DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

June 25, 2025

Adela Flores-Brennan
Medicaid Director
Colorado Department of Health Care Policy and Financing
1870 Grant Street
Denver, CO 80203

Dear Director Flores-Brennan:

The Centers for Medicare & Medicaid Services (CMS) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Colorado Adult Prenatal Coverage in CHP+ (Project Number 21-W-00014/8) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section 1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to

alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The Colorado Adult Prenatal Coverage in CHP+ demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on January 27, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 25, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Demonstration Monitoring Calls

As STC 26 "Monitoring Calls" describes, CMS and the state may "hold monitoring calls," and the calls are intended "to discuss any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate

that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Colorado Adult Prenatal Coverage in CHP+ section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Ronna Bach, 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:

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

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

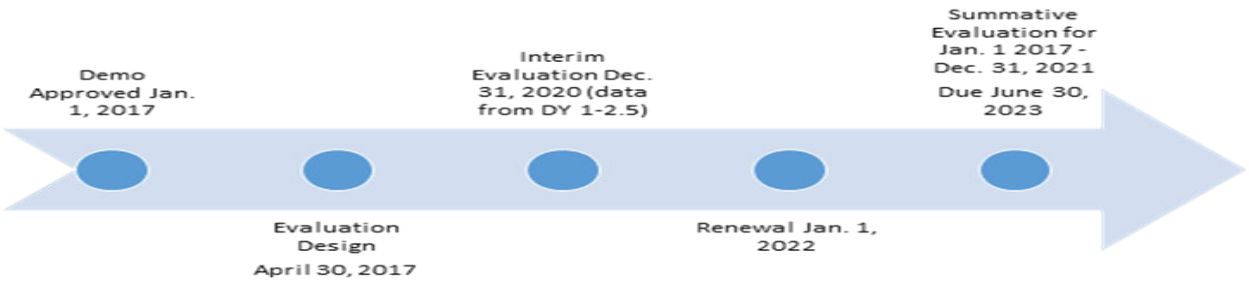
All states with section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to 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.

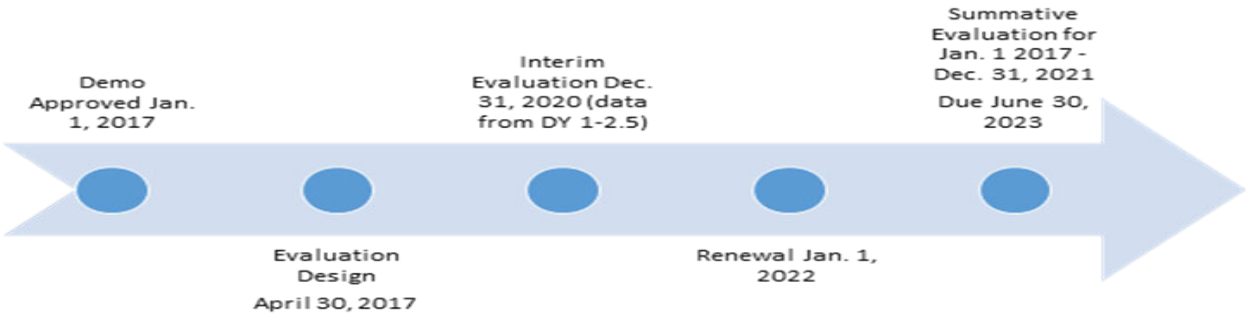
The format for the Interim and Summative Evaluation reports is as follows:

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

EVALUATION DESIGN PLAN FOR COLORADO'S ADULT PRENATAL COVERAGE IN CHILD HEALTH PLAN PLUS (CHP+) SECTION 1115 DEMONSTRATION WAIVER

FINAL DRAFT
JULY 8, 2022

HEALTH MANAGEMENT ASSOCIATES

EVALUATION TEAM MEMBERS:

MARK PODRAZIK, PRINCIPAL INVESTIGATOR

AKHILESH PASUPULATI
RYAN SANDHAUS
DEBBIE SAXE
BARRY SMITH

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Listing of Exhibits

Abbreviations List

Abbreviation	Meaning
ACA	Affordable Care Act
HMA-Burns	Burns & Associates, a Division of Health Management Associates
BIDM	Business Intelligence Data Management
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
CHP+	Child Health Plus
CMS	Centers for Medicare and Medicaid Services
CoHID	Colorado Health Information Dataset
CPT	Current Procedural Terminology
CY	Calendar Year
DOS	Date of Service
DR	Desk Review
DS	Descriptive Statistics
DXC	DXC Technologies (now Gainwell)
E&M	Evaluation & Management
ED	Emergency Department
EDW	Enterprise Data Warehouse
FFS	Fee-For-Service
FG	Focus Groups

Abbreviation	Meaning
FI	Facilitated Interviews
FPL	Federal Poverty Level
HCPCS	Healthcare Common Procedure Coding System
HCPF	Department of Health Care Policy & Financing
IBM	IBM Corporation (formerly Truven Health Analytics)
ITS	Single Segment Interrupted Time Series
LBW	Low Birth Weight
MAGI	Modified Adjusted Gross Income
MCO	Managed Care Organization
MMIS	Medicaid Management Information System
NCQA	National Committee for Quality Assurance
OR	Onsite Reviews
PCP	Primary Care Provider
PRAMS	Pregnancy Risk Assessment and Monitoring System
RAE	Regional Accountable Entity
RCT	Randomized Control Trials
SFY	State Fiscal Year
STC	Special Terms and Conditions
SUD	Substance Use Disorder
TJC	The Joint Commission

SECTION I: GENERAL BACKGROUND INFORMATION

I.A Waiver Demonstration Information[1]

Colorado has had a long-standing Section 1115(a) demonstration which was originally approved in 2002 and most recently extended from December 18, 2020 through July 31, 2025. The demonstration waiver was selected as a mechanism to allow Colorado to continue to provide coverage to uninsured pregnant women with family income using Modified Adjusted Gross Income (MAGI) equivalent between 141 and 195 percent of the federal poverty level (FPL). Colorado continues to use the Child Health Plus (CHP+) 1115 Demonstration to improve the health status of low-income pregnant women and their newborns by using the goals as described in Section I.B to guide the administration and implementation of the demonstration.

Name: Colorado Adult Prenatal Coverage in Child Health Plus (CHP+)
Project Number: 21-W-00014/8
Approval Date: December 21, 2020
Time Period Covered by Evaluation: December 18, 2020 through July 31, 2025

I.B Waiver Demonstration Goals[2]

Colorado's goals in operating the demonstration are to improve the health status of low-income Coloradoans by enabling a:

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

I.C Brief Description and History of Implementation[3]

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

[1] Colorado Adult Prenatal Coverage in Child Health Plan Plus (CHP+) Section 1115(a) Demonstration Special Terms and Conditions, accessed at https://www.CHP+.gov/CHP+-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/co/co-adult-prenatal-coverage-ca.pdf
[2] Ibid, page 5 of 31
[3] Ibid, page 4 of 31

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 CHP+ 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 CHP+ state plan to move pregnant women from 133 to 185 percent of the FPL from coverage under the CHIP section 1115 demonstration to the CHP+ 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, the Centers for Medicare and Medicaid Services (CMS) grandfathered title XXI coverage for this population of uninsured pregnant women (at the 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 141-195% of the FPL) in accordance with section 2112(f) of the Act.

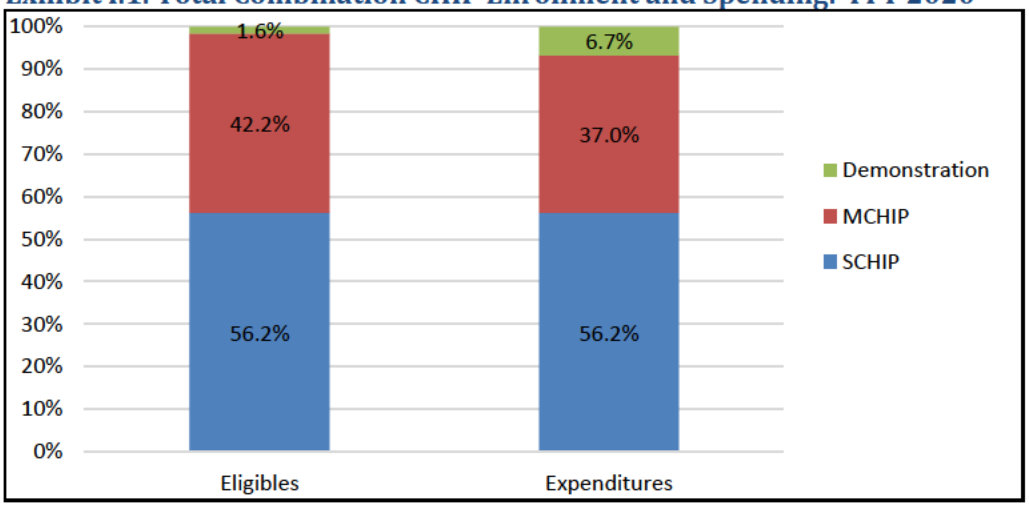
This demonstration furthers the objectives of title XXI by improving access to high-quality prenatal, delivery, and postpartum care services to low-income pregnant women that is producing positive health outcomes for beneficiaries. For example, the state's interim evaluation report for the 2015 – 2020 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.

I.D Population Groups Impacted

Overview of Colorado's CHP+ Program

The Department of Health Care Policy & Financing (HCPF) has responsibility for the administration and oversight of Colorado's CHIP as well as the CHP+ program under the waiver and state plan authorities. As seen in Exhibit I.1, during federal fiscal year (FFY) 2020, CHP+ comprised 1.6% of the total enrollment of 135,265 and 6.7% of the total of $330 million in expenditures for Colorado's total combined CHIP program.

