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

December 21, 2020

Tracy Johnson
Medicaid Director
Colorado Department of Health Care Policy and Financing; Medicaid & Child Health Plan (CHP+)
1570 Grant Street
Denver, CO 80203-1818

Dear Ms. Johnson:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not "stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. Section 1115 of the Act allows the Secretary to waive compliance with Medicaid and Children's Health Insurance Program (CHIP) requirements of sections 1902 or 2102 of the Act, to the extent and for the period he finds necessary to carry out such demonstration project. In addition, section 1115 of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under sections 1903 or 2105 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Colorado's request for an extension of its section 1115 CHIP demonstration, entitled "Colorado Adult Prenatal Coverage in CHP+," Project Number 21-W-00014/8. Approval of this extension is granted under the authority of section 1115(a) of the Act and is based on the determination that the expenditure authority granted therein is likely to assist with promoting an objective of title XXI of the Act by improving access to high-quality prenatal, delivery, and postpartum care services to low-income pregnant women. This approval is effective as of the date of this letter through July 31, 2025.

Our approval of this demonstration extension is subject to the enclosed Special Terms and Conditions (STCs) and the limitations specified in the associated list of title XXI expenditure and non-applicable authorities. The state may deviate from CHIP state plan requirements only to the

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

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

Extent and Scope of the Demonstration

The Colorado Adult Prenatal Coverage in CHP+ demonstration was initially approved on September 27, 2002 to provide coverage to uninsured pregnant women with family income above the Medicaid state plan level, from 133 to 185 percent of the federal poverty level (FPL). On July 30, 2012, CMS approved Colorado to expand coverage to uninsured pregnant women from 200 percent to 250 percent of the FPL.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) added section 2112 to the Act, which created the option for states to cover pregnant women in the CHIP state plan, but, pursuant to section 2112(b)(1)(A), only if the state covered pregnant women in Medicaid up to at least 185 percent of the FPL. Section 2112(f) permitted the continuation of other state options for providing *pregnancy-related services through the application of any waiver authority (as in effect on June 1, 2008).* Consistent with section 2112 to the Act, Colorado extended coverage in the CHIP state plan to pregnant women with family income up to 260 percent of the FPL, and amended its Medicaid state plan to move pregnant women from 133 to 185 percent of the FPL from coverage under the CHIP section 1115 demonstration to the Medicaid state plan (effective January 1, 2013). Concurrently, in accordance with section 2112(f), CMS grandfathered Colorado's title XXI section 1115 demonstration coverage for pregnant women at the income band of 133 to 185 percent of the FPL and Colorado continues to maintain its provision of pregnancy-related services to this population in the same manner as in effect on June 1, 2008.

Objectives of the CHIP Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XXI. The purpose of CHIP is to provide funds to enable each state, as far as practicable under the conditions in such state, (1) "to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children." Act §2101(a); and (2) "to provide pregnancy-related assistance" for "targeted low-income pregnant women" should the state elect to do so via amendment to its State child health plan. Act §2112(a). These provisions make clear that an important objective of CHIP is to furnish medical assistance and other services to vulnerable populations. As discussed more fully below, this demonstration would continue to do

that by expanding access to high-quality prenatal, delivery, and postpartum care services to low-income pregnant women.

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

Section 1115 demonstration projects also provide an opportunity for states to test policies that fulfill the purposes of CHIP as stated above in accordance with sections 2101(a) and 2112(a) of the Act, while making it more practicable for states to furnish insurance coverage to a broader range of persons in need. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover. By the same token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes of beneficiaries. Demonstration projects that seek to improve beneficiary health improve the well-being of CHIP beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their programs and to provide more medical services to more CHIP beneficiaries. Accordingly, such demonstration projects advance the objectives of CHIP.

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

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstration is likely to assist with promoting the objectives of CHIP. This extension of the Colorado Adult Prenatal Coverage in CHP+ section 1115 demonstration improves access to prenatal, obstetric, and postpartum services for low-income women beneficiaries and their newborns who otherwise would not have access to these services.

