

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



September 28, 2018

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

Dear Mr. Snyder:

The Centers for Medicare & Medicaid Services (CMS) is pleased to inform you that Mississippi's request to extend its section 1115 demonstration, entitled "Healthier Mississippi" (No. 11-W-00185/4) has been approved. CMS' approval of this demonstration extension is granted under the authority of section 1115(a) of the Social Security Act (the "Act") and is based on the determination that the expenditure authority granted therein is likely to assist with promoting the objectives of title XIX of the Act because providing benefits to the low-income aged, blind, and disabled population will improve the health outcomes for vulnerable, low-income populations in the state. This approval is effective as of the date of this letter through September 30, 2023.

The Healthier Mississippi demonstration operates statewide and provides Medicaid services to aged, blind, and disabled individuals who have no Medicare coverage and who are not otherwise eligible for Medicaid. Mississippi held its public comment period from July 21, 2017 to August 20, 2017, which included two public hearings. The state also sent a tribal notice letter to the Mississippi Band of Choctaw Indians. The state did not receive any comments during its public comment period, nor did it receive any comments during the public hearings or from the tribe. CMS held its federal public comment period from October 17, 2017 to November 16, 2017. CMS did not receive any comments during the federal public comment period.

CMS has made several changes to the Healthier Mississippi Special Terms and Conditions (STCs) to reduce the state's administrative burden associated with the section 1115 approval and monitoring processes while also assuring adequate federal oversight and evaluation. These STC updates include granting a five-year extension of the demonstration, streamlining monitoring requirements to an annual reporting cycle, and establishing templates for annual monitoring reporting as well as for evaluating demonstration outcomes that will facilitate the state's data development, collection, and reporting capacity. As expressed in the STCs, the state will submit

a draft evaluation design to CMS 120 days after receipt of this letter. The draft evaluation design must be developed in accordance with Attachment A of the STCs, “Developing the Evaluation Design.”

CMS’ approval of this demonstration is subject to the state’s compliance with the enclosed set of STCs and associated expenditure authorities. All Medicaid title XIX requirements as expressed in law, regulation, and policy statement not expressly identified as not applicable in these approval documents shall apply to the Healthier Mississippi demonstration. The state’s authority to deviate from Medicaid requirements is limited to the expenditure authorities and requirements specifically listed as not applicable to the expenditure authorities described in the enclosed approval documents, and to the purpose(s) indicated. This award letter is subject to your written acknowledgement of the award and acceptance of the STCs and associated expenditure authorities within 30 days of the date of this letter.

Your project officer for this demonstration is Mr. Emmett Ruff, who can be contacted to answer any questions concerning the implementation of this demonstration at 410-786-4252 or at [emmett.ruff@cms.hhs.gov](mailto:emmett.ruff@cms.hhs.gov). Official communications regarding program matters and correspondence concerning the demonstration should be submitted to him at the following address:

Mr. Emmett Ruff  
Centers for Medicare & Medicaid Services  
Center for Medicaid & CHIP Services  
Mail Stop: S2-25-26  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Official communications regarding this demonstration should be sent simultaneously to Ms. Emmett Ruff and to Ms. Shantrina Roberts, Associate Regional Administrator (ARA) for the Division of Medicaid and Children’s Health in our Atlanta Regional Office. Ms. Roberts’ contact information is as follows:

Ms. Shantrina Roberts  
Centers for Medicare & Medicaid Services  
Atlanta Federal Center, Suite 4T20  
61 Forsyth Street, South West  
Atlanta, GA 30303-8909

If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services at (410) 786-9686.

