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

November 21, 2022

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

Dear Mr. Randol:

The Centers for Medicare & Medicaid Services (CMS) is approving Montana's "Waiver for Additional Services and Populations" section 1115 demonstration extension (Project Number 11-W-00181/8), in accordance with section 1115(a) of the Social Security Act ("the Act"). The demonstration will continue to provide expenditure authority for: 1) 12-month continuous eligibility and full state plan benefits, except retroactive eligibility, for the Waiver Mental Health Services Plan (WMHSP) population up to a limit of 3,000 beneficiaries, who have been diagnosed with a severe disabling mental illness (SDMI) of schizophrenia, bipolar disorder, major depression or another SDMI; and 2) dental treatment services above the $1,125 state plan dental treatment cap to individuals determined categorically eligible for the aged, blind, and disabled (ABD) eligibility group, to which retroactive eligibility requirements will continue to apply. The state will maintain the authority to not provide retroactive eligibility for the WMHSP demonstration population, and will be required to evaluate the effects of this policy on beneficiary receipt of services and medical debt. This approval is effective through December 31, 2027, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.

CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (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.

Budget Neutrality

Although there are no programmatic changes in this demonstration extension, CMS will now consider expenditures for the WMHSP demonstration eligibility group to be "hypothetical" for purposes of budget neutrality. Because these expenditures could be covered under the Medicaid state plan and thereby would be eligible to receive federal financial participation (FFP), CMS will effectively treat these expenditures as if they were approved in the Medicaid state plan for

purposes of the budget neutrality calculation. Hypothetical expenditures, therefore, will not necessitate savings to offset the authorized spending, nor will the state be able to generate "savings" from this expenditure authority.

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstration is likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs in that state likely would have been without the demonstration. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" (WOW) costs).

CMS is revising the approach to adjusting the budget neutrality calculation in the middle of a demonstration approval period. Historically, CMS has limited its review of state requests for "mid-course" budget neutrality adjustments to situations that necessitate a corrective action plan, in which projected expenditure data indicate a state is likely to exceed its budget neutrality expenditure limit. CMS has updated its approach to mid-course corrections in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (e.g., expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (e.g., unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (e.g., a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

Monitoring and Evaluation

The demonstration's Interim Evaluation Report[1] highlighted overall increases in beneficiary access to care, as well as decreases in utilization of emergency departments and crisis stabilization facilities for beneficiaries with SDMI. At least 84 percent of surveyed beneficiaries with SDMI noted that they were satisfied with their ability to access mental health services and

[1] Montana Section 1115 Waiver for Additional Services and Populations (WASP) Demonstration Waiver: Interim Evaluation Report. June 2022. This report is currently under CMS review and will be publicly posted once approved by CMS.

the quality and appropriateness of care provided. However, the report also found a 3.3 percent decrease in the percentage of SDMI beneficiaries receiving community-based mental health services from 2019 to 2020, which potentially could be associated with the disruptions in health care in 2020 due to the COVID-19 pandemic. For the ABD population, there was a slight increase in the percent of beneficiaries receiving dental services, and nearly all beneficiaries remained under the maximum dental benefit threshold from March 2017 through February 2021.

As outlined in the demonstration extension STCs, the state will undertake systematic monitoring and a comprehensive evaluation of the various demonstration components, per applicable CMS guidance and technical assistance. In particular, the state must collect necessary data to accommodate CMS's evaluation expectations to rigorously assess the effects of the state's retroactive eligibility "not applicable" policy on beneficiaries and providers, for example, by examining outcomes such as likelihood of enrollment and enrollment continuity, health status, and financial status. The state must also continue to monitor demonstration components through Annual Monitoring Reports. Such monitoring will provide data to demonstrate how the state is progressing toward meeting the demonstration's goals, and must cover all key policies under this demonstration.

The state must develop an Evaluation Design for this demonstration extension period by incorporating well-crafted hypotheses, research questions, and analyses that support understanding the effects of the demonstration and its key policy components on beneficiary coverage, access to and quality of care, and health outcomes, including outcomes related to mental health and wellness. Evaluation of the continuous eligibility policy must focus on outcomes including coverage, enrollment and churn (i.e., temporary loss of coverage in which beneficiaries are disenrolled but then re-enroll within 12 months) as well as population-specific appropriate measures of service utilization and health outcomes. Hypotheses for the retroactive eligibility "not applicable" policy must include (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, health status, and medical debt. To evaluate the dental program, the state must develop hypotheses related, but not limited to: utilization of preventive dental care services and dental-related emergency department visits. To address these hypotheses and research questions, CMS underscores the importance of the state undertaking a well-designed beneficiary survey to assess, for instance, beneficiary understanding of the various demonstration policy components and beneficiary experiences with access to and quality of care.

The state is required to contract with an independent evaluator to conduct the demonstration's Interim and Summative Evaluation Reports, in alignment with the approved Evaluation Design, to assess whether the demonstration initiatives are effective in producing the desired outcomes for beneficiaries and the state's Medicaid program overall. Additionally, the state and CMS will work collaboratively so the state's demonstration monitoring and evaluation efforts accommodate data collection and analyses stratified by key subpopulations of interest—to the extent feasible—to inform a fuller understanding of existing disparities in access, utilization, and health outcomes, as well as how the demonstration might support the bridging of such inequities.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, services, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary. As enacted by the Affordable Care Act (ACA), and incorporated under section 1115(d)(2)(A) and (C) of the Act, comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments (42 CFR 431.416(d)(2)).

One comment was received during the federal public comment period which opened on July 14, 2022 and closed on August 13, 2022. The commenter was in favor of the Montana's request to extend their Section 1115 Demonstration and to provide twelve-month continuous eligibility for those with a SDMI. The commenter also opined that continuous eligibility for those with SDMI supports better quality measurement of the care received by the SDMI population annually and helps to establish consistent Medicaid eligibility and continuity of care for this vulnerable population.

After carefully reviewing the public comments submitted during the federal comment period, CMS has concluded that the demonstration is likely to assist in promoting the objectives of Medicaid.

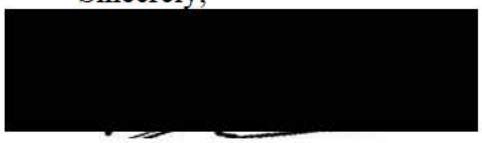
Other Information

The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer is Ms. Wanda Boone-Massey 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: wanda.boone-massey@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 Additional Services and Populations 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,



Daniel Tsai
Deputy Administrator and Director

Enclosure

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: **11-W-00181/8**

TITLE: **Section 1115 Waiver for Additional Services and Populations**

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

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures madeby the state for the items identified below, which are not otherwise included as expenditures under section 1903, shall, for the period of this demonstration extension, be regarded as expenditures under the state's Medicaid title XIX state plan. These expenditure authorities and the not applicables are effective January 1, 2023 through December 31, 2027.

The state shall claim expenditures for federal matching at the regular matching rate. The expenditure authorities listed below promote the objectives of title XIX of the Social Security Act by providing flexibility for Montana to extend coverage to certain low-income individuals,and provide twelve-month continuous eligibility period to individuals in the demonstration.

The following expenditure authorities shall enable Montana to implement this section 1115demonstration.

1. Expenditures for the Waiver Mental Health Services Plan Program (WMHSP)Population

Expenditures for coverage of health care services for no more than 3,000 individuals age 18 or older, not otherwise eligible for Medicaid who have been diagnosed with a severe disabling mental illness (SDMI) of schizophrenia, bipolar disorder, major depression, or another severe disabling mental illness, and either: 1) have income above 133 up to and including 150 percent of the FPL, or 2) are eligible for or enrolled in Medicare and have income at or below 133 percent of the FPL.

2. Expenditures for the Twelve-Month Continuous Eligibility Period Population

Expenditures for health care related costs for individuals initially determined eligible under the demonstration as WMHSP population, but who no longer meet the standards during some portion of a twelve-month continuous enrollment period.

3. Expenditures for Dental Services above the Dental Treatment Services Limit for theAged, Blind, and Disabled (ABD) Population

Expenditures for Montana to provide dental treatment services above the state plan dental treatment services annual limit of $1,125 for beneficiaries determined categorically eligible as ABD.

MEDICAID REQUIREMENTS NOT APPLICABLE TO THE DEMONSTRATION ELIGIBLE POPULATION

All requirements of the Medicaid program expressed in statute, regulation and policy statement, not expressly waived in this list, shall apply to the demonstration project beginning as of January1, 2023, through December 31, 2027. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

The following requirements of the demonstration will be applicable to those beneficiaries who are made eligible for services solely by virtue of the demonstration project, except those requirements specified below:

1. Reasonable Promptness (enrollment limit) Section 1902(a)(8)

To enable the state to maintain enrollment up to the designated enrollment limit for the WMHSP population. No waiver of reasonable promptness is authorized for the ABD population receivingdental services through this demonstration.

2. Retroactive Eligibility Section 1902(a)(34)

To permit the state not to offer retroactive eligibility to WMHSP individuals. No waiver of retroactive eligibility is authorized for the ABD population receiving dental services through this demonstration.

