, which may require adjustments or corrections to the model. For example, because of known challenges involved in the application and interpretation of non-linear DID models, especially regarding interaction terms (Athey and Imbens, 2006; Ai and Norton, 2003), linear models are often used to preserve interpretability of the treatment effect coefficient. Bootstrapping adjustments can be made to correct for heteroscedasticity and autocorrelation that arise from linear modeling under these circumstances (Bertrand, Duflo, and Mullainathan, 2004). However, other corrections or alternative models may be necessary.

Qualitative Analysis

The appropriate methods for qualitative analysis will depend on the external evaluator's primary data collection instrument. If the external evaluator develops a survey with a limited number of open-ended questions, the external evaluator may review open-ended responses to supplement or expand upon quantitative survey results analyzed using descriptive statistics. If the external evaluator adopts a less prescriptive approach, such as focus groups or interviews, more advanced qualitative techniques will be required, such as thematic content analysis. Thematic content analysis is a qualitative analytic approach that identifies and codes patterns or themes in the data using inductive or deducting reasoning (Vaismoradi, Turunen, & Bondas, 2013). A strength of thematic content analysis is its ability to examine similarities and differences in the perspectives of study participants (Nowell, Norris, White, & Moules, 2017). As with quantitative approaches to data analysis, the external evaluator should incorporate subgroup analyses, where applicable.

Methodological Limitations

Considerations for Statistical Testing

Most measures in this evaluation draw on the entire HTW population. ¹⁸ As a result, observed changes in the evaluation measures reflect the population parameter rather than a sampling estimate. Parametric tests of hypotheses rely on sampling theory to produce estimates of sampling error, which make statistical testing, coefficient estimators, and standard errors meaningful. With population-level data, the application of sampling theory that undergirds inferential statistics (e.g., t-tests) is not meaningful in the traditional sense because there is no sample from which to make inferences about the population. Nevertheless, the external evaluator may apply statistical testing to observed population differences to better understand the magnitude of observed changes.

Threats to Internal and External Validity

Results from the analyses above should be interpreted alongside several limitations. The most salient threat to internal validity for most evaluation measures is history—the possibility that other external factors affected the selected measure rather than activities carried out under the HTW Demonstration. For example, economic shocks such as a recession could increase the population eligible for the HTW Demonstration without producing a concomitant rise in HTW providers, affecting network adequacy measures. The external evaluator will attempt to identify and control for simultaneous influences on selected measures over the study period. For example, measures with a comparison group may be able strengthen causal inference by comparing to trends among individuals exposed to the same external factors. Ultimately, however, sufficiently accounting for all external factors, particularly for measures without a viable comparison group to net out their influence, may not be possible.

An additional threat to internal validity is selection, or systematic differences in client characteristics that confound the observed effect. For example, minor changes to the HTW eligibility criteria from the pre- to post-Demonstration periods

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¹⁸ Only measures under Hypothesis 1.2, Hypothesis 3.2, and Hypothesis 5.1 rely on samples rather than full population data. Samples under these hypotheses come from primary data collection, PRAMS survey data, and the random sample of comparison group births used for pregnancy-related measures.

may introduce subtle changes to the volume and makeup of the caseload over time. The most substantial change in eligibility criteria from pre- to post-Demonstration is the revised minimum age criterion, which can be replicated in the historical reference group. However, more modest changes to the eligibility criteria, such as the implementation of a reasonable opportunity period or the use of MAGI for income eligibility determinations, may impact HTW caseloads in subtle ways. Because the transition to MAGI eligibility criteria did not happen immediately upon implementation, fade-in effects from this change may not be separable from broader effects of the HTW Demonstration. Another example of selection is the systematic difference between Medicaid deliveries to women previously enrolled in HTW and those to women not previously enrolled in HTW (Measures 3.2.2-3.2.5). Despite inherent differences between these groups, results from the DID model are not subject to bias if selection effects are consistent over time; nevertheless, the external evaluator should consider the use of matching techniques to further reduce selection threats, if feasible.

To help counter threats to internal validity, the HTW evaluation examines access, utilization, and health outcomes through multiple measures, study populations, and evaluation designs to better understand observed changes under the HTW Demonstration. The use of multiple methods acts as a robustness check on any single measure or technique and helps to strengthen evaluation conclusions.

Given the statewide nature of the HTW Demonstration, external validity concerns are negligible since observed results will necessarily apply to eligible populations in the state. However, subgroup analysis will provide insight into how selected measures vary by demographic and geographic characteristics, and whether the HTW Demonstration has differential effects across these groups.

Data Source Limitations

The HTW evaluation relies primarily on secondary data from HHS sources given the availability of this information for the entire HTW population. However, the central purpose of administrative claims and encounters data is to collect information for billing purposes, not to conduct research. Claims and encounters, for example, do not include specific health information such as a newborn's birthweight or a patient's A1c levels, only a broad birthweight category or that an A1c test was performed. This limitation is widely recognized in health services research. Nevertheless, many of the evaluation measures are validated and commonly used for research purposes.

Another limitation associated with the use of administration data is data lags, which pose a challenge to measuring and reporting changes in a timely manner (Schoenberg, Heider, Rosenthal, Schwartz, & Kaye, 2015). Measures using FFS claims or MMC encounters require an approximate 8-month data lag for claims adjudication. Measures related to deliveries and pregnancy outcomes are subject to longer data lags of approximately one year due to the time required to combine information from FFS claims, MMC encounters, and DSP data. To the extent that newborn claims are also needed to identify adverse birth outcomes, a mother-baby crosswalk must be constructed using an established methodology of conditional probabilistic matching, which is subject to additional lag. In addition to data lags, birth spacing measures require additional time to allow for the identification of subsequent births.¹⁹

Unintended pregnancy measures based on the PRAMS survey are also limited by the source data. PRAMS data are based on a sample of all Texas births, approximately half of which are paid by Medicaid. These data have the ability to report unintended pregnancies for Medicaid births as a group but are not able to specifically identify those to former HTW clients, making the measure crudely targeted to the HTW program. At the Medicaid subgroup level, confidence intervals associated with the rate of unintended pregnancy are fairly wide (e.g., 5-6 percentage points), hampering the ability to detect meaningful changes in the point estimates over time. In addition, PRAMS data are collected annually, but published on a two-year time lag due to federally required timelines. Together, these data limitations create problems examining changes over time and reduce the likelihood of detecting statistically significant differences.

Conclusions derived from qualitative data analysis will be susceptible to common threats to validity, such as selection or sampling bias, recall bias, and social desirability bias. Primary data collection is also limited to post-Demonstration perspectives due to the timeline of primary data collection activities. Primary data collection cannot begin until after the external evaluation contract is finalized (by October 1, 2021). Given the groundwork involved in instrument development, sampling, and logistics, the external evaluator will likely initiate primary data collection in DY3. Asking respondents to recall events two or three years in the past and compare those past events to the current Demonstration environment may

¹⁹ HHSC has identified Demonstration year 2 (Calendar year 2021) as the latest available post-period year for birth spacing measures due to the observation time needed to identify subsequent births.

introduce inaccuracies and bias due to mood or emotional state, inaccurate memories, or priming by the data collection process (Polkinghorne, 2005). As a result, using primary data collection to estimate client and provider perspectives prior to the HTW Demonstration presents problems for study validity. Lastly, the number of survey waves will be limited due to study timelines, survey logistics, and the level of effort required to conduct and analyze primary data collection.

Finally, measures 1.1.1, 1.1.2, 2.1.1, 2.1.2, 2.2.1, 3.1.4, 3.2.1, 3.2.4, and 3.2.5 make use of state data sources to identify or develop suitable benchmarks or contextual references. Benchmarks may represent different populations than the clients served by HTW in terms of age, race/ethnicity, income, supplemental insurance, region, or other relevant characteristics. Benchmarks are provided to contextualize measures, and changes in measures over time, but should not be used for direct comparison to the HTW Demonstration due to these differences.

Cost

This section details the methods for Hypothesis 4.1, which assesses cost in the HTW evaluation. One goal of the HTW Demonstration is to ensure the effective use of public funds in the delivery of women's health care in Texas. The state uses the CMS-specified annual expenditures limits to operationalize the effective use of public funds and hypothesizes that the HTW Demonstration will remain below these limits.

Evaluation Measure

Table 5 presents the evaluation measure, study population, data sources, and analytic methods for Hypothesis 4.1. Additional details regarding the proposed measures can be found in Appendix E: Detailed Tables.

Table 5. HTW Evaluation Measure - Hypothesis 4.1

Evaluation Hypothesis	Measures	Study Population	Data Sources or Data Collection Methods	Analytic Methods			
	Evaluation Question 4: Did the HTW Demonstration effectively use public funds to provide women's health care in Texas?						
4.1 The HTW Demonstration will remain at or below the CMS-specified annual expenditures limits.	4.1.1 Per member per month costs	HTW clients	 Demonstration Budget Neutrality Worksheet HHSC calculated per member per month costs in pre-period 	 Descriptive statistics Time series analysis 			

For each year of the HTW Demonstration, CMS assigned a budget neutrality expenditure target that acts as an annual ceiling on per capita costs. The annual per member per month (PMPM) expenditure limits specified in STC 50 are presented in Table 6.

Table 6. Budget Neutrality Annual PMPM Expenditure Limits²⁰

Trend	DY1	DY2	DY3	DY4	DY5
4.6%	\$27.13	\$30.87	\$33.44	\$34.63	\$36.09

As part of the budget neutrality test, HHSC will calculate the actual PMPM cost for each Demonstration year and compare those costs to the CMS-specified annual expenditure limits. PMPM cost measures will also be calculated for the pre-period years 2017-2019.

Study Population

The study population for PMPM costs will be all clients enrolled in HTW.

Data Sources

Budget Neutrality Worksheet. PMPM cost measures for complete
Demonstration years will be sourced from the HTW Demonstration Budget
Neutrality Worksheet that is calculated and reported annually by HHSC
System Forecasting. In addition, the HTW evaluation will use pre-period
PMPM costs generated by HHSC Forecasting using the same methodology.

Analytic Methods

Descriptive Statistics and Descriptive Trend Analysis

PMPM costs will be analyzed for the pre- and post-Demonstration study periods through descriptive statistics and DTA. Descriptive statistics will be used to test for statistical changes between individual time points, or between the pre- and post-periods in aggregate. DTA will be used to assess changes in the annual PMPM measure over time. DTA examines time series data collected at equally spaced intervals to explain patterns in longitudinal data. Trend analyses typically focus on identification and quantification of a trend through the use of correlation coefficients and ordinary least squares regression.

 $^{^{20}}$ Annual PMPM expenditure limits include costs associated with HTW Plus. If CMS does not approval the HTW Plus amendment, annual expenditures should reflect amounts specified in STCs.

Methodological Limitations

As with other measures, PMPM cost measures rely on the entire HTW population. As a result, observed changes reflect the population parameter rather than a sampling estimate. Therefore, the application of sampling theory that undergirds statistical testing (e.g., t-tests) is not meaningful in the traditional sense because there is no sample from which to make inferences about the population. Nevertheless, the external evaluator may apply statistical testing to observed population differences to better understand the magnitude of observed changes.

Cost measures are also limited by threats to internal validity from history—the possibility that other external factors affected the selected measures rather than activities carried out under the HTW Demonstration. For example, an economic recession might increase the number of eligible applicants, some of whom would be automatically enrolled in HTW when applying for Medicaid benefits; these clients may not utilize HTW services at the same rate as existing clients, driving PMPM costs down. To the extent possible, the external evaluator will attempt to identify and account for external influences on cost over the study period.

Provider Eligibility Criteria

The fifth goal of the HTW Demonstration is to implement the state policy to avoid direct or indirect use of state funds that promote or support elective abortions. This section details the methods for Hypothesis 5.1, which assesses the impact of provider eligibility criteria associated with the state policy on access to and utilization of services provided through the HTW Demonstration.

Background

Texas Human Resource Code §32.024(c-1), as added by Senate Bill 7, 82nd Legislature, First Called Session, 2011, requires HHSC to ensure that any funds spent for the purposes of the Medicaid Women's Health Program, or a successor program, are not used to: 1) perform or promote elective abortions; 2) contract with any entity that performs or promotes elective abortions; or 3) contract with any entity that affiliates with entities that perform or promote elective abortions. Senate Bill 7 established September 28, 2011 as the effective date for §32.024(c-1) and HHSC implemented §32.024(c-1) through rules that were effective on March 14, 2012. The current HTW Demonstration began January 22, 2020, almost eight years after the state's provider eligibility criteria went into effect.

The most direct method for examining the impact of the provider eligibility criteria is to examine the period before and after the policy first went into effect. This method would compare the Women's Health Program that operated under a previous 1115 Demonstration from January 1, 2007 to December 31, 2012 to the general-revenue funded Texas Women's Health Program that was implemented on January 1, 2013, soon after the provider eligibility criteria were implemented. HHSC analyzed outcomes associated with the women's health programs over this period in a previously published report in accordance with House Bill 1, 84th Legislature, Regular Session, 2015 (Article II, Health and Human Services Commission, Rider 41; Texas Health and Human Services Commission, 2017). Recreating this analysis would not yield additional information and is outside the scope of the current evaluation, which examines the degree to which the current HTW Demonstration maintains or improves upon the performance of its predecessor program.

Current options for assessing the impact of the of the provider eligibility criteria on the HTW Demonstration are limited to estimates of a hypothetical counterfactual in which the provider eligibility criteria do not exist, or descriptive analyses of the current program environment under HTW provider eligibility criteria.

Estimating A Counterfactual Case through Comparison Groups

As with other demonstration hypotheses, the longstanding nature of the HTW program is problematic for identifying a counterfactual condition that would allow the external evaluator to isolate changes in access and utilization due to the HTW provider eligibility criteria. To do so, the external evaluator would need to compare clients in the HTW Demonstration to a comparison group of similar clients in which the provider eligibility criteria do not exist. HHSC considered several potential comparison groups, each of which raises significant methodological challenges.

1115 Women's Health Program: 2007-2012

One counterfactual for examining the impact of the provider eligibility criteria is the historical women's health care program that existed prior to the implementation of those criteria. While such an analysis is technically feasible, it is methodologically fraught for a number of reasons. Women's health care programs have undergone significant changes since the state policy first went into effect, including changes to program eligibility, covered services, and the surrounding program environment. The program most like the current HTW Demonstration began July 1, 2016, when HHSC consolidated two women's health programs (TWHP and EPHC) into Healthy Texas Women. Texas modeled the HTW Demonstration after the existing Healthy

Texas Women program. It is not possible to determine whether differences between the 2007-2012 Women's Health Program and the current HTW Demonstration are due to the provider eligibility criteria or other factors inherent to the different programs, such as covered services, client characteristics, and historical events (e.g., the 2007-2012 Women's Health Program coincided with the Great Recession and the HTW Demonstration coincides with the COVID-19 pandemic). Ultimately, using a historical cohort from the 2007-2012 Women's Health Program to assess the impact of provider eligibility criteria under the HTW Demonstration would be severely impaired by threats to validity from history, maturation, and other confounds identified above.

Current Medicaid Clients

Another approach to estimating the impact of the provider eligibility criteria is to compare HTW Demonstration clients to current Medicaid clients receiving HTW-like services who are not subject to the provider eligibility criteria. This approach would avoid problems related to confounding factors from historical changes in women's health programming. However, as discussed in the Methodology section, there is no suitable comparison group for the HTW Demonstration in other state programs. Because the HTW Demonstration is available statewide and clients are placed in the most comprehensive program for which they are eligible, individuals receiving full Medicaid benefits have different selection characteristics known to impact health-related outcomes relevant to the evaluation. HHSC considered the viability of two non-HTW comparison groups (FPP and MMC clients), but differing eligibility requirements, program structures, and funding mechanisms present significant problems for comparative analysis.

