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

State Demonstrations Group

June 25, 2025

Cindy Bradsaw
Executive Director
Division of Medicaid
Mississippi Department of Human Services
Walters Sillers Building, 550 High Street, Suite 1000
Jackson, MS 39201

Dear Director Bradshaw:

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

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

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

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Healthier Mississippi (Project Number 11-W-00185/4) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, and in alignment

with the Healthier Mississippi demonstration's STCs CMS is retaining the cadence of annual monitoring reporting for this demonstration (see also section 1115(d)(2)(D)-(E) of the Act). However, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

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

The next annual monitoring report will be due on March 30, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting due date.

Structured Monitoring Report Template

As noted in STC 24, "Annual Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

Demonstration Monitoring Calls

As STC 27 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the

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

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

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

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

Sincerely,

[redacted]

Acting Director

Enclosure
cc: Tandra Hodges, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY LIST

NUMBER: 11-W-00185/4

TITLE: Healthier Mississippi Medicaid Section 1115 Demonstration

AWARDEE: Mississippi Division of Medicaid

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Mississippi for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, from the date of the approval letter through September 30, 2029, be regarded as expenditures under the state's title XIX plan.

The following expenditure authority shall enable Mississippi to implement its section 1115 Healthier Mississippi demonstration.

1. **Demonstration Population 1.** Expenditures for health care services provided to individuals with income at or below 135 percent of the federal poverty level who are aged, blind, or disabled, are not eligible for Medicare, and are not eligible under the Medicaid state plan.

Title XIX Requirements Not Applicable

1. **Amount, Duration, and Scope** **Section 1902(a)(10)(B)**

   To enable the state to provide a different benefit package to individuals covered under the demonstration.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00185/4**

TITLE: **Healthier Mississippi Demonstration**

AWARDEE: **Mississippi Division of Medicaid**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Healthier Mississippi section 1115(a) Medicaid demonstration extension (hereinafter "demonstration"). The parties to this agreement are the Mississippi Division of Medicaid (state) and the Centers for Medicare & Medicaid Services (CMS). 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 for the demonstration extension are effective as of October 1, 2024, through September 30, 2029, unless otherwise specified. All previously approved STCs are superseded by the STCs set forth below.

The STCs have been arranged into the following subject areas:

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Healthier Mississippi demonstration was approved in September 2004 and provides coverage for aged, blind, or disabled individuals with incomes at or below 135 percent of the federal poverty level (FPL) who are not eligible for Medicare and do not otherwise qualify for Medicaid.

In the 2004 legislative session, the Mississippi Legislature voted to discontinue Medicaid coverage for the optional Poverty Level Aged and Disabled (PLAD) group effective July 1, 2004. Concerned that this population was at risk for costly adverse events, including institutional placement, if medical regimens were not maintained, the state applied and received approval for a section 1115 demonstration to continue coverage for this population.

The demonstration was predicated on the assumption that continued access to medical care by the PLAD population will delay deterioration in health status which drives hospitalization and/or institutionalization in a nursing facility. Under the 2010 extension, the state requested, and CMS increased the enrollment cap from 5,000 to 5,500. Under the 2015 extension, CMS increased the enrollment limit from 5,500 to 6,000, and added to the benefit package the following previously excluded services: podiatry, eyeglasses, dental, and chiropractic services. In 2018, CMS extended the demonstration with no changes.

On September 24, 2024, the demonstration was extended for five years through September 30, 2029, with no programmatic changes. During the demonstration extension period, Mississippi expects to achieve the following goal and objectives:

> **Goal:** To prevent hospitalizations and increase access to ambulatory and preventive healthcare by providing insurance coverage, for individuals who are aged, blind or disabled, not eligible for Medicare and do not qualify for Medicaid.
>
> **Objective 1**: Decrease hospitalizations by two percent for the duration of the demonstration.
> **Objective 2:** Increase the utilization of ambulatory/preventive health visits by two percent each demonstration year.
> **Objective 3:** Increase the number of preventive health screenings by two percent each demonstration year.
> **Objective 4:** Increase the proportion of adults with diabetes who have a hemoglobin A1c (HbA1c) measurement at least once a year by three percent each demonstration year.
> **Objective 5:** Increase the proportion of adults with diabetes who have an annual dilated eye examination by three percent each demonstration year.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited

to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP program 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 law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable.

   In addition, CMS reserves the right to amend these STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration per STC 7. CMS will notify the state thirty (30) days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

   a) To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as 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 subparagraph.

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

    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 shall 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 at least twelve (12) months in advance from the Governor of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit 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 effective date and reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. At least six (6) months before the effective date of the demonstration's suspension or termination, the state must submit to CMS its proposed transition and phase-out plan, together with intended notifications to demonstration enrollees. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the thirty (30) day public comment period has ended, the state must provide a summary of public comments received, the state's response to the comments received, and how the state incorporated the received comments into the transition and phase-out plan submitted to CMS.

    b) Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices including information on the beneficiary's appeal rights, the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries determined eligible, as well as any community outreach activities 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 fourteen (14) calendar days after CMS approval of the 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 making a determination of ineligibility as required under 42 CFR 435.916(f)(1), or for children in CHIP consider eligibility for other insurance affordability programs under 42 CFR 457.350. For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures

set forth in 42 CFR 435.1200(e) or for CHIP found at 42 CFR 457.340(e), including information about a right to review consistent with 42 CFR 457.1180. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.

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

f) Enrollment Limitation during Demonstration Phase-Out: If the state elects to suspend, terminate, or not extend this demonstration, during the last six (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 suspended by the state, FFP shall 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/Expenditure Authority.** CMS reserves the right to amend or withdraw waiver 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. CMS will promptly notify the state in writing of the determination and the reasons for the amendment or 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 or amended, 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 participants.

11. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems applicable to the demonstration; 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 section 447.205 for changes in statewide methods and standards for setting payment rates.

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

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

14. **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, managed care organizations (MCOs), and any contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies of the demonstration.

15. **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, BENEFITS AND COST SHARING

16. Demonstration Eligibility.

a) The group described in STC 16(b), which is made eligible for the demonstration by virtue of the expenditure authority expressly granted in this demonstration, is subject to all applicable Medicaid laws or regulations in accordance with the state plan, except as specified as not applicable in the expenditure authority for this demonstration.

b) Eligibility for the Healthier Mississippi demonstration is limited to aged, blind, or disabled individuals who are not eligible for Medicare and do not otherwise qualify

for Medicaid, who are not inpatients in a long term care institution, and whose:

i. Income is at or below 135 percent of the FPL for an individual or couple, calculated using a methodology based on the Supplemental Security Income (SSI) program, as well as income exclusions approved under the state plan under the authority of section 1902(r)(2) of the Social Security Act; and,

ii. Resources are below $4,000 for an individual and $6,000 for a couple.