NUMBER: 11-W-00181/8

TITLE: Montana Section 1115 Waiver for Additional Services and Populations

AWARDEE: Montana Department of Public Health and Human Services

I. PREFACE

The following are the special terms and conditions (STCs) for Montana's Section 1115 Waiver for Additional Services and Populations (hereinafter referred to as "demonstration") to enable Montana to operate this demonstration for the period of January 1, 2023, through December 31, 2027. The parties to this agreement are the Montana Department of Public Health and Human Services ("state") and the Centers for Medicare & Medicaid Services ("CMS"). CMS has granted a waiver of specific requirements under section 1902(a) of the Social Security Act (the Act). All requirements of the Medicaid and CHIP programs expressed in law, regulation and policy statement, not expressly waived or made not applicable in the list of Waivers and Expenditure authorities, shall apply to the demonstration project.

The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs are effective as of the approval letter's date, unless otherwise specified. Amendment requests, correspondence, documents, reports, and other materials that are submitted for review or approval shall be directed to the CMS Central Office project officer and the Regional Office state representative at the addresses shown on the award letter. All previously approved STCs, waivers, and expenditure authorities are superseded by the STCs set forth below. The STCs are effective the date of approval through December 31, 2027.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Benefits
V. Continuous Eligibility
VI. Enrollment
VII. Cost Sharing
VIII. Delivery Systems for WMHSP Enrollees
IX. Monitoring and Reporting Requirements
X. Evaluation of the Demonstration
XI. General Financial Requirements Under Title XIX

II. PROGRAM DESCRIPTION AND OBJECTIVE

The Montana Section 1115 Waiver for Additional Services and Populations is a statewide section 1115 demonstration administered by the state. The demonstration began in 1996, under the authority of an 1115 welfare reform demonstration referred to as Families Achieving Independence in Montana (FAIM). Under FAIM, Montana provided for all mandatory Medicaid benefits and a limited collection of optional services to approximately 8,500 able-bodied adults (aged 21 through 64 and neither pregnant nor disabled), eligible under the state plan because they are parents and caretaker relatives of dependent children at or below the state standard of need (i.e., otherwise eligible for Medicaid under section 1925 or 1931 of the Social Security Act).

The FAIM welfare reform demonstration expired on January 31, 2004, and was replaced (without change) by a section 1115 Medicaid demonstration titled "Montana Basic Medicaid forAble-Bodied Adults," which was approved for the period of February 1, 2004, through January 31, 2009. The demonstration was continued through a series of Temporary Extensions through November 30, 2010.

On January 25, 2008, Montana proposed to renew the Basic Medicaid for Able-Bodied Adults demonstration for eligible parents and caretaker relative adults eligible under the state plan, and in subsequent communications proposed to use demonstration savings generated through the use of a limited service delivery network and the elimination of certain benefits to expand eligibility. On July 30, 2009, and August 13, 2010, the state submitted revised proposals to CMS. Under the revised proposals, demonstration savings are used to provide basic Medicaid coverage to up to 800 individuals, aged 18 through 64, with incomes at or below 150 percent of the federal poverty level (FPL), who have been diagnosed with a severe disabling mental illness (SDMI) of schizophrenia, bipolar disorder, or major depression, and who would not otherwise be eligible for Medicaid benefits. Prior to enrollment of the WMHSP population in the section 1115 demonstration, these individuals received a very limited mental health benefit through enrollment in a state-financed Mental Health Services Plan (MHSP).

On the basis of the state's July 30, 2009, and August 13, 2010, proposals, CMS approved the extension of the Basic Medicaid demonstration under authority of section 1115(a) of the Social Security Act (the Act). The demonstration was renewed for 3 years, from December 1, 2010, through December 31, 2013.

On October 31, 2013, Montana submitted a completed application for a renewal of the

demonstration. The state proposed to extend its demonstration with some changes, which included increasing enrollment in the WMHSP from 800 to 2,000 individuals and covering home infusion services, which are services that were previously excluded under the benefits package in the demonstration. On November 8, 2013, the demonstration renewal was approved for 3 years, from January 1, 2014, through December 31, 2016.

On June 30, 2014, Montana submitted a formal amendment to increase enrollment in the WMHSP from 2,000 to 6,000 individuals. The amendment updated eligible diagnostic codes and add severe disabling mental illness (SDMI) diagnoses to the enrollment process, updated the per member per month cost, and updated the money for maintenance of effort amount. This amendment request was approved on December 16, 2014.

On July 19, 2016, CMS approved Montana's amendment request to reduce the enrollment cap from 6,000 to 3,000 and change the populations eligible for benefits only under the demonstration. The demonstration provides for coverage of health care services for no more than 3,000 individuals age 18 or older, not otherwise eligible for Medicaid who have been diagnosed with a SDMI of schizophrenia, bipolar disorder, major depression, or another SDMI, and at the time of their initial enrollment were receiving (or meet the qualifications to receive) a limited mental health services benefit package through enrollment in the state-financed MHSPP, and either: 1) have income above 133 up to and including 150 percent of the FPL, or 2) are eligible for or enrolled in Medicare and have income at or below 133 percent of the FPL. The demonstration offers a benefit package that aligns with the Medicaid state plan. In addition, the demonstration provides 12 months of continuous eligibility for parents and caretaker relative adults initially determined eligible under the state plan based on modified adjusted gross income (MAGI). CMS's approval of this amendment reflects Montana's recent approval of Medicaid expansion, which began January 1, 2016.

On December 5, 2016, CMS approved Montana's third amendment request to change the name of the demonstration, from "Montana Basic Medicaid for Able-Bodied Adults" to the "Section 1115 Waiver for Additional Services and Populations," and provides dental treatment services above the state plan dental services annual limit of $1,125 for beneficiaries determined categorically eligible as aged, blind, and disabled (ABD).

On December 15, 2017, CMS approved Montana's extension request to continue the demonstration for 5 years with no changes.

On March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act) as amended (42 U.S.C. 1320b-5). This authority took effect as of 6:00 PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. On March 18, 2020, the FFCRA was enacted. Section 6008 of the FFCRA offers a temporary Federal Medical Assistance Percentage (FMAP) point increase through the last day of the calendar quarter in which

the COVID-19 public health emergency ends as long as the state adheres to the requirements of section 6008(b) of the FFCRA. Section 6008(b)(3) includes the requirement that states maintain the enrollment of beneficiaries who were enrolled in Medicaid as of or after March 18, 2020, through the end of the month in which the COVID-19 PHE ends.[1]

On September 3, 2021, Montana submitted an amendment for the section 1115 demonstration titled, Montana Waiver for Additional Services and Populations (WASP) to remove expenditure authority for the 12-month continuous eligibility for all non-expansion Medicaid-covered individuals whose eligibility is based on MAGI. This amendment sunsets the parents and caretaker relatives (PCR) group from any coverage under WASP, as this was the only benefit they received under the demonstration. The state requested a retroactive approval effective July 1, 2021, as directed by Montana's 2021 Legislature. The state understands that it is required to maintain continuous enrollment of Medicaid beneficiaries during the COVID-19 PHE as a condition of receiving a temporary 6.2 percentage point FMAP increase under the FFCRA.

This amendment also seeks to remove cost sharing and copayments for demonstration enrollees, to align with the removal of cost sharing from the Montana Medicaid plan effective January 1, 2020. This will apply to WMHSP individuals (individuals previously covered under a State-funded program who had schizophrenia, severe depression, or bipolar disease) as well as the categorically eligible ABD individuals who receive expanded dental treatment services through the WASP waiver.

While the state requested approval on July 1, 2021, in order to comply with section 6008(b)(3) of the FFCRA and section 1902(a)(4) and (a)(19) of the Social Security Act, the approval for the authority to discontinue continuous eligibility for parents and caretaker relatives may not be implemented until the end of the continuous enrollment requirements, on the first day of the first calendar quarter after the end of the COVID-19 PHE or until the state is no longer claiming enhanced FMAP under 6008(a) of the FFCRA.

On June 30, 2022, Montana submitted a request to extend the WASP demonstration for 5 years. CMS approved Montana's extension request on October 31, 2022, to continue the demonstration for 5 years without programmatic changes. The demonstration will continue to provide authority for: 1) 12-month continuous eligibility and full state plan benefits, except retroactive eligibility, for the SDMI population; and 2) dental treatment services above the $1,125 state plan dental treatment cap to individuals determined categorically eligible for the ABD eligibility groups.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with

[1] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-G/section-433.400
https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf

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), and 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 and CHIP programs 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 policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 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.**

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such 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) as a result of the change in FFP.
    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the 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 amendments (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 assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS 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 the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

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

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

    c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current 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 detailed 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;

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

    e. 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 of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

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

   a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30 day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30 day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

   b. **Transition and Phase-out Plan 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 appeal rights), 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 affected beneficiaries, including community resources that are available.

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

   d. **Transition and Phase-out Procedures.** The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid or 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) and 457.350. The state must also comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230.