The use of Medicaid clients to estimate a counterfactual condition in which provider eligibility criteria do not exist would be impaired by numerous validity issues. Even with the use PSM or other balancing techniques designed to correct for selection between groups, it is not possible to sufficiently isolate the impact of provider eligibility criteria from confounding factors. In comparison to HTW clients, Medicaid clients are subject to substantially different eligibility requirements, service packages, delivery systems, and provider networks. As a result, there is no quasi-experimental design that would produce unbiased estimates of the interaction between provider eligibility criteria and evaluation measures using current or historical agency programs.

Focus of Current Evaluation

Given the inability to estimate the impact of the provider eligibility criteria through comparison groups, the evaluation will use primary data collection to solicit client and provider perspectives related to accessing and delivering services under the HTW Demonstration. Primary data collection is the most direct and valid approach to understanding current impacts of the provider eligibility criteria in the absence of claims-based comparative analyses. In addition to primary data collection, the evaluation will estimate the proportion of active family planning providers in Medicaid who deliver services under HTW. Family planning providers in Medicaid include providers delivering services through HTW and other FFS or MMC programs. This measure will provide insight into the scale of the Medicaid provider network operating under the HTW provider eligibility criteria.

Evaluation Measures

All evaluation measures included in this report reflect the state of access, utilization, and health outcomes under the provider eligibility criteria. However, this section presents a subset of measures focused specifically on exploring the implications of those criteria. Table 9 presents the evaluation measures, study population, data sources, and analytic methods related to Hypothesis 5.1. Additional details regarding the proposed measures can be found in Appendix E: Detailed Tables.

Table 7. HTW Evaluation Measures - Hypothesis 5.1

Evaluation Hypothesis	Measures	Study Population	Data Sources or Data Collection Methods	Analytic Methods
	5: How does implementation			
5.1 The implementation of HTW provider eligibility criteria does not adversely affect access to and utilization of women's health and	5.1.1 Proportion of active family planning providers in Medicaid delivering services through HTW	 HTW certified providers HTW active billing providers Medicaid active billing providers 		Descriptive statistics Descriptive trend analysis
family planning services.	 5.1.2 Appointment wait times 5.1.3 Barriers to receiving care 5.1.4 Providers accepting new clients 5.1.5 Barriers to providing care 	HTW clients HTW active billing providers	Primary data collection	 Descriptive statistics Thematic content analysis, where applicable Subgroup analysis, where applicable

Study Population

Evaluation Question 5 will rely on four distinct populations. To help contextualize access to family planning services in the HTW provider network, Measure 5.1.1 will use HTW certified providers, HTW active billing providers, and Medicaid active billing providers to estimate the proportion of active family planning providers in Medicaid delivering services through HTW. The universe of active family planning billing providers for this measure is limited to providers delivering HTW-defined family planning services in either HTW, traditional FFS Medicaid, or MMC, as these benefits are most directly related to women's reproductive health services. Importantly, it is unknown why Medicaid providers offering similar services in Medicaid do not participate in HTW; while some providers may decline to participate due to various program criteria, others may be unaware of the program, unable to accept additional clients, or only offer HTW-like services to specialized populations.

Measures 5.1.2 to 5.1.4 will use random samples of HTW active billing providers and HTW clients. HHSC and the external evaluator will review random samples along key client and provider characteristics and adjust as necessary to ensure samples are representative of their respective populations. Table 8 presents the definitions and approximate population sizes for the various study populations under consideration.

Table 8. Study Populations

Study Population	Definition	Total Population Size ¹
HTW clients²	Women ages 18 to 44 who are U.S. citizens or qualified immigrants and reside in Texas; are not pregnant; have a net family income at or below 200 percent of the FPL; are not eligible for or receiving benefits under Medicaid, CHIP, Medicare Part A or B; do not have other creditable health insurance coverage; and are enrolled in HTW.	244,153
HTW certified providers ³	Texas Medicaid providers who have completed the HTW certification process.	33,876
HTW active billing providers ⁴	Texas Medicaid providers with HTW paid claims.	3,085

Study Population	Definition	Total Population Size ¹
Non-HTW certified Medicaid active billing providers delivering HTW-like services ⁵	Medicaid active billing providers who: are delivering HTW family planning services to women ages 18 to 44 who are not pregnant; did not complete the HTW certification; and do not have an HTW paid claim.	TBD

Note. ¹ Total population sizes do not reflect sample sizes to be used for Measures 5.1.2 to 5.1.4. ² Reflects average monthly unduplicated clients in state fiscal year (SFY) 2018. ³ Reflects unique full NPI-TPI combinations certified to provide HTW services in SFY18. ⁴ Reflects unique full NPI-TPI combinations with HTW paid claims in SFY18. ⁵ HHSC does not track this population as part of Medicaid oversight or monitoring activities. The total population size will be determined by the external evaluator.

Data Sources

The HTW evaluation will leverage administrative data sources and primary data collection to examine effects of the HTW provider eligibility criteria.

- **FFS Claims and MMC Encounter Data.** FFS claims and MMC encounter data have been processed by TMHP since January 1, 2004. TMHP performs internal edits for data quality and completeness. The client-level claims/encounter data contain CPT codes, ICD-10-CM codes, place of service codes, and other information necessary to identify HTW active billing providers and Medicaid active billing providers. An approximate eight-month time lag is needed for claims and encounter data adjudication.
- Provider-level enrollment files. Provider-level enrollment files contain
 information on HTW provider certification, NPI, TPI, provider location,
 provider type, provider specialty, and other information relevant to assessing
 network adequacy. Provider data will be sourced from TMHP and an HHSC
 SQL database and are subject to an approximate one-month lag.

• **Primary data collection.** A sample of HTW clients and HTW providers will be surveyed regarding their experience obtaining or providing HTW-related services under the HTW Demonstration. The external evaluator will identify the method of primary data collection best suited to the evaluation and develop corresponding data collection tools. The external evaluator may include questions related to Evaluation Question 5 in other planned primary data collection activities. Additional details on the requirements for primary data collection, including possible methods, sampling strategy, data analysis, and timing of primary data collection activities, can be found in Appendix D: Primary Data Collection Protocol.

Analytic Methods

Descriptive Statistics and Descriptive Trend Analysis

Descriptive statistics will be used to examine measure 5.1.1 over the pre- and post-Demonstration study periods, and to summarize responses within or across waves of primary data collection under the HTW Demonstration (measures 5.1.2 to 5.1.5).²¹ Descriptive statistics include estimates of central tendency and dispersion. Potential inferential analyses include bivariate statistics, parametric tests (e.g., paired or unpaired t-tests), and non-parametric tests (e.g., McNemar's test, Wilcoxon signed-rank test). The external evaluator will select the appropriate statistical test depending on whether the measure is categorical or continuous, and whether the data meet the assumptions of parametric tests (e.g., normality, independence).

DTA will be used to assess and describe changes in measure 5.1.1 before and after the HTW Demonstration. DTA examines time-series data collected at equally spaced intervals to explain patterns in longitudinal data. Trend analyses typically focus on identification and quantification of a trend through the use of correlation coefficients and ordinary least squares regression. The primary intervention point for DTA will be the evaluation post-period (January 1, 2020), however the external evaluator should attempt to account for or provide context for confounding environmental and historical factors, as necessary.

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²¹ The external evaluator will conduct one or a few waves of primary data collection, depending on study timelines and logistical feasibility.

Thematic Content Analysis

Thematic content analysis will be used to evaluate responses to any open-ended primary data collection questions related to access to and utilization of women's health and family planning services. Through this method, the external evaluator will code responses, and then group codes together using inductive or deductive reasoning as themes emerge (Vaismoradi, Turunen, & Bondas, 2013). Thematic content analysis is well-suited to analyzing diverse and nuanced information collected from study participants.

Methodological Limitations

The most pronounced methodological limitation to examining Hypothesis 5.1 is the lack of a suitable counterfactual to directly assess the effects of the provider eligibility criteria on client-level outcomes. The evaluation estimates the proportion of active family planning providers in Medicaid delivering services through HTW. However, it is unknown why Medicaid providers offering similar services in Medicaid are not also HTW providers; existing data do not provide information on whether providers delivering family planning services outside of HTW meet HTW provider eligibility criteria or whether they would participate in HTW under a different set of criteria. The evaluation also summarizes client and provider perspectives under the provider eligibility policy, but whether their perspectives would differ in the absence of this policy is unknown.

Primary data collection is also limited to post-Demonstration perspectives only due to the anticipated timeline of primary data collection activities. Primary data collection will likely begin in DY3 after the external evaluation contract is finalized (by October 1, 2021). Asking respondents to recall events two or three years in the past and compare those past events to the current Demonstration environment presents problems for study validity. Moreover, the provider eligibility criteria were in effect during both the pre- and post-Demonstration periods; even if client and provider perspectives on the pre-Demonstration period could be collected without bias, differences in perspectives over time would be unrelated to the provider eligibility criteria.

Additionally, due to the reliance on primary data collection, Evaluation Question 5.1 may be susceptible to common threats to validity for survey data, such as selection or sampling bias, recall bias, and social desirability bias. The number of survey waves will also be limited due to study timelines, survey logistics, and the level of effort required to conduct and analyze primary data collection.

Finally, measures 5.1.2, 5.1.3, and 5.1.4 make use of state data sources for benchmarks. Benchmarks may represent different populations than the clients served by HTW in terms of age, race/ethnicity, income, supplemental insurance, region, or other relevant characteristics. Benchmarks are provided to contextualize measures, and changes in measures over time, but should not be used for direct comparison to the HTW Demonstration due to these differences.

Special Methodological Considerations

As noted throughout this evaluation design, the primary challenge to a robust evaluation of the HTW Demonstration is the similarity of its predecessor program. Since 2007, Texas has offered an evolving procession of women's health programs. While the HTW Demonstration seeks to enhance access to these services, it does not substantively change them or the populations receiving them. The proposed evaluation design attempts to capture changes resulting from the HTW Demonstration, but observed changes are likely to be modest given the similarity of the counterfactual condition.

The HTW evaluation will also coincide with program changes associated with the state's other 1115 waiver, known as the Texas Healthcare Transformation and Quality Improvement Program Demonstration Waiver (1115 Transformation Waiver). One component of the 1115 Transformation waiver is the Delivery System Reform Incentive Payment (DSRIP) program, which incentivizes hospitals and providers to meet access-and outcome-related goals. Some providers participating in DSRIP may also provide HTW services. The DSRIP program is scheduled to phase out during the HTW Demonstration. HHSC has developed a DSRIP transition plan that aims to build on delivery system reform through alternate financing models and supporting infrastructure for improving access to care. These efforts are intended to identify strategies, programs, and policies to sustain successful DSRIP activities, however it is possible that the phase-out of DSRIP funding could lead to changes in clinics or providers available to serve HTW clients. HHSC will monitor network adequacy as part of the HTW Demonstration and communicate with CMS regarding any necessary adjustments to the HTW evaluation.

HHSC began providing a set of enhanced, cost effective, and limited postpartum care services (HTW Plus) to a subset of HTW clients in September 2020, approximately eight months after the HTW Demonstration began. Given the overlap between the goals of the HTW Demonstration and HTW Plus, the addition of HTW Plus will likely impact a variety of measures included in the HTW evaluation. Not all

women enrolled in HTW are eligible for HTW Plus; only HTW clients who were pregnant in the year prior to HTW enrollment are eligible for HTW Plus. As a result, the introduction of HTW Plus creates variation in the HTW Demonstration benefit packages available to enrolled clients. The HTW evaluation directs the external evaluator to identify and account for differences resulting from the introduction of HTW Plus, where applicable and feasible. However, because clients eligible for HTW Plus are also postpartum, it may be unclear whether differences in subgroup analyses are the result of HTW Plus services or inherent differences between postpartum and non-postpartum HTW clients. Findings of the evaluation should be interpreted with appropriate context due to these programmatic changes that occurred for a subset of the HTW population after the HTW Demonstration began.

Finally, it should be noted that the HTW Demonstration is being implemented amidst environmental and historical factors which may alter women's health services across the state of Texas. These factors, such as the COVID-19 pandemic and emerging state policies, present significant confounding factors to evaluating the HTW Demonstration. The COVID-19 pandemic presents the largest challenge given its wide-ranging impacts and close proximity to the start of the HTW Demonstration. The pandemic has reordered priorities for both clients and providers in the state. One immediate consequence of the COVID-19 pandemic may be to depress HTW utilization shortly after the onset of the HTW Demonstration due to social distancing measures and shifting health care concerns. The external evaluator may use public use data files on COVID-19 confirmed cases and hospitalizations in Texas to better understand the impact of the pandemic on HTW utilization. For example, if HTW utilization decreases alongside rising COVID-19 cases in Texas (or vice versa), COVID-19 related contextual data could be used to help interpret and contextualize HTW Demonstration findings.

The evaluator should also take care to interpret evaluation findings alongside emerging state policies. For example, a bill was passed during the 87th Texas Legislature, Regular Session, that extends eligibility for Medicaid for Pregnant Women, which may impact the timing of HTW enrollment for clients who transition to HTW following the expiration of Medicaid for Pregnant Women coverage. Additionally, policy-related changes to women's health services outside of the HTW

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 $^{^{22}}$ At the time of writing, the state's amendment seeking to incorporate HTW Plus services into the HTW 1115 Demonstration was pending CMS approval. Based on CMS direction, HHSC incorporated HTW Plus services into the evaluation design. If CMS does not approve the amendment, adjustments to this evaluation design may be necessary.

Demonstration may bias perceptions and feedback related to the HTW Demonstration and women's health services obtained through primary data collection.

Earlier sections of this report have discussed the validity threats associated with time series designs and alluded to the potential for confounding factors to undermine causal inference. COVID-19 and changes to the broader policy landscape in Texas may present such threats. The external evaluator will take care to interpret and present pertinent findings within the appropriate context, carefully formulate primary data collection tools, and adjust the evaluation, where applicable and feasible, such that findings reflect the effects of HTW Demonstration policies.

Communication, Dissemination, and Reporting

The Interim and Summative Evaluation reports will be produced in alignment with the Attachment B of the STCs, *Preparing the Evaluation Report*, and the schedule of deliverables listed in Table 9.

Table 9. Schedule of Evaluation Deliverables

Deliverable	Date
STCs approved for the Healthy Texas Women 1115 waiver	January 22, 2020
HHSC submits draft Evaluation Design Plan to CMS for comments and posts to the state's Demonstration website (within 120 calendar days after approval of Demonstration)	May 21, 2020
HHSC receives comments from CMS	September 3, 2020
HHSC submits draft Evaluation Design (within 97 calendar days of receipt of CMS comments) ¹	December 9, 2020
HHSC receives comments from CMS	September 8, 2021
HHSC submits final Evaluation Design (within 60 calendar days of receipt of CMS comments) and posts to the state's Demonstration website	November 5, 2021
HHSC procures an independent evaluator	February 1, 2022 ²
HHSC submits draft Interim Evaluation Report to CMS for comment	December 31, 2023
HHSC receives comments from CMS (estimated within 60 calendar days) ³	February 29, 2024
HHSC submits final Interim Evaluation Report to CMS (within 60 calendar days of receipt of comments)	April 29, 2024
HHSC submits draft Final Evaluation Report to CMS for comment	June 30, 2026
HHSC receives comments from CMS (estimated within 60 calendar days ³	August 29, 2026
HHSC submits Final Evaluation Report to CMS (within 60 calendar days of receipt of comments)	October 28, 2026

Note. ¹ The Evaluation Design was originally due to CMS within 60 calendar days of receipt of CMS feedback (11/2/2020). CMS approved a 30-calendar day extension on 9/18/2020 and an additional 7-calendar day extension on 12/3/2020, extending the deadline to 12/9/2020. ² The procurement of the external evaluator was originally slated to be completed by 10/1/2021. However, due to delays in receiving CMS feedback on the Evaluation Design Plan, HHSC postponed this date to 2/1/2022. ³ Timeline assumes CMS will provide comments on evaluation deliverable to HHSC within 60 calendar days of initial submission. Should CMS require additional time to provide comments, submission date of final evaluation deliverables will be adjusted accordingly. STC = Special Terms and Conditions. HHSC = Health and Human Services Commission. CMS = Centers for Medicare and Medicaid Services.