Colorado's evaluation data shows the state realized an 8.6 percent increase in the proportion of eligible beneficiaries accessing postpartum care from the state's baseline to demonstration year one. After the first demonstration year, this proportion remained relatively stable across the

remaining demonstration years. Another positive outcome is the proportion of beneficiaries who gave birth to a low birth weight (LBW) baby decreased each year of the demonstration. In this extension period, Colorado intends to further improve its plan for evaluation by expanding its objectives and modifying measures to target an increase in prenatal and postpartum care, such as increasing healthcare and consultation to pregnant women. A new evaluation design approved by CMS is required post-approval per the accompanying STCs and CMS is working with the state on its improved design.

Therefore, the Secretary has determined that the Colorado Adult Prenatal Coverage in CHP+, section 1115 demonstration is likely to assist in promoting the objectives of CHIP.

Consideration of Public Comments

To increase the transparency of demonstration projects, section 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

As enacted by the Affordable Care Act (ACA), and incorporated under sections 1115(d)(2)(A) & (C) of the Act, comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposed no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments. 42 CFR 431.416(d)(2)

Colorado received nine public comments during its public comment period and two during its post award forum that were all in support of the continuation of the Colorado Adult Prenatal Coverage in CHP+ demonstration. Some of the supporting comments offered recommendations for how the state may improve the evaluation design such as refining certain measures and including comparison populations to further analyze and understand results. In response to the public comments, Colorado expressed its appreciation for the supporting comments offered by stakeholders. The state also acknowledged that it could improve its proposed plan to evaluate the demonstration based on the feedback received and committed to work with CMS on finalizing an evaluation design that incorporates the recommendations. Colorado also completed consultation with federally-recognized tribes and there were no concerns raised or comments received.

The federal public comment period for this extension request began August 13, 2020 and ended September 12, 2020. CMS received two comments supporting the demonstration extension during the federal public comment period. One comment from Children's Hospital Colorado cited several Colorado-specific studies and findings. One study determined that nearly one in five Colorado babies were born to a mother who did not have early prenatal care; another found that maternal mortality rates were disproportionally higher among African American and

American Indian mothers; and another found that roughly 3 in 5 pregnancy-related deaths were preventable. Given these statistics, they expressed their belief that the Colorado Adult Prenatal Coverage in CHP+ demonstration is critical to improving health outcomes for low-income Coloradan mothers and their babies by providing essential prenatal, delivery and postpartum care to eligible beneficiaries. The second comment from the American College of Obstetricians and Gynecologists (ACOG) similarly cited statistics pertaining to higher mortality rates among uninsured pregnant women and commented that Colorado's demonstration is imperative to efforts to eliminate inequities in maternal health outcomes.

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

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-01-16
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: joyce.jordan@cms.hhs.gov

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

Sincerely,

[redacted]

Anne Marie Costello
Acting Deputy Administrator and Director

Enclosure

cc: Curtis Volesky, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE AND MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 21-W-00014/8

TITLE: Adult Prenatal Coverage in Child Health Plan Plus (*CHP+*)

AWARDEE: Colorado Department of Health Care Policy and Financing

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Colorado identified below, which are not otherwise included as expenditures under section 2105 of the Act, shall for the period of this demonstration extension, beginning from December 18, 2020 through July 31, 2025, be regarded as expenditures under the state's title XXI state plan. The expenditure authority granted below enables the state to operate its Colorado Adult Prenatal in CHP+ section 1115 demonstration and may only be implemented consistent with the below parameters for this authority and the accompanying Special Terms and Conditions (STCs).

All requirements of the Children's Health Insurance Program (CHIP) expressed in law, regulation and policy statements, not expressly waived or identified as not applicable to the below expenditure authority, shall apply to the Colorado Adult Prenatal Coverage in CHP+ demonstration for the period of this approved extension.

The expenditure authority listed below promotes the objectives of title XXI by improving access to high-quality prenatal, delivery, and postpartum care services to low-income pregnant women. This expenditure authority is contingent upon the continued provision of pregnancy-related services to the below mentioned population of pregnant women consistent with coverage that was in effect in the state on June 1, 2008.

This demonstration authorizes title XXI expenditures for health benefits coverage to pregnant women age 19 and over, with family income above 141 percent through 195 percent of the Federal Poverty Level (FPL), who are covered under the Medicaid state plan.