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

f. **Enrollment Limitation during Demonstration Phase-Out.** If the state elects to suspend, terminate, or not extend this demonstration, during the last 6 months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title 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 will 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 section 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.

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

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

15. **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.

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

IV. ELIGIBILITY AND BENEFITS

17. **Use of Modified Adjusted Gross Income (MAGI) Based Methodologies for Demonstration Groups.** For individuals eligible for continuous eligibility or the Waiver Mental Health Services Plan (WMHSP) only under the demonstration, financial eligibility is determined using modified adjusted gross income (MAGI), and otherwise applicable non-financial standards that would be applicable for state plan populations apply, except as expressly inconsistent with the demonstration eligibility criteria.

18. **Demonstration Eligible Populatio**n. Individuals eligible under the demonstration are:

    a. Waiver Mental Health Services Plan beneficiaries who, at the beginning of a 12-month period of enrollment (subject to paragraph V), have been diagnosed with a SDMI, are age18 and older, who at the time of their enrollment meet the financial and clinical eligibility criteria for the MHSP, but are otherwise ineligible for Medicaid benefits by either:

    i. Having income above 133 up to and including 150 percent of the FPL; or

ii. Having an income up to and including 133 percent of the FPL, while being eligible for or enrolled in Medicare; and

19. **Continuous Eligibility Funding.** Continuous eligibility population funding will be matched at the regular Federal Medical Assistance Percentage (FMAP) rate, and expenditures within the agreed upon per member per month limit for parents and caretaker relatives receiving continuous eligibility in the demonstration will not count against the state's accumulated savings for budget neutrality.

b. Aged, Blind, Disabled beneficiaries to provide dental treatment services limitation above the state plan dental services cap of $1,125.

20. **Benefits for WMHSP Enrollees.** All individuals enrolled in the demonstration will receive all Medicaid state plan services. This coverage is considered Minimal Essential Coverage (MEC).

21. **Dental Benefit for Aged, Blind, and Disabled Enrollees.** All individuals enrolled in the state plan aged, blind, and disabled population will receive dental treatment services without limitation above the state plan dental services cap of $1,125.

22. **Cost-Effective Insurance.** When a demonstration individual has access to cost-effective health coverage through a cost-effective group health plan, the state may obtain benefits for the individual by providing premium assistance to the individual for this purpose in accord with the state plan for the provision of alternative cost-effective coverage authorized for state plan eligible populations under section 1906 of the Act.

V. CONTINUOUS ELIGIBILITY

23. **Duration.** The state is authorized to provide a 12-month continuous eligibility period for individuals who qualify for or are enrolled in WMHSP, under the demonstration. The continuous eligibility period begins on the effective date of the individual's eligibility under 42 CFR §435.915 or the effective date of the most recent renewal of eligibility. Given individuals are continuously eligible regardless of changes in circumstances, except as otherwise listed in section 3, the state will conduct renewals of eligibility consistent with 42 CFR §435.916 at the end of each individual's continuous eligibility period.

24. **Continuous Eligibility Exceptions.** If any of the following circumstances occur during an individual's 12-month continuous eligibility period, the individual's Medicaid eligibility shall, after appropriate process, be terminated:
    a. The individual is no longer a Montana resident.
    b. The individual requests termination of eligibility voluntarily.

c. The individual dies.
d. The agency determines that eligibility was erroneously granted at the most recent determination, redetermination or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the beneficiary or the beneficiary's representative.

VI. ENROLLMENT

25. **General Requirements**

a. Unless otherwise specified in these STCs, all processes for eligibility, enrollment, redeterminations, terminations, fair hearings, etc. must comply with federal law and regulations governing Medicaid and CHIP.

b. Any individual who is denied eligibility in any health coverage program authorized under this demonstration must receive a notice from the state that gives the reason for denial, and includes information about the individual's right to a fair hearing, consistent with the requirements at 42 CFR part 431 subpart E and 42 CFR 435.917.

c. There is no separate enrollment process required for individuals enrolled in the state plan aged, blind, and disabled population to receive dental services through this demonstration.

26. **Imposing WMHSP Waiver Enrollment Limit and Lifting Enrollment Limit.** The state will facilitate enrollment of up to 3,000 eligible individuals into the WMHSP demonstration population. With 30 days prior notice, the state may impose an enrollment limit upon the WMHSP demonstration population of less than 3,000 in order to phase in enrollment and remain under the budget neutrality limit/ceiling for expenditures established for the demonstration. The state must submit an amendment to this demonstration in order to increase WMHSP enrollment above 3,000 slots.

27. **Prioritization for WMHSP Enrollment.** The state will enroll individuals into the WMHSP program using the following process:

a. The individual meets the financial and clinical eligibility criteria established for the WMHSP program.

b. Priority of WMHSP enrolled individuals being moved into the WMHSP demonstration population will be based upon a current SDMI primary diagnosis of schizophrenia spectrum disorder. At the state's discretion, available slots in the demonstration will then be open to eligible individuals with a SDMI bipolar disorder type. The state may then open enrollment of any remaining slots to individuals with a diagnosis of a SDMI major depression type. The state may then open enrollment of any remaining slots

to individuals with a SDMI diagnosis outside of these three groups.

c. The state uses a computer based random drawing to select the individuals (based on priority of diagnosis established in subparagraph b) to fill the available statewide slots.

28. **Enrollment into Primary Care Case Management (PCCM) or Primary Care Case Management entity (PCCM entity).** The state may enroll demonstration eligibles into PCCMs and PCCM entities. By cross-reference, the enrollment, benefits, and cost sharing in the associated CMS-approved state plan in place in these STCs will apply to this demonstration.

VII. COST-SHARING

29. **Cost-sharing.** Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

VIII. DELIVERY SYSTEMS FOR WMHSP ENROLLEES

30. **Freedom of Choice of Health Care Providers.** Individuals enrolled in the demonstration:

    a. May also be enrolled in the PCCM or PCCM entity which are Montana Medicaid's primary care case management programs. Under the PCCM programs, Medicaid members are required to choose one primary care provider and develop an ongoing relationship that provides a "medical home." With some exceptions, all services to PCCM and PCCM entity enrollees must be provided or approved by the individual's primary care provider.

31. **Delivery System of a Cost-Effective Insurance Plan.** Demonstration-enrolled individuals receiving services through a cost-effective insurance plan will receive plan covered services through the delivery systems provided by their respective insurance plan and additional services as necessary to ensure access to the full benefit package otherwise available. All additional services may be obtained from any physical or behavioral health provider participating with the Montana Medicaid program.

32. **Dental Services.** This demonstration does not impact the delivery system of dental services for individuals enrolled in the state plan aged, blind, and disabled population who receive dental services through this demonstration.

IX. MONITORING AND REPORTING REQUIREMENTS

33. **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) 30 calendar 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) 30 calendar 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 deliverables.

    b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable. The extension request must explain the reason why the required deliverable was not submitted, the steps the state has taken to address such issue, and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan 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 plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, 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 with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified 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.

34. **Submission of Post-approval Deliverables.** The state must submit all required analyses, reports, design documents, presentations, and other items specified in these STCs ("deliverables"). The state must use the processes as stipulated by CMS and within the timeframes outlined within these STCs.

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

    a. Revise the reporting templates and submission processes to accommodate timelycompliance with the requirements of the new systems;

    b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and

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

36. **Monitoring Reports.** The state must submit one Annual Monitoring Report each DY. The Annual Monitoring Report is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 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 Annual 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 must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, 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.** Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress towards meeting the demonstration's annual goals and overall targets, and will cover key policies under this demonstration. The monitoring and performance metrics must be included in the Monitoring Reports, and will follow – as applicable – 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 annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately on the CMS-64.

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

37. **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. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS will withdraw an authority, as described in STC 11, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

38. **Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.

    a. The Close-Out Report must comply with the most current guidance from CMS.

    b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to

phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 46 and 47, respectively.

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

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

e. The final Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments, if any.

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 33.

39. **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, enrollment and access, 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.

40. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within 6 months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 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 Monitoring 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 year in which the forum was held.

X. EVALUATION OF THE DEMONSTRATION

41. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must 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 and providing data and analytic files to CMS, including 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 must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they will make such 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 33.

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

43. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after approval of the demonstration. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, as applicable.

    The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 46 and 47.

    For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved

Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

44. **Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS's approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Annual Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring reports.

45. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. The evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the demonstration's goals. For example, to evaluate continuous eligibility, the state should evaluate how the continuous eligibility policy affects coverage, enrollment and churn (i.e., temporary loss of coverage in which beneficiaries are disenrolled but then re-enroll within 12 months) as well as population-specific appropriate measures of service utilization and health outcomes. Hypotheses for the waiver of retroactive eligibility must include (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, enrollment when people are healthy, and medical debt. To evaluate the dental program, the state should develop hypotheses related, but not limited to: utilization of preventive dental care services and dental-related emergency department visits. To address these hypotheses and research questions, CMS underscores the importance of the state undertaking a well-designed beneficiary survey to assess, for instance, beneficiary understanding of the various demonstration policy components, beneficiary experiences with access to and quality of care.