Sincerely,

/s/

Timothy B. Hill  
Acting Director

Enclosures

cc: Shantrina Roberts, Associate Regional Administrator, CMS Atlanta Regional Office

**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 October 1, 2018 through September 30, 2023, 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
- III.** General Program Requirements
- IV.** Eligibility, Benefits, and Cost Sharing
- V.** Delivery Systems
- VI.** General Reporting Requirements
- VII.** General Financial Requirements
- VIII.** Monitoring Budget Neutrality for the demonstration
- IX.** Evaluation of the Demonstration
- X.** Schedule of State Deliverables

Attachment A: Developing the Evaluation Design  
Attachment B: Preparing the Evaluation Report  
Attachment C: Evaluation Design (reserved)

## 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 renewal, the state requested and CMS increased the enrollment cap from 5,000 to 5,500. Under the 2015 renewal, CMS approved two changes: increasing the enrollment limit from 5,500 to 6,000 and adding to the benefit package the following previously excluded services: podiatry, eyeglasses, dental, and chiropractic services.

With this demonstration, Mississippi expects to achieve the following goals:

1. Reduce hospitalizations, and improper use of the emergency department;
2. Increase the utilization of ambulatory/preventive health visits each demonstration year.
3. Increase the number of preventive health screenings each demonstration year.
4. Increase the proportion of adults with diabetes who have a hemoglobin A1c (HbA1c) measurement at least once a year each demonstration year.
5. Increase the proportion of adults with diabetes who have an annual dilated eye examination 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, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid 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), must apply to the demonstration.
- 3. Changes in Medicaid 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.

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 align with mandated changes in Medicaid law, regulation, and policy that directly impact this demonstration program.

#### **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, the changes must 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 law.

**5. State Plan Amendments.** The state will not be required to submit a title XIX state plan amendment for changes to any populations made eligible solely through the demonstration. If a population eligible through the Medicaid 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.

**6. Changes Subject to the Amendment Process.** Changes related to program design, eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, 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. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

**7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or

delay approval of a demonstration amendment based 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 8, to reach a decision regarding the requested amendment;
- b) 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;
- c) A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and,
- d) If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

**8. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 Code of Federal Regulations (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 section 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state’s approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

**9. Extension of the Demonstration.** No later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR section 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 10.

**10. Demonstration Transition and Phase Out.** The state may only suspend or terminate this demonstration, in whole or in part, at any time prior to the date of expiration.

- 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) Phase-out Plan Approval: The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of phase-out activities. Implementation of phase-out activities must be no sooner than fourteen (14) days after CMS approval of the phase-out plan.
- d) Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR sections 431.206, 431.210, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR sections 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR section 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as found in 42 CFR section 435.916.
- e) Exemption from Public Notice Procedures 42.CFR section 431.416(g): CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR section 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.

- 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 terminating the demonstration including services and administrative costs of disenrolling participants.

**11. CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration, in whole or in part, at any time before the date of expiration, whenever it determines following a hearing that the state has materially failed to comply with the terms of the demonstration project. CMS must promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

**12. Finding of Non-Compliance.** 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. Specifically:

- a) Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.
- b) For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).
  - 1) CMS may decline the extension request.
  - 2) Should CMS agree in writing to the state’s request, a corresponding extension of the deferral process described below can be provided.
  - 3) If the state’s request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
- c) The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
- d) When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
- e) As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state’s failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

- f) CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example what quarter the deferral applies to, and how the deferral is released.

**13. 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.

**14. 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.

**15. Federal Financial Participation (FFP).** No federal matching for administrative or medical assistance payments for services provided under this demonstration will take effect until the effective date identified in the CMS demonstration approval documents.

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

#### **IV. ELIGIBILITY, BENEFITS AND COST SHARING**

##### **17. Demonstration Eligibility.**

- a) The group described in STC 17(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 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.

**18. 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.

**19. 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.

<b>Services Not Covered for Adults</b>
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.

**20. 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

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

## VI. GENERAL REPORTING REQUIREMENTS

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

**23. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 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, 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. Cooperation with Federal Evaluators.** As required under 42 CFR section 431.420(f), the state shall cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents 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 shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall 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 12.

