DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

December 21, 2021

Marie Matthews
Medicaid Director
Montana Department of Public Health and Human Services
111 North Sanders
Room 301
Helena, MT 59620

Dear Marie Matthews:

The Centers for Medicare & Medicaid Services (CMS) is approving an amendment and one-year temporary extension of Montana's section 1115 demonstration (Project Number 11-W-00300/8), titled Montana Health and Economic Livelihood Partnership (HELP), in accordance with section 1115(a) of the Social Security Act. Approval of this amendment and temporary extension authorizes a one-year period for the state to phase out its requirement for Medicaid beneficiaries to pay monthly premiums beyond those authorized under the Medicaid statute; the state's section 1115 authority for charging premiums will not extend past December 31, 2022. It also enables the state to remove expenditure authority for twelve-month continuous eligibility, pursuant to state legislative action. While continuous eligibility will no longer be authorized in the demonstration, the state must maintain the coverage of current beneficiaries consistent with the requirements of the Families First Coronavirus Response Act for the period that it elects to receive the associated Federal Medical Assistance Percentage enhancement. Additionally, the temporary extension period allows time for the state to determine the need for section 1115 authorities in the future. As a whole, the HELP demonstration will continue through December 31, 2022, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.

CMS does not intend to renew the authority to charge premiums to the adult group after this extension period. The time-limited temporary extension of the premium authority is intended to give the state a reasonable period to implement necessary changes to wind down the premium requirement, as further discussed below. The intention not to approve such premium requirements in the future is based on CMS's determination that premiums can present a barrier to coverage, and therefore, charging premiums beyond those specifically permitted in the Medicaid statute are not likely to promote the objectives of Medicaid.

This policy determination is informed by findings in recent research across different states with section 1115 demonstrations, which show that charging beneficiaries premiums beyond those

authorized under the statute resulted in shorter enrollment spells[1] and were associated with lower initial enrollment rates and increased obstacles to accessing care in several states.[2] Further, premium requirements can exacerbate health disparities, as historically under-resourced populations may be disproportionately affected by these policies. For example, research from several states shows that premium policies led to decreased enrollment and shorter enrollments spells for Black beneficiaries compared to their white counterparts, and beneficiaries with lower incomes compared to those with higher incomes.[3]

Additionally, beneficiaries in several states, including in Montana, have reported misperceptions about the affordability of Medicaid coverage and concerns about their ability to make monthly contributions under section 1115 demonstrations with premium requirements.[4] In fact, data reported for 2017 show that 2,884 Montanans lost their Medicaid coverage in that year due to failure to pay premiums.[5] Furthermore, paying monthly premiums was reported to be challenging for many Montana HELP beneficiaries, particularly those with the lowest incomes, although some HELP beneficiaries noted that the opportunity to contribute toward their coverage

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[1] **Dague, L. (2014).** The Effect of Medicaid Premiums on Enrollment: A Regression Discontinuity Approach. Journal of Health Economics. 37: 1-12. Retrieved from https://www.sciencedirect.com/science/article/pii/S0167629614000642.

[2] **Bradley, K., Niedzwiecki, M., Maurer, K., Chao, S., Natzke, B., & Samra, M. (2020).** Medicaid Section 1115 Demonstrations Summative Evaluation Report: Premium Assistance, Monthly Payments, and Beneficiary Engagement. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/alt-medicaid-exp-summ-eval-report.pdf; **Social & Scientific Systems, Inc. and the Urban Institute. (2020).** Federal Evaluation of Indiana's Healthy Indiana Plan — HIP 2.0. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-indiana-2020.pdf; **University of Michigan Institute for Healthcare Policy & Innovation. (2018).** Report on the Impact of Cost Sharing in the Healthy Michigan Plan: Healthy Michigan Plan Evaluation Domains V/VI. Retrieved from https://www.michigan.gov/documents/mdhhs/Domain_IV_-_2018_Eligible_But_Unenrolled_Report_652005_7.pdf; and **Cliff, B.Q., Miller, S., Kullgren, J.T., Ayanian, J.Z., & Hirth, R. (2021).** Adverse Selection in Medicaid: Evidence from Discontinuous Program Rules. National Bureau of Economic Research. Working Paper 28762. Retrieved from https://www.nber.org/papers/w28762.