    The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for

Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF). Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and geography)—to the extent feasible—to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

46. **Evaluation Budget**. A budget for the evaluations must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be excessive.

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

    a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.

    b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration / phase-out, the Interim Evaluation Report may include an evaluation of the authority, to be collaboratively determined by CMS and the state.

    c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or 1 year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension to the demonstration, an Interim Evaluation Report is due 1 year prior to the end of the demonstration.

    d. The state must submit a revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.

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

48. **Summative Evaluation Report.** The state must submit a draft Summative

Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs, and in alignment with the approved Evaluation Design.

a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

b. The state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days of approval by CMS.

49. **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. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. 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 further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

50. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

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

52. **Additional Publications and Presentations.** For a period of 12 months following CMS's approval of the 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. 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 30 calendar days to review and comment on publications before they are released. CMS may choose to decline to comment on 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.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

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

53. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

54. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

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

b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.

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

55. **State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.

d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, consistent with section 1903 of the Act, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating

expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

56. **Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

57. **Requirements for Health Care-Related Taxes and Provider Donations.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).

b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).

c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the and 42 CFR 433.72.

d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).

e. All provider related-donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.

58. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS

regarding payments under the demonstration no later than 60 days after demonstration approval. This report must include:

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state or other entities relating to each locality tax or payments received funded by the locality tax;

b. Number of providers in each locality of the taxing entities for each locality tax;

c. Whether or not all providers in the locality will be paying the assessment for each locality tax;

d. The assessment rate that the providers will be paying for each locality tax;

e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;

f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under Section 1903(w) of the Act.

This deliverable is subject to the deferral as described in STC 33.

59. **Extent of Federal Financial Participation 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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in section XII:

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 Medicaid state plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

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

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

Table 1: Master MEG Chart

MEG	To Which BN Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Waiver Mental Health Services Plan (WMHSP) Enrollees	Hypo 1	X		X	See Expenditure Authority #1
Expenditures for Dental Services above the Dental Treatment Services Limit for the Aged, Blind, and Disabled (ABD) Population	Hypo 2	X		X	See Expenditure Authority # 2
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and are not described elsewhere, and are not subject to budget neutrality

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

62. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS 11-W-00181/8. Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. **Cost Settlements**. The state will report any cost settlements attributable to the demonstration 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), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. **Pharmacy Rebates.** Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table,

administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** As part of the Annual Monitoring Reports described in section X, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 2: MEG Detail for Expenditure Reporting and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Waiver Mental Health Services Plan (WMHSP) Enrollees	Expenditure #1	N/A	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/2023	12/31/2027
Expenditures for Dental Services above the Dental	Expenditure #2	N/A	Follow CMS-64.9 Base Category	Date of payment	MAP	Y	1/1/2023	12/31/2027

Treatment Services Limit for the Aged, Blind, and Disabled (ABD) Population			of Service Definition					
ADM	Report additional administrative costs that are directly attributable to the demonstration, are not described elsewhere, and are not subject to budget neutrality	N/A	Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	1/1/2023	12/31/2027

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group;

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

Table 3: Demonstration Years		
Demonstration Year 1	January 1, 2023 to December 31, 2023	12 months
Demonstration Year 2	January 1, 2024 to December 31, 2024	12 months
Demonstration Year 3	January 1, 2025 to December 31, 2025	12 months
Demonstration Year 4	January 1, 2026 to December 31, 2026	12 months
Demonstration Year 5	January 1, 2027 to December 31, 2027	12 months

64. **Calculating the Federal Medical Assistance Percentage (FMAP) for Continuous Eligibility for the Adult Group**. Because not all "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) would be eligible for the entire continuous eligibility period if the state conducted redeterminations, CMS has determined that 97.4 percent of expenditures for individuals defined in 42 CFR 433.204(a)(1) will be matched at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6) and 2.6 percent will be matched at the state's regular Title XIX FMAP rate. Should state data indicate that there is an estimate more accurate than 2.6 percent by which to adjust claiming for individuals

defined in 42 CFR 433.204(a)(1), CMS will work with the state to update this percentage to the more accurate figure, as supported by the state's proposed methodology and data.

65**. State Reporting for the Continuous Eligibility FMAP Adjustment**. 97.4 percent of expenditures for "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) shall be claimed at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6), unless otherwise adjusted as described in STC 12.13 above. The state must make adjustments on the applicable CMS-64 waiver forms to claim the remaining 2.6 percent or other applicable percentage of expenditures for individuals defined in 42 CFR 433.204(a)(1) at the state's regular Title XIX FMAP rate.

66**. Budget Neutrality Monitoring Tool.** The state must provide CMS with an annual budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.[2]

67**. Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

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

    a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will

[2] 42 CFR 431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

reflect the phase out of impermissible provider payments by law or regulation, where applicable.

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

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

69. **Budget Neutrality Mid-Course Adjustment Request.** No more than once a demonstration year, the state may request an adjustment to its budget neutrality expenditures for CMS review. based on changes to its expenditures. The state does not have to submit an amendment pursuant to STC 7; however, the state must provide a description of the problem and applicable expenditure data demonstrating that actual costs have exceeded the budget neutrality cost estimates established at demonstration approval. The adjustment will be applied retrospectively, as appropriate, to when the condition began and prospectively for future demonstration years, as appropriate. CMS will evaluate each request based on its merit and will allow for changes that affect budget neutrality that are outside of the state's control.

a. **Types of Allowable Changes.** Adjustments will only be made for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments CMS may consider allowable include the following:

i. Provider rate increases;

ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly, or unintended omission of certain applicable costs of services for individual MEGs;

iii. Changes in federal statute or regulations that impact expenditures;

iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;

v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;

vi. High cost innovative medical treatments that states are now covering and have increased expenditures; or,

vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

b. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

ii. Description of the rationale for the mid-course correction.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

70. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, one or more Hypothetical Budget Neutrality Tests, and a Capped Hypothetical Budget Neutrality Test, if applicable, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

71. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table X. Master MEG Chart. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

72. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

73. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

74. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

75**. Hypothetical Budget Neutrality Test .** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test . MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or

"Both" are counted as expenditures against this budget neutrality expenditure limit.

Table 4: Projected PMPM Costs and trend rate for Determining the Budget Neutrality Ceiling

Hypothetical Budget Neutrality Test 1

	Trend Rate	DY19 PMPM (2022)	DY20 PMPM (2023)	DY21 PMPM (2024)	DY22 PMPM (2025)	DY23 PMPM (2026)	DY24 PMPM (2027)
Waiver Mental Health Services Plan (WMHSP) Enrollees	4.5%	$613.32	$651.96	$693.04	$736.70	$783.11	$832.45
Expenditures for Dental Services above the Dental Treatment Services Limit for the Aged, Blind, and Disabled (ABD) Population	4.5%	$5.00	$5.23	$5.47	$5.72	$5.98	$6.25

76. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

77. **Exceeding Budget Neutrality**. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from January 1, 2023 to December 31,2027. The budget neutrality test for this demonstration period may incorporate net savings from the immediately prior ten-year demonstration period of February 1, 2013 to January 31, 2023. If at the end of the demonstration approval period the

budget neutrality limit or the capped hypothetical budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

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

Table 6: Budget Neutrality Test Mid-Course Correction Calculation		
Demonstration Year	**Cumulative Target Definition**	**Percentage**
DY 1	Cumulative budget neutrality limit plus	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus	1.5 percent
DY 1 though DY 3	Cumulative budget neutrality limit plus	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus	1.0 percent
DY 5	Cumulative budget neutrality limit plus	0 percent

XIII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION EXTENSION

I. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Due Date	Deliverable	Reference
30 calendar days after approval date	State acceptance of demonstration waiver, expenditure authority, and STCs	Approval Letter
180 calendar days from the demonstration approval date	Draft Evaluation Design	STC# 41

60 calendar days after receipt of CMS's comments on the Draft Evaluation Design	Revised Evaluation Design	STC #43
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC #43
December 31, 2026 or With Extension Application	Draft Interim Evaluation Report	STC # 46 (c)
60 calendar days after receipt of CMS's comments on the Draft Interim Evaluation Report	Revised Interim Evaluation Report	STC #46 (d)
Within 18 months after December 31, 2027	Draft Summative Evaluation Report	STC #46 (d)
60 calendar days after receipt of CMS's comments on the Draft Summative Evaluation Report	Revised Summative Evaluation Report	STC #47
Monthly Deliverables	Monitoring Call	STC #47 (a)
90 calendar days after the end of each 4th quarter	Annual Monitoring Reports	STC # 36

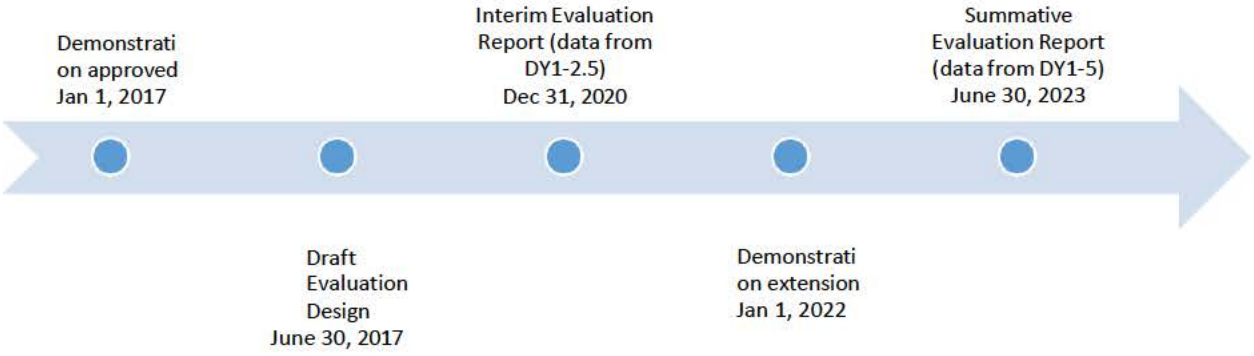
Attachment A
Developing the Evaluation Design

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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 30 calendar 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.