CHIP Requirements Not Applicable to the CHIP Expenditure Authorities:

All CHIP requirements apply, except the following requirement that is not applicable:

1. **Minimum Income Standard for Pregnant Women in CHIP** — **Section 2112(b)(2)**

   To permit the state to have income levels for eligibility for the above specified demonstration population that are lower than applicable Medicaid levels, to the extent necessary to provide title XXI coverage for the Medicaid benefit package for pregnant women.

2. CHIP Secondary Payer to Medicaid **Section 2105(c)(6)(B)**

To permit the state to make payment under title XXI primary to payment under Medicaid for this demonstration population, to the extent necessary to provide title XXI coverage for the Medicaid benefit package to pregnant women with incomes above 141 percent of the FPL through 195 percent of the FPL.

CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 21-W-00014/8

TITLE: Adult Prenatal Coverage in Child Health Plan Plus (*CHP+*)

AWARDEE: Colorado Department of Health Care Policy and Financing

The following are the Special Terms and Conditions (STCs) for the Colorado Adult Prenatal Coverage in CHP+ section 1115(a), title XXI funded, Children's Health Insurance Program (CHIP) demonstration (hereinafter "demonstration"), to enable the Colorado Department of Health Care Policy and Financing (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority under section 2105 of the Social Security Act (Act), authorizing federal matching of demonstration costs not otherwise matchable, 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 the demonstration. The STCs for this demonstration extension are effective as of December 18, 2020 and approved through July 31, 2025.

The STCs have been arranged into the following subject areas:

I. Program Description And Objectives
II. General Program Requirements
III. Eligibility for the Demonstration
IV. Benefits, Cost-sharing, Delivery System
V. General Reporting Requirements
VI. Monitoring the Demonstration
VII. General Financial Requirements
VIII. Monitoring Allotment Neutrality
IX. Evaluation of the Demonstration
X. Schedule of Deliverables

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: Demonstration Evaluation Plan (reserved for CMS approval)

I. PROGRAM DESCRIPTION AND OBJECTIVES

The Colorado Adult Prenatal Coverage in CHP+ demonstration was initially approved on September 27, 2002 to provide coverage to uninsured pregnant women with family income above the Medicaid state plan level, from 133 to 185 percent of the federal poverty level (FPL). At the time of initial approval, states only had the option to cover pregnant women above the Medicaid state plan level under title XXI (i.e., CHIP) through a section 1115 demonstration.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) added section 2112 to the Act, which created the option for states to cover pregnant women in the CHIP state plan, but only if the state covered pregnant women in Medicaid up to at least 185 percent of the FPL. Consistent with CHIPRA, Colorado extended coverage in the CHIP state plan to pregnant women with family income up to 250 percent of the FPL, but had to amend its Medicaid state plan to move pregnant women from 133 to 185 percent of the FPL from coverage under the CHIP section 1115 demonstration to the Medicaid state plan (effective January 1, 2013). To support Colorado with continuing its pre-CHIPRA coverage of pregnant women from 133 to 185 percent of the FPL, CMS grandfathered title XXI coverage for this population of uninsured pregnant women (at the Modified Adjusted Gross Income (MAGI) equivalent eligibility level of above 141 percent through 195 percent of the FPL) with the July 30, 2012 extension of the demonstration. Grandfathering title XXI coverage for these pregnant women is consistent with section 2112(f) of the Act (enacted by CHIPRA) that authorizes the continuation of other state options for providing medical assistance to pregnant women, including *pregnancy-related services through the application of any waiver authority (as in effect on June 1, 2008)*. Colorado continues to operate the Adult Prenatal Coverage in CHP+ demonstration within the program authorities and implementation parameters in existence on June 1, 2008. In accordance with section 2112(f) of the Act, CMS approved a five-year extension of Colorado's grandfathered title XXI coverage in September 2015 (through July 31, 2020; temporarily extended through December 31, 2020) and is approving another five-year extension through July 31, 2025 with these STCs and associated expenditure and non-applicable authorities. The program authorities granted with this approval are solely limited to, and contingent upon, Colorado's continued implementation of its pre-CHIPRA coverage of pregnant women from 133 to 185 percent of the FPL (at the MAGI equivalent of 141 percent through 195 percent of the FPL) in accordance with section 2112(f) of the Act.