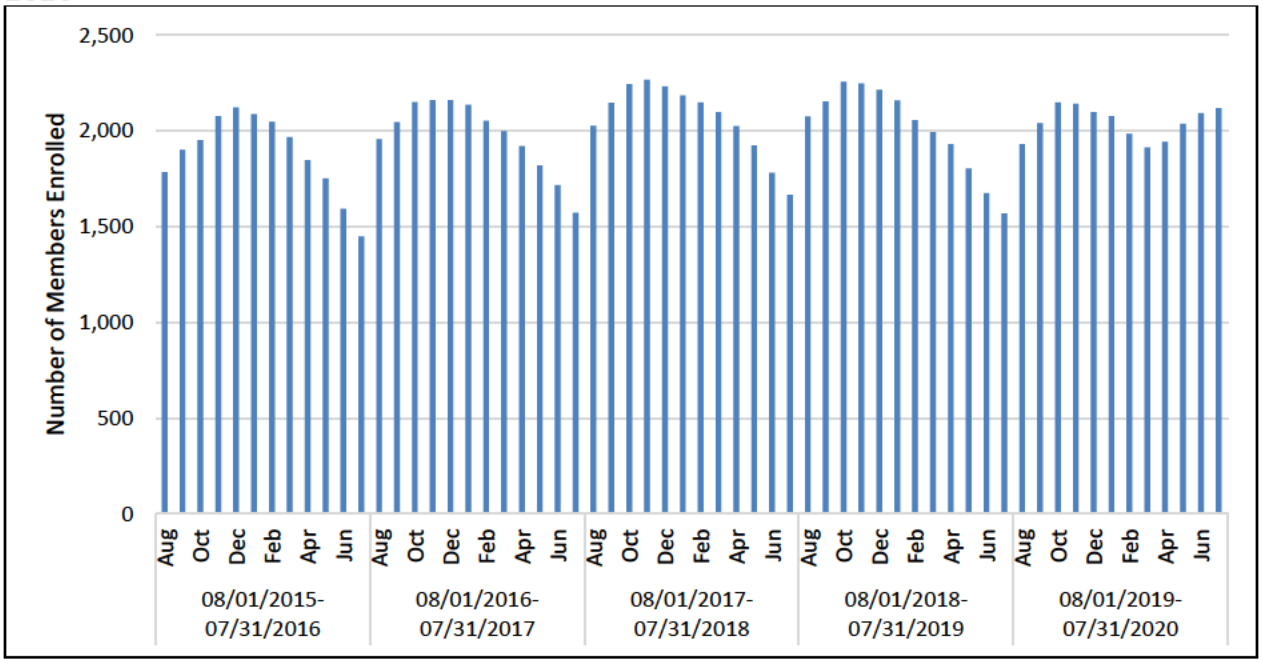
Exhibit I.1. Total Combination CHIP Enrollment and Spending: FFY 2020



Source: CHP+ Demonstration Extension Application and FFY 2020 Allotment Neutrality Report

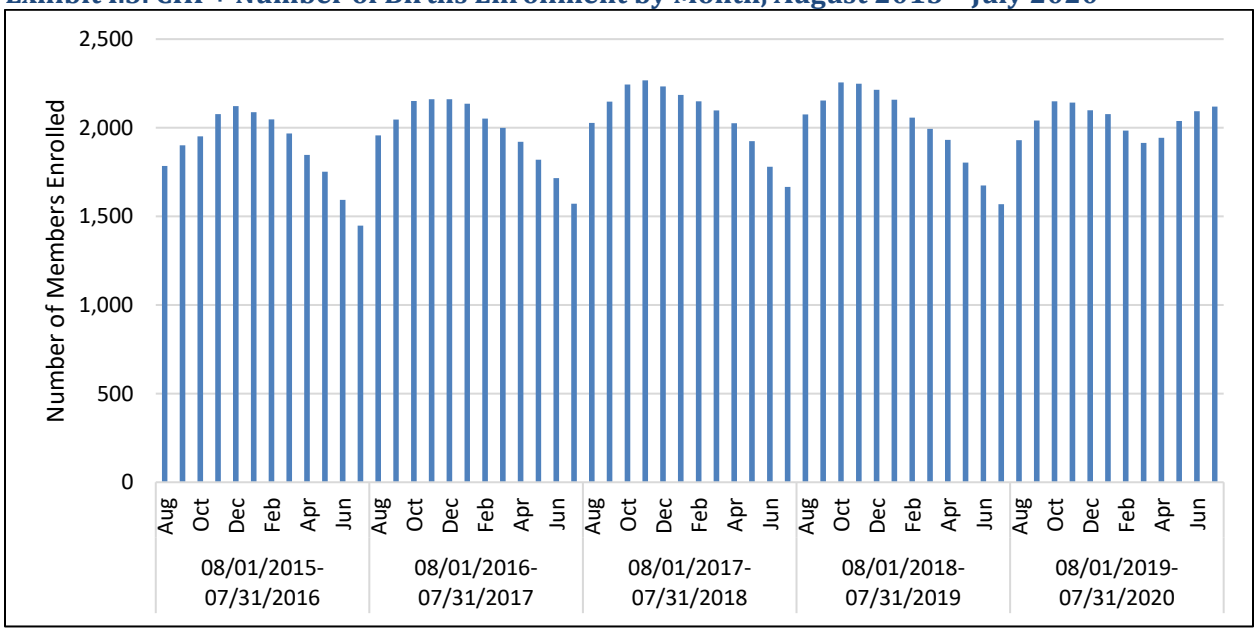
In the most recent demonstration year, there were 2,938 unduplicated pregnant women enrolled. Since 2015, monthly enrollment of pregnant women and births has trended upward as found in Exhibits I.2 and I.3.

Exhibit I.2. CHP+ Number of Women Enrolled in Prenatal Demonstration, August 2015 – July 2020



Source: CHP+ Client Data

Exhibit I.3. CHP+ Number of Births Enrollment by Month, August 2015 – July 2020

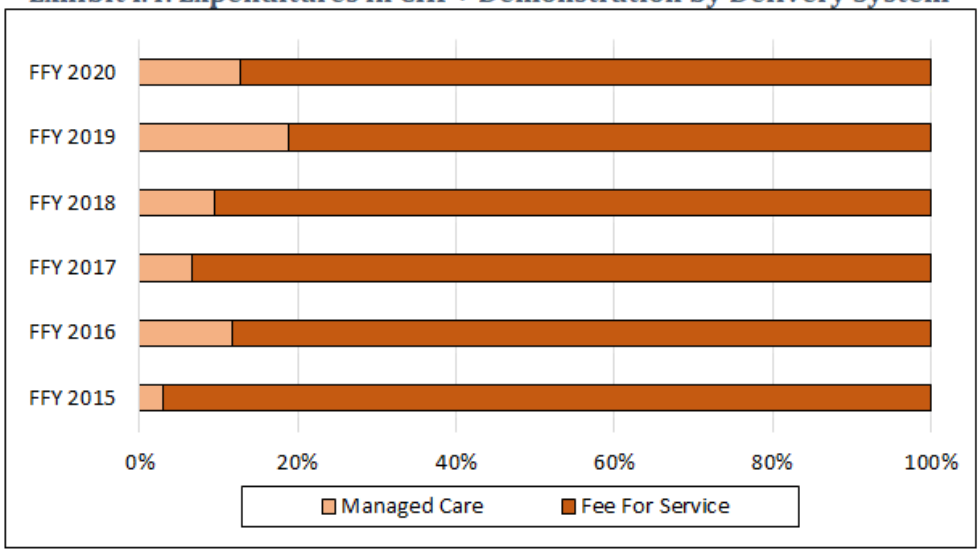


Source: CHP+ Client Data

CHP+ enrollees are entitled to receive all mandatory and optional state plans services approved under the Medicaid state plan. Services are provided through a combination of fee-for-service (FFS) and managed care delivery systems that vary geographically.

During this same time, the majority of Colorado's CHP+ demonstration expenditures were for care provided through the FFS delivery system, although the proportion of payments to managed care plans is increasing over time (refer to Exhibit I.4).

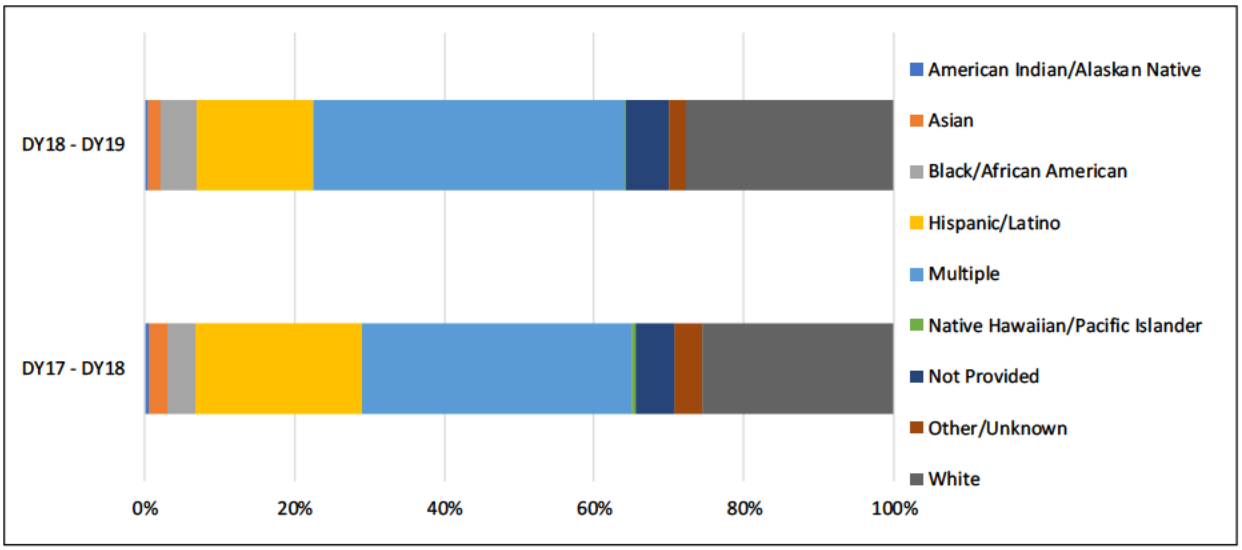
Exhibit I.4. Expenditures in CHP+ Demonstration by Delivery System



Source: CO CHP+ Allotment Neutrality Report

Of those members enrolled in the demonstration from 2018 to 2019, the most predominant race/ethnicity reported was multiple (41.6% of the total), followed by White (27.7%), Hispanic/Latino (15.5%), Black/African American (4.8%), Asian (1.7%), American Indian/Alaskan Native (0.4%) and Native Hawaiian/Pacific Islander (0.2%), and other/unknown or not provided (8.1%) (refer to Exhibit I.5 on the following page).