State Presentations for CMS

As specified in STC 63, if requested by CMS, Texas will participate in discussions with and/or present to CMS the Evaluation Design plan and/or evaluation findings.

Public Access

Texas will post final versions of the Evaluation Design Plan, Interim Evaluation Report, and Summative Evaluation Report on the state website within 30 days of approval by CMS (STC 64).

Additional Publications and Presentations

The state will comply with CMS requirements relating to review of publications and presentations involving findings from the final evaluation reports (STC 65). In some cases, HHSC may not be aware of publication or presentation activities undertaken by its external evaluator—especially after the external evaluation contract has expired. However, HHSC will keep CMS apprised of any known publication or presentation activities by HHSC or its external evaluator and provide CMS 10 business days to review and comment on such materials where applicable.

Appendix A. Document History Log

Table A1. Document History Log

Status¹	Document Revision ²	Effective Date	Description ³
Baseline	n/a	May 21, 2020	Original Draft Evaluation Design (STC 56)
Revision	2.1	December 9, 2020	Updated based on CMS feedback received September 3, 2020
Revision	3.1	November 5, 2021	Updated based on CMS feedback received September 8, 2021

Note. ¹ Status should be represented as "Baseline" for initial issuances, "Revision" for changes to the Baseline version, and "Cancellation" for withdrawn versions.

STC=Special Terms and Conditions. CMS=Centers for Medicare and Medicaid Services.

² Revisions should be numbered according to the version of the issuance and sequential number of the revision - e.g., "1.2" refers to the first version of the document and the second revision.

³ Brief description of the changes to the document made in the revision.

Appendix B. Independent Evaluator and Budget

The STCs state the HTW Demonstration evaluation must be conducted by an independent evaluator. To meet this requirement, HHSC will identify and contract with an independent external evaluator.

External Independent Evaluator

Required Qualifications

HHSC will select an independent evaluator with the expertise, experience, and impartiality to conduct a scientifically rigorous program evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. The independent evaluator will be required to comply with evaluation reporting requirements and standards outlined in the STCs and summarized in Table 9 above.

Potential evaluation entities will be assessed on their relevant work experience, staff expertise, data management and analytic capacity, experience working with state agency program and research staff, proposed resource levels and availability of key staff, track record of related publications in peer-reviewed journals, and the overall quality of their proposal. In the process of identifying, selecting, and contracting with an independent external evaluator, Texas will act appropriately to prevent a conflict of interest with the independent external evaluator, including the requirement to sign a declaration of "No Conflict of Interest."

HHSC will pursue an interagency contract to secure independent evaluation services from a state university. The contracting process includes development of a project proposal and quote request specifying the Scope of Work, vendor qualifications, vendor requirements, timelines, milestones, and cost estimate template. The cost estimate template will include a breakdown of costs for staffing, fringe benefit, travel, equipment and supplies, data collection, other administrative, and indirect costs. The project proposal and quote request will be sent to a list of Texas state universities, allowing 30 calendar days for response. A team of reviewers at HHSC will be identified prior to the submission deadline of proposals. Each proposal submitted in response to the request will be reviewed by the HHSC review team, which will identify respondents with the best proposal and value. HHSC will make a final decision for contract award based on the strength of the overall proposal and the abilities of the external entity to satisfy the requirements of the project proposal

and quote request and conduct the independent evaluation in the timeframe required. The contracting process begins once an evaluator is selected.

The timeframe for soliciting and contracting for an independent evaluator is 6-12 months from the date an Evaluation Design Plan is approved by CMS. ²³

Evaluation Budget

As required by CMS under STC 59, the evaluation budget must include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. The total budget for the external independent evaluator is estimated to be approximately \$5 million²⁴ for the period from February 1, 2022 to October 31, 2026;²⁵ however, the final budget will not be available until the external evaluation contract is executed. The estimated budget amount will cover all evaluation expenses, including salary, fringe, administrative costs, other direct costs such as software or travel expenses related to primary data collection, as well as indirect costs related to data collection, analysis, and report development.

As part of the contracting process, potential contractors will populate the budget shell [Table B1].

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²³ In September 2021, HHSC determined that waiting to begin the contracting process until the Evaluation Design Plan is approved by CMS would result in serious risks to the evaluator's ability to carry out components of the Evaluation Design Plan, and may jeopardize delivery of the Interim Evaluation Report as required by the STCs. As a result, HHSC began the contracting process without an approved Evaluation Design or final scope of work.

²⁴ The estimated evaluation budget may require revisions to account for expanding federal research interests, especially with regard to resource-intensive components such as primary data collection.

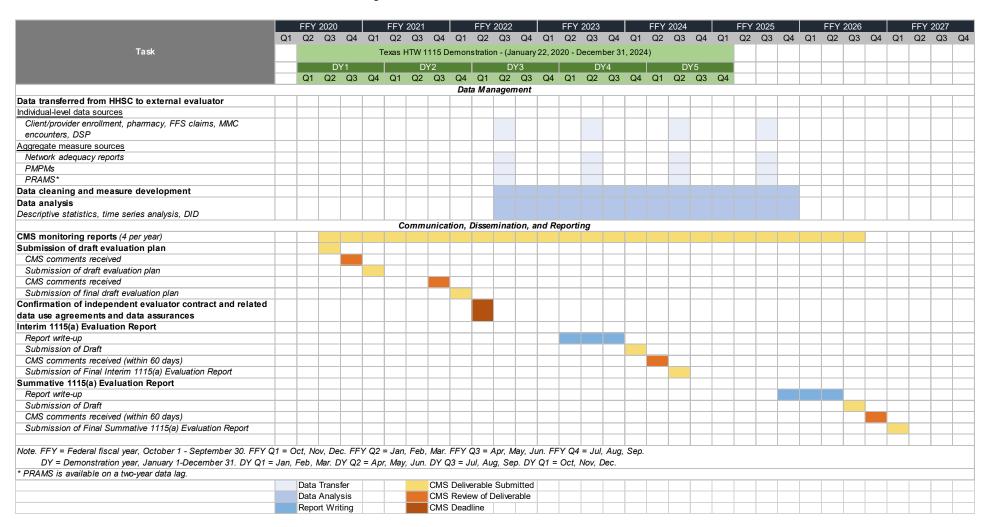
²⁵ The external evaluator timeframe, February 1, 2022 to October 31, 2026, is based on estimated date the contract with the External Evaluator will be executed. The contract timeframe extends through CMS approval of the final Summative Evaluation Report, allowing time for the external evaluator to address any CMS comments/questions.

Table B1. Proposed Evaluation Budget

Category	Total Cost
Personnel	
Fringe	
Travel	
Indirect Costs	
Data Collection	
Equipment/Supplies	
Other Administrative Costs	
TOTAL EVALUATION COST	

Evaluation Milestones

Table B2. Estimated Evaluation Timeline and Major Milestones



Appendix C. Potential Comparison Groups

Table C1. Potential Comparison Group Assessment

	Family Planning Program	Medicaid Managed Care
Population	Clients receiving FPP services	STAR or STAR+PLUS non- pregnant females ages 18-44 with procedure code related to family planning
Advantages	 Eligibility criteria include a similar FPL (<250% FPL) Covered services are similar to HTW 	 May receive full HTW service array Ability to track Medicaid IDs over time
Disadvantages	 Eligibility determined at FPP clinics. Program does not have "enrolled" clients, only utilizers. While uncommon, some utilizers may also be HTW clients. Program relies on programspecific IDs that cannot be crosswalked to Medicaid IDs. Clients cannot be "followed" into Medicaid claims or birth records. Program has annual funding cap that results in seasonal variation in paid claims utilization. No pharmaceutical treatment for diabetes, high blood pressure, or high cholesterol. Program primarily serves non-citizens up to 250% FPL, or citizens between 200 and 250% FPL, due to enrollment hierarchy that would otherwise place clients in Medicaid or HTW. 	 Potential comparison clients have very lowincome (14%-16% FPL) or are recipients of SSI for the Aged and Disabled. HTW does not include similar clients, as they would be enrolled in Medicaid instead. Potential comparison clients receive more comprehensive services under the Medicaid state plan; positive outcomes observed in the HTW population would likely be due to population characteristics (selection bias) rather than the HTW benefit package.

Appendix D. Primary Data Collection Protocol

Primary data collection is a critical component of the HTW evaluation. The evaluation design relies on primary data collection to address 2 evaluation questions, 2 hypotheses, and 11 corresponding measures, outlined in Table D1 below. While the external evaluator is ultimately responsible for developing and executing the primary data collection protocol, this appendix outlines the expectations of HHSC and CMS related to primary data collection for the HTW evaluation. The external evaluator's ability to execute the primary data collection protocol outlined in this appendix is dependent on completion of prerequisite preparations for primary data collection (e.g., execution of the external evaluation contract, development and CMS approval of primary data collection tools, and IRB approval). Delays in these processes may alter this primary data collection protocol. Necessary adjustments or refinements to the plans outlined in this Appendix will be relayed to CMS in Quarterly Monitoring Reports for the HTW Demonstration. CMS may provide feedback on proposed adjustments or refinements to the primary data collection protocol, when necessary.

Methods of Primary Data Collection

Primary data collection activities for the HTW evaluation will rely primarily on a beneficiary survey and a provider survey. If feasible given available resources and timelines, the evaluator may also conduct focus groups with HTW clients to gather more in-depth or specific information about beneficiaries' perceptions of the HTW Demonstration. The evaluator should use focus groups only when there is an appropriate need, such as measures which would benefit from greater exploration (e.g., impacts of various Demonstration policies on access to care, or perceptions on barriers to care). Table D1 outlines possible primary data collection methods by evaluation question.

Table D1. Proposed Methods of Primary Data Collection

Evaluation Hypothesis	Purpose of Primary Data Collection	Corresponding Measures	Targeted Populations	Method(s) of Primary Data Collection
Evaluation Question 1: Did the HTW Demonstration increase access to family planning, family planning- related, preconception care, and postpartum services for low- income women in Texas?	Gather perceptions on the extent to which outreach and engagement activities support understanding of the HTW Demonstration.	 1.2.1 Motivating factors for HTW enrollment and renewal 1.2.2 Understanding of eligibility requirements 1.2.3 Understanding of HTW benefits 1.2.4 Awareness of how to obtain services 1.2.5 Effectiveness of outreach channels 1.2.6 Effectiveness of HTW Demonstration resources 	 HTW beneficiaries HTW providers 	 Print and/or online beneficiary survey Print and/or online provider survey Focus groups with beneficiary survey respondents, if feasible
Evaluation Question 5. How does implementation of the HTW provider eligibility criteria outlined in Goal 5 of the HTW Demonstration affect access to and utilization of women's health and family planning services?	Gather perceptions on access and barriers to receiving and delivering care under the HTW provider eligibility criteria.	 5.1.2 Appointment wait times 5.1.3 Barriers to receiving care 5.1.4 Providers accepting new clients 5.1.5 Barriers to providing care 	 HTW beneficiaries HTW providers 	 Print and/or online beneficiary survey Print and/or online provider survey Focus groups with beneficiary survey respondents, if feasible

Development of Primary Data Collection Tools

The external evaluator will develop corresponding surveys and/or guides to fully address evaluation questions, hypotheses, and measures relying on primary data collection. Appendix D: Detailed Tables provides required topics and example questions for measures relying on primary data collection to support development of primary data collection tools. To the extent possible, the external evaluator will model questions after existing and previously validated tools. The external evaluator should also incorporate Mathematica's best practices for designing and administering beneficiary surveys specific to 1115 demonstration evaluations (Matulewicz, Bradley, & Wagner, 2019). Additionally, the external evaluator should assess relevant external factors at the time of administration, in order to develop and frame corresponding surveys and/or guides carefully, and add contextual background, where necessary, to ensure feedback reflects the HTW Demonstration, rather than external factors such as other state policies or the COVID-19 pandemic, which may confound evaluation results. Draft survey instruments will be shared with CMS prior to implementation.

Sampling Strategy

The external evaluator will develop and execute a sampling strategy for each method of primary data collection (i.e., beneficiary survey, provider survey, and beneficiary focus groups, if feasible). Table outlines expectations for the sampling plan, including the sampling technique, minimum sample requirements, and targeted response rate for each method of primary data collection. The external evaluator may adjust the proposed sampling strategy outlined in Table where necessary based on final client and provider demographics, however care should be taken to ensure the sample is representative at the statewide level (e.g., survey weights may be used to ensure demographic subgroups are appropriately represented in the statewide samples). The evaluator should detail the executed sampling strategy, including any modifications to Table , in Semi-Annual Monitoring Reports submitted to HHSC, ²⁶ and subsequently through the Interim and Summative Evaluation Reports submitted to CMS.

 $^{^{26}}$ HHSC will document details on the executed sampling strategy to CMS via Quarterly Monitoring Reports for the HTW Demonstration.

Table D2. Proposed Sampling Strategy for Primary Data Collection

Method of Primary Data Collection	Study Population (N)	Sampling Technique	Target Analytic Sample ^{1,2}
Print and/or online beneficiary survey	HTW clients (244,153) ³	Stratified random sample of all HTW clients based on key demographic subgroups (e.g., region, age, race/ethnicity)	1,500
Print and/or online provider survey	HTW active billing providers (3,085) ⁴	Stratified random sample of all HTW providers based on key demographic subgroups (e.g., region, provider type) or convenience sample ⁵	300
Focus groups with beneficiary survey respondents, if feasible	Beneficiary survey respondents (1,500)	Purposive sample of beneficiary survey respondents with varying perspectives on the HTW Demonstration (e.g., Maximum Variation Sampling; Etikan, Musa, & Alkassim, 2015)	100

Notes. 1 Target analytic samples for the beneficiary and provider surveys meet conventional criteria for statistical power (0.80) at $\alpha=0.05$. 2 The external evaluator will apply survey weights to ensure survey samples are representative of all HTW clients and providers. 3 Reflects average monthly unduplicated clients in state fiscal year (SFY) 2018. 4 Reflects unique full NPI-TPI combinations with HTW paid claims in SFY18. 5 HHSC is exploring the viability of using provider emails for survey distribution. If valid emails are available for a sufficient sample of HTW active billing providers that is representative of all HTW active billing providers, the external evaluator may choose to send the survey to all HTW active billing providers with a valid email address on record with HHSC.

Primary Data Collection Analytic Methods

Descriptive Statistics

Closed-ended survey questions may be examined through a variety of descriptive statistics. The external evaluator will apply survey weights to close-ended survey items to ensure aggregate results are representative of the HTW client population. Descriptive statistics include estimates of central tendency and dispersion. For survey questions modeled from existing and previously validated tools, the external evaluator should use publicly available state or national benchmarks, where feasible, to support interpretation of findings.

Qualitative Analysis

The appropriate methods for qualitative analysis will depend on the method of primary data collection and type of information gathered. The external evaluator may review open-ended beneficiary and provider survey responses using deductive content analysis. Deductive content analysis is used when the coding structure is based on previous theory and findings and/or a predefined set of hypotheses (Elo & Kyngas, 2008) which may be appropriate for some survey questions (e.g., focused or narrowly defined open-ended items). However, more advanced qualitative techniques will be required for stand-alone open-ended survey questions and HTW client focus groups, if conducted, such as thematic content analysis. Thematic content analysis is a qualitative analytic approach that identifies and codes patterns or themes in the data using inductive or deducting reasoning (Vaismoradi, Turunen, & Bondas, 2013). A strength of thematic content analysis is its ability to examine similarities and differences in the perspectives of study participants (Nowell, Norris, White, & Moules, 2017). As with quantitative approaches to data analysis, the external evaluator should incorporate subgroup analyses, where applicable.