This demonstration furthers the objectives of title XXI by improving access to high-quality prenatal, delivery, and postpartum care services to low-income pregnant women that is producing positive health outcomes for beneficiaries. For example, the state's interim evaluation report for the 2015 – 2020 demonstration period shows that the state realized an 8.6 percent increase in the proportion of eligible beneficiaries accessing postpartum care from the state's baseline to demonstration year one. After the first demonstration year, this proportion remained relatively stable across the remaining demonstration years. Another positive outcome is the proportion of beneficiaries who gave birth to a low birth weight (LBW) baby decreased each year of the demonstration.

The state is continuing the same program objectives with this demonstration extension, which are to:

- Decrease the uninsurance rate for pregnant women;
- Increase prenatal and postpartum care for pregnant women enrolled in the demonstration; and;
- Increase the number of healthy babies born to pregnant women enrolled in the demonstration.

II. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes**. The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (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 Patient Protection and Affordable Care Act (section 1557).

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

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy**. The state must, within the timeframes specified in law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the 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 as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state shall accept the changes in writing.

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

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified allotment neutrality worksheet for the demonstration as necessary to comply with such change. The modified allotment neutrality agreement will be effective upon the implementation of the change.

    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 earlier

of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner..

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

6. **Changes Subject to the Amendment Process**. Changes related to demonstration features, such as 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 amendment to the demonstration or through an amendment to the Medicaid or CHIP state plan, as applicable. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

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

    a) The state must provide a detailed description of the amendment (with sufficient supporting documentation) that minimally includes: what the state intends to demonstrate via this amendment; the impact on beneficiaries; the objective of the change and desired outcomes; if a conforming title XIX and/or title XXI state plan amendment is necessary to effectuate the change; and a list waivers and expenditure authorities that are being requested or terminated for the amendment with a justification that includes the applicable federal citations and description of how these waiver and/or expenditure authorities are necessary to effectuate the change.

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

c) An up-to-date CHIP (title XXI funding) allotment neutrality worksheet that reflects the associated cost of implementing the amendment as proposed by the state; and;

d) An updated demonstration evaluation design plan that 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 amendment provisions.

8. Extension of the Demonstration. No later than 12 months prior to the expiration date of the demonstration, the Governor of the state must submit to CMS either a demonstration extension request in accordance with the transparency requirements set forth at 42 CFR 431.408 and 431.412(c) and the public notice and tribal consultation requirements outlined in STC 12, or a transition and phase-out plan consistent with the requirements of STC 9.

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

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

b. Transition and Phase-out Plan: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206,

431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

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

f) Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XXI. CMS will 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 dis-enrolling 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 Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid state plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

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

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

III. ELIGIBILITY FOR THE DEMONSTRATION

15. **Eligibility Groups Affected By the Demonstration**. This demonstration affects pregnant women with family income from 141 percent through 195 percent of the FPL covered under the Colorado Medicaid state plan. All mandatory and optional state plan eligibility groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan, except as expressly waived in this demonstration and as described in these STCs.

16. **Changes to Mandatory and Optional Eligibility Groups Included in the Medicaid State Plan.** The program authorities granted with this approval are solely limited to, and contingent upon, Colorado's continued implementation of its June 1, 2008 pre-CHIPRA coverage of pregnant women, from 133 to 185 percent of the FPL (at the MAGI equivalent of 141 to 195 percent of the FPL), in accordance with section 2112(f) of the Act. Should the state amend the Medicaid state plan to make any changes to eligibility for Medicaid mandatory or optional populations, upon submission of the state plan amendment (SPA), the

state must notify CMS in writing of the pending SPA and include an assessment of how the proposed SPA does not impact eligibility for the pregnancy-related services provided through this demonstration consistent with the CMS-approved June 1, 2008 grandfathered demonstration authority.

CMS reserves the right to render its own determination of whether the impact of the pending SPA aligns with the parameters of the approved expenditure authority. In addition, CMS reserves the right to exercise its authority under STC 10 if it determines the SPA, upon CMS approval, is not consistent with the parameters of the approved expenditure authority.

IV. BENEFITS, COST SHARING, DELIVERY SYSTEM

17. Demonstration Benefits. Individuals enrolled in this demonstration derive their eligibility from the Colorado Medicaid state plan and will receive comprehensive benefits as provided under the Medicaid state plan.