The state should attempt to involve partners who understand the cultural context in developing an evaluation approach and interpreting findings. Such partners may include community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration. For example, the state's Request for Proposal for an independent evaluator could encourage research teams to partner with impacted groups.

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

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 Logic Model or 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 goal, the primary drivers that contribute directly to achieving the goal, 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.
5. Include implementation evaluation questions to inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

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. The evaluation approach should also consider principles of equitable evaluations, and involve partners—such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context—in developing an evaluation approach.

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. *Focus and Comparison Populations* – Describe the characteristics of the focus 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 Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, 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.

E. 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.

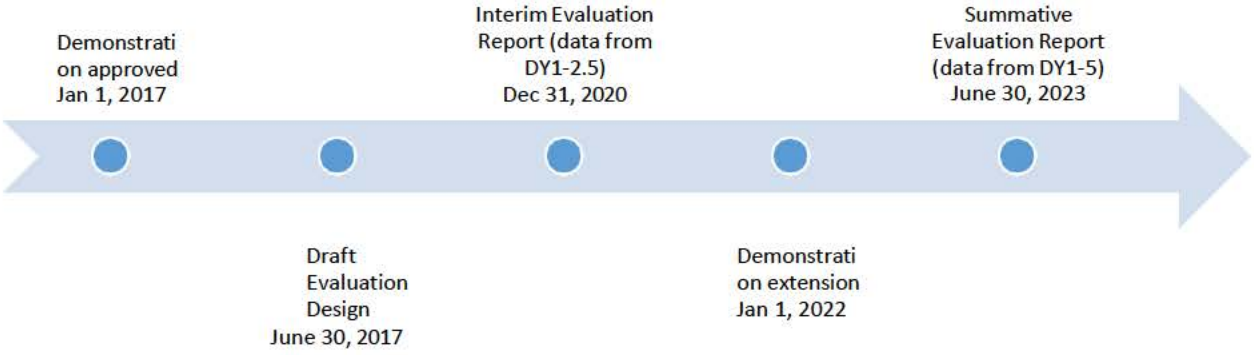
Attachment B
Preparing the Interim and Summative Evaluation Reports

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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus 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 extension, 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).

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, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. 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 Logic Model or 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. The state also 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 was measured and how, in sufficient detail so that another party could replicate the results. 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. *Focus and Comparison Populations* – Describe the focus 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.

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

F. Results – In this section, the state presents and uses the quantitative and qualitative data to 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 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. Interpreting the implications

of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

I. **Lessons Learned and Recommendations** – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
    1. What lessons were learned as a result of the demonstration?
    2. What would you recommend to other states which may be interested in implementing a similar approach?

Attachment C
Approved Evaluation Design

Montana
Section 1115 Waiver for Additional Services and Populations (WASP) Demonstration (formerly Basic Medicaid)
Draft Evaluation Design

Submitted 6/29/2023

Introduction

Montana's Waiver for Additional Services and Populations (WASP), formally known as the Basic Medicaid Waiver, has remained a positive source of Medicaid coverage since the program's inception in 1996. The Basic Program was comprised of mandatory Medicaid benefits and a collection of optional services available for emergencies and when necessary, for seeking and maintaining employment. These services were available to Able-Bodied Adults (neither pregnant nor disabled) who were parents and/or caretaker relatives of dependent children. This waiver has undergone multiple changes over the years.

Changes that directly impacted this waiver's services in 2016 were precipitated by the implementation of Medicaid expansion, called the Health and Economic Livelihood Partnership (HELP) Plan. Due to Medicaid expansion, many Basic Medicaid / WASP Program members became eligible for Montana Medicaid. At the same time, significant changes were made to the Basic Program / WASP Program. An amendment effective January 1, 2016, reduced the number of persons covered, changed the nature of the population eligible and changed the plan of benefits for WASP members. Basic Medicaid previously did not cover or had very limited coverage of some services. This amendment aligned the Basic Medicaid benefit package with the Standard Medicaid benefit package.

An additional amendment, effective March 1, 2016, changed the name of the Basic Waiver to Waiver for Additional Services and Populations. It also added dental treatment coverage, above the Medicaid State Plan cap of $1,125, for categorically eligible ABD individuals, as a pass-through cost. The benefits for this demonstration are offered though a fee for service model to individuals who qualify.

WASP Populations Covered

1. The WASP Mental Health Services Plan (MHSP) provides Medicaid coverage for individuals aged 18 or older, with SDMI who are otherwise ineligible for Medicaid benefits and either:
    - Have income 0-138% of the FPL and are eligible for or enrolled in Medicare; or
    - Have income 139-150% of the FPL regardless of Medicare status (they can be covered or not covered by Medicare and be eligible).
2. Provide a 12-month continuous eligibility period for all non-expansion Medicaid-covered individuals whose eligibility is based on MAGI.
3. Individuals determined categorically eligible for ABD for dental treatment services above the $1,125 State Plan dental treatment cap.

Detailed History and Key Dates of Approval/Operation

The Montana Medicaid Program is authorized under 53-6-101, Montana Codes Annotated, and Article XII, Section 3 of the Montana Constitution. The Department of Public Health and Human Services (DPHHS) administers the Medicaid Program. The Basic Medicaid Program was the medical services provided for able-bodied adults (neither pregnant nor disabled) and who were parents and/or caretaker relatives of dependent children, eligible for Medicaid under Sections 1925 or 1931 of the Social Security Act. The Basic Program was operated under a Section 1115 waiver, offering all mandatory services and a reduced package of Medicaid optional services through a fee-for-service delivery. Amount, duration, and scope of services, under Section 1902(a)(10)(B) of the Act were waived enabling Montana to carry out the 1115 demonstration.

In February 1996, Montana implemented its state-specific welfare reform program known as Families Achieving Independence in Montana (FAIM). This sweeping change involved the cash assistance, food stamp, and Medicaid programs that were administered on the federal side by several agencies under multiple statutes. As part of welfare reform, Montana obtained a Section 1115 waiver, approved in February 1996. On October 23, 2003, the DPHHS submitted an 1115 waiver application to CMS requesting

approval to continue the Basic Medicaid Program. CMS approved the waiver application on January 29, 2004, for a five-year period from February 1, 2004, through January 31, 2009. Terms of the request and the approval was consolidated into an Operational Protocol document as of February 2005. The waiver structure remained constant throughout the life of the Basic Program. The State was required to submit a quarterly Basic Medicaid report as one of the Operational Protocol conditions.

A HIFA proposal was submitted on June 27, 2006. 1115 Basic Medicaid Waiver amendments were submitted on March 23, 2007, and January 28, 2008, requesting seven new optional and expansion populations. Tribal Consultation was completed on December 14, 2007.As a result of discussions with CMS, Montana submitted a revised 1115 Basic Medicaid Waiver amendment on June 6, 2008, requesting four new populations. July 30, 2009, and August 6, 2010, submittals requested only one population, Mental Health Service Plan (MHSP) Waiver individuals (individuals with schizophrenia and individuals with bipolar), in addition to Able Bodied Adults. CMS approved the waiver extension and the request to insure the additional population, effective December 1, 2010.

The 1115 Basic Medicaid Waiver renewal was submitted in June of 2013 and approved by CMS effective January 1, 2014. The renewal includes raising the enrollment cap from "up to 800" to "up to 2000"; the primary Severe Disabling Mental Illness (SDMI) clinical diagnosis of major depressive disorder as a covered diagnosis; and home infusion as a covered service.

In June 2014, Montana submitted an amendment to the Section 1115 Basic Medicaid Waiver (Amendment #1) which was approved by CMS with an August 1, 2014, effective date. This amendment increased the enrollment cap for individuals who qualify for the State only MHSP Program from "up to 2,000" to "up to 6,000" It also updated the eligible diagnosis codes to allow all MHSP Program individuals with SDMI; added a random drawing with the diagnosis code hierarchy selection of schizophrenia first, bipolar second, major depressive disorder third, and then all remaining diagnosis codes. It also updated the per member per month costs of all waiver populations; updated the amount of money (Maintenance of Effort) the State needed to continue to spend on benefits for the mental health waiver population; updated the budget neutrality; revised the CMS approved evaluation design; updated the Federal Poverty Level from 33% FPL to approximately 47% FPL for Able Bodied Adults; and lastly, updated general waiver language.