[3] **University of Wisconsin-Madison Institute for Research on Poverty. (2019).** Evaluation of Wisconsin's BadgerCare Plus Health Coverage for Parents & Caretaker Adults and for Childless Adults 2014 Waiver Provisions. Retrieved from https://www.irp.wisc.edu/wp/wp-content/uploads/2019/11/BC-2014-Waiver-Provisions-Final-Report-08302019.pdf; **Finkelstein, A., Hendren, N., & Shepard, M. (2019).** Subsidizing Health Insurance for Low-Income Adults: Evidence from Massachusetts. American Economic Review. 109(4): 1530-67. Retrieved from https://www.aeaweb.org/articles?id=10.1257/aer.20171455; and **The Lewin Group, Inc. (2020).** Healthy Indiana Plan Interim Evaluation Report. Retrieved from https://www.in.gov/fssa/hip/files/IN_HIP_Interim_Evaluation_Report_Final.pdf.

[4] **Social & Scientific Systems, Inc. and the Urban Institute. (2020).** Federal Evaluation of Montana Health and Economic Livelihood. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf; **University of Michigan Institute for Healthcare Policy & Innovation. (2018).** Report on the Healthy Michigan Voices 2016-17 Survey of Individuals No Longer Enrolled in the Healthy Michigan Plan. Retrieved from https://www.michigan.gov/documents/mdhhs/Domain_IV_-_2018_Eligible_But_Unenrolled_Report_652005_7.pdf; and **The Lewin Group Inc. (2017).** Health Indiana Plan 2.0: POWER Account Contribution Assessment. Retrieved from https://www.medicaid.gov/sites/default/files/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-POWER-acct-cont-assesmnt-03312017.pdf.

[5] **Norris, L. (2021).** Montana and the ACA's Medicaid Expansion. Healthinsurance.org. Retrieved on December 8, 2021 from https://www.healthinsurance.org/medicaid/montana/; and **Galewitz, Phil. (2018).** Tens of Thousands of Medicaid Recipients Skip Paying New Premiums. KHN. Retrieved from https://khn.org/news/tens-of-thousands-of-medicaid-recipients-skip-paying-new-premiums/

reduced the stigma or personal guilt associated with relying on government for traditional Medicaid coverage.[6]

Covering the first two years of the Montana HELP approval period (2016-2017), a federal evaluation of this demonstration found that—overall—the demonstration resulted in significantly more coverage growth for its adult population compared to similar beneficiaries in states that did not expand Medicaid, or expanded Medicaid with different section 1115 demonstrations (with or without premiums). However, this evaluation focused on the effects of the demonstration as a whole, and *did not* isolate how premiums directly impacted health coverage.[7] These gains in coverage in Montana are also consistent with the overall expansion in Medicaid (and CHIP) enrollment in the state during this period. But enrollment in Montana stabilized in 2018 and early 2019, after which point it declined until the start of the COVID-19 public health emergency.[8] It is not clear whether and how substantially the premium policy was a factor driving the enrollment trends observed in the state. Nevertheless, CMS is not aware of evidence from Montana or other states to indicate that charging beneficiaries premiums beyond those authorized under the statute are likely to directly or indirectly promote coverage.

On balance, the evidence from recent research across several states on premium policies in section 1115 demonstrations suggests that premiums can reduce access to coverage and care among populations that Medicaid aims to serve, and therefore, we do not have reason to believe that charging beneficiaries premiums beyond those authorized under the statute are likely to directly or indirectly promote coverage. As such, the temporary extension of the Montana HELP demonstration stipulates that the authority for premiums under the demonstration will expire on December 31, 2022, and CMS does not intend to renew the premium authority after that date. This time-limited temporary extension will support the state with a planned phase-out of the policy, allow the state adequate time to conduct communication outreach for this policy change, and implement any operational changes or resource reallocations, as well as to make necessary system changes.

Consistent with CMS requirements for section 1115 demonstrations, and as outlined in the demonstration's special terms and conditions (STCs), the state is required to conduct monitoring and evaluation of the demonstration components. Due to the unique limited scope of this amendment and one-year temporary extension of the Montana HELP demonstration, the STCs outline streamlined but meaningful monitoring and evaluation activities that are relevant to the demonstration. In addition to the state monitoring metrics related to enrollment and premium payment/non-payment, the demonstration's evaluation will focus on descriptive assessments of research questions and hypotheses related to: trends in enrollment, disenrollment, and reenrollment; assessments of the methods and processes for beneficiary outreach related to the

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[6] **Social & Scientific Systems, Inc. and the Urban Institute. (2020).** Federal Evaluation of Montana Health and Economic Livelihood. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf.