18. Minimum Essential Coverage. Section 5000A(f)(1)(E) of the Internal Revenue Code grants the Secretary of Health and Human Services, in coordination with the Secretary of Treasury, the authority to recognize otherwise non-specified health benefits coverage as minimum essential coverage (MEC) for the purposes of purposes of section 5000A of the Internal Revenue Code. In accordance with this authority, CMS informed the state in written correspondence, dated February 12, 2016, to State Medicaid Director, Gretchen Hammer that CMS concluded that the health benefits coverage provided under this demonstration meets the criteria for MEC.

19. Cost Sharing. The demonstration population is only subject to cost-sharing to the extent allowable under Medicaid state plan.

20. Delivery of Services. Pregnant women enrolled in this demonstration receive Medicaid state plan services through a combination of fee-for-service and managed care delivery systems that may vary by geographic area of the state. The service delivery systems are authorized under other managed care authorities, including section 1915(a), section 1915(b) and section 1932(a) of the Act.

V. GENERAL REPORTING REQUIREMENTS

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

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

a) CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverable(s).

b) For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

c) If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

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

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

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

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

a) Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b) Ensure all section 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and,

c) Submit deliverables to the appropriate system as directed by CMS.

24. Closeout Report. Within 120 days after the end of the demonstration (for any reason), the state must submit a draft Closeout 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 Closeout report.

c) The state must take into consideration CMS' comments for incorporation into the final Closeout Report.

d) The final Closeout Report is due to CMS no later than 30 days after receipt of CMS' comments.

e) A delay in submitting the draft or final version of the Closeout Report may subject the state to the penalties described in STC 21.

VI. MONITORING OF THE DEMONSTRATION

25. Annual Monitoring Reports. The state must submit an Annual Monitoring Report for each demonstration year. The Annual Monitoring Report is due no later than 90 days following the end of the demonstration year (i.e., due by November 29 each year). The reports will include all required elements by 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 Annual Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and must be provided in a structured manner that supports federal tracking and analysis.

a) Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Annual 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 Annual Monitoring Report should also include a summary of all public comments received through post-award public forums conducted in accordance with required by 42 CFR 431.420(c) regarding the progress of the demonstration.

b) Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per

42 CFR 431.428, the Annual 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 monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow – as applicable – the framework provided by CMS to support federal tracking and analysis.

c) Allotment Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Annual Monitoring Reports must document the financial performance of the demonstration. The state must include its total annual demonstration expenditures for the completed year in alignment with the quarterly expenditures reported by the state on the Form CMS-21 for the population(s) affected by this demonstration. Administrative costs should be reported as a separate line item.

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

26. Monitoring Calls. CMS and the state will hold monitoring calls no later than 60 days after submission of the Annual Monitoring Reports described in STC 25 to discuss the program update provided in the Annual Monitoring Reports and any issues associated with the continued operation of the demonstration. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration such as implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, allotment neutrality, and progress on evaluation activities. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration. The state and CMS will jointly develop the agenda for the calls.

27. Post Award Forum. As required by 42 CFR 431.420(c), within six months of the demonstration's initial implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 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 Annual Monitoring Report associated with the demonstration period in which the forum was held.

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

VII. GENERAL FINANCIAL REQUIREMENTS

29. Extent of Federal Financial Participation (FFP) for the Demonstration. CMS will provide FFP at the applicable federal matching rate only for the medical assistance services as described in STC 17 and associated administrative expenditures that are compliant with section 1903(w) of the Act and applicable regulations.

30. Sources of Non-Federal Share. The state certifies that the non-federal share is obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that such funds must not be used to match any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, CMS reserves the right to prohibit the use of any sources of non-federal share funding that it determines impermissible.

a) If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to fund the demonstration.

b) If CMS determines that any non-federal share funding sources are not consistent with applicable federal regulations, the state must address CMS's concerns within the timeframe allotted by CMS.

c) Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

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

i. Units of state or local government, including health care providers that are units of state or local government, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

ii. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XXI demonstration payments, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state would identify those costs eligible under this demonstration for purposes of certifying public expenditures.

iii. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under this demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy

demonstration expenditures. If the CPE is claimed under a Medicaid or CHIP authority, the federal matching funds received cannot be used as the non-federal 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.

iv. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local revenues and are transferred by units of government within the state. Any transfers from units of government must be made in an amount not to exceed the non-federal share of title XXI payments.

v. 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 governments to return and/or redirect to the state any portion of the CHIP payments. This confirmation of CHIP payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to CHIP and in which there is no connection to CHIP payments, are not considered returning and/or redirecting a CHIP payment.