17. **Enrollment Cap.** The Healthier Mississippi enrollment cap is 6,000. When enrollment reaches 6,000, further enrollment is suspended and individuals making an application are placed on a waiting list. Individuals are moved off the waiting list and enrolled in the demonstration as openings become available.

18. **Benefit Package.** Children (ages 0 through 20) enrolled in the demonstration receive all Medicaid state plan benefits, including Early and Periodic Screening, Diagnostic and Treatment (EPSDT). Adults (ages 21 and older) enrolled in the demonstration receive most services covered under the Medicaid state plan with the same service limits per the Medicaid state plan. Maternity and newborn care are available to individuals who need them by enrolling in Medicaid on a different basis.

Services Not Covered for Adults
Swing bed in a skilled nursing facility
Long-term care services (nursing facility, home and community-based waiver, and ICF/IID services)
Maternity and Newborn Care

Admission to Nursing Facilities: Expenditures incurred for any services received while a Healthier Mississippi enrollee is an inpatient in a long-term care institutional setting will not be claimed under the demonstration. Any individual enrolled in Healthier Mississippi who is admitted to a nursing facility or other long term care setting, either temporarily (for less than 30 days) or for a longer admission, will be assessed for eligibility under a Medicaid State Plan covered category. Such individuals will be disenrolled from the demonstration upon admission to an institution and assessed for re-enrollment into the demonstration upon discharge from the institutional setting.

19. **Cost Sharing.** There are no cost-sharing requirements for children enrolled in the demonstration. Adult recipients are subject to cost sharing requirements that would be applicable if they were provided coverage under the state plan. A family's total annual out-of-pocket cost sharing cannot exceed five percent of the family's gross income. There is no premium charged for any recipient under the demonstration.

V. DELIVERY SYSTEMS

20. Service Delivery. Demonstration services are delivered through the state's fee-for-service provider network.

VI. MONITORING AND REPORTING REQUIREMENTS

21. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals 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 found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration 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.

In the event that either (1) thirty (30) calendar days after the deliverable(s) were due if the state has not submitted a written request to CMS for approval of an extension as described below, within thirty (30) calendar days after the deliverable was due, or (2) the state has not submitted a revised resubmission or a plan for corrective action to CMS within thirty (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 including the information needed to bring the deliverable(s) into alignment with CMS requirements the following process is triggered:

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

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

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

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

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

22. Submission of Post-approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs, unless CMS and the state mutually agree to another timeline. The state shall use the processes stipulated by CMS and within the timeframes outlined within these STCs.

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

a) Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b) Ensure all 1115 demonstrations, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and,

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

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

a) **Operational Updates.** Per 42 CFR 431.428, the Annual 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, Annual Monitoring Reports should describe key achievements, as well as conditions and efforts to which these successes can be attributed. The Annual Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b) **Performance Metrics**. The performance metrics will provide data to demonstrate how the state is progressing toward meeting the demonstration's goals. Per 42 CFR 431.428, the Annual Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as the impact of the demonstration on beneficiaries' utilization of services, outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals. .

The state and CMS will work collaboratively to finalize the list of metrics to be reported in the Annual Monitoring Reports. The required monitoring and performance metrics must be included in the Annual Monitoring Reports and will follow the CMS framework provided by CMS to support federal tracking and analysis. The reporting of the monitoring metrics must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, sexual orientation and gender identity, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

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

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

25. Corrective Action Plan Related to Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid,

CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing preventive services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial 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.

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

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

b) 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 56 and 57, 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) A revised Close-Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.

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

27. 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.

28. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its Medicaid website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

VII. GENERAL FINANCIAL REQUIREMENTS

29. 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.

30. 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 thirty (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.

31. 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.

32. 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, 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 in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. 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.

33. 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 433.55 are 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 Act 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 Act, 42 CFR 433.66, and 42 CFR 433.54.

34. 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 sixty (60) days after demonstration approval. This deliverable is subject to the deferral as described in STC 21. 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 that are 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.

35. 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 the STCs in section VIII:

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.

36. 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.

37. Medicaid Expenditure Groups (MEGs). MEGs) 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	**Which BN Test Applies?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
Demonstration Population 1	Hypo	X		X	Aged, blind, or disabled individuals enrolled in the demonstration at or below 135 percent of the FPL who are not eligible for Medicare and do not otherwise qualify for Medicaid

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

38. **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-00185/4). 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 included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

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 MEG Charts and in the STCs in section VIII, 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 Quarterly and Annual Monitoring Reports described in STC 24 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 per person, 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 and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
Demonstration Population 1	Aged, blind, or disabled individuals enrolled in the demonstration at or below 135 percent of the FPL who are not eligible for Medicare and do not otherwise qualify for Medicaid.	None	Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	09/10/04	09/30/29

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

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

Table 3: Demonstration Years		
Demonstration Year 21	October 1, 2024 to September 30, 2025	12 months
Demonstration Year 22	October 1, 2025 to September 30, 2026	12 months
Demonstration Year 23	October 1, 2026 to September 30, 2027	12 months
Demonstration Year 24	October 1, 2027 to September 30, 2028	12 months
Demonstration Year 25	October 1, 2028 to September 30, 2029	12 months

40. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly 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 the

demonstration's actual expenditures to the budget neutrality expenditure limits described in section VIII. CMS will provide technical assistance, upon request.[1]

41. 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.

42. 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 guidance, 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 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

[1] Per 42 CFR 431.420(a)(2), 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.

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.

43. Budget Neutrality Mid-Course Correction Adjustment Request. No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a) **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 42.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within one-hundred and twenty (120) days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b) **Types of Allowable Changes.** Adjustments will be made only 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 that CMS might approve include the following:

i. Provider rate increases that are anticipated to further strengthen access to care;

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, not directly associated with Medicaid, which 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 required to cover; 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.

c) **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, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

VIII. MONITORING BUDGET NEUTRALITY

44. 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 consists of a Hypothetical Budget Neutrality Test as described below. CMS's assessment of the state's compliance with this test 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.

45. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1, Master MEG Chart and Table 2, MEG Detail for Expenditure and Member Month Reporting. 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.

46. 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.

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

48. **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), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them 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 expenditures on those services. When evaluating budget neutrality, however, 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.