**25. Annual Monitoring Reports.** The state must submit one (1) Annual Report each DY. The Annual Report is due no later than ninety (90) days following the end of the DY. The state shall also submit semi-annual report(s) *at the request* of CMS. If semi-annual reports are requested, the state will have ninety (90) days to submit the first semi-annual report following the CMS request, and subsequent semiannual reports must be submitted in six-month intervals following the first semiannual report. In addition, CMS reserves the right to increase the frequency of reporting as deemed necessary by CMS (e.g., to require quarterly reports). If CMS increases the frequency of required reports (e.g., to

semiannual or quarterly), all required reports must meet the requirements for the Annual Reports. The Annual 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 Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

- a) Operational Updates – Per 42 CFR section 431.428, the Annual Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Annual Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b) Performance Metrics – Per 42 CFR section 431.428, the Annual Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Annual Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c) Budget Neutrality and Financial Reporting Requirements – Per 42 CFR section 431.428, the Annual Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, 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.
- d) Evaluation Activities and Interim Findings – Per 42 CFR section 431.428, the Annual 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.

**26. Close out Report.** Within 120 days after the expiration of the demonstration, the state

must submit a draft Close Out Report to CMS for comments.

- a) The draft report must comply with the most current guidance from CMS.
- b) The state will present to and participate in a discussion with CMS on the Close-Out report.
- c) The state must take into consideration CMS' comments for incorporation into the final Close Out Report.
- d) The final Close Out Report is due to CMS no later than thirty (30) days after receipt of CMS' comments.
- e) A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 12.

**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, 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 section 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 report on its website with the public forum announcement. Pursuant to 42 CFR section 431.420(c), the state must include a summary of the comments in its compiled Annual Report.

## **VII. GENERAL FINANCIAL REQUIREMENTS**

**29. Quarterly Expenditure Reports.** The state must provide quarterly expenditure reports using Form CMS-64 to report total expenditures for services provided through this demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in Section VIII.

**30. Expenditures Subject to the Budget Neutrality Expenditure Limit.** All expenditures for health care services for demonstration participants, as defined in STC 31(d), are subject to the budget neutrality agreement.

**31. Reporting Expenditures Subject to the Budget Neutrality Expenditure Limit.** The following describes the reporting of expenditures subject to the budget neutrality agreement:

a) **Tracking Expenditures.** In order to track expenditures, the state must report demonstration expenditures through the Medicaid and Children’s Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64. 9 Waiver and/or 64. 9P Waiver, identified by the demonstration project number (11-W-00185/4) assigned by CMS, including the project number extension which indicates the demonstration year (DY) in which services were rendered.

b) **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64. 9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the state Medicaid Manual.

c) **Pharmacy Rebates.** The state may propose 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 reasonably 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. The portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64. 9 Waiver for the demonstration, and not on any other CMS-64. 9 form (to avoid double counting). Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

d) **Use of Waiver Forms.** For each DY, a Waiver Form CMS-64.9 Waiver and/or 64. 9P Waiver must be submitted each quarter to report title XIX expenditures associated with the demonstration. The expression in quotations marks, for the Population below, is the waiver name to be used to designate this waiver form in the MBES/CBES system.

i. **Demonstration Population 1 “Medicaid Only”**: 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.

- e) **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must 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.
- f) **Claiming Period.** All claims for expenditures subject to the budget neutrality agreement (including any cost settlements) must be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must 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.

**32. Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both the Medical Assistance Payments (MAP) and state and Local Administrative Costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter that just ended. CMS shall reconcile expenditures reported on the 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.

**33. Extent of FFP.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the limits described in section

- a) Administrative costs, including those associated with the administration of the demonstration; and,
- b) Net expenditures and prior period adjustments, made under an approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration.

**34. Sources of Non-federal Share.** The state provides assurance that the matching non-federal share of funds for the demonstration is state/local monies. The state further assures that such funds shall not be used as the match for any other federal grant or



contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

- d) CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
- e) Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- f) The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan.

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

- a) Units of government, including governmentally-operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration;
- b) To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures;
- c) To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match;
- d) The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally-operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments; and,
- e) Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures.

Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes, including health care provider-related taxes, fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

**36. Monitoring the Demonstration.** The state must provide CMS with information to effectively monitor the demonstration, upon request, in a reasonable timeframe.