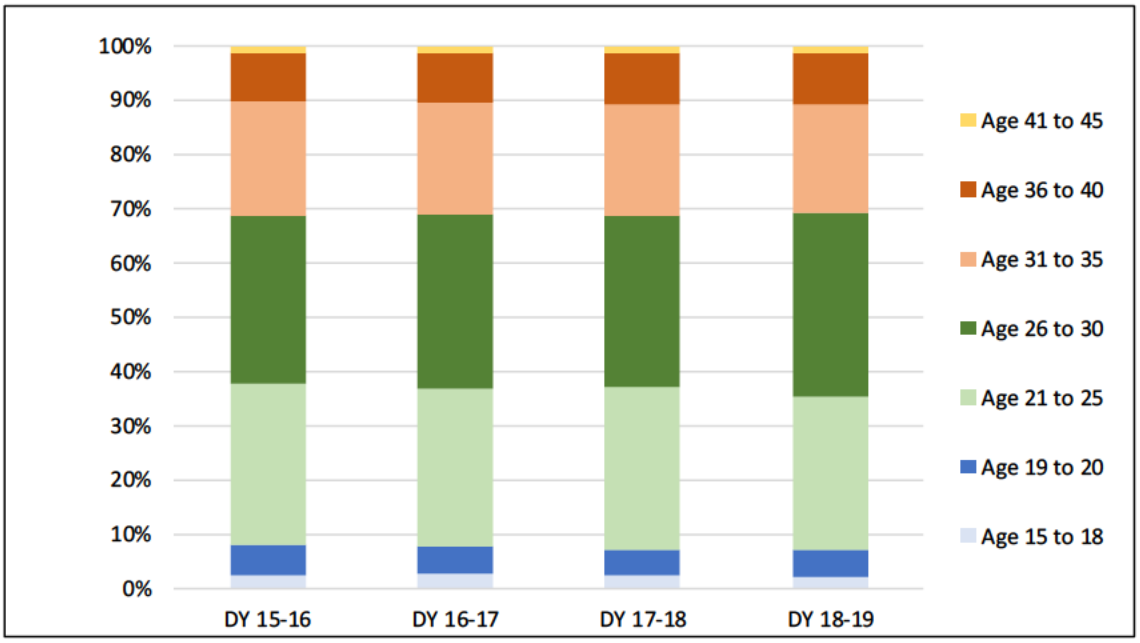
Exhibit I.5. Demonstration Population by Race/Ethnicity



Source: CO CHP+ Client Data

Exhibit I.6 distributes enrollment in the demonstration by the age of the members. Just over 60 percent of the women enrolled are between the ages of 21 and 30 (green portions of exhibit).

Exhibit I.6. Demonstration Population by Age Group



Source: CO CHP+ Client Data

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Defining Relationships: Waiver Policy, Short-term and Longer-term Outcomes

As part of the examination of the relationships between demonstration goals and the maturity of evaluating a long-term demonstration, the evaluation team at Burns & Associates, a Division of Health Management Associates (HMA-Burns) constructed logic models delineating short-term and longer-term outcomes associated with the three principle policy objectives of the demonstration.

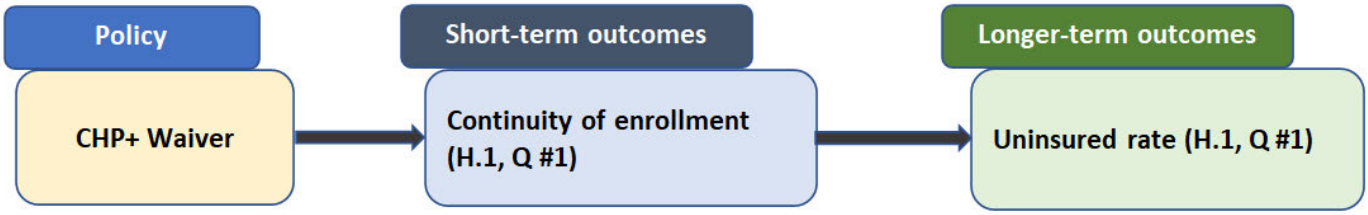
1. Maintain Continuity of Enrollment,
2. Maintain Access to Care, and
3. Maintain or Improve Health Outcomes

The determination of whether an outcome is short-term or longer-term is dependent on the measure specifications, including measurement period, and the data needed to adequately assess trends with the waiver policy. For example, because national outcome measures tend to have annual measurement periods, they are considered in this evaluation to be longer-term indicators of policy outcomes. Each of the three principle policy objectives are described in detail below and include logic models to illustrate both short-term and longer-term outcomes. Each logic model also provides a reference to specific hypotheses and research questions that will be described in Section II.B.

Maintain Continuity of Enrollment

HMA-Burns chose Maintain Continuity of Enrollment as the first policy objective as it is responsive to Waiver Goal #1, decreasing the rate of pregnant women who do not have insurance. Exhibit II.1 illustrates the baseline assumption that continuing the demonstration will not have an adverse impact on trends in the continuity of CHP+ enrollment in the short term. On a longer-term basis, the assumption is that trends in prenatal care paid by some type of insurance will not worsen over the course of the demonstration. Both process and outcome measures are proposed to assess impact.

Exhibit II.1. Logic Model 1: Maintain Continuity of Enrollment

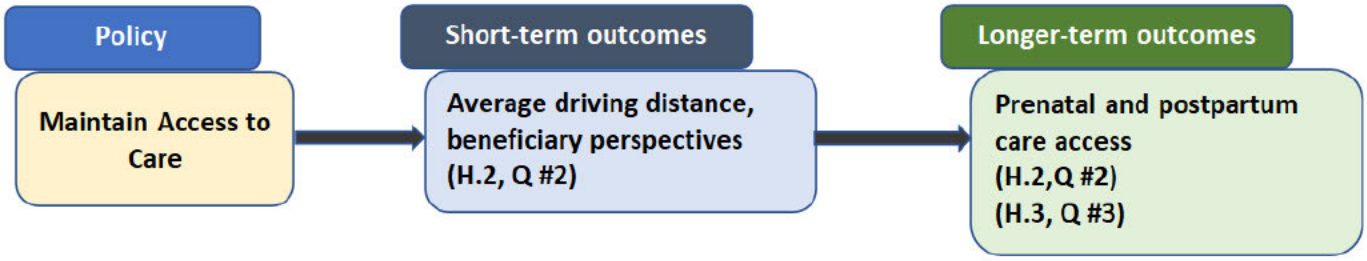


Maintain Access to Care

Maintain Access to Care is the second policy objective and it is based on Waiver Goal #2, increase in prenatal and postpartum care during the demonstration. Exhibit II.2 on the following page illustrates the assumption that trends in access to care sustain or do not worsen. HMA-Burns is proposing to use outcome measures to assess trends in access to care. In the short term, trends in average driving

distance to prenatal care services and beneficiary perspectives on lived experiences of maternity care will be assessed. To evaluate access to care on a longer-term basis, HMA-Burns is proposing to use established outcome measures of access and utilization.

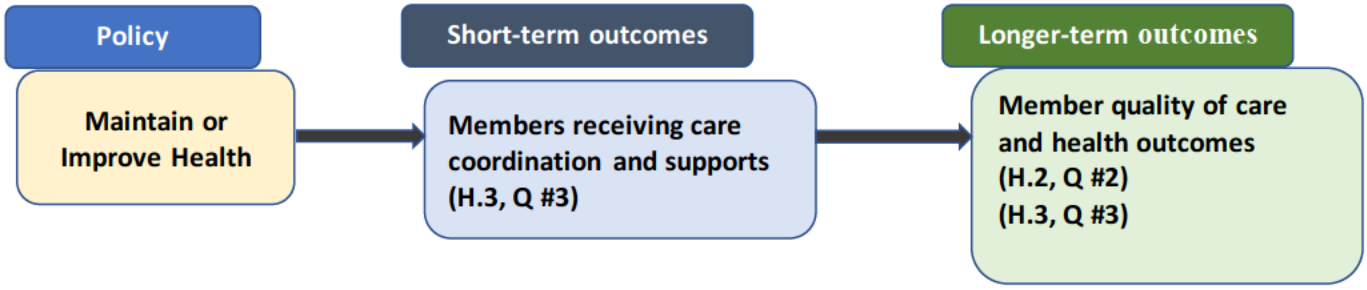
Exhibit II.2. Logic Model 2: Maintain or Improve Access



Maintain or Improve Health Outcomes

The third policy objective is Maintain or Improve Health Outcomes and it encompasses Waiver Goal #3, increase in the number of healthy babies born to pregnant women enrolled in the demonstration. Exhibit II.3 illustrates the assumption that CHP+ beneficiaries enrolled in the demonstration will maintain or improve health outcomes. In the short term, a process measure will measure access to care coordination and supports. On a longer-term basis, national health outcome metrics and HMA-Burns customized process measures focusing on care coordination will complete the assessment of the third principle policy objective.

Exhibit II.3. Logic Model 3: Maintain or Improve Health Outcomes



HMA-Burns found that there are existing, nationally-recognized outcome measures associated with principle policy objectives two and three. The specifications and data sources for many of these were already described as part of Colorado CHP+'s Quality Strategy. In addition to using nationally recognized outcome measures, HMA-Burns will fill gaps with custom measures developed by us where needed.

A more detailed description of the data, measures, and analyses to be used are described in Section III of the Evaluation Design document.

II.B Hypotheses and Research Questions

The three principle policy areas depicted in the logic models in Section II.A were converted into four hypotheses (H) and four research questions (Q). Each research question has assigned measures and a targeted analytic methodology which is described in detail in Section III. Methodology. Exhibit II.4

provides a high-level overview of each hypothesis and the associated research question. In most cases, the research question assesses impact on both a short- and longer-term basis, except for Q #4 which has measures that only assess longer-term impact.