49. **Hypothetical Budget Neutrality Test 1: Demonstration Population 1.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. 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. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 4: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 21	DY 22	DY 23	DY 24	DY 25
Demonstration Population 1	PC	Both	4.84%	$1,923.69	$2,016.72	$2,114.25	$2,216.50	$2,323.69

50. 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 or 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.

51. Corrective Action Plan. 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 5: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 21	Cumulative budget neutrality limit plus:	2.0 percent
DY 21 through DY 22	Cumulative budget neutrality limit plus:	1.5 percent
DY 21 through DY 23	Cumulative budget neutrality limit plus:	1.0 percent
DY 21 through DY 24	Cumulative budget neutrality limit plus:	0.5 percent

DY 21 through DY 25	Cumulative budget neutrality limit plus:	0.0 percent

IX. EVALUATION OF THE DEMONSTRATION

51. Cooperation with Federal Evaluators and Learning Collaborative. 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 must 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 21.

52. Independent Evaluator. Upon approval of the demonstration, 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 accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

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

54. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design no later than one-hundred and eighty (180) calendar days after the 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 be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

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 56 and 57.

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 one-hundred and eighty (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 approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

In the event of demonstration extensions, for components that are continuing from the prior demonstration approval period, the state's Evaluation Design must reframe and refocus as needed the evaluation hypotheses and research questions to appropriately factor in where it can reasonably expect continued improvements, and where the demonstration's role might be more to help stabilize outcomes. Likewise, for continuing policies, the state must revisit its analytic approaches compared to those used in the prior approval period evaluation activities, to ensure that the evaluation of those policies taps into the longer implementation time span.

55. Evaluation Design Approval and Updates. The state must submit to CMS a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments, if any. Upon CMS approval of the final Evaluation Design, the document will be included as Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Annual Monitoring Reports as required by STC 24, including any required rapid cycle assessments specified in these STCs. 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.

56. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding of the demonstration's impact and its effectiveness in achieving the goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate

and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of preventive services. Proposed measures should be selected from nationally-recognized sources and national measure sets, where possible. Measures sets could include those from the Dental Quality Alliance;[2] CMS's Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by National Quality Forum (NQF).

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with the demonstration, and beneficiary experiences with access to and quality of care. In addition, the state is strongly encouraged to evaluate the implementation of the demonstration components in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. Implementation research questions can also focus on beneficiary and provider experience with the demonstration. The implementation evaluation can 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.

Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography), and by demonstration component, to the extent feasible. Such stratified analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes and help inform how the demonstration's various policies might support reducing such disparities.

57. 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 of the demonstration, the Interim Evaluation Report should be posted to the state's Medicaid website with the application for public comment.

a) The Interim Evaluation Report, in alignment with the CMS-approved Evaluation Design, will discuss evaluation progress and present findings to date.

b) For demonstration authority or any components within the demonstration that

[2] https://www.ada.org/resources/research/dental-quality-alliance/dqa-dental-quality-measures

expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report must 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. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and a description of how the design was adapted should be included. If the state is not requesting an extension of the demonstration, the Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

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

e) Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within thirty (30) calendar days.

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

58. Summative Evaluation Report. '""The state must submit to CMS a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs.

a) The Summative Evaluation Report, in alignment with the Evaluation Design, will evaluate the entirety of the demonstration period.

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

c) Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within thirty(30) calendar days.

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

59. 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 an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A state corrective action plan could include a temporary suspension of implementation of demonstration initiatives, 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.

60. **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. Presentation may be conducted remotely.

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

62. **Additional Publications and Presentations.** For a period of twelves (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) calendar days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

X. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Deliverable	Timeline	STC Reference
Quarterly Expenditures Reports	Within 30 days following the end of each quarter using Form CMS-64	STC 38
Annual Monitoring Report	Annual Deliverable – Due 90 calendar days following the end of each demonstration year	STC 24
Draft Evaluation Design	Within 180 calendar days after demonstration approval	STC 54
Revised Evaluation Design	Within 60 days following receipt of CMS comments on Draft Evaluation Design	STC 55
Draft Interim Evaluation Report	Within one year prior to the end of the demonstration or with submission of a demonstration extension request.	STC 57
Revised Interim Evaluation Report	Within 60 calendar days following receipt of CMS comments on the Draft Interim Evaluation Report.	STC 57
Summative Evaluation Report	Within 18 months following the end of the demonstration approval period identified in these STCs.	STC 58
Revised Summative Evaluation Report	Within 60 calendar days after receipt of CMS comments on the Draft Summative Evaluation Report.	STC 58

ATTACHMENT A
Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

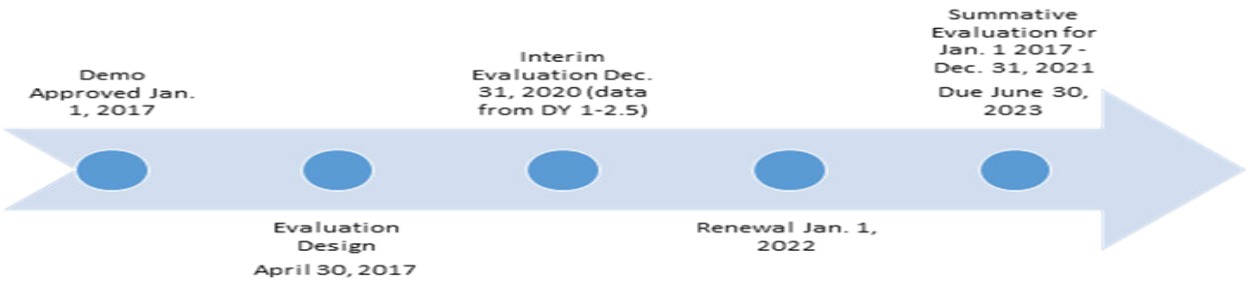
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

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

Submission Timelines

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



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

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

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

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

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

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

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

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

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
a. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
b. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
c. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

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

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

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

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and

b. No or minimal appeals and grievances; and
c. No state issues with CMS 64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