[7] **Social & Scientific Systems, Inc. and the Urban Institute. (2020).** Federal Evaluation of Montana Health and Economic Livelihood. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf.

[8] **KFF**. Total Monthly Medicaid/CHIP Enrollment and Pre-ACA Enrollment: Montana. Retrieved from https://www.kff.org/health-reform/state-indicator/total-monthly-medicaid-and-chip-enrollment.

policy change; and a discussion of any challenges encountered related to programming or systems changes, or issues with the state's contractors during the premium policy phase out process.

CMS's approval of this section 1115(a) demonstration amendment is subject to the limitations specified in the attached expenditure authorities, STCs, and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been specifically listed as not applicable under the demonstration.

Consideration of Public Comments

The state provided public notice for this amendment in accordance with the processes described in the September 27, 1994 Federal Register notice (59 FR 49249) as generally acceptable methods of state public notice for demonstration amendments.

The state's public comment period for the amendment to the Montana HELP demonstration was open from July 3, 2021 through August 31, 2021, and the state received 443 comments. The federal comment period was open from September 20, 2021 through October 20, 2021. Comments were submitted for both the Montana HELP and Montana Additional Services and Populations (WASP) amendments seeking to remove continuous eligibility. Fourteen comments directly mentioned the HELP demonstration and more than one hundred comments mentioned the general removal of continuous eligibility without mentioning either the Montana HELP or Montana WASP demonstration by name. Though all comments submitted were in opposition of the removal of twelve-month continuous eligibility, the state is not obligated to provide continuous eligibility.

After careful review of the public comments submitted during the federal comment period and the information received from the state, CMS has concluded that temporary extension is likely to promote the objectives of Medicaid by supporting the state in systematically unwinding its premiums policies while minimizing disruption to the coverage of its current demonstration beneficiaries.

Other Information

The award is subject to CMS receiving written acceptance of this award within thirty (30) days of the date of this approval letter. Your project officer is Ms. Felicia Pailen who is available to answer any questions concerning implementation of the state's section 1115(a) demonstration and her contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop S2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Email: Felicia.Pailen@cms.hhs.gov

We appreciate your state's commitment to improving the health of people in Montana, and we look forward to our continued partnership on the Montana Health and Economic Livelihood Partnership section 1115(a) demonstration. If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

Chiquita Brooks-LaSure

Enclosures

cc: Barbara Prehmus, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER:	**No. 11-W-00300/8**
TITLE:	**Montana Health and Economic Livelihood Partnership (HELP) Program Demonstration**
AWARDEE:	**Montana Department of Public Health and Human Services**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration populations. The waiver will continue through December 31, 2022, unless otherwise stated.

The following waivers shall enable Montana to implement the Montana Health and Economic Livelihood Partnership (HELP) Program section 1115 demonstration.

Title XIX Waivers

1. Premiums — **Section 1902(a)(14) and Section 1916**

To enable the state to charge premiums at levels not more than two percent of household income to individuals with income greater than 50 percent of the federal poverty level (FPL). Total cost-sharing (including premiums) for a household is subject to a quarterly aggregate cap of five percent of household income. This waiver authority will sunset on December 31, 2022.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **No. 11-W-00300/8**

TITLE: **Montana Health and Economic Livelihood Partnership (HELP) Program Demonstration**

AWARDEE: **Montana Department of Public Health and Human Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Montana Health and Economic Livelihood Partnership (HELP) Program section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable Montana to operate this demonstration program. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of requirements under section 1902(a) of the Social Security Act (the Act) which are separately enumerated. These STCs set forth conditions and limitations on those waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers, nor expand upon those separately granted.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Demonstration Programs and Benefits
VI. Delivery System
VII. Premiums
VIII. General Financial Requirements
IX. General Reporting Requirements
X. Evaluation of the Demonstration
XI. Schedule of Deliverables

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: Approved Evaluation Design *[reserved]*

II. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration provides authority for the state to charge premiums to enrollees in the new adult group with income greater than 50 percent of the federal poverty level (FPL).