Timing of Primary Data Collection Activities

After the external evaluation contract is executed, the external evaluator will begin obtaining data use agreements, developing survey instruments, and applying for IRB approval within their institution and with HHS, after which the external evaluator will execute the sampling plan, and prepare for primary data collection administration through survey printing and/or online survey development. HHSC estimates the beneficiary and provider surveys will be deployed approximately one year after the external evaluation contract is executed (February 2023, at the beginning of DY4), with a possible second wave of both surveys 12 months after initial implementation (February 2024). Focus groups would take place after the first wave of the beneficiary survey, if deemed feasible and necessary by the external evaluator. All primary data collection will end by the middle of DY 5 (July

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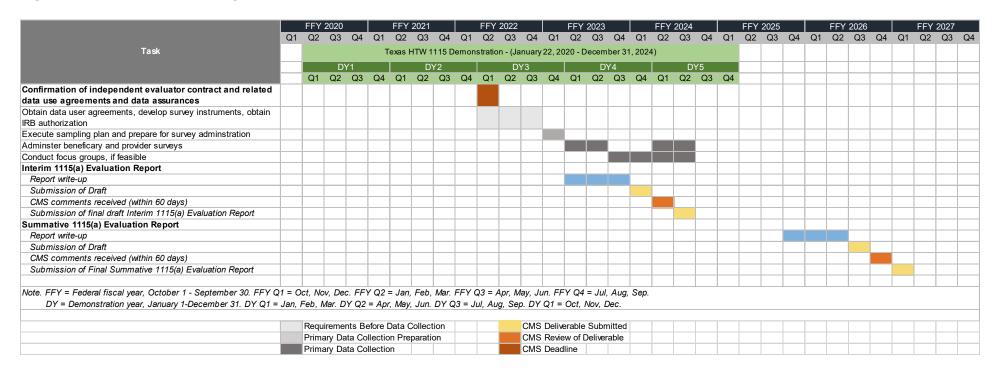
²⁷ The timeline presented assumes the external evaluator will obtain IRB approval by August 2022. Delays in approval of primary data collection tools and subsequent IRB approval may substantially limit the external evaluator's ability to execute primary data collection activities, including the ability to conduct a second wave of beneficiary and provider surveys.

2024) to ensure the external evaluator has sufficient time for data analysis.²⁸ Given that primary data collection may not begin until February 2023, limited findings will be available for the Interim Evaluation Report due to CMS on December 31, 2023. The external evaluator will include preliminary primary data collection findings, if any, in the Interim Evaluation Report, but comprehensive findings will not be available until the Summative Evaluation Report due to CMS on July 30, 2026. Figure depicts the estimated timeline for primary data collection activities alongside major HTW Demonstration deliverables.

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²⁸ HHSC estimates the evaluator will require nine to twelve months to complete data analysis given the multi-method and multi-modal approach proposed, and the large labor investment required for qualitative data analysis.

Figure D1. Estimated Primary Data Collection Timeline



Appendix E. Detailed Tables

Evaluation Question 1. *Did the HTW Demonstration increase* <u>access</u> to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas?

Hypothesis 1.1: The HTW Demonstration will maintain or increase access to family planning, family planning-related, preconception care, and postpartum services for low-income women in Texas.

Measure 1.1.1	HTW clients
Definition	The unique count of women enrolled in HTW
Study Population	HTW clients
Measure Steward or Source	N/A
Technical Specifications	HTW enrollment files summarize eligibility segments each month. Clients are enrolled in HTW for 12 continuous months
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 Client characteristics (age, race/ethnicity, region, etc.), where applicable The population eligible for the HTW Demonstration ¹
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in women enrolled in HTW would suggest access to the HTW Demonstration was maintained or improved
Benchmark	None; Trends in Texas Medicaid caseloads and uninsured women may be used as contextual references ²

Note. ¹ Estimates of the population eligible for the HTW Demonstration are provided in the HTW Demonstration Population section of the evaluation design; updated estimates are available upon request. ² Texas Medicaid caseloads are available via Texas HHSC Healthcare Statistics: https://hhs.texas.gov/about-hhs/records-statistics/data-statistics/healthcare-statistics. HHSC estimates the number of uninsured women in Texas ages 15-44 using on the American Community Survey Samples for Texas. HHSC will produce annual estimates of uninsured women in Texas upon request. Contextual references should be interpreted with caution due to differences between these populations and HTW clients. HTW = Healthy Texas Women.

Measure 1.1.2	HTW clients who received any HTW service
Definition	Proportion of HTW clients who received any HTW service
Study Population	HTW clients
Measure Steward or Source	N/A
	HTW clients with paid FFS claim for HTW service or prescription filled for HTW-covered medication Present as unduplicated number of clients served, and as proportion of all HTW clients:
Technical Specifications	Numerator: Total number of unduplicated HTW clients with paid FFS claims for HTW service or prescription filled for HTW-covered medication Denominator: Total number of unduplicated HTW clients Rate: (numerator / denominator) * 100
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	FFS claims data Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Separated by HTW service categories, if feasible¹ Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in HTW clients receiving any HTW service would suggest access to HTW Demonstration services was maintained or improved
Benchmark	None; Trends in Texas Medicaid caseloads and uninsured women may be used as contextual references ²

Note. ¹ Service categories may reflect HTW service groupings provided in the Demonstration Covered Services section of the evaluation design or alternative service groupings determined by the evaluator. ² Texas Medicaid caseloads are available via Texas HHSC Healthcare Statistics: https://hhs.texas.gov/about-hhs/records-statistics/data-statistics/healthcare-statistics. HHSC estimates the number of uninsured women in Texas ages 15-44 using on the American Community Survey Samples for Texas. HHSC will produce annual estimates of uninsured women in Texas upon request. Contextual references should be interpreted with caution due to differences between these populations and HTW clients. Note for Measure 1.1.2 continued on the next page.

HTW = Healthy Texas Women. FFS = Fee-for-service. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 1.1.3	HTW active billing providers
Definition	The unique count of providers billing any HTW services
Study Population	HTW active billing providers
Measure Steward or Source	N/A
Technical Specifications	 Unique count of providers listed as: Billing provider on paid claims for HTW service, or Prescribing provider for filled HTW-covered prescription.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	FFS claims data Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 • Explore changes following HTW Plus implementation (9/1/2020) Provider characteristics (region, type of provider etc.)
	Provider characteristics (region, type of provider etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in HTW active billing providers would suggest access to providers under the HTW Demonstration was maintained or improved
Benchmarks	None

Note. HTW = Healthy Texas Women. FFS = Fee-for-service. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 1.1.4	Network adequacy
Definition	The percentage of HTW clients meeting prescribed network distance standards
Study Population	HTW active billing providers HTW clients

Measure 1.1.4	Network adequacy
Measure Steward or Source	N/A
Technical Specifications	Network adequacy measures are modeled after existing distance standards Texas uses for the STAR MMC program. HHSC creates robust and meaningful distance standards between enrolled HTW clients' residence and service delivery addresses of active HTW PCPs and pharmacies. Network adequacy reports include: • Number of enrolled HTW clients for whom distance was calculated (99.1% of all HTW clients in DY1) • Distance standards for active HTW PCPs and pharmacies • Percentage of HTW clients within the specified distance from at least two active PCPs and one enrolled pharmacy • Performance standards (starting DY2) HHSC reviews and/or updates distances standards annually for different MMC services areas and county types (metro, micro, rural).
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Network adequacy reports
Comparison Group(s)/ Subgroup(s)	Explore changes following HTW Plus implementation (9/1/2020) HTW clients' MMC service area
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	A high percentage of clients meeting distance standards would suggest network adequacy standards are being met under the HTW Demonstration.
Benchmark	Baseline established DY1 and performance standards established DY2 ^{1,2}

Note. ¹ Network adequacy standards and reports will be finalized in DY2 based on DY1 baseline data. ² No comparable data exists for benchmarking given the unique benefit package offered under the HTW Demonstration and the wide variation in network adequacy methodologies across programs and states. HTW = Healthy Texas Women. MMC = Medicaid Managed Care. HHSC = Health and Human Services Commission. PCP = Primary care providers. DY = Demonstration year. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period. MMC = Medicaid managed care.

Hypothesis 1.2: The state's outreach and engagement activities support understanding of the HTW Demonstration.

Note. ¹ Mathematica White Paper, Beneficiary Survey Design and Administration for Eligibility and Coverage Demonstration Evaluations. HTW = Healthy Texas Women.

Measure 1.2.2	Understanding of eligibility requirements
Definition	HTW clients' and providers' understanding of and experiences with applying for the HTW Demonstration
Study Population	HTW clients HTW active billing providers
Measure Steward or Source	N/A – External evaluator will develop survey. Survey questions may be adapted from examples provided by Mathematica ¹
Technical Specifications	 HTW clients' and providers' knowledge of HTW eligibility requirements: Client eligibility requirements - age, citizenship, residency, health coverage, pregnancy status, and income Provider eligibility requirements - Medicaid enrollment, HTW certification process affirming compliance with Texas Human Resources Code §32.024(c-1)², and compliance with Texas' requirements for all Medicaid providers (e.g., submission of claims, compliance with civil rights, etc.) Experiences applying to receive/provide HTW services
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)
Comparison Group(s)/ Subgroup(s)	Client characteristics (age, race/ethnicity, region, etc.), and provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable
Interpretation	The proportion of respondents reporting familiarity with HTW eligibility requirements will demonstrate the extent to which outreach and engagement activities support understanding of HTW eligibility The proportion of respondents reporting satisfactory experiences applying for HTW will demonstrate the extent to which outreach and engagement activities support understanding of the HTW application process
Benchmark	None

Note. ¹ Mathematica White Paper, Beneficiary Survey Design and Administration for Eligibility and Coverage Demonstration Evaluations. ² Texas Human Resources Code §32.024(c-1) directs HHSC to ensure no money spent for the purpose of HTW is used to perform or promote elective abortions or to contract with entities that perform or promote elective abortions or affiliate with entities that perform or promote elective abortions. HTW = Healthy Texas Women.

Measure 1.2.3	Understanding of HTW benefits
Definition	HTW clients' and providers' understanding of services available through the HTW Demonstration
Study Population	HTW clients HTW active billing providers
Measure Steward or Source	N/A – External evaluator will develop survey
Technical Specifications	HTW clients' and providers' understanding of which services are available under the HTW Demonstration. Services may be summarized according to the HTW Demonstration Covered Services presented on page 9Error! Bookmark not defined.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)
Comparison Group(s)/ Subgroup(s)	Client characteristics (age, race/ethnicity, region, etc.), and provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable
Interpretation	The proportion of respondents reporting familiarity with HTW benefits will demonstrate the extent to which outreach and engagement activities support understanding of HTW benefits
Benchmark	None

Note. HTW = Healthy Texas Women.

Measure 1.2.4	Awareness of how to obtain services
Definition	HTW clients' understanding of how to access HTW Demonstration services
Study Population	HTW clients
Measure Steward or Source	N/A – External evaluator will develop survey
Technical Specifications	HTW clients' understanding of how to find HTW certified providers and pharmacies, including: provider specialties, languages spoken, and location/directions to office/clinic
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)

Measure 1.2.4	Awareness of how to obtain services
Comparison Group(s)/ Subgroup(s)	Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable
Interpretation	The proportion of respondents reporting an understanding of how to find HTW certified providers and pharmacies will demonstrate the extent to which outreach and engagement activities support awareness of obtaining HTW services
Benchmark	None

Note. HTW = Healthy Texas Women.

Measure 1.2.5	Effectiveness of outreach channels
Definition	HTW clients' and providers' familiarity with and perceptions about communication channels used to distribute information related to the HTW Demonstration
Study Population	HTW clients HTW active billing providers
Measure Steward or Source	N/A – External evaluator will develop survey
Technical Specifications	HTW clients' and providers' recollection of and perceptions about the utility and influence of different communication channels in providing information about the HTW Demonstration, including: • Letters or email correspondence • Program flyers or handouts • Digital/social media posts • Outreach and educational events (if applicable)
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)
Comparison Group(s)/ Subgroup(s)	Client characteristics (age, race/ethnicity, region, etc.), and provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable

Measure 1.2.5	Effectiveness of outreach channels
Interpretation	The proportion of respondents who recall various outreach channels, as well as respondent feedback on the utility and influence of those channels, will demonstrate the extent to which outreach and engagement activities are effective in providing information about the HTW Demonstration
Benchmark	None

Note. HTW = Healthy Texas Women.

Measure 1.2.6	Effectiveness of HTW Demonstration resources
Definition	HTW clients' and providers' familiarity with and perceptions about resources that provide information related to the HTW Demonstration
Study Population	HTW clients HTW active billing providers
Measure Steward or Source	N/A – External evaluator will develop survey
Technical Specifications	HTW clients' awareness of and perceptions about the accessibility and utility of HTW Demonstration resources, including: Direct communication from HTW representatives Community-based organizations The 2-1-1 call line YourTexasBenefits.com The TMHP call line The HTW website HTW providers' perceptions about the accessibility and utility of HTW Demonstration resources, including: Direct communication from HTW representatives Community-based organizations The TMHP call line or website
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator) ¹
Comparison Group(s)/ Subgroup(s)	Client characteristics (age, race/ethnicity, region, etc.), and provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable
Interpretation	The proportion of respondents reporting awareness of HTW resources, and respondent feedback on the accessibility and utility of those resources, will

Measure 1.2.6	Effectiveness of HTW Demonstration resources
	demonstrate the extent to which resources support understanding of the HTW Demonstration
Benchmark	None

Note. ¹ If feasible, the external evaluator may use website analytics, such as website hits, to supplement primary data collection on the effectiveness of HTW resources. HTW = Healthy Texas Women. TMHP = Texas Medicaid & Healthcare Partnership.

Evaluation Question 2. *Did the HTW Demonstration increase* <u>utilization</u> of family planning, preconception care, and postpartum services?

Hypothesis 2.1: The HTW Demonstration will maintain or increase utilization of family planning services among HTW clients.

Provision of most effective or moderately	
Measure 2.1.1	effective contraceptive methods
Definition	The percentage of HTW clients of childbearing age and at risk of unintended pregnancies who receive most effective or moderately effective methods of contraception annually
Study Population	HTW clients age 18 to 44 at end of DY at risk for an unintended pregnancy and continuously enrolled in HTW during DY
Measure Steward or Source	Office of Population Affairs; National Quality Forum-like measure (Contraceptive Care – All Women) The codes used to calculate this measure are publicly available on the Medicaid website: • 2020 Medicaid and CHIP Child Core Set (18-20): https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-and-chip-child-coreset-manual.pdf • 2020 Medicaid and CHIP Adult Core Set (21-44): https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-adult-core-set-manual.pdf
Technical Specifications	Numerator: Total number of unduplicated HTW clients provided a most (sterilization, IUD/IUS, implant) or moderately (injectables, oral pills, patch, ring, or diaphragm) effective method of contraception in DY Denominator: Total number of unduplicated HTW clients age 18 to 44 at end of DY who were: Not pregnant during DY, Pregnant during DY, but whose pregnancy ended in first 10 months, or

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Measure 2.1.1	Provision of most effective or moderately effective contraceptive methods
	Pregnant during DY but whose pregnancy ended in ectopic pregnancy, stillbirth, miscarriage, or induced abortion Rate: (numerator / denominator) * 100
Exclusion Criteria	HTW clients with one or more gaps in HTW enrollment lasting more than 45 days (or more than one month if enrollment determined monthly) during DY HTW clients determined not at risk of pregnancy because they: • Are infertile due to non-contraceptive reasons such as natural menopause or oophorectomy. • Had live birth in last 2 months of DY
	Were still pregnant at end of DY Client-level enrollment files
Data Source(s)/Data Collection Methods	DSP data, if applicable FFS claims data MMC encounter data Pharmacy claims data Vital statistics, if applicable
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 – 12/31/2019 • Post: 1/1/2020 – 12/31/2024 Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in utilization of effective contraceptive methods would suggest utilization of family planning services was maintained or increased
Benchmark	Texas CMS Core Measure, 2018 Medicaid Adult State Rate: • Most or Moderate, Ages 21-44: 29.6%

Note. ¹ Texas CMS Core Measure rates available via the Texas Healthcare Learning Collaborative Portal: https://thlcportal.com/measures/cmscoremeasuredashboard; additional benchmark years should be reported as available. The benchmark should only be used to provide context and support understanding of outcomes among HTW clients. The benchmark should not be used to justify inappropriate promotion of specific types of contraceptives or contraceptive use. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. CHIP = The Children's Health Insurance Program. IUD = Intrauterine device. IUS = Intrauterine system. DSP = Delivery supplemental payment. FFS = Fee-for-service. MMC = Medicaid managed care.