Exhibit II.4. Hypotheses and Research Questions

		Outcomes	
Hypothesis	**Research Question**	**Short-term**	**Longer-term**
H.1: Trends in continuity of enrollment in the demonstration sustains (or do not worsen) for pregnant women in the current waiver period.			
	Q #1: *Does the waiver improve or maintain the uninsured rate of pregnant women in Colorado during the demonstration period?*	X	X
H.2: Trends observed in access to health care for pregnant women sustains (or does not worsen) in the current waiver period.			
	Q #2: *Do CHP+ members achieve similar (or improved) access and health outcomes in the current waiver period?*	X	X
H.3: Trends observed in the health of the mother sustains (or does not worsen) in the current waiver period.			
	Q #3: *Do CHP+ members achieve similar (or improved) pregnancy and postpartum outcomes in the current waiver period?*	X	X
H.4: Trends observed in the number of healthy babies (i.e., over 2500 grams) sustains (or does not worsen) in the current waiver period.			
	Q #4: *Do CHP+ members achieve similar (or improved) birth outcomes in the current waiver period?*		X

II.C Alignment with Demonstration Goals

Building upon the matrix shown in Section II.B, each hypothesis was cross-referenced to demonstration goals. This was to ensure that the evaluation hypotheses and research questions are responsive to the CMS guidance in the approved waiver STCs. As demonstrated in Exhibit II.5 on the next page, each hypothesis addresses at least one demonstration goal and, in one case crosses two goals.

Exhibit II.5. Alignment of Hypotheses with Demonstration Goals

		Hypotheses			
		H.1	H.2	H.3	H.4
		Continuity of Enrollment	Acces to Health Care	Outcomes for Mother	Outcomes for Baby
Waiver Goals					
G.1	Decrease the uninsurance rate for pregnant women	X			
G.2	Increase prenatal and postpartum care for pregnant women enrolled in the demonstration		X		
G.3	Increase the number of healthy babies born to pregnant women enrolled in the demonstration			X	X

II.D How Hypotheses and Research Questions Promote Objectives of Titles XIX and XXI

The Evaluation Design Plan hypotheses were also cross referenced with the objectives of the CHP+ program[4] to ensure that the plan promotes the objectives of Titles XIX and XXI of the Social Security Act as required in Attachment A of the approved waiver STCs. Each hypothesis supports the principle objective to improve access to services that promote positive health outcomes. In the case of CHP+, the demonstration provides access to health care services for pregnant women and their newborns who otherwise would not qualify for these services.

[4]Accessed at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html

SECTION III: METHODOLOGY

III.A Evaluation Design

The evaluation design is a mixed-methods approach, drawing from a range of data sources, measures and analytics to best produce relevant and actionable study findings. HMA-Burns tailored the approach for each of the research questions described in Section II, Evaluation Questions and Hypotheses. The evaluation plan reflects a range of data sources, measures and perspectives. It also defines the most appropriate study population and sub-populations, as well as describes the analytic methods included in the evaluation design.

The analytic methods proposed for use across the four hypotheses and four research questions include the following:

1. Descriptive statistics (DS),
2. Statistical tests (ST),
3. Desk reviews (DR), and
4. Facilitated interviews (FI).

Exhibit III.1 below presents a chart displaying which method(s) are used for each hypothesis. It also includes a brief description of the indicated methods as well as the sources of data on which they rely.

Exhibit III.1. Summary of Four Analytic Methods by Hypothesis

		Method				Analytic Method Examples
	Hypothesis Description	DS	ST	DR	FI	
1	Trends in continuity of enrollment in the demonstration sustains (or does not worsen) for pregnant women in the current waiver period.	X		X		**DS**: trends in frequencies and percentages of enrollment duration and insurance status stratified by subpopulations of interest. Data sources: enrollment and CO PRAMS data.
2	Trends observed in access to health care for pregnant women sustains (or does not worsen) in the current waiver period.	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests of significance; ITS. **DR/FI**: Prenatal Care focus study (2 rounds). Data sources: claims data and enrollment data, beneficiary interviews.
3	Trends observed in the health of the mother sustains (or does not worsen) in the current waiver period.	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests of significance; interrupted time series. **DR/FI**: Prenatal Care focus study (2 rounds). Data sources: claims and enrollment data, reports submitted by MCOs/RAEs validated by HMA-Burns.
4	Trends observed in the number of healthy babies (over 2500 grams) sustains (or does not worsen) in the current waiver period.	X	X	X		**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests of significance; interrupted time series. Data sources: claims and enrollment data, state vital records, and CoHID.

DS = Descriptive Statistics; ST = Statistical Tests; DR = Desk Reviews; FI = Facilitated Interviews

As described in Section II.A, the majority of the hypotheses and associated research questions focus on whether the 1115 Demonstration made an impact on key CHP+ waiver goals (i.e., short-term and longer-term outcomes). In order to facilitate evaluation on whether a statistically significant difference between the pre-waiver and current waiver period can be detected, the data, measures and methods for these research questions will be tested using healthcare claims, member enrollment data, managed care organization (MCO) or regional accountable entity (RAE) report submissions, and provider enrollment data. The proposed metrics blend nationally-recognized measure specifications with custom metrics developed by HMA-Burns (where national metrics are unavailable). Analytic methods include interrupted time series (ITS) and descriptive statistics using chi-square tests or t-tests as applicable.

The focus shifts to assessing member perception of access to insurance, and quality. Given that these require information beyond what is available in claims or other public data sets, this section draws upon a set of mixed methods to evaluate progress. Where possible, measures will be incorporated into a reporting dashboard that tracks results from the pre-waiver period and the waiver-to-date period. Wherever possible, data will be tracked and reported on a quarterly basis.

III.B Target and Comparison Populations

Target Population

The target population is any Colorado CHP+ beneficiary enrolled in the demonstration in the study period. HMA-Burns will use Section III in the approved waiver STCs as the basis for identification of beneficiaries enrolled in the demonstration. HMA-Burns will create flags to identify CHP+ members and providers that will be part of the analytics. Flags will be assigned to attribute individuals to each sub-population group which includes, but is not limited to:

- MCO or RAE enrolled with
- Member race and ethnicity
- New member enrollment due to COVID
- Birthweight of newborn
- Member age (for specified age groups)
- Member home location (e.g., city/county/region)
- Substance Use Disorder

There will also be flags assigned to providers. The provider type and specialty will be tracked. HMA-Burns will use these indicators and create other flags that may require the joining of existing variables to assign providers by:

- Regional location
- Level of care
- Newly-enrolled and long-standing enrolled providers

The matrices included in Section III.G identify the target population and stratification proposed for each hypothesis and research question.

Comparison Groups

Two ideal comparison groups described in the CMS technical advisory guidance on selection of comparison groups include another state CHIP population and/or prospectively collected information

prior to the start of the intervention.[5] Specifically, a CHP+ population with similar demographics but in another state without those waiver flexibilities described in Colorado would be an ideal comparator. However, identifying whether such a state exists or the ability to obtain data from another state given the sensitivity of privacy concerns as it relates to data sharing is not feasible; therefore, it is outside the scope of this evaluation.

The other example of a control group described in the design guide is to collect prospective data. To our knowledge, there is no known prospective data collection on which to build baselines. Given the lack of an available and appropriate comparison group, HMA-Burns will use an analytic method which creates a pre-waiver and current waiver (intervention) group upon which to compare outcomes. See Section III.F for more details on the analytic methods.

Available results from CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP and the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults will be used as a benchmark comparator for those nationally-recognized metrics included in the evaluation design. Results of these measures are reported at a statewide level by CHIP program, as well as national values. In this case, comparator states will be identified and included, along with national values, within the Summative Evaluation. Comparator states will be chosen in consultation with the State, CMS and other stakeholders. For non-Core measures that align with Colorado Medicaid goals and initiatives for pregnant women, HMA-Burns will compute a benchmark using Colorado Medicaid as the comparator population. For average driving distance, HMA-Burns will use Colorado Medicaid and CHIP managed care organization, and Accountable Care Collaborative RAE distance standards to benchmark access.

III.C Evaluation Period

A pre-waiver and current wavier period will be defined as three calendar years before and five calendar years after waiver implementation. The pre-waiver period is defined as enrollment or dates of service from August 1, 2017 through December 17, 2020. The current waiver period is defined as enrollment or dates of service from December 18, 2020 through July 31, 2025. In support of the analytic methods described in Section III.F, the calendar year data will be further defined into both monthly and quarterly segments such that both the pre-periods will include 12 quarters or 36 months from the pre-waiver period, and 20 quarters or 60 months from the current waiver period.

To simplify the analytic plan, HMA-Burns is making an assumption about the first six months of 2020 prior to the current waiver being approved. For annual measures in which a national steward has defined measure specifications, HMA-Burns will consider August 1, 2019 to July 31, 2020 in the period prior to the current approved demonstration that became effective December 18, 2020. Although CMS approved Colorado's 1115 waiver in December 2020, waiver-related activities were moving forward in anticipation of approval of the extension throughout 2020. For ease of conducting and describing the analysis, the evaluation period will be defined as follows:

- For monthly and quarterly metrics, the six months in the 2020 calendar year prior to December 18, 2020 approval will be defined as the current waiver period (not the pre-waiver period).

[5] Comparison Group Evaluation Design. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/ evaluation-reports/comparison-grp-eval-dsgn.pdf.

- For annual metrics, August 1, 2020 through July 31, 2025 will be considered the demonstration period.

It should be noted that, while this is the expected current evaluation period, modifications may be warranted to better reflect differences in the time period upon which one would expect to see a change in outcomes resulting from waiver activities. At this time, there was little data or similar studies available on which to base specific alternatives to the proposed current evaluation period. HMA-Burns, therefore, will examine time series data in order to identify whether the current evaluation period should be delayed. For example, if review of the data shows a distinctive change in the first and second quarter of 2021, then the current period would be adjusted such that the third and fourth quarter data would not be considered in the interrupted time series analysis described in Section III.F.