Effective January 1, 2016, Montana submitted an amendment (Amendment #2), to remove the Able-Bodied Adult population, remove the SDMI population eligible for State Plan expansion, give the MHSP Waiver population the Standard Medicaid benefit, and close the Basic benefit. This amendment proposed to cover individuals aged 18 or older, with SDMI who qualify for or are enrolled in the state financed MHSP but are otherwise ineligible for Medicaid benefits and either: 1) have income 0-138% of the federal poverty level (FPL) and are eligible for or enrolled in Medicare; or 2) have income 139-150% of the FPL regardless of Medicare status. The MHSP Waiver enrollment cap was reduced from 6,000 to 3,000. The amendment provided for 12-month continuous eligibility period for all non-expansion Medicaid-covered individuals whose eligibility is based on modified adjusted gross income (MAGI).

On March 7, 2016, an amendment was submitted (Amendment #3) that proposed to: change the name of the Waiver to Section 1115 Montana Waiver for Additional Services and Populations and cover individuals determined categorically eligible for ABD for dental treatment services above the Medicaid State Plan cap of $1,125, as a pass-through cost. This amendment was approved with an effective date of March 1, 2016.

Following the third quarter report for DY13, the decision was made to change the reporting for this demonstration to a January through December calendar year as opposed to the prior February through January schedule. Therefore, the DY13 Annual Report covered an abbreviated year, 02/01/2016 through 12/31/2016. The DY14 Annual Report was applicable to the entire calendar year of 2017.

The Montana WASP Medicaid Demonstration was granted an extension on December 15, 2017. This extension, including new Special Terms and Conditions, was accepted by Montana DPHHS, January 12, 2018, and is effective January 1, 2018, through December 31, 2022.

After Montana's 2021 Legislative Session, Montana requested an amendment to the Montana WASP Medicaid Demonstration to discontinue the PCR population with a retroactive approval effective July 1, 2021, as directed by the Legislature. Montana received the approval letter 3/30/2022. The state was required to maintain continuous enrollment of Medicaid beneficiaries during the COVID-19 PHE as a condition of receiving a temporary 6.2 percentage point FMAP increase under the FFCRA. With the PHE ending effective May 11, 2023, the WASP PCR population will be phased out and discontinued effective

December 31, 2023.

The Montana WASP Medicaid Demonstration was granted another extension on November 21, 2022. The extension, including new Special Terms and Conditions, was accepted by Montana DPHHS December 15, 2022, and is effective January 1, 2023 through December 31, 2027. Due to the COVID-19 PHE and eligibility redetermination process beginning May 12, 2023, the baseline data for the demonstration period evaluation for the WMHSP and ABD populations will start with DY 21 (January 1, 2024, through December 31, 2024). With the baseline data of DY 21, the volatility of the redetermination process resulting from the COVID-19 PHE is removed from the evaluation results. Montana DPHHS added a metric to the previous evaluation report to analyze the expanded list of available telehealth services which resulted from the need for access during the COVID-19 PHE. The metric will examine the increase or decrease of telehealth utilization before, during and after the COVID-19 PHE.

Enrollment Counts from DY15 through DY19

Note: Enrollment counts are person counts, not member months.

Demonstration Populations (as hard coded in the CMS 64)	Newly Enrolled (annual count) DY15	Disenrolled (annual count) DY15	Enrollment Annual Total* DY15	% Change in Total Enrollment from Prior DY	Newly Enrolled (annual count) DY16	Disenrolled (annual count) DY16	Enrollment Annual Total* DY16	% Change in Total Enrollment from Prior DY	Newly Enrolled (annual count) DY17	Disenrolled (annual count) DY17	Enrollment Annual Total* DY17	% Change in Total Enrollment from Prior DY
Parent and Caretaker Relatives	6,078	10,482	23,578	N/A	10,880	7,127	27,486	16.6%	10,824	5,389	27,287	-0.7%
Dental	3,932	4,736	30,856	N/A	4,136	4,401	30,724	-0.4%	8,363	5,355	30,238	-1.6%
MHSP Adults	132	144	1,325	N/A	116	158	1,283	-3.2%	59	101	1,156	-9.9%

Demonstration Populations (as hard coded in the CMS 64)	Newly Enrolled (annual count) DY18	Disenrolled (annual count) DY18	Enrollment Annual Total* DY18	% Change in Total Enrollment from Prior DY	Newly Enrolled (annual count) DY19	Disenrolled (annual count) DY19	Enrollment Annual Total* DY19	% Change in Total Enrollment from Prior DY
Parent and Caretaker Relatives	5,268	5,592	27,458	0.6%	4,299	1,438	26,245	-4.4%
Dental	4,314	4,545	29,664	-1.9%	3,059	2,787	29,457	-0.7%
MHSP Adults	49	90	1,100	-4.8%	18	50	1,044	-5.1%

*The annual enrollment totals are more than any single quarterly total because the quarterly totals are based on enrollment on the last day of the quarter while the annual total counts members enrolled at any point during the year.

Demonstration Objectives/Goals

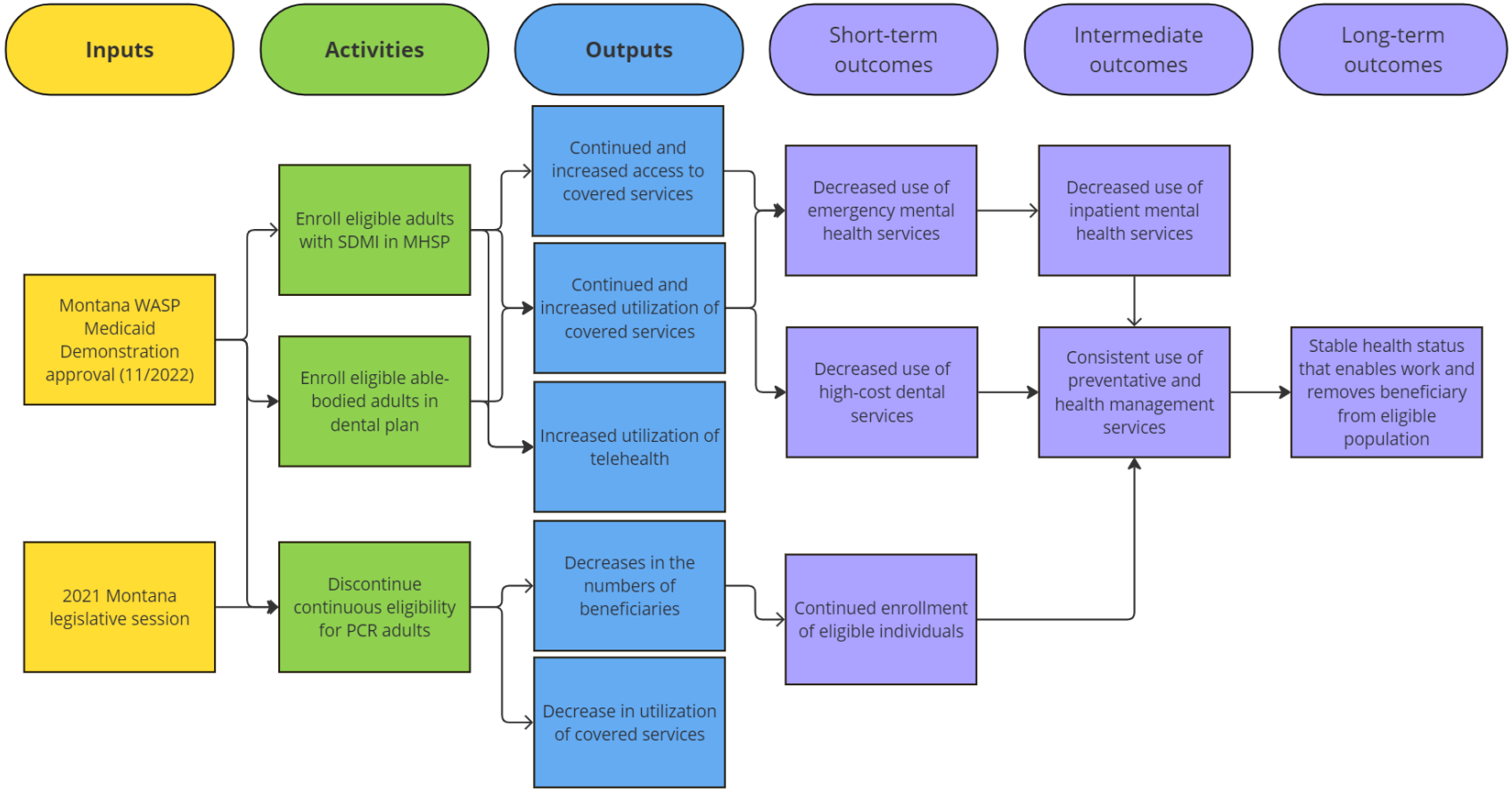
The goal of the Waiver for Additional Services and Populations (WASP) Demonstration mirrors the state's Medicaid goal, that is to assure medically necessary medical care is available to all eligible Montanans within available funding resources.