Measure 2.1.2	Long-acting reversible contraceptive use
Definition	The annual percentage of HTW clients of childbearing age and at risk of unintended pregnancies who receive long-acting reversible method of contraception
Study Population	HTW clients age 18 to 44 at end of DY at risk for unintended pregnancy and continuously enrolled in HTW during DY
	Office of Population Affairs; National Quality Forum-like measure (Contraceptive Care – All Women)
Measure Steward or Source	The codes used to calculate this measure are publicly available on the Medicaid website: • 2020 Medicaid and CHIP Child Core Set(18-20): https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-and-chip-child-coreset-manual.pdf • 2020 Medicaid and CHIP Adult Core Set (21-44): https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-adult-core-set-manual.pdf
Technical Specifications	Numerator: Total number of unduplicated HTW clients provided a LARC in DY Denominator: Total number of unduplicated HTW clients age 18 to 44 at end of DY who were: Not pregnant during DY, Pregnant during DY, but whose pregnancy ended in first 10 months, or Pregnant during DY but whose pregnancy ended in ectopic pregnancy, stillbirth, miscarriage, or induced abortion Rate: (numerator / denominator) * 100
Exclusion Criteria	HTW clients with one or more gaps in HTW enrollment lasting more than 45 days (or more than one month if enrollment determined monthly) during DY HTW clients determined not at risk of pregnancy
	 because they: Are infertile due to non-contraceptive reasons such as natural menopause or oophorectomy Had live birth in last 2 months of DY Were still pregnant at end of DY
Data Source(s)/Data Collection Methods	Client-level enrollment files DSP data, if applicable FFS claims data MMC encounter data Pharmacy claims data Vital statistics, if applicable

Measure 2.1.2	Long-acting reversible contraceptive use
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in utilization of LARCs would suggest utilization of family planning services was maintained or increased
Benchmark	Texas CMS Core Measure, 2018 Medicaid Adult State Rate: • LARC, Ages 21-44: 5.3%

Note. ¹ Texas CMS Core Measure rates available via the Texas Healthcare Learning Collaborative Portal: https://thlcportal.com/measures/cmscoremeasuredashboard; additional benchmark years should be reported as available. The benchmark should only be used to provide context and support understanding of outcomes among HTW clients. The benchmark should not be used to justify inappropriate promotion of specific types of contraceptives or contraceptive use. LARC = Long-acting reversible contraceptive use. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. CHIP = The Children's Health Insurance Program. DSP = Delivery supplemental payment. FFS = Fee-for-service. MMC = Medicaid managed care.

Measure 2.1.3	Tests for any sexually transmitted infection/disease
Definition	The percentage of HTW clients who had at least one test for any sexually transmitted disease during DY
Study Population	HTW clients
Measure Steward or Source	N/A
Technical Specifications	Numerator: Total number of unduplicated HTW clients with at least one test for any sexually transmitted disease during DY Denominator: Total number of unduplicated HTW clients during DY Rate: (numerator / denominator) * 100
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 Client characteristics (age, race/ethnicity, region, etc.), where applicable

Measure 2.1.3	Tests for any sexually transmitted infection/disease
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in tests for any sexually transmitted disease would suggest utilization of family planning services was maintained or increased
Benchmark	None

Note. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. FFS = Feefor-service.

Hypothesis 2.2: The HTW Demonstration will maintain or increase utilization of preconception care services.

Measure 2.2.1	Compliance with cervical cancer screening recommendations
Definition	The percentage of women enrolled in HTW age 21 to 64 screened for cervical cancer in past 3 (cervical cytology) or 5 years (cervical cytology/human papillomavirus cotesting)
Study Population	HTW clients age 21 or older by end of DY
Measure Steward or Source	National Committee for Quality Assurance (Healthcare Effectiveness Data and Information Set ®-like measure: Adults' Cervical Cancer Screening) The codes used to calculate this measure are publicly available on the Medicaid website: • 2020 Medicaid and CHIP Adult Core Set: https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-adult-core-set-manual.pdf
Technical Specifications	Numerator 1: Total number of unduplicated HTW clients age 21 or older at end of DY who had cervical cytology during DY or in the previous two DYs Numerator 2: Among HTW clients who do not meet criteria in numerator 1, total number of unduplicated HTW clients age 30 or older at end of DY who had cervical cytology and a human papillomavirus test with service dates four or fewer days apart during DY or in the previous four DYs (and who were age 30 or older on date of both tests) Final Numerator: Numerator 1 + Numerator 2 Denominator: Total number of unduplicated HTW clients age 24 or older at end of DY Rate: (numerator / denominator) * 100

Measure 2.2.1	Compliance with cervical cancer screening recommendations
	HTW clients with one or more gaps in HTW enrollment lasting more than 45 days (or more than one month if enrollment determined monthly) during DY
	HTW clients receiving hospice care
Exclusion Criteria	Optional: Hysterectomy with no residual cervix, cervical agenesis, or acquired absence of cervix (Absence of Cervix Value Set) any time during the beneficiary's history through end of DY (value sets available here: https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-core-set-reporting-resources/index.html)
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data MMC encounter data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 – 12/31/2019 • Post: 1/1/2020 – 12/31/2024 Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in the rate of compliance with cervical cancer screening recommendations would suggest utilization of preconception services was maintained or increased
Benchmark	Texas CMS Core Measure, 2018 Medicaid Adult State Rate: Cervical Cancer Screening (ages 21 to 64): 53.8% ²

Note. ¹ Texas CMS Core Measure rates available via the Texas Healthcare Learning Collaborative Portal: https://thlcportal.com/measures/cmscoremeasuredashboard; additional benchmark years should be reported as available. ² The state rate is applicable to women ages 21-64 years old. The benchmark should be interpreted with caution due to differences between this population and HTW clients. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. CHIP = The Children's Health Insurance Program. FFS = Fee-for-service. MMC = Medicaid managed care.

Hypothesis 2.3: The HTW Demonstration will increase utilization of HTW Plus postpartum care services among HTW clients.

Measure 2.3.1	HTW clients eligible for HTW Plus
Definition	The unduplicated count of women enrolled in HTW who have been pregnant in the 12 months prior to HTW enrollment
Study Population	HTW clients
Measure Steward or Source	N/A
Technical Specifications	HTW enrollment files summarize eligibility segments each month. Clients eligible for HTW Plus are identified in the client-level enrollment file using spenddown code = H. Women in HTW are automatically enrolled for 12 months. Women who were pregnant in the 12 months prior to HTW enrollment will be eligible for HTW Plus for the duration of the HTW certification period.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files
Comparison Group(s)/ Subgroup(s)	No comparison available, HTW Plus services began 9/1/2020 Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	This measure is a direct indicator of increases in women eligible for enhanced postpartum care services
Benchmark	None

Note. HTW = Healthy Texas Women. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 2.3.2	HTW clients utilizing any HTW Plus postpartum services
Definition	The percentage of HTW clients eligible for HTW Plus with a paid claim or filled prescription for any HTW Plus service
Study Population	HTW clients eligible for HTW Plus
Measure Steward or Source	N/A
Technical Specifications	HHSC will provide evaluator a list of procedure codes and National Drug Codes to identify HTW Plus services Numerator: Total number of unduplicated HTW clients with at paid FFS claim or filled prescription for any HTW Plus service Denominator: Total number of unduplicated HTW clients eligible for HTW Plus Rate: (numerator / denominator) * 100
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	No comparison available, HTW Plus services began 9/1/2020 Separated by HTW Plus service types, if feasible ¹ Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	This measure is a direct indicator of increases in utilization of enhanced postpartum care services
Benchmark	None ort HTW Plus service groupings provided in Demonstration Covered

Note. ¹ Service categories may reflect HTW Plus service groupings provided in Demonstration Covered Services section of the evaluation design or alternative evaluator-determined service groupings. HTW = Healthy Texas Women. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period. FFS = Fee-for-service.

Measure 2.3.3	Frequency of utilization of HTW Plus postpartum services
Definition	Average number of HTW Plus paid procedures per HTW client receiving HTW Plus services
Study Population	HTW clients receiving HTW Plus services
Measure Steward or Source	N/A
Technical Specifications	Numerator : Total number of paid HTW Plus procedures Denominator : Total number of unduplicated HTW clients with any paid FFS claim for any HTW Plus service
Exclusion Criteria	HTW Plus prescriptions filled
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data
	No comparison available, HTW Plus services began 9/1/2020
Comparison Group(s)/ Subgroup(s)	Separated by HTW Plus service types, if feasible
	Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	This measure is a direct indicator of increases in utilization of enhanced postpartum care services
Benchmark	None

Note. HTW = Healthy Texas Women. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period. FFS = Fee-for-service.

Evaluation Question 3. Did the HTW Demonstration improve women's health and pregnancy outcomes?

Hypothesis 3.1: The HTW Demonstration will maintain or improve women's health among HTW clients.

Measure 3.1.1	Hypertension medication adherence
Definition	The percentage of HTW clients with a prescription for a blood pressure medication who fill their prescription often enough to cover 80 percent or more days
Study Population	HTW clients
Measure Steward or Source	Pharmacy Quality Alliance-like measure: Medication Adherence for Hypertension. Evaluator will use the same Pharmacy Quality Alliance-like measure specifications for all DYs
Technical Specifications	Numerator: Number of HTW clients with a proportion of days covered at 80 percent or higher for blood pressure medications during the DY Denominator: Number of HTW clients with at least two blood pressure medication fills on unique dates of service during the DY Rate: (numerator / denominator) * 100 Blood pressure medication means an angiotensin converting enzyme inhibitor, an angiotensin receptor blocker, or a direct renin inhibitor drug. Percentage is not calculated if there are 30 or fewer HTW clients in denominator.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in hypertension medication adherence would suggest management of hypertension, and overall health, was maintained or improved

Measure 3.1.1	Hypertension medication adherence
Benchmark	None

Note. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 3.1.2	Diabetes medication adherence
Definition	The percentage of HTW clients with diabetes who fill their prescription often enough to cover 80 percent or more days
Study Population	HTW clients
Measure Steward or Source	Pharmacy Quality Alliance-like measure: Medication Adherence for Diabetes Medications. Evaluator will use the same Pharmacy Quality Alliance-like measure specifications for all DYs
Technical Specifications	Numerator: Number of HTW clients with a proportion of days covered at 80 percent or higher for diabetes medications during the DY Denominator: Number of HTW clients with at least two fills of diabetes medication(s) on unique dates of service during the DY Rate: (numerator / denominator) * 100 Diabetes medication means a biguanide drug, a sulfonylurea drug, a thiazolidinedione drug, a dipeptidyl peptidase-IV inhibitor, an incretin mimetic drug, a meglitinide drug, or a sodium-glucose transport protein 2 inhibitor. Percentage is not calculated if there are 30 or fewer HTW clients in denominator.
Exclusion Criteria	HTW clients who take insulin
Data Source(s)/Data Collection Methods	Client-level enrollment files Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis

Measure 3.1.2	Diabetes medication adherence
Interpretation	No change or an increase in diabetes medication adherence would suggest management of diabetes, and overall health, was maintained or improved
Benchmark	None

Note. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 3.1.3	Cholesterol medication adherence
Definition	The percentage of HTW clients with a prescription for a cholesterol medication (a statin drug) who fill their prescription often enough to cover 80 percent or more days
Study Population	HTW clients
Measure Steward or Source	Pharmacy Quality Alliance-like measure: Medication Adherence for Cholesterol (Statins). Evaluator will use the same Pharmacy Quality Alliance-like measure specifications for all DYs
Technical Specifications	Numerator: Number of HTW clients with a proportion of days covered at 80 percent or higher for statin cholesterol medication(s) during the DY Denominator: Number of HTW clients with at least two statin cholesterol medication fills on unique dates of service during the DY Rate: (numerator / denominator) * 100 Percentage is not calculated if there are 30 or fewer HTW clients in denominator.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Client-level enrollment files Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis

Measure 3.1.3	Cholesterol medication adherence
Interpretation	No change or an increase in cholesterol medication adherence would suggest management of cholesterol, and overall health, was maintained or improved
Benchmark	None

Note. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 3.1.4	Antidepressant medication management
Definition	The percentage of HTW clients who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment
Study Population	HTW clients with continuous enrollment 105 days prior to Index Prescription Start Date (IPSD; earliest prescription dispensing date for antidepressant medication where the date is in the Intake Period and there is a Negative Medication History)
Measure Steward or Source	National Committee for Quality Assurance (Healthcare Effectiveness Data and Information Set ®-like measure: Antidepressant Medication Management) The codes used to calculate this measure are publicly available on the Medicaid website: • 2020 Medicaid and CHIP Adult Core Set: https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-adult-core-set-manual.pdf
Technical Specifications	Numerator 1: Total number of unduplicated HTW clients with at least 84 days (12 weeks) of treatment with antidepressant medication beginning on the IPSD through 114 days after the IPSD (115 total days). This allows gaps in medication treatment up to a total of 31 days during the 115-day period. Gaps can include either washout period gaps to change medication or treatment gaps to refill the same medication. Numerator 2: Total number of unduplicated HTW clients with at least 180 days (6 months) of treatment with antidepressant medication beginning on the IPSD through 231 days after the IPSD (232 total days). This allows gaps in medication treatment up to a total of 52 days during the 232-day period. Gaps can include either washout period gaps to change medication or treatment gaps to refill the same medication.

Measure 3.1.4	Antidepressant medication management
	Denominator: Total number of unduplicated HTW clients with any of the following (Note: Many of the following services are not covered by or relevant to HTW but are used to identify eligible population for measure): • An acute or nonacute inpatient stay with any diagnosis of major depression • An outpatient visit with any diagnosis of major depression • An intensive outpatient encounter or partial hospitalization with any diagnosis of major depression • A community mental health center visit with any diagnosis of major depression • Electroconvulsive therapy with any diagnosis of major depression • Transcranial magnetic stimulation visit with any diagnosis of major depression • A telehealth visit with any diagnosis of major depression • An observation visit with any diagnosis of major depression • An ED visit with any diagnosis of major depression • A telephone visit with any diagnosis of major depression • A telephone visit with any diagnosis of major depression • At the provided that the provi
Exclusion Criteria	HTW clients with one or more gaps in HTW enrollment lasting more than 45 days (or more than one month if enrollment determined monthly) 105 days prior to IPSD through 231 days after IPSD HTW clients in hospice HTW clients who did not have an encounter with a diagnosis of major depression during the 121-day period from 60 days prior to the IPSD, through the IPSD and the 60 days after the IPSD
	HTW clients who filled a prescription for an antidepressant medication 105 days prior to the IPSD

Measure 3.1.4	Antidepressant medication management
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data MMC encounter data Pharmacy claims data
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in antidepressant medication adherence would suggest management of depression, and overall health, was maintained or improved
Benchmark	Texas CMS Core Measure, 2018 Medicaid Adult State Rate:

Note. ¹ Texas CMS Core Measure rates available via the Texas Healthcare Learning Collaborative Portal: https://thlcportal.com/measures/cmscoremeasuredashboard; additional benchmark years should be reported as available. HTW = Healthy Texas Women. DY=Demonstration year, January 1-December 31. IPSD = Index prescription start date. CHIP = The Children's Health Insurance Program. FFS = Fee-for-service. MMC = Medicaid managed care. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Hypothesis 3.2: The HTW Demonstration will maintain or improve pregnancy outcomes and maternal health among HTW clients.