For individuals with income greater than 50 percent of the FPL, premiums may not exceed two percent of family household income. Participants with income at or below 100 percent of the FPL who fail to pay premiums will not be disenrolled from coverage. Participants with incomes above 100 percent of the FPL who fail to pay premiums may be disenrolled from coverage. Such individuals may re-enroll for coverage when payment is made for the overdue premiums or after the state assesses past due premium amounts. Assessments must occur no later than the end of the quarter.

The following individuals are excluded from all provisions of this demonstration; those who: 1) have been determined to be medically frail; 2) live in a region (which could include all or part of an Indian reservation) where there may not be sufficient providers; 3) require continuity of coverage that is not available or could not be effectively delivered; and 4) are otherwise exempted from premiums or cost-sharing by federal law, and not within the scope of a waiver of that exemption, including individuals with incomes up to 50 percent of the FPL. These individuals, hereinafter referred to as "Excluded Populations," will be served under the Medicaid state plan and subject to the terms and conditions therein.

The one-year temporary extension enables a planned phase out of the premium requirement, by allowing the state adequate time to conduct communication outreach for this policy change, and implement any operational changes or resource reallocations, as well as to make necessary changes to its Medicaid eligibility and enrollment processes. The amendment enables state to remove expenditure authority for twelve-month continuous eligibility.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (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 law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into

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

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

    i. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such a change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of change in FFP.

    ii. 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.** The state will not be required to submit title XIX or XXI state plan amendment (SPAs) 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 and CHIP state plans govern.

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

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

    i. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such an 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;

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

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

    iv. An up-to-date CHIP allotment neutrality worksheet, if necessary;

    v. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring, and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer in accordance with the requirements of 42 CFR §431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.

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

    i. 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 plan to CMS. The state must submit the

notification letter and a draft 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.

ii. Transition and Phase-out Plan Requirements. 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 fair hearing rights, if any), the process by which the state will conduct redeterminations 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 beneficiaries, including community resources that are available.

iii. 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.

iv. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. 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.

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

vi. Enrollment Limitations 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 limitations of enrollment into the demonstration does not impact the states obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

vii. Federal Financial Participation (FFP)**.** If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating 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 waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and 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 disenrolling beneficiaries.

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

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

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

13. **Federal Financial Participation.** No federal matching for service expenditures for this demonstration, including for administrative and medical assistance expenditures, will be

available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

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

15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities which may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs or procedures, or possible changes in methods or level of payment for 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 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected By the Demonstration.** This demonstration affects individuals ages 19 through 64 who are eligible in the new adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act, and 42 CFR 435.119, and who receive all benefits described in an alternative benefit plan (ABP) under the state plan.

    All affected 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 listed as waived in this demonstration, subject to the operational limits as described in these STCs. All Medicaid eligibility standards and methodologies for these eligibility groups remain applicable.

Table 1. Medicaid State Plan Groups Affected by the Demonstration

Medicaid State Plan Group	Population Description	Funding Stream
Adult group.	Individuals ages 19 through 64 who are eligible in the new adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act.	Title XIX

The following populations are excluded from all portions of the demonstration.

a. Individuals who are medically frail;

b. Individuals who the state determines have exceptional health care needs, as identified through the application process or by an individual notifying the State at any time, including but not limited to a medical, mental health, or developmental condition;

c. Individuals who live in a region (that may include all or part of an Indian reservation), where the state is unable to contract with sufficient providers);

d. Individuals who the state determines, in accordance with objective standards approved by CMS, require continuity of coverage that is not available;

e. Individuals exempted by federal law from premium or cost sharing obligations, whose exemption is not waived by CMS, including all individuals with incomes up to 50 percent of the FPL.

V. BENEFITS

17. Montana HELP Program Demonstration Benefits. Individuals in the demonstration will receive benefits through the state plan alternative benefits plan (ABP).

18. Minimum Essential Coverage. All individuals affected by this demonstration receive coverage that meets the requirements of minimum essential coverage (MEC).

VI. DELIVERY SYSTEM

19. Medicaid State Plan. Eligible enrollees in the Montana HELP Program will receive services approved in the state's ABP through the state's Fee-for-service system (FFS).