The three populations covered under WASP differ significantly from each other and the benefit each population derives from inclusion in WASP also differ. The MHSP population receives the broadest service package and is therefore the principal focus of this evaluation design.

Overall evaluation design

The proposed evaluation design and approach is consistent across the three populations covered under WASP, and the outcomes and associated research questions and measures are specific to each program. The logic model presented in Figure 1 provides a high-level depiction of the planned Inputs, Activities, Outputs, and Outcomes of the WASP Demonstration, and operationalizes each stage in the change process for each of the three WASP populations.

Figure 1. Logic model



Consistent across the evaluation approach for all three populations is the baseline period (calendar year 2019) and the evaluation period (January 1, 2023 to December 31, 2027). Because of the long-standing nature of the WASP Demonstration, within-individual change before and after enrollment will only be evaluated for individuals who are were enrolled in 2019 (for the baseline comparison) or later. The two consistent analytical approaches taken are within-individual change in service utilization before and after enrollment in the WASP demonstration and within-population change in access to services and service utilization over time. 2019 was chosen as a baseline period to provide a point of comparison before the current evaluation period that is also before the Covid-19 PHE. Although WASP was in place in 2019, there have been substantial changes throughout the health coverage and care systems between 2019 and 2023, so we consider 2019 a baseline period different enough from the evaluation period starting in 2023 that it is an appropriate benchmark against which to measure stability and improvement in access to and utilization of covered services.

Limitations: There are some anticipated limitations for this evaluation plan, mostly related to data availability for control groups. There are not appropriate control groups within the Montana Medicaid population, and there is not consistent data access for claims from the privately insured population. Data access that can enable comparisons with similar populations in other states that do not have commensurate waiver programs is uncertain at this time. The evaluation contractor anticipates some data availability challenges in terms of time lags and misaligned indicators across locations. We will address this limitation by utilizing CMS data sources (for example, Summary Statistics on Use and Payments from data.cms.gov) whenever possible. We also anticipate challenges associated with small sample sizes for some specific services in the MHSP waiver. In particular, claims for the use of crisis stabilization facilities, crisis intervention teams, and the Montana state hospital are likely to be small numbers at certain times due to limited capacity across the state. We will apply statistical tests of normality and other assumptions when calculating each specific indicator and will report no results if there is an inadequate sample size.

Mental Health Services Plan (MHSP) Population

Demonstration Goal: The goal of WASP for the MHSP population is threefold. The goals include improving (1) access to mental health care, (2) utilization of mental health care, and (3) mental health outcomes for the MHSP individuals aged 18 or older, with Severe Disabling Mental Illnesses (SDMI) are

enrolled in the Section 1115 Waiver for Additional Services and Populations (WASP) by providing coverage to receive Standard Medicaid benefits for mental health services. The evaluation plan utilizes three research questions that seek to understand how the provision of Standard Medicaid benefits coverage for the MHSP population of WASP impacts their (1) access to mental health care, (2) utilization of mental health care, and their (3) mental health outcomes. The evaluation design and research questions enable an understanding of the impact of WASP on the MHSP population by hypothesizing that the provision of Standard Medicaid benefits will enable the MHSP population to receive timely and appropriate mental health care, including community-based mental health care services and psychotropic prescription drug services, that improves their mental health outcomes by reducing the MHSP population's utilization of emergency rooms, crisis facilities, inpatient behavioral health units and the Montana State Hospital for mental health care.

The State will conduct the evaluation for the MHSP population using survey responses and claims data specific to the MHSP population over a defined period. The distinct measurements evaluate access to, and utilization of services covered by Standard Medicaid benefits, which would be unavailable to the MHSP population without WASP. The defined data sources ensure that the evaluation design utilizes measurements primarily effected by the provision of Standard Medicaid benefits to ensure the evaluation is isolated from other initiatives within the State.

Hypotheses:

1. Access to care will be maintained or improved for members of the WASP population who receive Standard Medicaid benefits for mental health services.
2. Utilization of community-based mental health services and psychotropic prescription drug services will increase.
3. Utilization of emergency department services for mental health services and admission to crisis stabilization facilities, inpatient psychiatric facilities, and the Montana State Hospital will decrease for members of the WASP population who receive Standard Medicaid benefits for mental health services.
4. Access to care will improve for members of the WASP population who receive Standard Medicaid benefits for telehealth for mental health services.

Table 1 lists the evaluation questions, measures, analytical plans, and data sources that will be used to test each of the hypotheses listed above. Details on the proposed statistical methods are included in a methodological appendix.

Table 1. Research questions, data sources, and analytical plan for MHSP population

Measure	Data Source	Analytical Approach and Statistical Methods	Baseline	Comparisons
Research question for H1: *Does the provision of Standard Medicaid benefits coverage for MHSP enrollees impact their access to covered services?*				
Enrollee perception of difficulty accessing care	Mental Health Statistical Improvement Survey (MHSIP); Domain: Access	Calculate annual rates and track changes over time in beneficiaries' perceptions of their ability to access care Stratify rates and trends by age, sex, gender, geography Test for strength and significance of change over time using Kendall's tau (Thiel-Sen Line)	MHSP survey responses from 1/1/2023-7/31/2023 in the Access Domain of the survey	Within-population change over time
Research question for H2: *Does the provision of Standard Medicaid benefits coverage for WASP enrollees impact utilization of community-based mental health covered services and psychotropic prescription drug services?*				
Number of enrollees receiving community-based mental health services, specifically: Outpatient Therapy services Targeted Case Management services Behavioral Health Day Treatment services Rehabilitation & Support services Illness Management and Recovery services Behavioral Health Group Home services Program of Assertive	Community-based mental health services claim data from the MT claims reporting system	Calculate changes in individual utilization of services before and after coverage Calculate annual rates and track changes over time in utilization by all covered individuals Stratify rates and trends by age, sex, gender, geography Test for changes in individual utilization rates using interrupted time series model with autoregression Test for strength and significance of change over time in utilization rates in population using Kendall's tau (Thiel-Sen Line)	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-individual change pre- and post- WASP enrollment Within-population change over time Comparisons to states with similar policy and utilization environment Within-population change over time

Community Treatment services Peer Support services Adult Foster Care services				
Number of enrollees receiving psychotropic prescription drug services	Psychotropic prescription drug claims data from the MT claims reporting system			
Research question for H3: *Does the provision of Standard Medicaid benefits coverage impact health care outcomes in the WASP population?*				
Number of enrollees utilizing emergency department services for mental health emergencies	Emergency department claims data from the MT claims reporting system	Calculate changes in individual utilization of services before and after coverage Calculate annual rates and track changes over time in utilization by all covered individuals Stratify rates and trends by age, sex, gender, geography Test for changes in individual utilization rates using interrupted time series model with autoregression Test for strength and significance of change over time in utilization rates in population using Kendall's tau (Thiel-Sen Line)	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-individual change pre- and post- WASP enrollment Within-population change over time Comparisons to states with similar policy and utilization environment
Number of enrollees admitted to an inpatient psychiatric facility	Inpatient psychiatric facility claims data from the MT claims reporting system			
Research question for H4: *Does the addition of telehealth services to the provision of Standard Medicaid benefits coverage impact health care outcomes in the WASP population?*				
Number of enrollees receiving mental health services in the telehealth setting	Telehealth place of service claims data from the MT claims reporting	Calculate annual rates and track changes over time in utilization by all covered individuals Stratify rates and trends by age, sex, gender,	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-population change over time Comparisons to

Number of mental health services received via the telehealth setting	system.	geography Test for strength and significance of change over time in utilization rates in population using Kendall's tau (Thiel-Sen Line)		states with similar policy and utilization environment

PCR Population

Demonstration Goal: The goal of including the PCR population into the WASP coverage is to provide a 12-month continuous eligibility period for all non-expansion Medicaid-covered individuals whose eligibility is based on MAGI. The PCR population receives the standard Medicaid benefit already, without the aid of WASP eligibility. Including this population into the WASP coverage eliminates the redetermination burden on the member and the state while aligning these members with an annual redetermination schedule that mirrors most other Montana Healthcare Program members.

The PCR population began receiving this singular benefit under WASP on January 1, 2016. There are no similar groups for which to compare the PCR population, or any additional services covered for them under WASP, only the absence of an extra eligibility requirement. Likely, most PCR WASP members do not realize they are participants in the WASP as its action is invisible to them. Therefore, member satisfaction surveys and outside comparisons for this population are purposely excluded.