III.D Evaluation Measures

The measures included in the Evaluation Design Plan directly relate to the three principle policy objectives and short-term and longer-term outcomes described in Section II.

The measures fall into two primary domains: quality and access. Exhibit III.2 summarizes the list of measures included in the evaluation plan. A comprehensive summary of measures, which includes measure stewards as well as a description of numerators and denominators, can be found in the detailed matrices in Section III.G. Where possible, measure results will be stratified by race, ethnicity and region.

Exhibit III.2. Evaluation Measures by Domain

Quality
• Timeliness of Prenatal Care (PPC)
• Postpartum Care (PPC)
• Utilization of emergency department among PPC population
• At risk of poor maternal and/or infant health outcome
• Percentage of women who follow ACOG guidelines
• Proportion of at-risk deliveries
• Live births weighing less than 2,500 grams
• Well-child visits in the first 15 months of life

Access
• Utilization of prenatal care services per 1000 members
• Average driving distance to prenatal care services
• Proportion of enrollees continuously enrolled in CHP+
• Enrollment duration during pregnancy
• Prenatal care paid by type of insurance
• Proportion of PPC women, prenatal, using emergency department
• Proportion of PPC women, postpartum, using emergency department
• Beneficiary perspectives on lived experiences of maternity care

III.E Data Sources

As described in Section III.A, Evaluation Design, HMA-Burns will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Colorado CHP+ administrative data, i.e., enrollment, claims and encounter data. Supplemental administrative data, such as survey data, will also be incorporated. Primary data will be limited and will include data created by desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses follow.

Colorado CHP+ Administrative Data

Claims and encounters with dates of service (DOS) from August 1, 2017 and ongoing will be collected from the Colorado Medicaid Management Information System (MMIS) Data Warehouse (EDW), facilitated by HCPF's MMIS vendor, Gainwell (formerly DXC) Technologies and IBM Corporation (formerly Truven Health Analytics) Business Intelligence Data Management (BIDM). A data request specific to the 1115 Evaluation Design Plan will be given to HCPF and the data will be delivered to the evaluators in an agreed-upon format. The initial EDW data set will include historical data up to the point of the delivery date. Subsequent data will be sent to HMA-Burns on a periodic basis. The last query of

the EDW will occur on August 1, 2026 for claims with DOS in the study period. All data delivered to HMA-Burns from the HCPF will come directly from the EDW, including Vital Statistics data matched to CHP+ enrollees. HMA-Burns will leverage all data validation techniques used by Gainwell before the data is submitted to the EDW. HMA-Burns will also conduct its own validations upon receipt of each monthly file from the HCPF to ensure accuracy and completeness when creating our multi-year historical database.

When additional data is deemed necessary for the evaluation, HMA-Burns will outreach directly to the MCOs and/or RAEs when they are determined to be the primary source. HMA-Burns will build data validation techniques specific to the ad hoc requests from the MCOs and/or RAEs.

Additional data from the MCOs and/or RAEs and the State will be collected on care coordination activities. There could be some data validity or quality issues with these sources as they are not as rigorously collected as claims and encounters data. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data, as well as provide detailed specifications and reporting tools to the MCOs, RAEs and the State to minimize potential for differences in reporting of the requested ad-hoc data.

Survey and Facilitated Interview Data

Colorado Pregnancy Risk Assessment Monitoring System (PRAMS)[6]

The Colorado Pregnancy Risk Assessment and Monitoring System (PRAMS) is a survey of women to assess their experiences before, during and after pregnancy and includes CHP+ beneficiaries. Data is reported for women and infants at a granular level including, but not limited to, demographics and insurance status, including CHP+, Medicaid, commercial insurance and uninsured breakouts. The data will be used to review for descriptive trends over time of the percent of Colorado women who report being uninsured prior to, during, and after their pregnancy.

Facilitated Interview Guides

The evaluation team will construct facilitated interview guide instruments as a means to collect primary data for the prenatal care focus study. The instruments will be provided to CMS for their feedback in advance of fielding. The types of respondents that the evaluators propose to interview are identified at the metric level in Section III. G. Respondents will include beneficiaries, the MCOs and RAEs. Beneficiary perspectives will be gathered using Colorado's Maternity Advisory Council, which leverages the lived experiences of maternity care to inform existing and emerging policy and is comprised primarily of Black, Indigenous and People of Color.[7] Where focused interviews are used to collect data, B&A will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. Although semi-structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

[6] Accessed at https://cdphe.colorado.gov/center-for-health-and-environmental-data/survey-research/pregnancy-risk-assessment-monitoring

[7] Accessed at https://hcpf.colorado.gov/maternity-advisory-committee

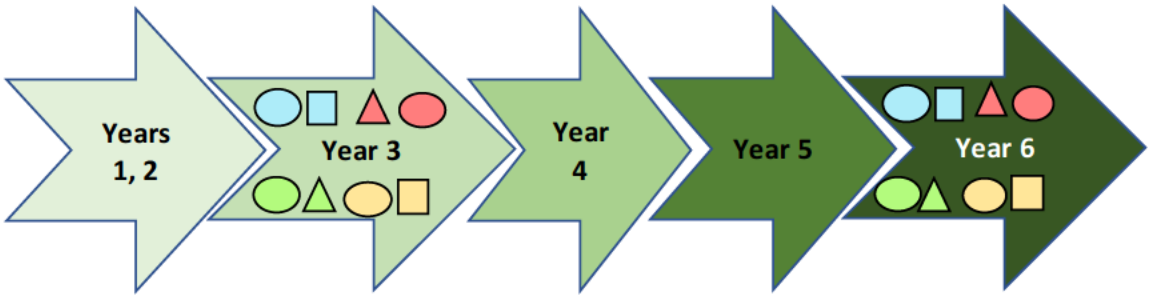
Whereas the Colorado CHP+ administrative data will be collected and used on a monthly basis throughout the waiver period and after the waiver concludes to produce the Summative Evaluation, HMA-Burns anticipates that data from our sources will be collected in CY 2023 and CY 2025 for use in evaluation activities. Exhibit III.3 that appears on the next page contains the proposed primary data collection activities by source, year, and hypotheses. Exhibit III.4 that appears on page III-7 demonstrates the proposed primary data collection timeline by type, year, and hypotheses.

Exhibit III.3. Proposed Primary Data Collection Activities, by Source, Year and Hypotheses

Hypotheses	Source	Desk Review			Facilitated Interviews / Focus Groups			
		MCOs RAEs	Other State Partners	State Agencies	Members	Other State Partners	State Agencies	MCOs RAEs
	Contract Year 1&2, CYs 2021-2022							
	All Hypotheses			X				
	Contract Year 3, CY 2023							
	1 Continuity of Enrollment		X	X	X			
	2 Trends in Access to Care			X	X			
	3 Trends in Outcomes for Mother	X		X			X	X
	4 Trends in Outcomes for Baby	X	X	X		X	X	X
	Contract Year 4, CY 2024							
	All Hypotheses			X				
	Contract Year 5, CY 2025							
	All Hypotheses			X				
	Contract Year 6, CY 2026							
	1 Continuity of Enrollment		X	X	X			
	2 Trends in Access to Care			X	X			
	3 Trends in Outcomes for Mother	X		X			X	X
	4 Trends in Outcomes for Baby	X	X	X		X	X	X

* Years shown correspond to Independent Evaluator contract years. Note: Presently, the State only has the authority to contract with HMA-Burns through December 31, 2022. There are deliverables due to CMS after this period reflected above.

Exhibit III.4. Proposed Primary Data Collection Timeline, by Type, Year and Hypotheses



Hypotheses

1 Continuity of Enrollment

2 Trends in Access to Care

3 Trends in in Outcomes for Mother

4 Trends in Trends in Outcomes for Baby

Methods

Desk Review

Member Survey

Facilitated Interview/Focus Group

Evaluator contract years. Note: Presently, the State only has the authority to contract with HMA-Burns through 12/31/22. There are deliverables due to CMS after this period which are reflected in this timeline.

III.F Analytic Methods

Exhibit III.1 depicted the analytic methods to be used in the analysis. A detailed discussion of each method is described below. This includes, where applicable, HMA-Burns' approach to address the impact of the COVID-19 pandemic within each method.

Method #1: Descriptive Statistics

In order to facilitate ongoing monitoring, all measures will be summarized on an ongoing basis over the course of the waiver. The descriptive statistics will be stratified by MCO, RAE and FFS delivery systems, and/or by region where possible. For reporting purposes, the descriptive studies will be subject to determination of a minimum number of beneficiaries in an individual reported cell (i.e., minimum cell size) and subject to blinding if the number falls below this threshold. While a conventional threshold is 10 or fewer observations, given the sensitivity of the small population size and the public dissemination of report findings, a higher threshold may be established by the evaluators upon review of the final data.

Results will primarily be reported in terms of longitudinal descriptive statistics of defined groups of beneficiaries and using regional maps where possible.

COVID-19 Considerations

For metrics where descriptive trends is the appropriate methodology, the evaluators propose to include a marker of pre- and post- COVID overlaid onto any graphs so one can visually inspect if there is an obvious change in the particular outcome starting mid-2020 and adding a comparator group.

In both cases, newly eligible members who became CHP+ eligible as a result of COVID will be identified and treated as a subpopulation in the analysis. This will allow the evaluators to continue to include those newly eligible members for which enrollment is unrelated to the pandemic.

Method 2: Statistical Tests

T-test or Chi-square test

Tests will be used to determine whether the observed differences in the mean value or rate differs for the most recent evaluation two-year period compared to the two-year period prior to waiver implementation. To assess if results for each metric compared to the pre-waiver timeframe are not due to chance alone, the evaluators will use chi-square tests for categorical data and t-tests for continuous data. Testing of the assumptions of normality and adjustments will be made before performing the final statistics and discussed below.

COVID-19 Considerations

For those metrics where simple statistics (chi square or t-test) is the appropriate quantitative methodology, the evaluators propose testing two separate post years to baseline to estimate the treatment effects before, during and after the pandemic. In both cases, members who became newly-

eligible for CHP+ as a result of COVID will be identified and treated as a subpopulation in the analysis. By doing this, HMA-Burns will be able to continue to include other newly-eligible members for which enrollment in CHP+ is unrelated to the pandemic.