VII. PREMIUMS

20. Time-Limited Premiums (Phase Down). Authority to charge premiums is contingent upon the state demonstrating the ability to electronically track aggregate out-of-pocket costs for all household members, on a quarterly basis. The state is permitted to charge demonstration beneficiaries monthly premiums of up to two percent of aggregate household income. In families with two enrolled individuals, the total of both beneficiaries' required premium contributions cannot exceed five percent of the household income. Notwithstanding the premium obligations, eligibility shall be determined consistent with state plan rules.

a. **Premiums for Individuals with Income at or Below 100 percent of the FPL**.

i. Non-payment of premiums by individuals with income at or below 100 percent of the FPL shall not result in disenrollment. Unpaid premiums may be considered a collectible debt that may be assessed by the state.

b. **Premiums for Individuals with Income Above 100 percent of the FPL**.

i. After appropriate notice and a 90-day grace period, individuals with income above 100 percent of the FPL who fail to make a premium payment may be dis-enrolled.

ii. Re-enrollment shall be permitted upon payment of arrears or when the debt is assessed. Assessment occurs when the Department of Revenue sends notice of debt to the individual, as the state will describe in the Operations Protocol in Attachment B and described in section VII .

iii. Assessment shall occur no less frequently than quarterly on a calendar basis; re-enrollment after assessment shall not require a new application for Medicaid.

iv. The state shall establish a process to exempt individuals from dis-enrollment for good cause.

c. **Income for Purposes of Premium Calculation.** If an individual's income changes the individual may report the change and the premium amount shall be recalculated for the following quarter.

21. Beneficiary Education. Program information, applicant information, and beneficiary information shall be tested to ensure it is comprehensible by the target audience and shall make clear:

a. That eligibility will begin consistent with state plan rules.

b. How premium payments should be made and the impact of change of income on premium payments owed.

c. The income guidelines for each component of the program (above 100 percent of the FPL and at and below 100 percent of the FPL and the relevant monthly income dollar figures so that applicants can understand which group they are likely to be in).

d. The consequences of non-payment of premiums for each income group.

e. The consequences of non-payment of co-payments for each income group.

f. How to re-enroll, if dis-enrolled for non-payment of premiums.

22. Beneficiary Outreach. The state must conduct an outreach and education campaign to potential applicants and beneficiaries to ensure that they understand the program policies regarding premiums and associated consequences.

23. Beneficiary Protections.

a. The state may attempt to collect unpaid premiums and the related debt from beneficiaries, but may not report the debt to credit reporting agencies, place a lien on an individual's home, refer the case to debt collectors, file a lawsuit, seek a court order to seize a portion of the individual's earnings for enrollees at any income level. The state also may not "sell" the debt for collection by a third-party.

b. Beneficiaries described in 42 CFR 447.56(a) (including American Indians/Alaska Natives, as described therein) must be exempt from all premium contribution requirements, as applicable.

c. Beneficiaries may not incur family cost sharing or premiums that exceeds five percent of the aggregate family's income, following rules established in 42 CFR 447.56(f).

d. The state may not pass along the cost of any surcharge associated with processing payments to the beneficiary. Any surcharges or other fees associated with payment processing must be considered an administrative expense by the state.

e. The state will ensure that all payments from the beneficiary, or on behalf of the individual, are accurately and timely credited toward unpaid premiums and related debt, and will provide the beneficiary an opportunity to review and seek correction of the payment history.

VIII. GENERAL FINANCIAL REQUIREMENTS

24. General Financial Requirements. The state must comply with all general financial requirements under Title XIX outlined in Section XI of these STCs.

25. Quarterly Expenditure Reports. The state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.

26. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures:

a. **Tracking Expenditures.** In order to track expenditures under this demonstration, Montana must report demonstration expenditures through the Medicaid Budget and Expenditure System (MBES) and state Children's Health Insurance Program Budget and Expenditure System (CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the

DY in which services were rendered or for which capitation payments were made. For this purpose, DY 7 is defined as the year beginning January 1, 2022, and ending December 31, 2022. DY 8 and subsequent DYs are defined accordingly. All title XIX service expenditures that are not demonstration expenditures and are not part of any other title XIX waiver program should be reported on Forms CMS-64.9 Base/64.9P Base.

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

c. **Use of Waiver Forms.** The following one (1) waiver Form CMS-64.9 Waiver and/or 64.9P Waiver must be submitted each quarter (when applicable) to report title XIX expenditures for individuals enrolled in the demonstration. The expression in quotation marks is the waiver name to be used to designate these waiver forms in the MBES/CBES system.