Measure 3.2.1	Unintended pregnancies
Definition	The percentage of mothers sampled who reported their pregnancy was unintended
Study Population	Texas residents with a recent live birth
Measure Steward or Source	N/A
Technical Specifications	Responses to Q12: Thinking back to just before you got pregnant with your new baby, how did you feel about becoming pregnant? (response re-code) a) I wanted to be pregnant later (unintended) b) I wanted to be pregnant sooner (intended) c) I wanted to be pregnant then (intended) d) I didn't want to be pregnant then or any other time in the future (unintended) e) I wasn't sure what I wanted (unsure) Payer of delivery (listed on the birth certificate) a) Medicaid b) Private insurance c) Self pay, other, unknown Responses to Q12 categorized by payer of delivery. Rates include a confidence interval.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	PRAMS Data Books
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2018 – 12/31/2020 • Post: 1/1/2021 – 12/31/2022¹ Women with Medicaid as the delivery payer vs. women with an alternate delivery payer
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or a decrease in unintended pregnancies would suggest pregnancy outcomes were maintained or improved
Benchmark	PRAMS, 2017 Texas State Rate: ² • Pregnancy intention: 29.5% (CI: 27.0-32.0%)

Note. ¹ PRAMS Annual Report/Databook is generally available two years after the end of each birth year. ² Texas PRAMS rates provided in Texas Prams Databooks available via: https://dshs.texas.gov/mch/PRAMS.aspx; additional benchmark years should be reported as available. PRAMS = Pregnancy Risk Assessment Monitoring System.

Measure 3.2.2	Birth spacing
Definition	The percentage of HTW clients with a subsequent Medicaid-paid live birth, who had a second or greater number of Medicaid-paid births within 27 months
Study Population	HTW clients Medicaid-paid deliveries
Measure Steward or Source	N/A
Technical Specifications	Numerator: Number of HTW clients in denominator with second- or higher-order live singleton Medicaid-paid delivery within 27 months of previous live birth ¹ Denominator: Number of women with live Medicaid-paid delivery who were enrolled in HTW during the previous year Rate: (numerator / denominator) * 100
Exclusion Criteria	HTW clients with multiple births (e.g., twins) or no Medicaid-paid births after HTW enrollment
Data Source(s)/Data Collection Methods	Client-level enrollment files DSP data, if applicable FFS claims data MMC encounter data Vital statistics, if applicable
Comparison Group(s)/ Subgroup(s)	 HTW pre/post comparison² Pre: HTW clients during CY 17 with live birth during CY 18 Post: HTW clients during CY 20 (DY1) 1with live birth during CY 21 (DY2) Medicaid-paid births (matched, if feasible): During CY 18 among women not previously in HTW during CY 17 During CY 21 among women not previously in HTW during CY 20 Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Difference-in-differences estimation
Interpretation	No change or a decrease in subsequent births within 27 months would suggest pregnancy outcomes and maternal health were maintained or improved

Measure 3.2.2	Birth spacing
Benchmark	None

Note. ¹ A live birth interval of 27 months corresponds to recommended timing between a live birth and next pregnancy (18 months). ² Measure 3.2.2 identifies intervention/comparison group status based on program enrollment the calendar year prior to the birth year to support attribution of birth spacing. Assigning group status based on prior year enrollment avoids several data complications that would arise by using the current birth year. Women are transitioned into HTW after their postpartum Medicaid coverage ends. Women who gave birth during the same calendar year as HTW enrollment may not have been enrolled in HTW prior to the birth so birth/pregnancy outcomes would not be influenced by HTW services. Moreover, only the first two months of the current birth year would be relevant for identifying prior HTW enrollment given the average length of gestation. HTW = Healthy Texas Women. DSP = Delivery supplemental payment. FFS = Fee-for-service. MMC = Medicaid managed care. CY = Calendar year, January 1-December 31. DY = Demonstration year.

Measure 3.2.3	Pregnancy complications
Definition	Rate per 100,000 live births with one or more of the identified pregnancy complications
Study Population	HTW clients Medicaid-paid deliveries
Measure Steward or Source	N/A
Technical Specifications	Numerators: Number of HTW clients diagnosed with any of the following during pregnancy: • High blood pressure • Gestational diabetes • Preeclampsia Denominator: Number of HTW clients with Medicaid-paid live birth occurring after HTW enrollment Rate: (Numerator / denominator) * 100,000
Exclusion Criteria	HTW clients with no Medicaid pregnancies occurring after HTW enrollment
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data MMC encounter data
Comparison Group(s)/ Subgroup(s)	 HTW Pre/post comparison¹ Pre: HTW clients during CY 17 with live birth during CY 18 Post: HTW clients during CY 20 (DY1) 1with live birth during CY 21 (DY2) Medicaid-paid births (matched, if feasible): During CY 18 among women not previously in HTW during CY 17 During CY 21 among women not previously in HTW during CY 20

Measure 3.2.3	Pregnancy complications
	Client characteristics (age, race/ethnicity, region, etc.) and HTW Plus utilization, where applicable
Analytic Methods	Descriptive statistics Difference-in-differences estimation
Interpretation	No change or a decrease in pregnancy complications would suggest pregnancy outcomes and maternal health were maintained or improved
Benchmark	None

Note. ¹ Measure 3.2.3 identifies intervention/comparison group status based on program enrollment the calendar year prior to the birth year to support attribution of pregnancy complications. Assigning group status based on prior year enrollment avoids several data complications that would arise by using the current birth year. Women are transitioned into HTW after their postpartum Medicaid coverage ends. Women who gave birth during the same calendar year as HTW enrollment may not have been enrolled in HTW prior to the birth so birth/pregnancy outcomes would not be influenced by HTW services. Moreover, only the first two months of the current birth year would be relevant for identifying prior HTW enrollment given the average length of gestation. HTW = Healthy Texas Women. FFS = Fee-for-service. MMC = Medicaid managed care. CY = Calendar year, January 1-December 31. DY = Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 3.2.4	Adverse birth outcomes
Definition	Rate per 100,000 live births with one or more of the identified adverse birth outcomes
Study Population	HTW clients Medicaid-paid deliveries
Measure Steward or Source	N/A
Technical Specifications	Numerators: Number of HTW clients diagnosed with one of the following during pregnancy in DY: • Low birth weight • Preterm birth Denominator: Number of HTW clients with Medicaid-paid live birth occurring after HTW enrollment in DY Rate: (Numerator / denominator) * 100,000
Exclusion Criteria	HTW clients with no Medicaid pregnancies occurring after HTW enrollment
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data MMC encounter data

Measure 3.2.4	Adverse birth outcomes
Comparison Group(s)/ Subgroup(s)	 HTW Pre/post comparison¹ Pre: HTW clients during CY 17 with live birth during CY 18 Post: HTW clients during CY 20 (DY1) 1with live birth during CY 21 (DY2) Medicaid-paid births (matched, if feasible): During CY 18 among women not previously in HTW during CY 17 During CY 21 among women not previously in HTW during CY 20 Client characteristics (age, race/ethnicity, region, etc.) and HTW Plus utilization, where applicable
Analytic Methods	Descriptive statistics Difference-in-differences estimation
Interpretation	No change or a decrease in adverse birth outcomes would suggest pregnancy outcomes were maintained or improved
Benchmark	Data prepared for the Healthy Texas Babies Initiative: ² • 2018 Preterm Birth Rate: • Texas: 10.8% • United States: 10.0% • 2018 Low Birth Weight Rate: • Texas: 8.5%% • United States: 8.3%

Note. ¹ Measure 3.2.4 identifies intervention/comparison group status based on program enrollment the calendar year prior to the birth year to support attribution of adverse birth outcomes. Assigning group status based on prior year enrollment avoids several data complications that would arise by using the current birth year. Women are transitioned into HTW after their postpartum Medicaid coverage ends. Women who gave birth during the same calendar year as HTW enrollment may not have been enrolled in HTW prior to the birth so birth/pregnancy outcomes would not be influenced by HTW services. Moreover, only the first two months of the current birth year would be relevant for identifying prior HTW enrollment given the average length of gestation. ² Data prepared for the Healthy Texas Babies Initiative are provided in Health Texas Mothers and Babies Data Books available via: https://www.dshs.texas.gov/healthytexasbabies/data.aspx; additional benchmark years should be reported as available. HTW = Healthy Texas Women. FFS = Fee-for-service. MMC = Medicaid managed care. CY = Calendar year, January 1-December 31. DY = Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 3.2.5	Severe maternal morbidity
Definition	Rate of severe maternal morbidity per 100,000 live births
Study Population	HTW clients Medicaid-paid deliveries
Measure Steward or Source	Severe maternal morbidity diagnosis codes drawn from the Centers for Disease Control and Prevention. The codes used to calculate this measure are available publicly on the Center for Disease Control and Prevention website: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/severe-morbidity-ICD.htm
Technical Specifications	Numerator: Number of HTW clients with one or more of the 21 diagnosis code indicators used to identify severe maternal morbidity during delivery hospitalizations Denominator: Number of HTW clients with Medicaid-paid live birth occurring after HTW enrollment Rate: (Numerator / denominator) * 100,000
Exclusion Criteria	HTW clients with no Medicaid-paid live births occurring after HTW enrollment
Data Source(s)/Data Collection Methods	Client-level enrollment files FFS claims data MMC encounter data
Comparison Group(s)/ Subgroup(s)	 HTW Pre/post comparison¹ Pre: HTW clients during CY 17 with live birth during CY 18 Post: HTW clients during CY 20 (DY1) 1with live birth during CY 21 (DY2) Medicaid-paid births (matched, if feasible): During CY 18 among women not previously in HTW during CY 17 During CY 21 among women not previously in HTW during CY 20 Client characteristics (age, race/ethnicity, region, etc.) and HTW Pus utilization, where applicable

Measure 3.2.5	Severe maternal morbidity
Analytic Methods	Descriptive statistics Difference-in-differences estimation
Interpretation	No change or a decrease in severe maternal morbidity would suggest maternal health was maintained or improved
Benchmark	Data prepared for the Healthy Texas Babies Initiative: ² • 2017 Texas Severe Maternal Morbidity Rate: • 169.7 per 10,000 delivery hospitalizations

Note. ¹ Measure 3.2.5 identifies intervention/comparison group status based on program enrollment the calendar year prior to the birth year to support attribution of severe maternal morbidity. Assigning group status based on prior year enrollment avoids several data complications that would arise by using the current birth year. Women are transitioned into HTW after their postpartum Medicaid coverage ends. Women who gave birth during the same calendar year as HTW enrollment may not have been enrolled in HTW prior to the birth so birth/pregnancy outcomes would not be influenced by HTW services. Moreover, only the first two months of the current birth year would be relevant for identifying prior HTW enrollment given the average length of gestation. ² Data prepared for the Healthy Texas Babies Initiative are provided in Health Texas Mothers and Babies Data Books available via: https://www.dshs.texas.gov/healthytexasbabies/data.aspx; additional benchmark years should be reported as available. HTW = Healthy Texas Women. FFS = Fee-for-service. MMC = Medicaid managed care. CY = Calendar year, January 1-December 31. DY = Demonstration year, January 1-December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eliqible women for the duration of the 12-month certification period.

Evaluation Question 4. *Did the HTW Demonstration effectively use <u>public</u> <u>funds</u> to provide women's health care in Texas?*

Hypothesis 4.1: The HTW Demonstration will remain at or below the CMS-specified annual expenditures limits.

Measure 4.1.1	Per member per month costs
Definition	Per member per month costs compared to CMS annual expenditure limits
Study Population	HTW clients
Measure Steward or Source	N/A
Technical Specifications	Actual per member per month costs during DY
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Demonstration Budget Neutrality Worksheet HHSC-calculated per member per month costs in pre- period
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 - 12/31/2019 • Post: 1/1/2020 - 12/31/2024 ○ Explore changes following HTW Plus implementation (9/1/2020) Demonstration per member per month annual expenditure limits:¹ • DY1: \$27.13 • DY2: \$30.87 • DY3: \$33.44 • DY4: \$34.63 • DY5: \$36.09
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	Per member per month costs at or below the CMS- specified annual expenditure limits would suggest effective use of public funds
Benchmark	None

Note. ¹ Per member per month annual expenditures include costs associated with HTW Plus. If CMS does not approve the HTW Plus amendment, annual expenditures should reflect amounts specified in STCs. CMS = Centers for Medicare & Medicaid Services. HTW = Healthy Texas Women. HHSC = Health and Human Services Commission. DY = Demonstration year, January 1–December 31. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Evaluation Question 5. How does implementation of the HTW <u>provider</u> <u>eligibility criteria</u> outlined in Goal 5 of the HTW Demonstration affect access to and utilization of women's health and family planning services?

Hypothesis 5.1: The implementation of the HTW provider eligibility criteria does not adversely affect access to and utilization of women's health and family planning services.

Measure 5.1.1	Proportion of active family planning providers in Medicaid delivering services through HTW
Definition	The proportion of active family planning providers in Medicaid delivering services through HTW. Active family planning providers in Medicaid are defined as providers in HTW or other FFS or MMC programs with a paid claim for family planning services covered by HTW.
Study Population	HTW certified providers HTW active billing providers Medicaid active billing providers delivering HTW-like family planning services under traditional FFS or MMC
Measure Steward or Source	N/A
Technical Specifications	 Unique count of HTW providers who: Are listed as billing provider on a paid claim for a HTW family planning service during CY Unique count of Medicaid providers who: Are listed as billing provider on a paid claim in traditional FFS or MMC for a family planning service covered under HTW during CY, and Are not listed as an HTW certified provider or do not have HTW paid claims during CY Numerator: HTW active billing providers delivering HTW family planning services during CY Denominator: HTW active billing providers delivering HTW family planning services during CY + Medicaid active billing providers delivering HTW-like family planning services in traditional FFS or MMC programs during CY Rate: (Numerator / denominator) * 100
Exclusion Criteria	Medicaid providers delivering services not included under HTW family planning services HTW-like services delivered to men, pregnant women, or women younger than 18 or older than 45 HTW-related prescriptions filled
Data Source(s)/Data Collection Methods	FFS claims data MMC encounter data Provider-level enrollment files

Measure 5.1.1	Proportion of active family planning providers in Medicaid delivering services through HTW
Comparison Group(s)/ Subgroup(s)	HTW Pre/post comparison • Pre: 1/1/2017 – 12/31/2019 • Post: 1/1/2020 – 12/31/2024 ○ Explore changes after HTW Plus implementation Provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Descriptive trend analysis
Interpretation	No change or an increase in the proportion of active family planning providers delivering services through HTW would suggest the HTW provider network is stable or expanding as a share of Medicaid family planning providers under the provider eligibility criteria
Benchmark	None

Note. HTW = Healthy Texas Women. CY = Calendar year, January 1–December 31. FFS = fee for service. MMC = Medicaid Managed Care. HTW Plus = An enhanced postpartum service package available to a subset of HTW clients who were pregnant in the 12 months prior to HTW enrollment. HTW Plus services are available to eligible women for the duration of the 12-month certification period.