VIII. MONITORING ALLOTMENT NEUTRALITY

31. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement. The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

a) Tracking Expenditures: In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 reporting instructions as outlined in section 2115 of the State Medicaid Manual.

b) Use of Waiver Forms: Title XXI demonstration expenditures will continue to be reported on separate Forms CMS-21 Waiver and/or CMS-21P Waiver, identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made).

c) Claiming Period: All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period,

the state must continue to identify separately, on the Form CMS-21 Waiver, net expenditures related to dates of service during the operation of the demonstration.

32. **Standard CHIP Funding Process.** The standard CHIP funding process will continue to be used during the demonstration. The state will continue to estimate matchable CHIP expenditures on the quarterly Form CMS-21B. On a separate CMS21B, the state shall provide updated estimates of expenditures for the demonstration populations. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-21 quarterly CHIP expenditure report. CMS will reconcile expenditures reported on the Form CMS-21 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

33. **Title XXI Administrative Costs.** Administrative costs will not be included in the allotment neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name "ADM". Total expenditures for outreach and other reasonable costs to administer the CHIP state plan and this demonstration that are applied against the state 's title XXI allotment may not exceed ten percent of total title XXI net expenditures.

34. **Limit on Title XXI Funding.** The state will be subject to a limit on the amount of federal title XXI funding that the state may receive on allowable demonstration expenditures during the demonstration period. Federal title XXI funds for the state's CHIP program (i.e., the approved title XXI state plan and this demonstration) are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must be first used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.

35. **Exhaustion of Title XXI Funds.** The state is eligible to receive title XXI funds for the demonstration population as described in STC 15, up to the amount of its title XXI allotment. Title XIX funds for these uninsured pregnant women are available if the state exhausts its title XXI allotment. The state shall provide CMS with written notice at least 120 days before it begins to draw down title XIX matching funds for this demonstration population.

IX. EVALUATION OF THE DEMONSTRATION

36. **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 21.

37. **Draft Evaluation Design.** The Draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a Draft Evaluation Design with implementation timeline, no later than 180 days after the effective date of these STCs.

38. **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.

39. **Evaluation Design Approval and Updates.** The state must submit a revised Draft Evaluation Design no later than 60 days after receipt of CMS' comments on the initial submission described in STC 37 and 38. Upon CMS approval of the Evaluation Design, the document will be included as Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Annual 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.

40. **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. 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).

41. **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 extension, 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) If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted in accordance with STC 8. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a demonstration extension, an Interim Evaluation report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of this demonstration approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

c) The state must submit a revised Interim Evaluation Report 60 days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's website.

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

42. 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 demonstration 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 a revised Summative Evaluation Report within 60 days of receiving comments from CMS on the draft.

b) Upon approval from CMS, the final Summative Evaluation Report must be posted to the state's designated Medicaid/CHIP website within 30 days of approval by CMS.

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

44. 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.

45. Public Access. The state shall post the final documents (e.g., Annual Monitoring Reports,

Closeout Report, Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's designated Medicaid/CHIP website within 30 days of approval by CMS.

46. **Additional Publications and Presentations.** For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten 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.

X. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after approval date	State acceptance of demonstration STCs and associated Expenditure Authority	Approval letter
180 calendar days after approval date	Draft Evaluation Design	STC 37
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 39
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC 39
July 31, 2024, or with extension application	Draft Interim Evaluation Report	STC 41
60 days after receipt of CMS comments	Revised Interim Evaluation Report	STC 41
Within 18 months of the end of the demonstration approval period represented by these STCs	Draft Summative Evaluation Report	STC 42
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 42
Annual Deliverables - Due 90 calendar days after end of each demonstration year	Annual Monitoring Reports	STC 25
Due 90 calendar days after end of each demonstration year as a part of the annual monitoring report	Allotment Neutrality Reports	STC 25(c)

ATTACHMENT A
DEVELOPING THE EVALUATION DESIGN

Introduction

For states that are testing new approaches and flexibilities in their Medicaid/CHIP 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/CHIP 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.