T-test

The t-test is a type of inferential statistics. It is used to determine whether there is a significant difference between the means of two groups. Conceptually, it represents how many standardized units of the means of the pre- and post- populations differ. There are generally five factors to contribute to whether a statistically significant difference between the pre- and post-periods will be considered significant:[8]

1. How large is the difference? The larger the difference, the greater the likelihood that a statistically significant mean difference exists, and confidence increased.
2. How much overlap is there between the groups? The smaller the variances between the two groups, the greater probability a difference exists, hence increasing confidence in results.
3. How many subjects are in the two samples? The larger the sample size, the more stable and hence, confidence in results.
4. What alpha level is being used to test the mean difference? It is much harder to find differences between groups when you are only willing to have your results occur by chance 1 out of 100 times ($p < .01$) as compared to 5 out of 100 times ($p < .05$) but confidence in results is less.
5. Is a directional (one-tailed) or non-directional (two-tailed) hypothesis being tested? Other factors being equal, smaller mean differences result in statistical significance with a directional hypothesis so less confidence can be assigned to the results.

The assumptions underlying the t-test include:

- The samples have been randomly drawn from their respective population.
- The scores in the population are normally distributed.
- The scores in the populations have the same variance (s1=s2). A different calculation for the standard error may be used if they are not.

There are two types of errors associated with the t-test:

- Type I error —whereby the evaluator would detect a difference between the groups when there really was not a difference. The probability of making a Type I error is the chosen alpha level; therefore, an alpha level at $p < .05$, results in a 5% chance that you will make a Type I error.
- Type II error —whereby the evaluator detects no difference between the groups when there really was one.

The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program. Assumptions will be tested and addressed if detected,

[8] T-test. https://researchbasics.education.uconn.edu/t-test/#. Accessed May 14, 2020.

including tests of normality and variance in the pre- and post- data. Metrics which are continuous will be tested using a t-test. The lowest level of reliable granularity available and reliability will be used for conducting tests (i.e., monthly or quarterly observations instead of annual).

Chi-square test

A chi-square test may be used in lieu of the t-test for some categorical variables. Chi-square may be preferable to t-test for comparing rates. All χ^2 tests are two sided.

The chi-square test for goodness of fit determines how well the frequency distribution from that sample fits the model distribution. For each categorical outcome tested, the frequency of patients in the pre- and post-period would be tested. The chi-square test for goodness of fit would determine if the observed frequencies were different than expected; in other words, whether the difference in the pre- and post-outcomes were significantly different statistically than what would have been expected given the pre-period. The null hypothesis, therefore, is that the expected frequency distribution of all wards is the same. Rejecting the null would indicate the differences were statistically significant (i.e., exceeded difference more than would be expected at a given confidence level).

The chi-square formula is: $\chi 2=\sum i=1k(O^i-E^i)2/E^i$

The assumptions of the chi-square are:

- Simple random sample
- Sample size. Small samples subject to Type II error.
- Expected cell count. Recommended 5-10 expected counts.
- Independence. Evaluation of the appropriateness of a McNemar's test may be warranted.

The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program. Annually-reported categorical metrics for chi-square testing will either be derived from pooled population data (i.e., create one rate in pooled years of pre- and post-data) or two calendar year time periods (i.e., compare last year pre-waiver to last year post-waiver). Final approach will be determined upon examination of the data.

Interrupted Time Series (ITS)

Interrupted time series (ITS) is a quasi-experimental method used to evaluate health interventions and policy changes when randomized control trials (RTC) are not feasible or appropriate.[9,10,11] As it would

[9] Bonell CP, Hargreaves J, Cousens S et al. Alternatives to randomisation in the evaluation of public health interventions: Design challenges and solutions. J Epidemiol Community Health 2009;65:582-87.
[10] Victora CG , Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. Am J Public Health 2004;94:400–05.
[11] Campbell M , Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. . Framework for design and evaluation of complex interventions to improve health. BMJ 2000;321:694.

not be ethical or consistent with CHP+ policy to withhold services resulting from waiver changes from a sub-set of beneficiaries for purposes of evaluation, an RTC is therefore, not possible. Per CMS technical guidance, the ITS is the preferred alternative approach to RTC in the absence of an available, adequate comparison group. The ITS method is particularly suited for interventions introduced at the population level which have a clearly defined time period and targeted health outcomes.[12,13,14]

An ITS analysis relies on a continuous sequence of observations on a population taken at equal intervals over time in which an underlying trend is "interrupted" by an intervention. In this evaluation, the waiver is the intervention, and it occurs at a known point in time. The trend in the post-waiver is compared against the expected trend in the absence of the intervention.

While there are no fixed limits regarding the number of data points because statistical power depends on a number of factors like variability of the data and seasonality, it is likely that a small number of observations paired with small expected effects may be underpowered.[15] The expected change in many outcomes included in the evaluation are likely to be small; therefore, the evaluators will use 72 monthly observations where possible and 24 quarterly observations where monthly data are not deemed reliable.

In order to determine whether monthly or quarterly observations will be created, a reliability threshold of having a denominator of a minimum number of 100 observations at the monthly or quarterly level will be used. If quarterly reporting is not deemed reliable under this threshold, the measure and/or stratification will not be tested using ITS. Instead, these measures will be computed using calendar year data in the pre- and post- period and reported descriptively.

ITS Descriptive Statistics

All demographic, population flags, and measures will be computed, and basic descriptive statistics will be created: mean, median, minimum, maximum, standard deviation. These data will be inspected for identification of anomalies and trends.

To identify underlying trends, seasonal patterns and outliers, scatter plots of each measure will be created and examined. Moreover, each outcome will undergo bivariate comparisons; a Pearson

[12] Soumerai SB. How do you know which health care effectiveness research you can trust? A guide to study design for the perplexed. Prev Chronic Dis 2015;12:E101.
[13] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.
[14] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098
[15] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw09 8

correlation coefficient will be produced for each measure compared to the others as well as each measure in the pre- and post- periods.

Regression Analysis

Wagner et al. described the single segmented regression equation as[16]:

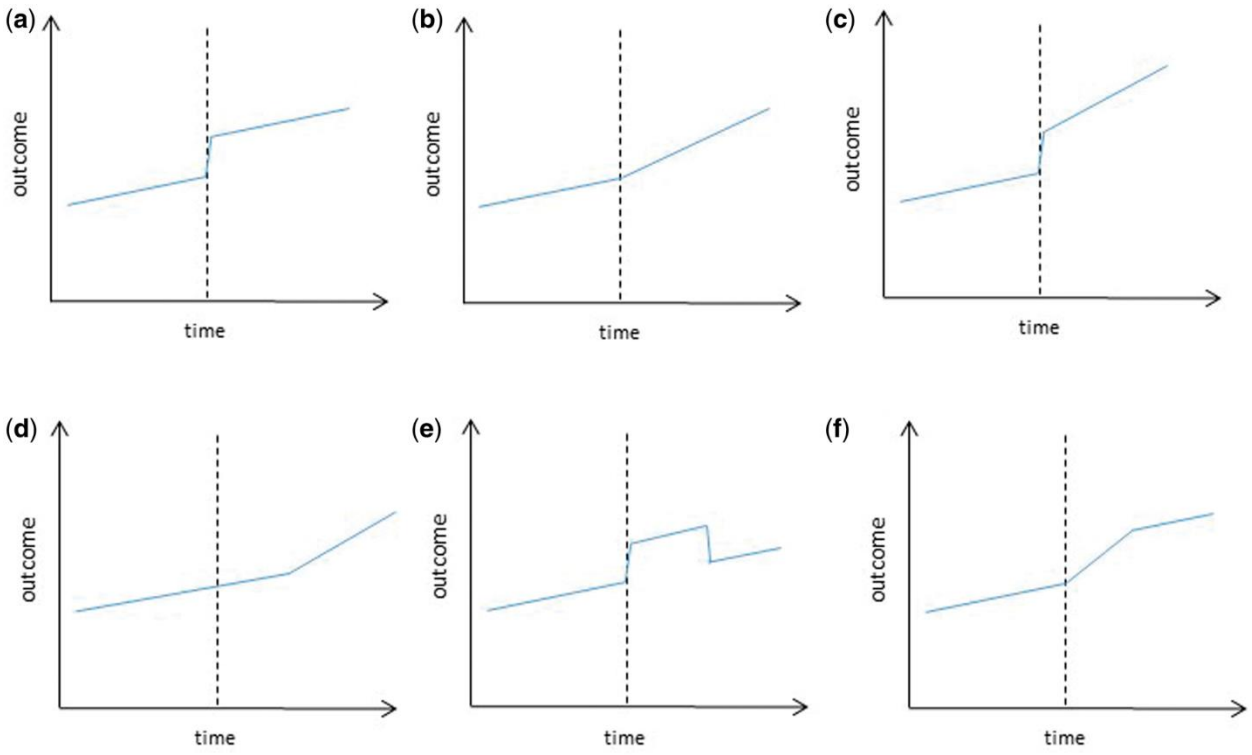
$$\hat{Y}_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time\_after\_intervention_t + e_t$$

Where: Y_t is the outcome *time* indicates the number of months or quarters from the start of the series *intervention* is a dummy variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment *time_after_intervention* is 0 in the pre-intervention segment and counts the quarters in the post-intervention segment at time t	β_0 estimates the base level of the outcome at the beginning of the series β_1 estimates the base trend, i.e., the change in outcome in the pre-intervention segment β_2 estimates the change in level from the pre- to post-intervention segment β_3 estimates the change in trend in the post-intervention segment e_t estimates the error

Visualization and interpretation will be done as depicted in the Exhibit III.5. Each outcome will be assessed for one of the following types of relationships in the pre- and post-waiver period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change.

[16] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

Exhibit III.5. Illustration of Potential ITS Relationships [17]



Seasonality and Autocorrelation

One strength of the ITS approach is that it is less sensitive to typical confounding variables which remain fairly constant, such as population age or socio-economic status, as these change relatively slowly over time. However, ITS may be sensitive to seasonality. To account for seasonality in the data, the same time period, measured in months or quarters, will be used in the pre- and post-waiver period. Should it be necessary, a dummy variable can be added to the model to account for the month or quarter of each observation to control for the seasonal impact.