**37. Program Integrity.** The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

## VIII. MONITORING BUDGET NEUTRALITY

**38. Limit on Title XIX Funding.** The state shall be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using a per capita cost method, and budget neutrality expenditure caps are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual limits is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS's assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

**39. Risk.** Mississippi shall be at risk for the per capita cost (as determined by the method described below) for demonstration eligibles under this budget neutrality agreement, but not for the number of demonstration eligibles. Because CMS provides FFP for all demonstration eligibles, Mississippi shall not be at risk for changing economic conditions that impact enrollment levels. However, by placing Mississippi at risk for the per capita costs for current, CMS assures that the federal demonstration expenditures do not exceed the level of expenditures had there been no demonstration.

**40. Demonstration Population Used to Calculate the Budget Neutrality Expenditure Cap.** The following describes the method for calculating the budget neutrality expenditure cap for the demonstration:

- a) For each year of the budget neutrality agreement an annual budget neutrality expenditure cap is calculated for each eligibility group (EG) described as follows:
  - i. An annual EG estimate must be calculated as a product of the number of eligible member months reported by the state under STC 29 for the demonstration

population, times the appropriate estimated per member per month (PMPM) costs from the table in subparagraph (ii) below.

- ii. The PMPM costs for the calculation of the annual budget neutrality expenditure cap for the eligibility group subject to the budget neutrality agreement under this demonstration are specified below. The PMPM was constructed based on the 2019 President’s Budget for Medicaid and the PMPMs in approved STCs from the previous eligibility period. The growth rate and PMPM amounts for the demonstration population are shown below. The demonstration population is a “pass-through” or “hypothetical” population. Therefore, the state may not derive savings from this population.

Eligibility Group	Growth Rate	DY 15	DY 16	DY 17	DY 18	DY 19
		10/01/2018 through 09/30/2019	10/01/2019 through 09/30/2020	10/01/2020 through 09/30/2021	10/01/2021 through 09/30/2022	10/01/2022 through 09/30/2023
Demonstration Population 1 – Medicaid only	4.1%	\$2,672.71	\$2,782.29	\$2,896.36	\$3,015.11	\$3,138.73

- iii. The annual budget neutrality expenditure cap for the demonstration as a whole is the sum of the projected annual expenditure cap for the demonstration population calculated in subparagraph (i) above.

- b) Composite 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 extension approval period, as reported on the forms listed in STC 31 above, by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the extension approval period, the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable Composite Federal Share may be used.
- c) The overall budget neutrality expenditure limit for the demonstration is the sum of the annual budget neutrality expenditure caps calculated in subparagraph (a)(iii). The federal share of the overall budget neutrality expenditure cap represents the maximum amount of FFP that the state may receive for expenditures on behalf of demonstration population described in STC 31(d) during the demonstration period reported in accordance with STC 30.

**41. Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.

**42. Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality over the life of the demonstration rather than on an annual basis. However, if the state’s expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state must submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

**43.**

<u>Year</u>	<u>Cumulative Target Expenditures</u>	<u>Percentage</u>
DY15	DY15 budget limit plus:	2 percent
DY16	DY15 and DY16 combined budget limit amount plus:	1.5 percent
DY17	DY15 through DY17 combined budget limit amount plus:	1.0 percent
DY18	DY15 through DY18 combined budget limit amount plus:	0.5 percent
DY19	DY15 through DY19 combined budget limit amount plus:	0 percent

**44. Exceeding Budget Neutrality.** If, at the end of this demonstration period, the cumulative budget neutrality expenditure cap has been exceeded, the excess Federal funds must be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision shall be based on the time elapsed through the termination date.

## **IX. EVALUATION OF THE DEMONSTRATION**

**45. Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with 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, draft 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.

**46. 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.

**47. Draft Evaluation Design.** The draft evaluation design must be developed in accordance with attachment A “Developing the Evaluation Design.” The state must submit, for CMS comment and approval, a draft evaluation design with an implementation timeline by no later than 120 days after the effective date of these STCs. Any modifications to an existing approved evaluation design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of an independent party in the development of the draft evaluation design.