Technical assistance resources for constructing comparison groups, identifying causal inferences, and phasing implementation to support evaluation are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html.

Expectations for Evaluation Designs

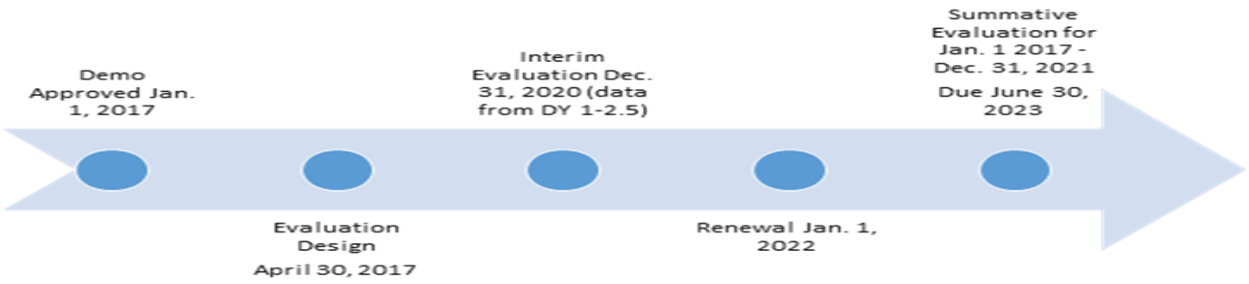
All states with section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

- **A.** General Background Information;
- **B.** Evaluation Questions and Hypotheses;
- **C.** Methodology;
- **D.** Methodological Limitations; and
- **E.** Attachments.

Submission Timelines

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



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

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

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

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

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

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

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

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

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
    b. Qualitative analysis methods may be used, and must be described in detail.
    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
    b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
d. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

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

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

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances;
    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 (only applicable if required in section IX of these STCs). This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include a "No Conflict of Interest" statement signed by the independent evaluator.

2) Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) Timeline and Major Milestones. Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B:
PREPARING THE EVALUATION REPORT

Introduction

For states that are testing new approaches and flexibilities in their Medicaid/CHIP 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/CHIP 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

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/CHIP policy in order to improve the health and welfare of Medicaid/CHIP 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

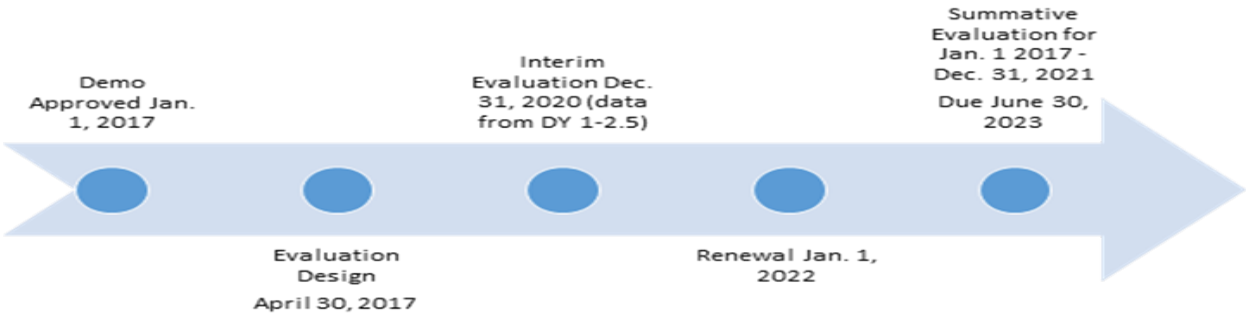
Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified 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/CHIP policy. Therefore, the state's submission must include:

a. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

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

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4) For extensions, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions/hypotheses of this demonstration promote the objectives of titles XIX and/or XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the

data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1) *Evaluation Design* – Will the evaluation be an assessment of pre/post, post-only, with or without comparison groups, etc?

2) *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.

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

4) *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?

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

6) *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

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

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

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

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

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

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

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall CHIP context and long range planning. This should include interrelations of the demonstration with other aspects of the state's CHIP, interactions with other CHIP demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under CHIP. 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/CHIP 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?

J. Attachment

1) Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C
APPROVED DEMONSTRATION EVALUATION PLAN

(RESERVED FOR CMS APPROVAL)