F. Attachments

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

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

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

ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

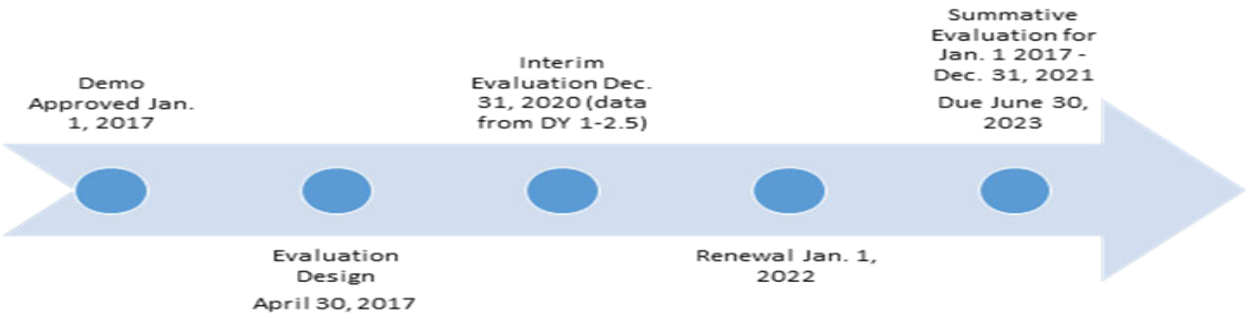
The format for the Interim and Summative Evaluation reports are as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;

D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design Attachment) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

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

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

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

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

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

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

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

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

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

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

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

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

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

E. Methodological Limitations

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

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

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

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

2. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

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

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

I. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1) What lessons were learned as a result of the demonstration?

2) What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

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

ATTACHMENT C:
Evaluation Design (reserved)

Healthier Mississippi Project

Section 1115 Demonstration

Project Number 11-W-00185/4

Evaluation Design

April 15, 2020

550 High Street, Suite 1000
Jackson, Mississippi 39201
Website: medicaid.ms.gov

The Mississippi Division of Medicaid responsibly provides access to quality health coverage for vulnerable Mississippians.

Table of Contents

Healthier Mississippi Project
Section 1115 Demonstration
Project Number 11-W-00185/4

Evaluation Design
April 15, 2020

I. Historical Background of the Demonstration

Legislation passed during the Mississippi 2004 Legislative Session discontinued the optional Poverty Level Aged & Disabled (PLAD) category of eligibility, effective June 30, 2004. Due to concerns that this population was at risk for costly adverse events, such as institutional placement if medical regimens were not maintained, the state applied and received approval for a section 1115 demonstration to continue coverage for this population. The Healthier Mississippi Waiver (HMW) was originally approved by the Centers for Medicare & Medicaid Services (CMS) for a five (5) year period beginning on October 1, 2004 through September 30, 2009. The HMW demonstration continued to operate under a series of temporary approvals for an additional five (5) years from October 1, 2009 through July 23, 2015. The Division of Medicaid received an approval for a five (5) year extension for the period of July 24, 2015 through September 30, 2018. Beginning with the July 24, 2015 through September 30, 2018 extension, the HMW enrollment limit increased from 5,500 to 6,000 and provided coverage for podiatry, eyeglasses, dental, and chiropractic services which were excluded from previous demonstration years. Currently, the demonstration's special terms and conditions (STCs) are approved from October 1, 2018 through September 30, 2023. There were no changes in the eligibility requirements or covered services from the previous demonstration.

Eligibility for the Healthier Mississippi demonstration is limited to aged, blind, or disabled individuals who are not eligible for Medicare, do not qualify for Medicaid, and are not in a long term care institution, and whose:

- Income is at or below 135% of the Federal Poverty Level (FPL) for an individual or a couple calculated using a methodology based on the Supplemental Security Income (SSI) program, as well as income exclusions approved under the State Plan under the authority of Section 1902(r)(2) of the Social Security Act, and
- Resources are below $4,000 for an individual and $6,000 for a couple.

Children (ages 0 through 20) enrolled in the demonstration receive all Medicaid state plan benefits, including Early and Periodic Screening, Diagnosis and Treatment (EPSDT). Adults (ages 21 and older) enrolled in the demonstration receive all services covered under the

Medicaid state plan with the same service limits with the exception of the following services:

- Long-term care services(nursing facility, home and community based waiver, and Intermediate Care Facility/Individuals with Intellectual Disabilities (ICF/IID) services),
- Swing bed services in a skilled nursing facility, and
- Maternity and newborn care services.

HMW beneficiaries who require long-term care, swing bed services in a skilled nursing facility, or maternity and newborn care services would qualify for Medicaid and, therefore, would be deemed ineligible for the waiver. HMW enrollees are assigned to a specific category of eligibility (045) to ensure the population is easily identifiable and to ensure the number of enrollees does not exceed the cap of 6,000.

II. Demonstration Goals and Evaluation Hypotheses and Research Questions

Mississippi Medicaid intends to measure the performance of the demonstration goals through the following quantifiable target percentages. These percentages were determined by using the percent change for demonstration years 12 through 14 (fiscal years 2016-2018):

1. Reduce hospitalizations and improper use of the emergency department (ED) by two percent (2%) for the duration of the demonstration.
2. Increase the utilization of ambulatory/preventive health visits by two percent (2%) for the duration of the demonstration.
3. Increase the number of preventive health screenings by one percent (1%) for the duration of the demonstration.
4. Increase the proportion of adults with diabetes who have a hemoglobin A1c (HbA1c) measurement at least once a year by two percent (2%) for the duration of the demonstration.
5. Increase the proportion of adults with diabetes who have an annual dilated eye examination by four percent (4%) for the duration of the demonstration.

The hypotheses and research questions listed below promote the objectives of Title XIX by:

- Providing payments for medical assistance to low-income aged, blind, and disabled individuals, not eligible for Medicaid or Medicare; and
- Providing access to needed medical services.

Evaluation Question 1: How do the rates of inpatient hospitalization and non-emergent use of emergency department visits evolve over time among the HMW beneficiaries? Will HMW beneficiaries who access ambulatory and preventive services have fewer hospitalizations and emergency department visits?

Hypothesis 1: The rates of hospitalization and improper use of the emergency department visits will fall among HMW beneficiaries over time, and the HMW beneficiaries will have fewer hospitalizations and emergency department visits after accessing ambulatory and

preventive services.

Evaluation Question 2: Will providing benefits under the HMW demonstration lead to an increase in the utilization of ambulatory/preventive health visits among HMW beneficiaries?

Hypothesis 2: HMW beneficiaries with access to benefits under the HMW demonstration will have an increase in the utilization of ambulatory/preventive health visits.

Evaluation Question 3: Will providing benefits under the HMW demonstration result in an increase in age appropriate preventive screenings?

Hypothesis 3: HMW beneficiaries with access to benefits will have an increase in the utilization of age appropriate preventive screenings.

Evaluation Question 4: Will providing benefits under the HMW demonstration increase the number of annual HbA1c tests among HMW beneficiaries diagnosed with diabetes?

Hypothesis 4: HMW beneficiaries diagnosed with diabetes are more likely to have an annual HbA1c test performed as a result of having access to HMW benefits.