Measure 5.1.2	Appointment wait times
Definition	Average amount of time HTW clients wait to obtain care from an HTW provider
Study Population	HTW clients
Measure Steward or Source	N/A – External evaluator will develop survey. Survey questions may be adapted from national surveys, such as the 2018 Biennial Health Insurance Survey
Technical Specifications	Possible questions include: • Thinking back to the last time you made an appointment with an HTW provider, how long did you have to wait to get this appointment?
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)
Comparison Group(s)/ Subgroup(s)	Separated by HTW service categories or HTW provider types, if feasible ¹ Client characteristics (age, race/ethnicity, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable

Measure 5.1.2	Appointment wait times
Interpretation	The proportion of respondents reporting short appointment wait times, or satisfaction with appointment wait times, will demonstrate the extent to which there is timely access to care under the HTW provider eligibility criteria
Benchmark	SFY 19-20 Texas Medicaid Appointment Availability Standards: • Routine Primary Care • Standard: within 14 calendar days • STAR Adult minimum threshold: 95.8%³ • Preventive Health Services for Adults • Standard: within 90 calendar days • STAR Adult minimum threshold: 99.0%³

Note. ¹ Service categories may reflect HTW service groupings provided in the Demonstration Covered Services section of the evaluation design or alternative service groups determined by the evaluator. ² Texas Medicaid appointment availability standards and minimum thresholds available via: https://hhs.texas.gov/about-hhs/process-improvement/improving-services-texans/medicaid-chip-quality-efficiency-improvement/appointment-availability. ³ Minimum thresholds are calculated by adding 10 points to the statewide mean. MCOs who fail to meet minimum thresholds are assessed for Corrective Action Plans. HTW = Healthy Texas Women. SFY = State Fiscal Year, September 1-August 31. MCO = Managed care organization.

Measure 5.1.3	Barriers to receiving care
Definition	Perceived barriers to receiving HTW services
Study Population	HTW clients
Measure Steward or Source	N/A – External evaluator will develop survey. Survey questions may be adapted from national surveys, such as the CAHPS-HPS, Adult Medicaid Survey 5.0, and the Medicare Current Beneficiary Survey
Technical Specifications	Perceived barriers, if any, to receiving HTW services or obtaining care when needed, including language barriers, non-emergency medical transportation, child care, etc. Suggested questions include: • Were you able to access and use the HTW provider directory? • Was it easy to find a doctor who provides HTW services? • Did you have to change your usual provider of care to receive HTW services? • When you needed care right away, how often did you get care as soon as you needed?

Measure 5.1.3	Barriers to receiving care	
	 How often were you able to get an appointment for a check-up or routine care at a doctor's office or clinic as soon as you needed? How often was it easy to get the care, tests, or treatment you needed? Have you had trouble getting needed care? If so, what type of care did you have trouble receiving? In the last 6 months, have you missed a scheduled appointment with an HTW provider? What caused you to miss the scheduled appointment? How easy is it for you to get to your doctor's office? Do you have trouble getting to your doctor's office? 	
Exclusion Criteria	None	
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)	
Comparison Group(s)/ Subgroup(s)	Separated by HTW service categories or HTW provider types, if feasible ¹ Client characteristics (age, race/ethnicity, region, etc.), and provider characteristics (provider type, region, etc.), where applicable	
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable	
Interpretation	Respondent perspectives provide direct insight into barriers receiving services under the HTW Demonstration	
Benchmark	Texas CMS Core Measure, 2018 Medicaid Adult State Rate: ² • Getting care needed – global proportion of % always: 55.0% • Getting care quickly needed – global proportion of % always: 59.6%	

Note. ¹ Service categories may reflect HTW service groupings provided in the Demonstration Covered Services section of the evaluation design or alternative service groups determined by the evaluator. ² Medicaid Texas rates available via the Texas Healthcare Learning Collaborative Portal: https://thlcportal.com/measures/cmscoremeasuredashboard; additional benchmark years should be reported as available. HTW = Healthy Texas Women.

Measure 5.1.4	Providers accepting new clients	
Definition	HTW active billing providers accepting new HTW clients	
Study Population	HTW active billing providers	
Measure Steward or Source N/A – External evaluator will develop survey. Surveys as: The 2018 National Electronic Health Records		
Technical Specifications	Proportion of HTW active billing providers accepting new HTW clients: Numerator: Total number of provider respondents currently accepting new HTW clients Denominator: Total number of unduplicated provider respondents Rate: (numerator / denominator) * 100	
Exclusion Criteria	None	
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)	
Comparison Group(s)/ Subgroup(s)	Provider characteristics (provider type, region, etc.), where applicable	
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable	
Interpretation	The proportion of respondents accepting new clients will demonstrate the extent to which there is adequate access to care under the HTW provider eligibility criteria	
Benchmark	2016 Texas State Rate - Physicians Accepting New Patients: 93%¹ • Among providers accepting new patients, providers accepting Medicaid patients: 41%	

Note. ¹ Texas Medical Association Physician survey available via: https://www.texmed.org/surveys/. Texas Medical Association conducts the survey every two years; additional benchmarks should be reported as available. HTW = Healthy Texas Women. CHIP = Children's Health Insurance Program.

Measure 5.1.5	Barriers to providing care
Definition	Perceived barriers to providing HTW services
Study Population	HTW active billing providers
Measure Steward or Source	N/A
Technical Specifications	Perceived barriers, if any, to providing HTW services including staff shortages or turnover, high client-to-provider rates, lack of trainings, or geographic location of office/clinic.
Exclusion Criteria	None
Data Source(s)/Data Collection Methods	Primary data collection (to be developed by external evaluator)
Comparison Group(s)/ Subgroup(s)	Provider characteristics (provider type, region, etc.), where applicable
Analytic Methods	Descriptive statistics Thematic content analysis, if applicable
Interpretation	Respondent perspectives provide direct insight into barriers delivering services under the HTW Demonstration
Benchmark	None

Note. HTW = Healthy Texas Women.

Appendix F. List of Acronyms

Acronym	Full Name
BCCS	Breast and Cervical Cancer Services
BRFSS	Behavioral Risk Factor Surveillance System
CAHPS	Consumer Assessment of Health Care Providers and Systems
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CPT Code	Current Procedural Terminology Code
CY	Calendar year
DID	Difference-in-differences
DSHS	Texas Department of State Health Services
DSP	Delivery supplemental payment
DSRIP	Delivery System Reform Incentive Program
DTA	Descriptive trend analysis
DY	Demonstration year
ЕРНС	Expanded Primary Health Care
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
FFS	Fee-for-service
FPL	Federal Poverty Level
FPP	Family Planning Program
HHSC	Texas Health and Human Services Commission
HTW	Healthy Texas Women
HTW Plus	HTW Enhanced postpartum service package
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification code
IPSD	Index prescription start date
IUD	Intrauterine device
IUS	Intrauterine system
LARC	Long-acting reversible contraceptive

Acronym	Full Name
MAGI	Modified Adjusted Gross income
мсо	Managed care organization
ммс	Medicaid Managed Care
NHIS	National Health Interview Survey
NPI	National provider identifier
PCP	Primary care provider
РМРМ	Per member per month
PRAMS	Pregnancy Risk Assessment Monitoring System
PSM	Propensity score matching
SFY	State fiscal year
SQL	Structured Query Language
STCs	Special Terms and Conditions
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TAC	Texas Administrative Code
THID	Texas Hospital Inpatient Discharge data
ТМНР	Texas Medicaid and Healthcare Partnership
TPI	Texas provider identifier
TWHP	Texas Women's Health Program

Appendix G. References

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Prompts	Summary
Key policies	
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.	 Key Policy Goals Tested Under the Demonstration The goals and objectives of the Healthy Texas Women (HTW) Demonstration are to: Increase access to women's health and family planning services to avert unintended pregnancies, positively affect the outcome of future pregnancies, and positively impact the health and well-being of women and their families. Increase access to preventive health care, including screening and treatment for hypertension, diabetes, and high cholesterol; positively impact maternal health; and reduce maternal mortality. Increase access to women's breast and cervical cancer services to promote early cancer detection. Implement the state policy to favor childbirth and family planning services that do not include elective abortions or the promotion of elective abortions within the continuum of care or services and to avoid the direct or indirect use of state funds to promote or support elective abortions. Reduce the overall cost of publicly funded health care (including federally funded health care) by providing low-income Texans access to safe, effective services consistent with these goals. State's Strategic Approach to Implement the Policies The state has implemented these policy goals through the HTW program, which provides family planning services and other women's health services that contribute to preconception care and better birth outcomes. The program launched with state funds on July 1, 2016. The

Prompts	Summary
	program's unique benefits package, eligibility requirements, and provider qualifications are a direct reflection of the key policy goals being tested under the HTW Demonstration.
	Benefits
	 Pregnancy testing Pelvic examinations Sexually transmitted infection services Breast and cervical cancer screenings Clinical breast examinations Screening and treatment for cholesterol, diabetes, and high blood pressure Human Immunodeficiency Virus (HIV) screenings Long-acting reversible contraceptives Oral contraceptive pills Permanent sterilizations Other contraceptive methods such as condoms, diaphragm, vaginal spermicide, and
	injectionsScreening and treatment for postpartum depressionImmunizations
	Eligibility
	A prospective client may apply for HTW services by completing an application form and providing documentation as required by HHSC. An applicant may obtain an application in the following ways:
	 Online at: www.HealthyTexasWomen.org

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	 www.yourtexasbenefits.com www.HHS.texas.gov; From a local HHS benefits office, an HTW provider's office, or any other location that makes HTW applications available; or By calling 2-1-1.
	Women who apply for HTW using the paper or electronic Form H1867, Texas Women's Health Program Application Form, agree to this statement when they sign the application: This form is not used to find out if I can get Medicaid, but I can apply for Medicaid at any time. The majority of HTW applicants use the YourTexasBenefits.com online application. YourTexasBenefits.com provides information about HTW, Medicaid, CHIP, the Supplemental Nutrition Assistance Program (SNAP) and Temporary Assistance for Needy Families (TANF). Women can apply for all of these programs using the same online application. Women who meet the following criteria are eligible for the HTW Demonstration: • Women 18 to 44 years of age • US Citizen or eligible immigrant • Texas resident • Not pregnant • Does not currently receive full Medicaid benefits, CHIP, or Medicare Part A or B • Does not have private health insurance that covers family planning services, unless filing a claim on the health insurance would cause physical, emotional, or other harm from a spouse, parent, or other person • Has a countable household income at or below 200 percent of the Federal Poverty Level (FPL)
	To provide continuity of care in the postpartum period, women 18 through 44 years of age whose Medicaid for Pregnant Women coverage period is ending are automatically enrolled in

Prompts	Summary
	the HTW demonstration if they are not otherwise eligible for full Medicaid benefits, Medicare, or CHIP, and they do not have other creditable health coverage.
	Women who are pregnant are not eligible to receive HTW benefits. If an HTW recipient reports she is pregnant during the 12-month continuous coverage period, HHSC will determine if she is eligible for Medicaid for Pregnant Women or CHIP Perinatal (CHIP-P) without requiring her to complete a new application. HTW will be terminated when the woman is certified for Medicaid for Pregnant Women or CHIP-P.
	Currently, if a woman applying for HTW benefits reports that she is pregnant on her HTW initial application (Form H1867), her HTW application will be denied. Her eligibility notification will reflect that she is being denied HTW because of her pregnancy and will direct her to complete a Form H1010, Texas Works Application for Assistance if she wants to be determined eligible for Medicaid or CHIP. When Medicaid eligibility requirements are fully implemented into the HTW program, women will only need to complete one application to be determined eligible for Medicaid, CHIP or HTW.
	Provider qualifications
	To be enrolled as an HTW provider, all providers must deliver the type of services available through the HTW program, be enrolled in Medicaid, and certify their compliance with Texas Human Resources Code §32.024(c-1). Texas Human Resources Code §32.024(c-1) directs the state to ensure that all money spent for the purpose of HTW is not used to perform or promote elective abortions, or to contract with entities that perform or promote elective abortions or affiliate with entities that perform or promote elective abortions.
	Timelines for Meeting Milestones Associated with Key Policies The key policies described above are already implemented statewide.

Prompts	Summary	
Other information	Other information	
The Implementation Plan should include but is not limited to ensuring: a) network adequacy including procedures for provider qualification;	Network adequacy Texas currently measures network adequacy for the HTW program by assessing the number of enrolled HTW clients; the number of HTW providers who billed for services statewide and in each health and human services (HHS) region; the number of clients served by age group and HHS region; and the average number of clients served per provider. The most recent analysis is available in the <i>Texas Women's Health Programs Report Fiscal Year 2019</i> : https://hhs.texas.gov/reports/2020/05/texas-womens-health-programs-report-fiscal-year-2019 For DY1, Texas intends to modify the approach previously utilized for the <i>Texas Women's Health Programs Report</i> to assess provider networks for specific provider types, including: Primary care provider, including OB/GYN; and Pharmacy. Texas will use DY1 (Quarter 1) MCO provider network data to develop specific distance standards by county designation for these provider types. Beginning in DY2, Texas will conduct annual reviews of network adequacy based on the established provider distance standards. HHSC will use geographic information system (GIS) technology to conduct assessments of waiver participant access to key network providers within	

¹ HHSC uses three county designations, based on population and density, and derived from modifications to county types used by Medicare.

Medicare Large Metro and Metro are combined to form HHSC Metro;

[•] Medicare Micro is used to form HHSC Micro; and

[•] Medicare Rural, and Counties with Extreme Access Considerations (CEAC) are combined to form HHSC Rural.

Prompts	Summary
	the required distance ² . Annual reviews for DYs 2-5 will be conducted based on Quarter 1 data for each DY.
	Texas will also establish benchmarks ³ for DYs 2-5 for the percentage of waiver participants in each service area ⁴ who must have access to the required provider types within the specified distance. If HHSC's annual assessment of provider networks indicates a deficiency in a given service area based on established benchmarks, HHSC will conduct provider outreach in these areas with a goal of increasing provider participation. HHSC will also conduct additional analyses on an ongoing basis, including a targeted review no later than Quarter 3 of the DY, for service areas for which a provider shortage has been identified, to ensure any deficiencies in provider networks are addressed.
	Provider qualification
	HHSC will ensure that all HTW providers are enrolled with the State as Medicaid providers consistent with the provider disclosure, screening, and enrollment requirements of 42 CFR 455, subparts B and E.
	In addition, all HTW providers must certify and attest annually that they do not perform or promote elective abortions, contract with entities that perform or promote elective abortions, or affiliate with individuals or entities that perform or promote elective abortions, as defined in Texas Health and Safety Code §245.002.
	The provider qualification process described above is already implemented statewide.

² HHSC GIS analysis is based on the travel time or distance from the waiver participant's residence to the provider's physical address, as listed in the Medicaid provider database files.

³ DY1 baseline data will be used to establish benchmarks for the percentage of waiver participants for whom a network provider is located within the required distance.

⁴ Service areas will be based on those used in Texas Medicaid managed care, which will allow HHSC to leverage current monitoring processes.

Prompts	Summary
b) access to care;	To ensure HTW beneficiaries receive adequate and appropriate access to care, the following measures will be monitored annually:
	 Contraceptive care for all women* – the percentage of women at risk of unintended pregnancy who: 1) were provided a most effective or moderately effective method of contraception, or 2) were provided a long-acting reversible method of contraception. Cervical cancer screening* – assesses women 21-64 who had a cervical cytology (Pap test) performed every three years. STD screening – the number of beneficiaries who obtained an STD test. *These are national measures with defined measure specifications that cannot be altered. The following data will be reported quarterly: Unduplicated number of enrollees by age group; and The number of enrollees by age group with any claim.
c) beneficiary communication strategies including outreach and education;	Potential and enrolled HTW clients receive communication from various channels. With the goal of helping to increase awareness and client enrollment, the HTW outreach campaign was designed to reach low-income women who may be eligible for HTW. The outreach campaign includes client outreach, provider outreach, community outreach, and website maintenance. The primary audience for the campaign is Texas women between the ages of 18 and 30 who are racially diverse, primarily low-income, often college students, and may already have children.