An assumption of linear regression is that errors are independent. When errors are not independent, as is often the case for time series data, alternative methods may be warranted. To test for the independence, the evaluators will review a residual time series plot and/or autocorrelation plots of the residuals. In addition, a Durbin-Watson test will be constructed to detect the presence of autocorrelation. If the Durbin-Watson test statistic value is well below 1.0 or well above 3.0, there is an indication of serial correlation. If autocorrelation is detected, an autoregressive regression model, like the Cochrane-Orcutt model, will be used in lieu of simple linear regression.

[17] From: Interrupted time series regression for the evaluation of public health interventions: a tutorial Int J Epidemiol. 2016;46(1):348-355. doi:10.1093/ije/dyw098. Int J Epidemiol.

Other assumptions of linear regression are that data are linear and that there is constant variance in the errors versus time. Heteroscedasticity will be diagnosed by examining a plot of residuals verses predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant variance, then the data may be nonlinear, and transformation of the dependent variable may be warranted. Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

Controls and Stratification

As described in Section III.B, the regression analysis will be run both on the entire target population and stratified by relevant sub-populations. The sub-population level analysis may reveal waiver effects that would otherwise be masked if only run on the entire population. Similarly, common demographic covariates such as age, gender, and race will be included in these models to the extent they improve the explanatory power of the ITS models.

COVID-19 Considerations

For those metrics where multivariate analysis is the appropriate quantitative methodology, the evaluators propose to construct a 0/1 dummy variable that indicates if the observations are post-March 2020 until a defined "post" COVID period for use as a control in the regression model. Members who became newly-eligible for CHP+ as a result of COVID will be identified by aid category and benefit plan and treated as a subpopulation in the analysis. This will allow the evaluators to continue to include those newly-eligible members for which enrollment is unrelated to the pandemic (e.g., aged, blind and disabled, pregnant women, newborns).

Method #3: Onsite Reviews

A limited number of desk reviews will supplement the other study methods included in the evaluation. These reviews will focus on hypotheses which are directed at assessment of process outcomes like avoidance of implementation delays, system changes according to schedules, transparency of policy and rates, and utility of stakeholder tools and analytics. Each desk review will use a questionnaire that asks for the information sought, the documentation reviewed, and the finding. Any gaps in information will also be noted as findings. The evaluators will review publicly-available information and/or documentation specifically requested from the HCPF and/or the MCOs and RAEs.

Method #4 Facilitated and/or Focus Group Interviews

As needed, the evaluators will construct facilitated interview guide instruments as a means to collect primary data for the focus studies. Intended respondents will include the MCOs, the RAEs, and beneficiaries eligible under this waiver demonstration. Where focused interviews are used to collect data, the evaluators will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-

structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

HMA-Burns will ensure that, for each population that interviews are conducted, there is sufficient representation within the population among those being surveyed. Sampling may be completed by using geographic location, provider size (large and small), and beneficiary age, to name a few.

III.G Other Additions

Beginning on the next page, Exhibit III.16 provides information on each measure selected for use in the evaluation, by research question and hypothesis.

Exhibit III.6. Summary of Evaluation Questions, Evaluation Hypotheses, Data Sources, and Analytic Approaches

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Does the waiver improve or maintain the uninsured rate of pregnant women in Colorado during the demonstration period?***						
Demonstration Goal: G.1 Decrease the uninsurance rate for pregnant women.						
Evaluation Hypothesis #1: Trends in continuity of enrollment in the demonstration sustains (or does not worsen) for pregnant women in the current waiver period.						
Short Term (Continuity of Enrollment)	Proportion of enrollees continuously enrolled in CHP+	HMA-Burns	Frequency distribution of enrollees continuously enrolled for the 9 months prior to delivery in the measurement period, stratified subpopulations of interest	Total number of enrollees during the measurement period.	Enrollment data	Descriptive statistics (trends in the proportion of enrollees continuously enrolled by subpopulations of interest)
	Enrollment duration during pregnancy	HMA-Burns	Frequency distribution of CHP+ enrollees by the number of months of eligibility in the measurement period, stratified by aid category and assignment plan.		Enrollment data	Descriptive statistics (trends in enrollment duration by subpopulations of interest)
Long Term (Continuity of Enrollment)	Prenatal care paid by type of insurance	Colorado PRAMS	Weighted percentage of respondents who reported the type of insurance coverage for prenatal care		Colorado PRAMS	Descriptive statistics (trends in Colorado reported percentages over the demonstration period); comparison to baseline period and available national and regional values

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Do CHP+ members achieve similar (or improved) access and health outcomes in the current waiver period?***						
Demonstration Goal: G.2 Increase prenatal and postpartum care for pregnant women enrolled in the demonstration.						
Evaluation Hypothesis #2: Trends observed in access to health care for pregnant women sustains (or does not worsen) in the current waiver period.						
Short Term (Access to Care)	Average driving distance to prenatal care services	HMA-Burns	Sum of the driving distances traveled from member home to their prenatal care provider	Sum of the unique trips to the member's prenatal care provider in the year	Claims data	Descriptive statistics (trends in average driving distance stratified by MCO/RAE and region)
	Beneficiary perspectives on lived experiences of maternity care	HMA-Burns	Beneficiary perspectives on lived experiences of maternity care gathered through the Maternity Advisory Council		Facilitated Interview / Focus Group	Descriptive statistics (frequencies and percentages)
Long Term (Access to Care)	Utilization of prenatal care services per 1000	HMA-Burns	Count of prenatal care services in the measurement period for CHP+ enrollees, and overall by sub-populations of interest	Total CHP+ enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Proportion of PPC women using the emergency department	HMA-Burns	Number of PPC Timeliness of prenatal care women who had an emergency department visit during the pregnancy	Number of PPC Timeliness of Prenatal Care members	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
Long Term (Improved Outcomes)	Prenatal care for pregnant women (PPC): Timeliness of Prenatal Care	NCQA	1. Timeliness of Prenatal Care. Number of women having a prenatal care visit as a member of the organization in the first trimester, on the enrollment start date or w/in 42 days of enrollment in the organization.	1. Timeliness of Prenatal Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Do CHP+ members achieve similar (or improved) pregnancy outcomes in the current waiver period?***						
Demonstration Goal: G.3 Increase the number of healthy babies born to pregnant women enrolled in the demonstration						
Evaluation Hypothesis #3: Trends observed in the health of the mother sustains (or does not worsen) in the current waiver period.						
Short Term (Improved Outcomes)	Percentage of women determined to be at risk of poor maternal and/or infant health outcome	HMA-Burns	Count of women determined to be at risk of poor maternal and/or infant health outcome	Count of women screened	MCO/RAE specific report	Descriptive statistics (trends in the proportion of members determined to be at risk by subpopulations of interest)
Long Term (Improved Outcomes)	Percentage of women who follow ACOG guidelines overall and by subpopulation of interest	HMA-Burns	Count of pregnant women who followed ACOG guidelines overall	Number of CHP+ members	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Proportion of at-risk deliveries	HMA-Burns	Number of at-risk deliveries	Number of deliveries of live births	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Prenatal care for pregnant women (PPC): Postpartum Care	NCQA	2. Postpartum Care. Number of women having a postpartum visit on or between 21 and 56 days after delivery.	2. Postpartum Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
Long Term (Access to Care)	Proportion of PPC women using the emergency department	HMA-Burns	Number of PPC Postpartum Care women who had an emergency department visit during the pregnancy	Number of PPC Postpartum Care members	Claims data	Descriptive statistics (frequencies and percentages) stratified by populations of interest; chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #4: ***Do CHP+ members achieve similar (or improved) birth outcomes in the current waiver period?***						
Demonstration Goal: G.3 Increase the number of healthy babies born to pregnant women enrolled in the demonstration						
Evaluation Hypothesis #4: Trends observed in the number of healthy babies (over 2500 grams) sustains (or does not worsen) in the current waiver period.						
Long Term (Improved Outcomes)	Live Births Weighing Less Than 2,500 Grams (LBW-CH)	CDC	Number of babies born low birthweight (less than 2500 grams).		State vital records, CoHID	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Well-Child Visits in the First 15 Months of Life (W15)	NCQA	Number of children who turned 15 months old during the measurement year who had 6 or more well-child visits with a PCP	Number of children who turned 15 months old during the measurement year.	Claims data	

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the 1115 waiver evaluation. That being said, the proposed design is feasible and is a rational explanatory framework for evaluating the impact of the 1115 waiver on the demonstration population. Moreover, to fill gaps left by the limitations of this study design, a limited number of desk reviews and facilitated interviews/focus groups are proposed to provide a more holistic and comprehensive evaluation. Some known limitations are addressed below.

Since Colorado's population will be small compared to other states, some metrics and/or sub-populations may not be meaningful for reporting and there will be a concern about insufficient statistical power to detect a difference. For any observational studies, it may be difficult to find statistically significant results, particularly if the population size is low. We will recommend a threshold for a minimum number of observations. For any measures below this threshold, the expectation of statistical testing would be waived.

While CMS prefers a true comparator group from another state, this would require significantly more resources and cooperation with another state on sharing data. Therefore, HMA-Burns is recommending the use of ITS and descriptive statistics including the use of chi square or t-tests as the starting point in development of the evaluation design. One exception to this would be to use available results from CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP and the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults as a benchmark comparator for nationally recognized metrics included in the evaluation design. While the populations and benefit packages may be similar, there will still be differences from Colorado's demonstration population. In this scenario, HMA-Burns would compare these trends to two other states and national values if desired and if the data is available. The determination of the states to compare to would be done in consultation with the State, CMS and other stakeholders, and will note the limitations associated with the selected benchmarks.

For non-Core measures that align with Colorado Medicaid goals and initiatives for pregnant women, HMA-Burns will compute a benchmark using Colorado Medicaid as the comparator population. Using Medicaid as the comparator has its limitations as the benefit package is identical, with the only difference being the demonstration population has income that is more than 141% to 195% FPL.