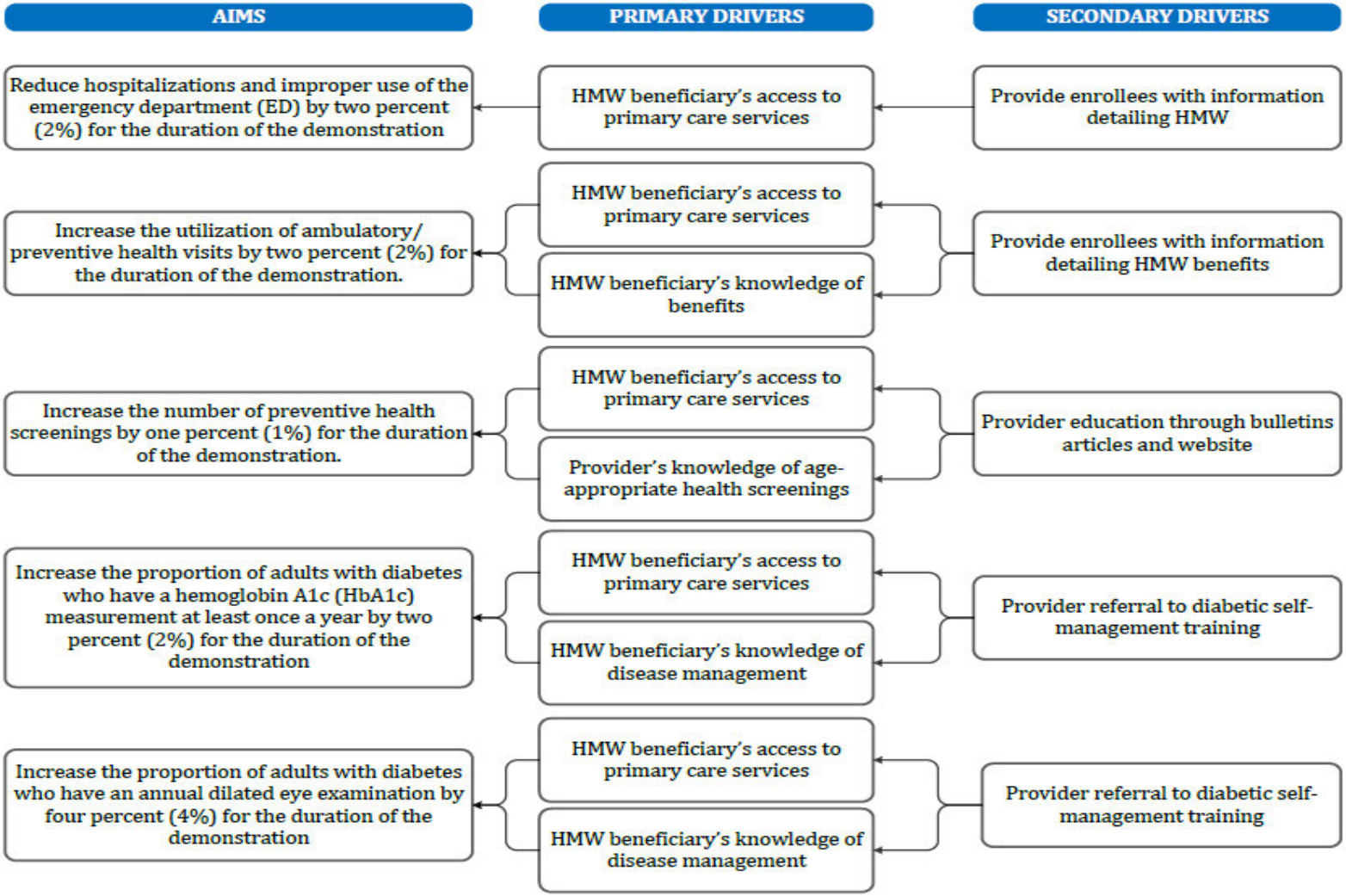
Evaluation Question 5: Will providing benefits under the HMW demonstration increase the number of annual dilated eye examinations among HMW beneficiaries diagnosed with diabetes?

Hypothesis 5: HMW beneficiaries diagnosed with diabetes are more likely to have an annual dilated eye examination as a result of having access to HMW benefits.

Evaluation Question 6: Are HMW beneficiaries satisfied with the demonstration services?

Hypothesis 6: HMW beneficiaries are more likely to report being satisfied than not with the benefits under the demonstration.

III. Healthier Mississippi Waiver Driver Diagram



Methodology

Evaluation Design

This evaluation will assess the performance of the demonstration goals using a one-group posttest-only design of HMW beneficiaries and their utilization of the available services provided under the HMW benefit plan. Also, the trend analysis will incorporate appropriate statistical testing to show if changes over time are statistically significant. Qualitative findings from three focus groups and key informant interviews will be used to complement and contextualize the descriptive quantitative analyses.

All findings over the period of the demonstration will be assessed against the target goals for changes in service utilization outlined under the objectives of the demonstration for the current period of performance in Section II above.

Target and Comparison Populations

The target population is individuals that are aged, blind, or disabled who are not eligible for Medicare or Medicaid, not in a long term care institution, and whose:

- Income is at or below 135% of the Federal Poverty Level (FPL) for an individual or a couple calculated using a methodology based on the SSI program, as well as income exclusions approved under the State Plan under the authority of Section 1902(r)(2) of the Social Security Act, and
- Resources are below $4,000 for an individual and $6,000 for a couple.

The state was unable to determine a population that was comparable to the HMW population; therefore, the state is using data from demonstration years 12 through 14 (FY 16-18) to analyze trends.

Evaluation Period

The evaluation will be conducted for the demonstration period of October 1, 2018 through September 30, 2023.