27. Administrative Costs. Administrative costs will not be included in the budget 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".

28. Claiming Period. All claims for expenditures (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 any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately on the CMS-64 waiver forms the net expenditures related to dates of service during the operation of the section 1115 demonstration, in order to account for these expenditures properly to determine budget neutrality.

29. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS 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-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

30. Extent of FFP for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined below:

a. Administrative costs, including those associated with the administration of the demonstration.

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan.

c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, cost sharing, pharmacy rebates, and all other types of third-party liability or CMS payment adjustments.

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

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

b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan.

d. Under all circumstances, health care providers must retain 100 percent of the Montana HELP Program reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

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

a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for Title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under Title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to fund the non-federal share of demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of Title XIX payments.

33. Contributions from third parties. Third parties are permitted to contribute toward a beneficiary's premium obligation. There are no limits on the amounts third parties can contribute toward a beneficiary's premium obligation. Such third -party contributions offset required beneficiary premium obligations only, and may not be used for any other purpose. Contributions that exceed such obligations will be returned to the contributing third party. The contribution must be used to offset the beneficiary's required contributions only, not the state's share. Health care providers or provider-related entities making contributions on individuals' behalf must have criteria for providing assistance that do not distinguish between individuals based on whether or not they receive or will receive services from the contributing provider(s) or class of providers. Providers may not include the cost of such payments in the cost of care for purposes of Medicare and Medicaid cost reporting and cannot be included or as part of a Medicaid shortfall or uncompensated care for any purpose.

IX. GENERAL REPORTING REQUIREMENTS

34. 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 $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in

these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

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

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

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

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

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

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

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

    i. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
    ii. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and
    iii. Submit deliverables to the appropriate system as directed by CMS.

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

    a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, and how challenges are being addressed. 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. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

    b. Performance Metrics - The performance metrics will provide data that will help track the state's progress towards unwinding its premiums policy. For example, the state should provide metrics data related to enrollment and premium payment/non-payment, as applicable. CMS can provide the state with the technical specifications for calculation of such metrics. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. The required monitoring and performance metrics must be

included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

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

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

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

39. Close Out Report. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

a. The draft report must comply with the most current guidance from CMS.

b. The state will present to and participate in a discussion with CMS on the Close Out Report.

c. The state must take into consideration CMS's comments for incorporation into the final Close Out Report.

d. The final Close Out Report is due to CMS no later than thirty (30) calendar days after

receipt of CMS's comments.

e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 34.

40. Monitoring Calls. CMS will convene periodic conference calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

41. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) calendar 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 quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

II. EVALUATION OF THE DEMONSTRATION

42. 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 34.

43. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than ninety (90) calendar days after approval of the

demonstration. The draft Evaluation Design also must include a timeline for key evaluation activities, including evaluation deliverables.

a. At a minimum, the draft Evaluation Design must include a discussion of the hypotheses that are being tested. The draft Evaluation Design will provide a plan for descriptively assessing the challenges and lessons learned associated with ending the premium policy. The Evaluation Design should incorporate information from key stakeholders and individuals managing and implementing the change in policy.

44. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as Attachment D to these STCs. Per 42 CFR 431.424(c), the state will publish to its website the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Monitoring Reports.

45. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. For example, the state should include research questions and hypotheses related to changes in enrollment, disenrollment, and reenrollment, all of which can largely be analyzed through descriptive qualitative and quantitative analyses. The state also should assess the methods and processes of communication and outreach related to the policy change. Additionally, the state should discuss any challenges it encountered related to programming or systems changes, or issues with its contractors, during the premium policy unwinding process.

46. **Evaluation Budget.** A budget for the evaluation shall be provided with the draft Evaluation Design. 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.

47. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with the applicable instructions in Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within twelve (12) months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

48. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.

49. Upon approval from CMS, the final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

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

51. 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 and/or the Summative Evaluation Report.