After Montana's 2021 Legislative Session, Montana requested an amendment to the Montana WASP Medicaid Demonstration to discontinue the PCR population with a retroactive approval effective July 1, 2021, as directed by the Legislature. Montana received the approval letter 3/30/2022. The state was required to maintain continuous enrollment of Medicaid beneficiaries during the COVID-19 PHE as a condition of receiving a temporary 6.2 percentage point FMAP increase under the FFCRA. With the PHE ending effective May 11, 2023, the WASP PCR population will be phased out and discontinued effective December 31, 2023. Due to the discontinuance of the PCR population, the baseline data used for the final evaluation report will be January 1, 2019 through December 31, 2019.

Table 2. Research questions, data sources, and analytical plan for PCR population

Evaluation Question	Measure	Data Source	Analytical Approach and Statistical Methods	Baseline	Comparisons
Did phasing out the PCR population change how beneficiaries utilize covered health services?	Number of beneficiaries who had at least one service encounter per year (both the numerator and the denominator will be a distinct count of PCR transitional beneficiaries, counting the beneficiary only once regardless of the number of services covered by their PCR transitional Enrollment) Average number of services utilized per beneficiary	PCR claims data from the MT claims reporting system and the total PCR transitional Enrollment Data from the eligibility system	Calculate annual rates and track changes over time in beneficiaries' utilization of covered services Stratify rates and trends by age, sex, gender, geography Test for strength and significance of change over time using Kendall's tau (Thiel-Sen Line)	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-population change over time

ABD Dental Population

Demonstration Goal: The goal of including the ABD Dental population into the WASP coverage is to provide individuals determined categorically eligible for ABD with dental treatment services above the $1,125 State Plan dental treatment cap.

The ABD population began receiving this singular benefit under WASP on March 1, 2016. There are no similar groups to compare with this ABD population or any additional services covered for them under WASP, only the absence of the dental treatment cap. Likely, most ABD WASP members do not realize they are participants in the WASP as its action is invisible to them. The ABD population is aged, blind and disabled. They are offered this additional annual coverage because of the hardship inherent in providing dental services incrementally. This population is especially difficult to serve with dental care, sometimes needs to be anesthetized, often prone to behavioral combativeness and emotional trauma. The service itself is offered at the request of providers who find this population especially in need of dental care that is not limited by timeframe or dollar amount. This is a population who, if offered a survey, would likely have

it completed by a proxy if able to complete one at all. Therefore, member satisfaction surveys and outside comparisons for this population are purposely excluded.

Table 3. Research questions, data sources, and analytical plan for ABD population

Measure	Data Source	Analytical Approach and Statistical Methods	Baseline	Comparisons
Research question: Do beneficiaries utilize covered dental health services?				
Number of beneficiaries who had at least one dental service encounter above the cap in each year of the demonstration (Both the numerator and the denominator will be a distinct count of ABD beneficiaries above the dental limit, counting the beneficiary only once regardless of the number of services covered by their ABD transitional Enrollment)	ABD dental claims data from the MT claims reporting system pulled from the database and the total counts of ABD eligible above the dental limit Enrollment Data pulled from the database that receives information from the eligibility system.	Calculate changes in individual utilization of services before and after coverage Calculate annual rates and track changes over time in utilization by all covered individuals Stratify rates and trends by age, sex, gender, geography Test for changes in individual utilization rates using interrupted time series model with autoregression Test for strength and significance of change over time in utilization rates in population using Kendall's tau (Thiel-Sen Line)	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-individual change pre- and post- WASP enrollment Within-population change over time
Average number of services utilized per beneficiary				
Top ten utilized dental services in each year of the demonstration/total number of beneficiaries				
Research question: Does the addition of telehealth services to the provision of Standard Medicaid benefits coverage impact health care outcomes in the WASP population?				
Number of enrollees receiving dental health services in the telehealth setting.	Dental telehealth procedure code claims data from the MT claims reporting system.	Calculate annual rates and track changes over time in utilization by all covered individuals Stratify rates and trends by age, sex, gender, geography Test for strength and significance of change over time in utilization rates in population using Kendall's tau (Thiel-Sen Line)	Claims with Dates of Service between 1/1/2019-12/31/2019	Within-population change over time
Number of dental health services received via the telehealth setting				

Evaluation budget and scope of work

Montana will need to find an outside evaluation contractor. The costs below are based on an estimate submitted by the proposed evaluator. The State will need to contract with an outside evaluator per the STCs of this approval period. The State intends to award a contract using the Sole Source procurement processes for the Interim and Summative Evaluations. The reporting requirements for the Interim and Summative Evaluations will be completed by an outside contractor but the annual reporting requirements and budget neutrality will continue to be completed in-house.

Activity	Cost	Due dates
Computer programming (cost per hour x hours)	No additional programming costs will be incurred for this evaluation.	
Data Extract (Completed by State Staff) (cost per hour x hours)	$35.00/hour x 40 hours = $1,400.00	By August 1, 2026 and February 1, 2028
Analysis of the data for interim reporting (cost per hour x hours)	$210.00/hour x 100 hours = $21,000.00	By November 30, 2026
Analysis of the data for final reporting (cost per hour x hours)	$210.00/hour x 70 hours = $14,700	By February 28, 2028
Preparation of the report for interim reporting (cost per hour x hours)	$210.00/hour x 60 hours = $12,600	By December 20, 2026
Preparation of the report for final reporting (cost per hour x hours)	$210.00/hour x 60 hours = $12,600	By March 31, 2028
Other (specify work, cost per hour, and hours). If work is outside the requirements of the basic evaluation this should be identified in the draft evaluation design along with justification for an increased budget match.	Survey task will be completed by a non-cost-allocated employee so no additional charge will be incurred for this data collection task. The cost of including this data in the report is covered under the "Preparation of the report" category.	
Total cost of state staff	**$1,400**	
Total cost of external evaluator	**$60,900**	

Deliverable Schedule

Montana Waiver for Additional Services and Populations Demonstration
Approved: November 2022
Approval Period: January 1, 2023 – December 31, 2027 Demonstration Year: January through December

Proposal				
Deliverable	**Timeframe**	**Due Date**	**STC**	**Content Included in the Report**
Post Award Forum	Within six 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 30 days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state can either use its Medical Care Advisory Committee, or another meeting that is open to the public and where an interested party can learn about the progress of the demonstration to meet the requirements of this STC.	**Annually Held**	Page 11, STC #10	N/A
Draft of the Evaluation Design	Due no later than one hundred twenty (120) calendar days after the effective date of these STCs	Originally due by 6/30/2023 First Draft submitted 6/29/2023 Adjusted due date 7/15/2024	Page 28- 29, STC# 1	N/A

Deliverable	Timeframe	Due Date	STC	Content Included in the Report
Annual Monitoring Report	Report is due no later than ninety (90) calendar days following the end of the DY	Due by March 31, 2024 (This report covers January 1, 2023-December 31, 2023)	Page 18-19, STC# 6	Must include Operational Updates, Performance Metrics, Budget Neutrality and Financial Reporting Requirements, and Evaluation Activities and Interim Findings. The state must also include a summary of the post award forum. (Page 11, STC #10)
		Due by March 31, 2025 (This report covers January 1, 2024-December 31, 2024)		
		Due by March 31, 2026 (This report covers January 1, 2025-December 31, 2025)		
		Due by March 31, 2027 (This report covers January 1, 2026-December 31, 2026)		
Budget Neutrality Report	Due with every Annual Report	Due by March 31, 2024 (This report covers January 1, 2023-December 31, 2023)	Page 18-19, STC# 6(b)(iii)	The state must provide an updated budget neutrality workbook with every Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs.
		Due by March 31, 2025 (This report covers January 1, 2024-December 31, 2024)		
		Due by March 31, 2026 (This report covers January 1, 2025-December 31, 2025)		
		Due by March 31, 2027 (This report covers January 1, 2026-December 31, 2026)		

Revised Draft of the Evaluation Design (if needed)	Due within sixty (60) calendar days after receipt of CMS' comments on the Draft Evaluation Design	Due 7/15/2024	Page 28- 29, STC# 1	N/A

Deliverable	Timeframe	Due Date	STC	Content Included in the Report
Final Evaluation Design	Due within sixty (60) calendar days after receipt of CMS' comments on the Draft Evaluation Design	This date is determined by the date Draft Evaluation Design comments are received from CMS.	Page # 29 STC# 4	N/A
Post the approved Evaluation Design for Current Approval Period to the state's website	Due within thirty (30) calendar days of CMS approval	**TBD**	STC #49	N/A
Application for Extension	Due one year before date of end of demonstration period	**Extension approval received for current reporting period from January 1, 2023 – December 31, 2027**	STC page #8	N/A
Interim Evaluation Report	Due when the application for extension is submitted. If the state is not requesting an extension of the demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.	**Due 12/31/2026** The state must provide an updated budget neutrality workbook with every Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs	Page 8-9 STC# 8	N/A
Draft Final Evaluation Report	Due within 120 days after expiration of the demonstration. (This covers the entire demonstration period of performance.)	**Due by April 30, 2028**	Page 29 STC# 4	N/A

Final Evaluation Report	Due within sixty (60) calendar days of receiving comments from	This date is determined by the date Draft Final Evaluation Report	Page 29 STC# 4	N/A
	CMS on the draft Summative Evaluation Report	Comments are received from CMS.		