Table 1: Evaluation Outcomes Measures

Metric	Description	Numerator/Denominator
Inpatient hospitalization rate	Beneficiaries under age 75 who had at least one acute care hospitalization during the measurement year	Number of HMW beneficiaries under age 75 with at least one inpatient hospitalization during the measurement year/Number of beneficiaries under age 75 during the measurement year
Non-emergent use of emergency department	Beneficiaries under age 75 who had at least one non-emergent ED visit during the measurement year	Number of HMW beneficiaries under age 75 with at least one non-emergent ED visit during the measurement year/Number of beneficiaries under age 75 during the measurement year
Inpatient hospitalization rate for beneficiaries who access ambulatory and preventive services	Number of hospitalizations for beneficiaries under age 75 who had at least one acute care hospitalization, who also accessed ambulatory and preventive services during the measurement year	Number of hospitalizations for HMW beneficiaries under age 75 that accessed ambulatory and preventive services during the measurement year/Number of hospitalizations for HMW beneficiaries under age 75 during the measurement year
Emergency department rate for beneficiaries who access ambulatory and preventive services	Number of ED visits for beneficiaries under age 75 who accessed ambulatory and preventive services during the measurement year	Number of ED visits for beneficiaries under 75 that accessed ambulatory and preventive services during the measurement year/Number of ED visits for HMW beneficiaries under age 75 during the measurement year
Ambulatory/Preventive Health Visits	Percentage of beneficiaries age 20 years and older who had at least one ambulatory or preventive care visit per year	Number of beneficiaries 20 and older who had at least one ambulatory or preventive care visit during the measurement year/Number of HMW 20 and older during the measurement year
Cervical Cancer Screening	Percentage of women 21-64 years of age who received one or more Pap test to screen for cervical cancer	Number of HMW women, ages 21-64, who received screenings for cervical cancer during the measurement year/Number of HMW women 21-64 years of age during the measurement year
Breast Cancer Screening	Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer once during the measurement year	Number of HMW women, ages 50-74, who had a mammogram during the measurement year/ Number of women, ages 50-74, during the measurement year
Colorectal Cancer	Percentage of beneficiaries 50-75	Number of HMW beneficiaries, ages 50-75, who received

Screening	years of age who had appropriate screening for colorectal cancer	screenings for colorectal cancer during measurement year/ Number of HMW beneficiaries, ages 50-75 during the measurement year
Comprehensive Diabetes Care: Eye Exam	Percentage of beneficiaries 18-75 years of age with diabetes who had a retinal or dilated eye exam during the measurement period	Number of HMW beneficiaries, ages 18 – 75, with diabetes who had a retinal or dilated eye exam during the measurement period/Number of HMW beneficiaries ages 18 - 75 with diabetes during the measurement year
Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing	The percentage of beneficiaries 18-75 years of age with diabetes who received an HbA1c test during the measurement year	Number of HMW beneficiaries, ages 18-75, with diabetes who received an HbA1c test during the measurement year/Number of HMW beneficiaries ages 18-75 with diabetes during the measurement year

Data Sources

The data will come from Medicaid claims, which are housed in the Medicaid Management Information Systems (MMIS) and Division Support System (DSS). DOM will carefully review claims data to ensure the best available data is used for reporting purposes. Data for the evaluation will be processed and validated throughout the demonstration period. Additionally, to contextualize and support the quantitative data analysis, we plan to use focus groups as a means to learn more in-depth about the beneficiary experience of the Healthy Mississippi Waiver. This will help gauge information on participant perception of their health, how they think the demonstration is helping with their specific health issues, and their experience with service delivery and access to care. The participants will be recruited accounting for geographic, race/ethnicity, age, tenure, and other relevant diversity criteria. A complete account of the participant selection criteria and recruitment protocol will be included in the demonstration's interim and summative evaluation reports.

To ensure the validity of the findings, our effort will adhere to the key principles of focus group methodology:

(1) Remain neutral and unbiased in recruitment, questions development, and analysis;
(2) Design strategies maximize the diversity of experiences represented;
(3) Maintain consistency throughout the focus group process; and
(4) Adhere to ethical obligation of confidentiality and informed consent.

The use of focus groups as a research tool to explore a particular topic by gathering the experiences and perceptions of a selected target population has certain advantages over other information gathering methods, such as (a) producing results more quickly, (b) group interaction is generally more comfortable for participants, (c) offers increased flexibility allowing the participant to individualize responses and researchers to probe deeper on particular points, (d) results are generally easier to understand than statistical findings, and (e) they complement more structured quantitative data.[1]

In order to facilitate the focus group activities, we plan to ask key informants, such as Medicaid administrators, service/support providers, advocates, and perhaps family members, to constitute a focus group advisory committee. The committee will help to:

(1) Refine the scope of the focus groups for clear project description;
(2) Draft questions needed to facilitate participant discussion around the goals;
(3) Recommend a recruitment protocol and plan;
(4) Develop appropriate support materials (scripts for recruitment and question delivery, consent, registration, and other forms, etc.);
(5) Identify appropriate focus group scheduling options;
(6) Determine if and what incentives should be utilized; and
(7) As key informants, to provide insightful feedback supporting Interpretations of both the quantitative findings and the information gathered from the focus groups.

[1] Ward, Helen and Atkins, Julie. 2002. "From Their Lives: A Manual on How to Conduct Focus Groups of Low-Income Parents." University of Southern Maine. Accessed on March 22, 2020 at: https://digitalcommons.usm.maine.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1100&context=facbooks.

Approximately two weeks after a sufficient number of the target population has successfully been recruited, the first focus group will be implemented. To facilitate convenience and thus, attendance, there will be in-person focus groups in three locations (north, central, and south) in the state. Approximately 14-16 participants will be recruited and confirmed for each group with the goal of having approximately eight beneficiaries participating in each. Staffing each focus group will be a primary facilitator, secondary facilitator, and a designated note-taker (that supports the electronic recording). A total of approximately 8-9 engagement, exploratory, and exit questions will be used to help participants get comfortable, acquire useful information, and solicit any additional comments. It is anticipated that each focus group session will last 60 - 90 minutes. A staff debriefing will occur after each session to provide guidance for subsequent sessions and identify any departures from protocol and to assess the group process. A final report of focus group findings will be drafted, analyzed, and included in the evaluation report for the demonstration. Progress of focus group activities and a summary of key findings will also be incorporated in the relevant monitoring reports due to CMS. If recommended by the advisory committee and authorized by the state, we plan to use an incentive (gift card or such) to promote and facilitate participation in the focus groups.

To better contextualize the quantitative data analysis, we plan to conduct the focus groups after we have initial indications of our quantitative findings. This way, we will be able to refine the scope and questions for focus groups further. It is anticipated that the focus group activities will begin in the first quarter of 2022, take approximately seven months to complete, and findings made part of the Interim Evaluation Report due in September later that year. A tentative timeline is illustrated in Attachment V of this document.

Analytic Methods

Proposed methods for addressing the evaluation questions and hypotheses of the demonstration are described in the following table.

The effects of the demonstration are isolated from other initiatives occurring in the state, as there are no other initiatives in Mississippi for this population. Enrollees in the HMW are not eligible for Medicaid.