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

53. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of deliverables, CMS will be notified prior to presentation of these reports or their findings, including in related publications (e.g., journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

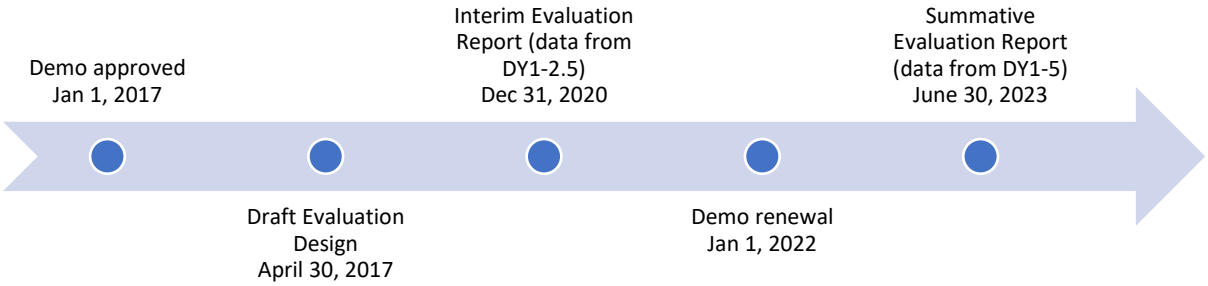
Attachment A
Developing the Evaluation Design

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about 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).

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 for a 5-year demonstration period. 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 thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with Medicaid section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. 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.

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 description of the population groups impacted by the demonstration.

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

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

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

1) Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.

2) Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.

3) 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 can be measured.

4) 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, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. 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.

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, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure.

Specifically, this section establishes:

1) *Methodological Design* – Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, incorporating 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. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

   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.) 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. 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.

5) *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative analysis measures that will 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).
    b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
    c. Include a discussion of how propensity score matching and difference-in-differences designs may be used to adjust for differences in comparison populations over time, if applicable.
    d. Consider the application of sensitivity analyses, as appropriate.
7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design for 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 more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these 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.

CMS also 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. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

1) When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. 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;

b. No or minimal appeals and grievances;

c. No state issues with CMS-64 reporting or budget neutrality; and

d. No Corrective Action Plans for the demonstration**Attachments**

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. 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 costs, 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, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.

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 milestones for the development and submission of the Interim and Summative Evaluation Reports. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation Report is due.

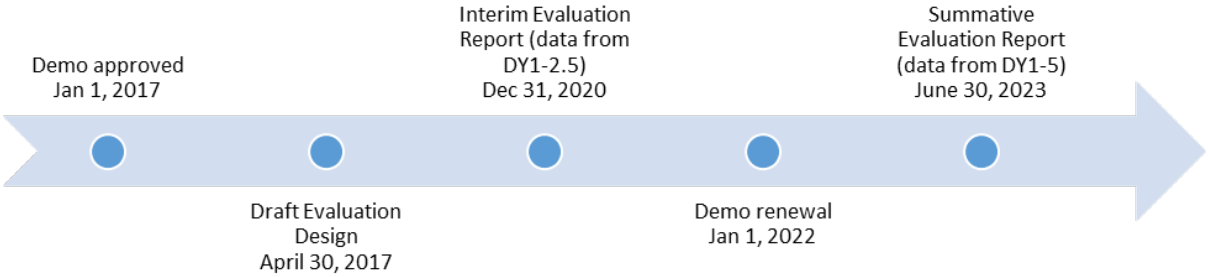
Attachment B
Preparing the Interim and Summative Evaluation Reports

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about 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).

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 a deliverables timeline for a 5-year demonstration. 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 Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are 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). 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. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. 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.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

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 evaluation report submissions must provide comprehensive written presentations 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.

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports 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. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy.

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).

States should include the following information in the following sections of their Interim and Summative Evaluation Reports:

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 issue/s 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 description of the population groups impacted by the demonstration.

4) 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.

5) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

1) Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.

2) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

3) 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.

4) 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.

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 (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An Interim Evaluation 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 Report.

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) *Methodological Design* – Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
2) *Target and Comparison Populations* – Describe the target and comparison populations, describing inclusion and exclusion criteria.
3) *Evaluation Period* – Describe the time periods for which data will be collected.
4) *Evaluation Measures* – List the measures used to evaluate the demonstration and their respective measure stewards.
5) *Data Sources* – Explain from where the data were obtained, and efforts to validate and clean the data.
6) *Analytic Methods* – Identify specific statistical testing which was undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7) *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.**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 demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.

G. Conclusions – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:

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?
    a. If the state did not fully achieve its intended goals, why not?
    b. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In

this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long-range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

I. Lessons Learned and Recommendations – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long-range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretations 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.

J. Attachment

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

Attachment C
Evaluation Design