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	HHSC uses social media to reach out to HTW-eligible women. This outreach includes information targeted at issues relevant to women in the primary audience such as diabetes, cholesterol, hypertension, breast cancer, cervical cancer, and contraception. Social media outreach aligns with nationwide outreach campaigns, such as breast cancer awareness month.
	Outreach efforts also include system-generated letters sent to women who are auto-enrolled in HTW to provide client education on the benefits offered and how to find a provider. This communication includes a detailed explanation of benefits, including some primary care benefits. Primary care benefits mentioned include unlimited office visits, vaccines, family planning services, breast and cervical cancer screening services, and screening and treatment for cholesterol, diabetes, high blood pressure, and postpartum depression. These women are also sent reminder letters to complete HTW re-enrollment on an annual basis.
	Direct outreach has been a useful tool to increase awareness of HTW. HHSC proactively contacts organizations that may interact with low-income women and families, such as community colleges, nonprofits, local shelters, food banks, public libraries, public health departments, and advocacy groups. This outreach method affords HHSC the opportunity to directly provide organizations with program materials through mail or electronic methods.
	As a Medicaid vendor, Texas Medicaid Healthcare Partnership (TMHP) also provides client and provider outreach and education and is the first line of contact for consumer questions and complaints. HHSC maintains its own HTW website, healthytexaswomen.org as the primary landing page for clients, and TMHP maintains its own HTW website, https://tmhp.com/pages/HTW as the primary landing page for providers.
	Finally, community-based organizations help provide community specific outreach for HTW. These organizations include local WIC offices, state SNAP eligibility offices, and HTW state

Prompts	Summary
	contracted providers. These locations provide eligibility services and education on HTW services.
d) maintenance of and beneficiary access to provider directories; and	HTW beneficiaries have continuous access to an online provider lookup feature on the HTW website, healthytexaswomen.org/find-a-doctor . The webpage allows clients to search for clinics within a selection of distances by miles and connects to Google Maps, which provides clinic name, address, contact number, programs served, provider specialty, languages spoken, and directions to the clinic. The data that populates this provider directory comes from TMHP, whose data files are updated regularly with the most accurate provider information available.
	If a beneficiary does not have access to the internet, she may call the TMHP hotline (1-800-335-8957) for help in locating an HTW provider. A TMHP representative will use the same provider data files as those the HTW website uses to locate an HTW clinic in the client's preferred location.
	Additionally, HHSC is implementing a new Provider Portal Redesign (PPR), called the Provider Enrollment & Management System (PEMS), to further enhance provider data integrity. To prevent multiple Texas Provider Identifiers (TPI's) per provider, Providers will be instructed to maintain updates with TMHP so that they maintain their enrollment at the NPI level.
	HHSC, in partnership with TMHP, is also implementing additional system changes that will indicate which names on the HTW provider list are active providers based on claims data filed within the past twelve months. This enhancement will ensure that only active providers are reflected in the online lookup.
	The TMHP contact center tracks the number of HTW inquiries, how many HTW inquiries are related to locating a provider, and any reported problems with the online provider directory.

Prompts	Summary
e) complaints and grievances.	 HTW clients may report complaints and grievances to: 2-1-1 for eligibility issues; HHS Office of the Ombudsman for issues with accessing benefits; or HHSC Office of Civil Rights for discrimination issues.
	Clients are informed of the complaints and appeals process in the enrollment letter they receive when they are enrolled into the HTW program. Information on how to file a complaint is also available on the HTW website: healthytexaswomen.org/contact.
	Additionally, the HTW program tracks all complaints and grievances received by the program and submits a monthly report of this data to the Office of the Ombudsman. The Office of the Ombudsman requires that 90% of complaints be resolved within 10 business days. Complaints are assigned to one of the following categories:
	 Access to Care (related to any obstacles that prevent a member from accessing care) Claims/Payment (related to claims payment issues) Customer Service (related to the assistance or advice provided to the complainant) Provider Contracting or Enrollment (related to issues resulting from the provider's contract with HHSC or provider enrollment) Quality of Care (related to the standard of care provided) Fraud Member Enrollment Member Health and Safety

Prompts	Summary
	 Prescription Services (related to member access to a covered outpatient drugs, biological products, certain limited home health supplies (LHHS), vitamins and minerals, or other services available in a pharmacy setting)
	For all other complaints and grievances, HTW uses the TMHP Complaints Process. This TMHP process is the same process used for Medicaid State Plan services and thus complies with federal Medicaid requirements.
	TMHP Complaints Process Overview
	 TMHP maintains a dedicated Appeals, Complaints and Resolution (ACR) team to: Process all complaints received by TMHP through multiple channels (contact center, provider relations, web, etc.); and
	 Process complaints forwarded from HHSC or other external sources. All complaints are managed using the Client Relationship Management (CRM) tool and reported monthly to HHSC.
	The ACR team follows a schedule of internal reporting deadlines to ensure timely completion of complaints.
	The CRM tool access is available for use by HHSC staff.
	• The ACR team must resolve complaints within 15 business days. Currently, the average resolution time for complaints is 4.4 business days.
	Complaints requiring escalation or routing to HHSC are shared via email.
	 The full TMHP appeals process can be found in the Texas Medicaid Provider Procedures Manual (TMPPM), at <u>Section 7, Appeals.</u>

Prompts	Summary
	HHSC will maintain a data-driven complaint monitoring process to inform strategies and operations of the HTW program and identify any trends or changes in complaint activity.
	Texas Administrative Code (TAC) Rules Governing Complaints and Appeals
	1 TAC, Part 15, Chapter 382, Subchapter A, Healthy Texas Women:
	 §382.13 Denial, Suspension, or Termination of Services and Client Appeals §382.23 Health-Care Provider's Request for Review of Claim Denial
	These administrative rules refer to Medicaid TAC rules, Chapter 357, <u>Subchapter A</u> , and Chapter 354, Subchapter I, <u>§354.2217</u> for HHSC hearings and appeals.
f) Notices	When a woman is certified for HTW, she is provided a Form TF001W, <i>Notice of Case Action</i> , which provides notification of her 12-month certification period. Along with the Form TF001W, the woman receives Form H1019-W, <i>Report of Change</i> , which states what changes are required to be reported for the HTW program. The Form H1019-W does not require the woman to report a change in income or household size.
	All Medicaid applicants receive a Form TF0001, <i>Notice of Case Action</i> , that informs them of the outcome of their Medicaid eligibility determination. The following language is included on all TF0001 forms.
	Women who can't get Medicaid or CHIP:
	Women age 15 to 44 who can't get Medicaid or CHIP might be able to get services in the Healthy Texas Women program. A Parent or legal guardian must apply for young women age 15 to 17. To learn more, go to HealthyTexasWomen.org or call 1-866-993-9972.

Prompts	Summary
	Note: Women ages 15-17 are not included in the HTW Medicaid 1115 Demonstration Waiver. Their services are state funded.
g) Verifications	HHSC verifies a woman's eligibility prior to her enrollment into HTW.
	HHSC accepts self-attestation for the following HTW eligibility criteria:
	• residency;
	• age; and
	household composition.
	HHSC makes every attempt to verify the following HTW eligibility criteria through electronic data sources before requesting additional verification.
	• immigration status;
	• citizenship;
	• identity;
	Social Security Number; and
	• income.
	A Reasonable Opportunity period is provided if all eligibility requirements are met except for verification of citizenship or alien status.
h) Renewals	HTW currently conducts redeterminations every 12 months and will continue to do so when Medicaid eligibility requirements are fully implemented into the HTW program. Women certified for HTW are sent a renewal packet during the 10th month of their 12-month

Prompts	Summary
	continuous eligibility period. Women must meet all HTW eligibility requirements to be certified for a new 12-month certification period.
Monitoring health outcomes	
Strategy for monitoring health outcomes, including a data-driven process for reviewing access to care and addressing: a) the extent to which beneficiary needs are fully met;	To ensure HTW beneficiary needs are being fully met, the following measures will be monitored annually: • Contraceptive care for all women* – the percentage of women at risk of unintended pregnancy who: 1) were provided a most effective or moderately effective method of contraception, or 2) were provided a long-acting reversible method of contraception. • Cervical cancer screening* – assesses women 21-64 who had a cervical cytology (Paptest) performed every three years. • STD screening – the number of beneficiaries who obtained an STD test *These are national measures with defined measure specifications that cannot be altered. The following data will be reported quarterly: • Unduplicated number of enrollees by age group • The number of enrollees by age group with any claim
b) the availability of care through enrolled providers;	Please see Network Advocacy section above.

Prompts		Summary
c)	changes in beneficiary service utilization;	To monitor changes in beneficiaries' service utilization, HHSC will report each quarter the unduplicated number of beneficiaries with any claim by age group. This measure will allow Texas to track the number of services received and will indicate if there are significant changes in utilization between quarters. The state will also monitor the number of services received per beneficiary overall and by relevant service categories.
d)	the characteristics of the beneficiary population; and	The characteristics of the beneficiary population include women ages 18 to 44 from each of the 11 HHS geographic regions in the state of Texas. HHSC reports annually on clients by age and region and will continue to do so. The state will include overall population demographics, broken down by relevant categories such as region, age group, and race/ethnicity, as part of this reporting.
e)	actual or estimated levels of provider payment available from other payers.	Texas has an established process for reviewing all fee-for-service reimbursement rates at least once every two years. Rates are calculated utilizing established methodologies that conform to the Social Security Act and related federal regulations, the federally approved Texas Medicaid State Plan, all applicable state statutes and rules, and other requirements. For example, when Texas Medicaid State Plan rates are reviewed, they are compared to Medicare rates, Medicaid rates for other states, and, as available, commercial rates for the same or a similar service. Texas accepts public comment on proposed rate changes both in writing and in person at public hearings. Comments may include invoices or other cost information that is used in the rate setting process as appropriate. Any proposed rate updates are approved through the Medicaid State Plan amendment process. Texas uses Medicaid State Plan rates for the Healthy Texas Women Demonstration. Rate setting and review processes, combined with network adequacy oversight, are intended to
		Rate setting and review processes, combined with network adequacy oversight, are intended to help ensure sufficient provider networks.

Prompts	Summary			
MAGI transition				
Timeline with milestones for aligning eligibility and application processes with the requirements of section 1943 of the Social Security Act (and implementing federal regulations at 42 CFR part 435)	As required by the terms and conditions of the HTW Medicaid 1115 Demonstration Waiver, HHSC must implement the following changes in the HTW program to ensure it aligns with the requirements of section 1943 of the Social Security Act. • Use Modified Adjusted Gross Income (MAGI) methodologies to determine household composition and financial eligibility. • Allow Reasonable Opportunity for individuals who declare they are U.S. citizens or have a qualifying alien status, but who do not have verification of their status. • Convert the Federal Poverty Level (FPL) income threshold from 200% to the equivalent MAGI standard. • Remove adjunctive eligibility as a method for determining financial eligibility. • Use reasonable compatibility when verifying income. • Allow administrative renewals. • Include HTW in the health care coverage eligibility cascade. • Allow women to access HTW notices electronically. Reasonable Opportunity A policy bulletin (MEPD and Texas Works Bulletin #20-02) was released and effective on February 18, 2020, to inform staff that Reasonable Opportunity now applies to the HTW program. This update did not require automation changes. The Reasonable Opportunity policy for Healthy Texas Women was incorporated into the Texas Works Handbook in July 2020. Reasonable Opportunity Period Process			

Prompts	Summary
	If an HTW applicant has a social security number, HHSC uses State Online Query (SOLQ) or Wire Third-Party Query (WTPY) to verify the woman's citizenship. HHSC's eligibility system, TIERS, attempts to first verify citizenship using SOLQ. If the SOLQ system is unresponsive or unavailable due to a system failure, HHSC will attempt to verify the woman's citizenship using WTPY.
	If the woman is not a U.S. citizen, HHSC uses the Systematic Alien Verification for Entitlements (SAVE) system to verify a woman's immigration status at application and will verify her status again at redetermination if her documentation has expired.
	HTW applicants who declare themselves to be U.S. citizens or declare to have an eligible alien status, but who do not have verification of their citizenship or alien status, are allowed a 95-day period of reasonable opportunity (90-day period plus 5 days from when the notice was sent) to obtain and provide verification of their citizenship or alien status. A woman who qualifies for a reasonable opportunity period and meets all other HTW eligibility requirements will be certified for HTW. The woman is sent a Form TF001W, <i>Notice of Case Action</i> , informing her of her certification period and her period of reasonable opportunity.
	The woman's HTW benefits will be terminated if she has not provided citizenship or alien status verification by the day the reasonable opportunity period expires. If this occurs, the woman is sent a Form TF001W, <i>Notice of Case Action</i> , which provides 30 days advance notice of the termination of her ongoing HTW benefits.
	Federal Poverty Level Income Threshold In coordination with CMS, HHSC must convert the current HTW FPL threshold (200%) to an equivalent MAGI standard. The state participated in bi-weekly conference calls with CMS to

Prompts	Summary
	finalize the conversion methodology. Using a MAGI converted threshold considers the loss of currently allowed deductions and helps to ensure that individuals who are currently eligible for the HTW state funded program remain eligible for the HTW Medicaid 1115 Demonstration Waiver program. The converted MAGI FPL threshold will be implemented with the automation changes described below.
	Automation Changes for Healthy Texas Women
	The HHSC eligibility system, Texas Integrated Eligibility Redesign System (TIERS), must be updated to ensure HTW meets Medicaid eligibility requirements. Anticipated automation changes include:
	 updating the HTW income threshold from 200% FPL to the MAGI converted FPL threshold;
	 adding HTW to the health care coverage eligibility cascade; using MAGI methodologies to determine household composition and financial
	eligibility;
	allowing women to access HTW notices electronically;
	 removing adjunctive eligibility as a method of determining financial eligibility; using reasonable compatibility when verifying income; and allowing administrative renewals.
	HHSC has started developing the TIERS business rules. It is estimated that TIERS automation changes will take six months to complete after the business rules are developed. The project will be prioritized in the automation release cycle on May 21, 2020. It is anticipated that the automation changes will start on September 24, 2020, with a completion date of March 13, 2021.

Applications Updates

The Healthy Texas Women application (Form H1867) and the Healthy Texas Women renewal application (Form H1867-R) will be retired when Medicaid requirements are fully implemented into the HTW program. Instead of using the Form H1867, women will apply for HTW using the Form H1010 - *Texas Works Integrated Application for Assistance* or Form H1205 – *Texas Streamlined Application for Healthcare Coverage* or can continue to apply using the online YourTexasBenefits.com application. Women will first be determined ineligible for Medicaid and CHIP before being determined eligible for HTW.

Updates are needed to the Texas Streamlined Application for Health Care Coverage (Form H1205) and the Texas Works Integrated Application for Assistance (Form H1010) to allow women to apply for HTW. The updated applications will be released when the automation changes are effective.

Policy and Texas Administrative Code Updates

Policy updates will be developed in conjunction with automation changes. A policy bulletin explaining the changes to the HTW program and a web-based staff training will be released a month before the automation changes are effective. The estimated release date for policy and training will be in February 2021. It is anticipated that HTW policy changes will be incorporated into the Texas Works Handbook on July 1, 2021.

The HTW eligibility criteria in the TAC will be updated to reflect the MAGI converted FPL threshold and that HTW uses MAGI methodologies for determining household composition and income. As part of the TAC change process, the rules must be presented to the Medicaid Care Advisory Committee and must be posted for at least two weeks in the Texas Register to allow for public comment. Policy, TIERS functionality, and applications can be updated before TAC rules are finalized. Timelines for implementing eligibility related TAC changes will be coordinated with the other HTW modifications that were made as a result of the waiver.

Prompts	Summary
	Communication About Eligibility Changes
	HHSC will communicate the HTW eligibility changes in the following ways.
	 A policy bulletin and related training will be issued to staff a month before the automation changes are effective.
	 The HTW section of <u>YourTexasBenefits.com</u> will be updated to reflect the MAGI converted FPL threshold. This change will be posted when automation changes are effective.
	 The eligibility section of the <u>HTW website</u> will be updated to reflect the MAGI converted FPL threshold and allowable MAGI deductions. Additionally, information about adjunctive eligibility will be removed. These changes will be posted when automation changes are effective.
	• A guidance document outlining the changes to HTW eligibility will be provided to 2-1-1 staff approximately 30 days before automation changes are effective.