Table 2: Summary of Evaluation Hypotheses, Research Questions, Outcome Measures, Population, Data Sources, and Analytic Approaches

Research Question	Outcome Measure(s)	Population	Data Sources	Analytic Approach
Hypothesis 1: The rates of hospitalization and improper use of the emergency department visits will fall among HMW beneficiaries over time, and the HMW beneficiaries will have fewer hospitalizations and emergency department visits after accessing ambulatory and preventive services.				
How do the rates of inpatient hospitalization and non-emergent use of emergency department visits evolve over time among the HMW beneficiaries? Will HMW beneficiaries who access ambulatory and preventive services have fewer hospitalizations and emergency department visits?	Emergency department visit and inpatient hospitalization Emergency department visit and inpatient hospitalization for beneficiaries who access ambulatory and preventive services	• Beneficiaries under age 75 • Beneficiaries under age 75 who access ambulatory and preventive services at least once during the past six months	Medicaid Fee for Service (FFS) claims data Enrollment data	Descriptive statistics (Central tendency measures such as mean and median; variability measures, such as standard deviation and range) Also, include subgroup analysis; compare beneficiaries under age 75 who had used ambulatory and preventive services at least once during the measurement year and those that did not. Regression adjusted trend analysis to show whether there is any noticeable pattern during the span of the demonstration.
Hypothesis 2: HMW beneficiaries with access to benefits under the HMW demonstration will have an increase in the utilization of ambulatory/preventive health visits.				

Research Question	Outcome Measure(s)	Population	Data Sources	Analytic Approach
Will providing benefits under the HMW demonstration lead to an increase in the utilization of ambulatory/ preventive health visits among HMW beneficiaries?	Percentage of beneficiaries ages 20 and older who had at least one ambulatory/preventive visit during the measurement year	HMW beneficiaries ages 20 and older	Medicaid Fee for Service (FFS) claims data Enrollment data	Descriptive statistics (central tendency measures such as mean and median; variability measures, such as standard deviation and range) Statistical tests will include (1) McNemar test Cochran-Armitage test for trends), or regression adjusted trend analysis to show whether there is any noticeable pattern during the span of the demonstration.

Research Question	Outcome Measures	Population	Data Sources	Analytic Methods
Hypothesis 3: HMW beneficiaries with access to benefits will have an increase in the utilization of age-appropriate screenings.				
Will providing benefits under the HMW demonstration result in an increase in age appropriate screenings?	Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer once during the measurement year	HMW women 50-74 years of age	Medicaid Fee for Service (FFS) claims data Enrollment data	Descriptive statistics (central tendency measure, such as mean and median; variability measures, such as standard deviation and range) Statistical tests will include McNemar test or multiple regression.
	Percentage of women 21-64 years of age received one or more Pap test to screen for cervical cancer	HMW women 21-64 years of age		
	Percentage of beneficiaries 50-75 years of age who had appropriate screening for colorectal cancer	HMW beneficiaries 50-75 years of age		
Hypothesis 4: HMW beneficiaries diagnosed with diabetes are more likely to have an annual HbA1c test performed as a result of having access to HMW benefits.				

Research Question	Outcome Measures	Population	Data Sources	Analytic Methods
Will providing benefits under the HMW increase the number of annual HbA1c tests among HMW beneficiaries diagnosed with diabetes?	Percentage of beneficiaries 18-75 years of age with diabetes (Type 1 and Type 2) who received an HbA1c test during the measurement year.	HMW beneficiaries 18-75 years of age with a diabetes diagnosis	Medicaid Fee for Service (FFS) claims data Enrollment data	Descriptive statistics (central tendency measures such as mean and median; variability measures, such as standard deviation and range). Statistical tests will include McNemar test/ Cochran-Armitage tests for trends or multiple regression.
Hypothesis 5: HMW beneficiaries diagnosed with diabetes are more likely to have an annual dilated eye examination as a result of having access to HMW benefits.				
Will providing benefits under the HMW demonstration increase the number of annual dilated eye examinations among HMW beneficiaries diagnosed with diabetes?	Percentage of beneficiaries 18-75 years of age with diabetes who had a retinal or dilated eye exam during the measurement year	HMW beneficiaries 18-75 years of age with a diabetes diagnosis	Medicaid Fee for Service (FFS) claims data Enrollment data	Descriptive statistics (central tendency measures such as mean and median; variability measures, such as standard deviation and range). Statistical tests will include McNemar test/ Cochran-Armitage tests for trends.
Hypothesis 6: HMW beneficiaries are more likely to report being satisfied than not with the benefits under the demonstration.				
Are HMW beneficiaries satisfied with the demonstration services?	Beneficiary experience with demonstration services and benefits	HMW beneficiaries who participate in focus groups	Focus group findings and key informant interviews	Transcribed reports of focus group comments, systematic, manually-driven analysis of focus group findings supported by key informant interviews.

IV. Methodological Limitations

The HMW was designed to provide health care coverage to ABD individuals that do not qualify for Medicaid State Plan or Medicare. Within two (2) years, the majority of this population becomes eligible for Medicare (and thus ineligible for HMW), which limits the state's ability to evaluate the long-term impact of the demonstration. Additionally, no existing data is available for these beneficiaries prior to their enrollment in the HMW to perform a pre-comparison assessment. DOM was also unable to find a comparable population that had the same eligibility criteria as the HMW population. Reflecting on these limitations the state faces with the HMW population, a one-group posttest only design method will be conducted and utilized.

It is planned to use results from beneficiary focus groups to complement and contextualize the quantitative findings.

V. Special Methodological Considerations

DOM would like CMS to take into consideration the limitations listed above when reviewing the evaluation draft for scientific and academic rigor. DOM will rely on a non-experimental design because of the following reasons:

- There is no comparison group for this population that has been identified for this evaluation;
- A cause and effect relationship among HMW beneficiaries cannot be demonstrated; and
- Due to the lack of control population, DOM can only rely on interpretation and observations to draw a conclusion about the effectiveness of the HMW demonstration over time.

Attachment I: Independent Evaluator

As a result of a recent request for quotes, the Division of Medicaid (DOM) has secured the services of an independent evaluator and executed a professional services contract on June 18, 2019 with the Parham Group, LLC, and its sub-contractor, Dr. Hwanseok Choi.

The contractor has worked specifically with the evaluation and analysis of Federal and State programs for 17 years, including evaluation and support services with the DOM waiver-related programs: MYPAC, Money Follows the Person (B2i), and Person-centered Practices Training for waiver providers. Dr. Choi is an Associate Professor in the School of Health Professions at the University of Southern Mississippi and holds a Ph.D. in Applied Statistics from the University of Alabama. For over 16 years, Dr. Choi has participated in the design, data entry design, data coding, data editing, analysis, and statistical reporting on nearly 100 studies using multiple statistical packages such as SAS, SPSS, STATA, and ArcGIS.