For average driving distance, HMA-Burns will use Colorado Medicaid and CHIP managed care organization, and Accountable Care Collaborative RAE distance standards to benchmark access. Using Medicaid, RAE and CHIP distance standards are comparators is limitations as they include a broader population than the demonstration.

Use of Colorado's Maternity Advisory Council to obtain beneficiary perspectives on lived experiences of maternity care offers a unique opportunity to collect qualitative information. However, the council is not specific to the demonstration population and will also include Medicaid beneficiary input. Therefore, it may not be possible to attribute qualitative observations solely to the demonstration population.

The use of Colorado PRAMS data as the source for insurance status was proposed because it is obtained using a standard survey instrument collecting data from pregnant women and includes CHP+ breakouts

as well as commercial insurance and Medicaid breakouts. While it can provide broad context, there is no ability to link the survey results to demonstration enrollees.

The fact that the 1115 waiver components have been in place during what would be considered the pre-waiver period for evaluation purposes will make identifying any changes in outcomes directly attributable to waiver implementation difficult. Therefore, it is expected that not all outcomes or process measures included in the study will show a demonstrable change descriptively, and in fact may show no change in trends from the prior demonstration period. Where possible, the use of national or benchmark trends may provide context in this instance.

Equally, observed changes in outcome metrics in the current waiver period will be difficult, if not impossible, to attribute to one specific demonstration component given the interrelationship of the components themselves and the longstanding nature of the demonstration. Therefore, it will be important to use statistical tests of significance so that findings are properly put into context.

Related to the issues mentioned above, many of the outcome measures are multi-dimensional and influenced by social determinants of health. In addition, the State has multiple efforts underway to address prenatal care and birth outcomes that may influence the results of the demonstration. While changes under the waiver related to access to care may be one dimension of various outcomes of interest, and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions, such as housing and employment.

Lastly, the evaluators recognize that the utilization patterns that will occur relatively early in this demonstration period will be severely disrupted due to the COVID-19 pandemic. The predictability of future utilization patterns remains uncertain as of the date of this document. The evaluators are prepared to work with CMS in the event that guidance is provided to states for all waiver evaluations as to options that CMS will offer with respect to how to account for the acute period of the pandemic. The initial plan for handling COVID-19 effects are addressed in Section III. Methodology.

ATTACHMENT A: INDEPENDENT EVALUATOR

Process

Burns & Associates, a division of HMA, (HMA-Burns) submitted a proposal through a competitive bid process to be retained for professional services to facilitate the research and design of the Colorado Adult Prenatal Coverage in CHP+ Section 1115 demonstration evaluation with the Colorado Department of Health Care Policy & Financing (HCPF). The current contract was entered into effective March 1, 2021 with an end date of December 31, 2022.

Vendor Qualifications

Burns & Associates (B&A) was founded in 2006 and was in continual operations until September 1, 2020 when it was acquired by Health Management Associates. The staff at Burns & Associates all migrated to Health Management Associates with this change. The B&A team, now a division of HMA, works almost exclusively with state Medicaid agencies or related social services agencies in state government. The B&A team has worked with 33 state agencies in 26 states. Current team members are also completing Section 1115 waiver evaluations in Delaware and Indiana. For Delaware, the evaluation of its 1115 Diamond State Health Plan Waiver Demonstration Project and its Substance Use Disorder waiver; for Indiana, the evaluation of its 1115 Substance Use Disorder waiver. For all three projects, the B&A team has developed the approved Evaluation Design Plan and completed CMS-approved Interim Evaluation and Mid-Point Assessment reports (in Indiana). B&A has also conduced independent assessments of Indiana's 1915(b) waiver for Hoosier Care Connect and served as the External Quality Review Organization (EQRO) for Indiana from 2007 to 2020.

Assuring Independence

In accordance with standard term and condition Section IX Evaluation of the Demonstration and Attachment A– Developing the Evaluation Design, HMA-Burns attests to having no conflicts to perform the tasks needed to serve as an independent evaluator on this engagement. The HMA-Burns Principal Investigator is prepared to deliver a signed attestation to this effect upon request.

ATTACHMENT B: EVALUATION BUDGET

As part of the procurement process, Burns & Associates, a Division of HMA (HMA-Burns) was required to submit a work plan that presents the level of effort to complete all deliverables associated with the independent evaluation of Colorado's Adult Prenatal Coverage in CHP+ Section 1115 demonstration evaluation. Presently, the State only has the authority to contract with HMA-Burns through December 31, 2022, and there are deliverables due to CMS after December 31, 2022 which are reflected in the Attachment C Timelines and Milestones.

In an effort to show the complete level of effort that would be proposed to complete all deliverables, Exhibit B.1 Proposed Costs for 1115 Waiver Evaluation found on the following page summarizes the total amount to complete all deliverables associated with the independent evaluation due to CMS through January 31, 2027.

Exhibit B.1 Proposed Costs for 1115 Waiver Evaluation through January 31, 2027

	Deliverable	Proposed Cost
SFY 21	2019-2020 Annual Monitoring Report	$30,000
	2020-2022 Project Work Plan	$3,875
	2020-2025 Evaluation Design	$15,200
	2020-2025 Final Evaluation Design	$4,950
SFY 22	2015-2020 Draft Summative Evaluation	$42,325
	2015-2020 Final Summative Evaluation	$3,300
	2020-2025 Project Charter	$2,750
	2020-2021 Annual Monitoring Report	$28,000
SFY 23	2021-2022 Annual Monitoring Report	$35,000
SFY 24	2022-2023 Annual Monitoring Report	$35,000
	2020-2025 Draft Interim Evaluation	$159,000
SFY 25	2023-2024 Annual Monitoring Report	$35,000
	2020-2025 Final Interim Evaluation	$16,000
SFY 26	2024-2025 Annual Monitoring Report	$35,000
SFY 27	2020-2025 Draft Summative Evaluation	$180,000
	2020-2025 Final Summative Evaluation	$20,000
	Total Year 1 (SFY 2021)	$54,025
	Total Year 2 (SFY 2022)	$76,375
	Total Year 3 (SFY 2023)	$35,000
	Total Year 4 (SFY 2024)	$194,000
	Total Year 5 (SFY 2025)	$51,000
	Total Year 6 (SFY 2026)	$35,000
	Total Year 7 (SFY 2027)	$200,000
	TOTAL	**$645,400**

ATTACHMENT C: TIMELINE AND MILESTONES

As part of the procurement process, Burns & Associates, a Division of HMA (HMA-Burns) was required to submit a work plan, including major tasks and milestones to complete the scope of work. Presently, the State only has the authority to contract with HMA-Burns through December 31, 2022. There are deliverables due to CMS after December 31, 2022.

HMA-Burns has built a work plan for the independent evaluation of Colorado's Adult Prenatal Coverage in CHP+ Section 1115 demonstration that is constructed around the development of each deliverable identified as part of CMS required deliverables and the State's obligations related to monitoring and evaluation (M&E) activities.

The main sections of the work plan are as follows:

- Section A, ***Project Management***, includes Tasks 1, 2 and 3. The tasks in the section will be conducted across the entire engagement.
    - Tasks in this section:
        - Kickoff meeting
        - Project management and project plan
        - Project charter
    - Deliverables in this section:
        - Monthly status and other project management reports
        - Project charter

- Section B, ***Annual Monitoring Activities and Ongoing Assistance***, includes Tasks 4 through 6. It is anticipated that the work in this section will start immediately upon contract execution and continue until January 31, 2027.
    - Tasks in this section:
        - Obtain and read in data for project
        - Create Annual Monitoring Reports
        - Ongoing consultation and technical assistance
    - Deliverables in this section:
        - Creation and maintenance of the analytic data warehouse specific to the Evaluation Design Plan and associated focus study
        - Compute and validate metrics specific to the Evaluation Design Plan on an annual basis
        - Annual Monitoring Reports (6 total)

- Section C, ***Summative Evaluation and Evaluation Design Plan Activities***, includes Tasks 7 through 8. It is expected that the work in this section will start immediately upon contract execution and continue until September 30, 2021.
    - Tasks in this section:
        - Prepare Summative Evaluation for 2015 to 2020 Demonstration
        - Develop Evaluation Design Plan for 2020 to 2025 Demonstration
    - Deliverables in this section:
        - Draft Evaluation Design for 2020 to 2025 Demonstration to CMS (May 15, 2021)
        - Final Evaluation Design for 2020 to 2025 Demonstration to CMS (July 14, 2021)
        - Draft Summative Evaluation for 2015 to 2020 to CMS (July 14, 2021)

        - Final Summative Evaluation for 2015 to 2020 to CMS (September 13, 2021)

- Section D, ***Interim Evaluation Activities,*** includes Task 9. It is expected that the work in this section will start in Q4 of CY 2023 and continue until July 31, 2024. Task 9 includes a pregnancy services focus study with an internal report to HCPF along with work to produce the Interim Evaluation itself. Results from the focus study will be included in the Interim Evaluation to CMS.
    - Tasks in this section:
        - Conduct one focus study (September 2023 – January 2024)
        - Prepare Interim Evaluation
    - Deliverables in this section:
        - Intermittent reports for the focus study during the 4-month period study period
        - Detailed outline of the Interim Evaluation (January 2024)
        - Draft Version of Interim Evaluation to CMS (June 31, 2024)
        - Final Version of Interim Evaluation to CMS (July 2024)

- Section E, ***Summative Evaluation Deliverables***, includes Task 10 and is expected to repeat the pregnancy services focus study as a follow-up to what was reported on in the Interim Evaluation It is expected that the work in this section will start in Q1 of CY 2026 and continue until January 31, 2027.
    - Tasks in this section:
        - Conduct one focus study (March 2026 – June 2026)
        - Prepare Summative Evaluation
    - Deliverables in this section:
        - Intermittent reports for the focus study during this 4-month study period
        - Detailed outline of the Summative Evaluation (July 2026)
        - Draft Version of Summative Evaluation to CMS (December 2026)
        - Final Version of Summative Evaluation to CMS (January 2027)