DOM has measures in place to assure that the independent evaluator will conduct a fair and impartial evaluation, prepare an objective evaluation report and that there is no conflict of interest. The primary means employed by the State to accomplish these goals are the contract and contract monitoring process. DOM will ensure compliance through the use of carefully crafted contractual language outlining benchmarks, report due dates, and the use of approved methods. With these measures in place, DOM will be able to monitor the independent evaluator's progress while maintaining a "no conflict of interest" status. DOM has also specified that any subcontractor who is involved in the demonstration will have to be approved by DOM. DOM has approved both the contractor and sub-contractor for this project.

Attachment II: Evaluation Budget

We estimate the total cost of the evaluation for the waiver approval period at $59,500 for the demonstration. The staffing, data collection, and administrative costs are listed in the accompanying table and described below.

Line Item	Components of Budget	Line Item Cost
1	Estimated staff	$58,000
2	Focus Group implementation and other misc. administrative costs	$1,500
	Total Amount	**$59,500**

Staffing

Project Director
Project Director will have overall responsibility for the evaluation, including the developing the evaluation design and data collection instruments, overseeing evaluation staff and analysis of the claims and survey data, and preparing the annual reports.

Associate Project Director
Associate Project Director will provide guidance on the evaluation design and data collection instruments and will assist with data analysis and conceptualizing results for the annual report, based on their experience as the lead evaluator.

Statistical Analyst
Statistical Analyst will be responsible for data management, data cleaning and analyzing the enrollment, claims and survey data for the annual reports.

Dissemination/Special Project Coordinator
Dissemination/Special Project Coordinator will coordinate the administration of the annual surveys with a Survey Research Unit, prepare protocols for review, and assist with preparing the annual reports.

Focus Group Implementation
With significant input from a newly developed advisory committee (composed primarily of key informants) the independent evaluator team will organize, develop, and implement three planned beneficiary focus groups and provide a written report that synthesizes findings and analyzes results.

Attachment III: Timeline and Major Milestones

Deliverable	Timeline	Projected Submission Date
Annual Monitoring Report	Within 90 days following the end of each demonstration year	December 31, 2019
Draft Evaluation Design Plan	Within 120 days after the approval of the demonstration extension	January 25, 2019
Final Evaluation Design Plan	Within 60 days following receipt of CMS comments on Draft Evaluation Design	Pending CMS Comment Period
Interim Evaluation Reports	With submission of a demonstration extension request.	September 30, 2022
Summative Evaluation Report	Within 18 months following the end of the demonstration approval period identified in these STCs.	March 31, 2025

Attachment IV: Healthier Mississippi Waiver Baselines

Criteria	FFY16	FFY17	FFY18	Average	Percent Change
Colorectal Screening (Age 50-75)					
Eligible	6,422	6,523	6,535	6,493	
No. Received	668	680	700	683	
% of Population Received Screening	10.4%	10.4%	10.7%	10.5%	0.96%
Cervical Screening (Females, Age 21-64)					
Eligible	4,619	4,726	4,692	4,679	
No. Received	440	422	439	434	
% of Population Received Screening	9.5%	8.9%	9.4%	9.3%	-0.35%
Mammogram (Females, Age 50-74)					
Eligible	3,550	3,639	3,626	3,605	
No. Received	634	802	793	284	
% Received Screening	17.9%	22%	21.9%	20.6%	7.45%
Ambulatory/Preventive Visit (Age ≥20)					
Eligible HMW Beneficiaries	8,570	8,738	8,742	8,683	
No. Received	6,752	6,846	6,916	6,838	
% Received Screening	78.8%	78.3%	79%	78.7%	0.08%
Diabetic & Annual A1c Test (Age 18-75)					
Eligible	2,285	2,344	2,305	2,311	
No. Received	1,552	1,648	1,626	1609	
% Received Test	68%	70.3%	71%	69.8%	1.47%
Diabetic & Annual Dilated Eye Exam (Age 18-75)					
Eligible	2,285	2,344	2,305	2,311	
No. Received	593	655	678	642	
% Received Exam	26%	28%	29%	27.7%	3.85%

Emergency Department (ED) Visits

0.47% Change	**FFY 16** *(n=5,809)*		**FFY 17** *(n=5,911)*		**FFY 18** *(n=5,891)*	
≥1 Preventive/ Primary Care Visit	**# Visits (% of Total Visits)**	**Recipient Count**	**# Visits (% of Total Visits)**	**Recipient Count**	**# Visits (% of Total Visits)**	**Recipient Count**
Yes	3,330 (57.3)	1,651	3,396 (57.5)	1,675	3,611 (61.3)	1,746
No	2,479 (42.7)	1,320	2,515 (42.5)	1,385	2,280 (38.7)	1,313

Hospitalizations (HMW Beneficiaries <75)

1.93% Change	**FFY 16** *(n=2,328)*		**FFY 17** *(n=2,460)*		**FFY 18** *(n=2,463)*	
≥1 Preventive/ Primary Care Visit	**# of Inpatient Claims**	**Recipient Count**	**# of Inpatient Claims**	**Recipient Count**	**# of Inpatient Claims**	**Recipient Count**
Yes	1,263 (54.3)	802	1,306 (53.1)	807	1,374 (55.8)	865
No	1,065	767	1,154	802	1,089	788

	(45.7)		(46.9)		(44.2)	

Attachment V

Estimated Timeline for Conducting Focus Group Activities

ACTIVITY	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
Plan and Organize							
▪ Establish the project Adv. Com.							
▪ Identify goals							
▪ Identify project description							
▪ Develop 10-12 group questions							
▪ Establish operating protocols							
▪ Develop materials/forms							
Recruitment							
▪ Identify diverse sample							
▪ Establish procedure							
▪ Decide on if and what incentive							
▪ Develop recruitment script							
▪ Recruit 32-36 participants							
Implementation							
▪ Focus group script /protocol							
▪ Reminders sent out							
▪ Dry run through/tweak as needed							
▪ Staffing in place							
▪ Transportation set							
▪ Site preparation and set up							
▪ Electronic recording and manual note-taking in place							
▪ Conduct focus groups (3)							

▪ Staff debrief of meeting and make adjustments as needed							
Analysis and Reporting ▪ With support from the Advisory Committee, prepare a manually-driven, written report that synthesizes findings and analyzes the results of the three focus groups. ▪ Incorporate the focus group findings report into the interim evaluation report.							