**48. Evaluation Design Approval and Updates.** The state must submit a revised draft evaluation design within 60 days after receipt of CMS’ comments. 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 final evaluation design within 30 days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each Annual Monitoring Report as required by STC 25, 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.

**49. Evaluation Questions and Hypotheses.** Consistent with attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report), the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS’ 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).

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

- a) The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
- b) For demonstration authority that expires prior to the overall demonstration’s

expiration date, the interim evaluation report must include an evaluation of the authority as approved by CMS.

- 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 how the design was adapted should be included. If the state is not requesting an extension of the demonstration, the draft 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) The state must submit the final interim evaluation report 60 days after receiving CMS comments on the draft interim evaluation report and post the document to the state's website.
- e) The interim evaluation report must comply with CMS' separately provided guidance entitled, "Preparing the Evaluation Report."

**51. Summative Evaluation Report.** The draft summative evaluation report must be developed in accordance with CMS' separately provided guidance entitled, "Preparing the Evaluation Report." The state must submit a draft summative evaluation report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The summative evaluation report must include information as outlined in the approved evaluation design.

- a) Unless otherwise agreed upon in writing by CMS, the state shall submit the final summative evaluation report within 60 days of receiving comments from CMS on the draft.
- b) The final summative evaluation report must be posted to the state's Medicaid website within 30 days of approval by CMS.

**52. 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 state's interim evaluation, and/or the summative evaluation.

**53. Public Access.** The state shall post the final documents (e.g., monitoring reports, approved evaluation design, interim evaluation report, summative evaluation report, and close-out report) on the state's Medicaid website within 30 days of approval by CMS.

**54. Additional Publications and Presentations.** For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles),

by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given 30 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

<b>Deliverable</b>	<b>Timeline</b>	<b>STC Reference</b>
Quarterly Expenditures Reports	Within 30 days following the end of each quarter using Form CMS-64	STC 29
Annual Monitoring Report	Within 90 days following the end of each demonstration year (unless CMS requests reports more frequently than annually)	STC 25
Draft Evaluation Design Plan	Within 120 days after the approval of the demonstration extension	STC 47
Final Evaluation Design Plan	Within 60 days following receipt of CMS comments on Draft Evaluation Design	STC 48
Interim Evaluation Reports	With submission of a demonstration extension request.	STC 50
Summative Evaluation Report	Within 18 months following the end of the demonstration approval period identified in these STCs.	STC 51



## **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**

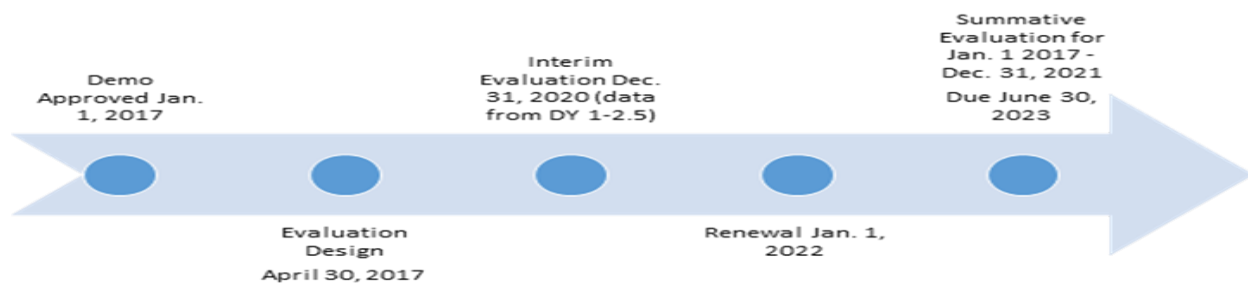
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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.
- c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
- d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
- f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

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

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

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
<b>Hypothesis 1</b>				
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
<b>Hypothesis 2</b>				
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 Evaluation Report**

### **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.

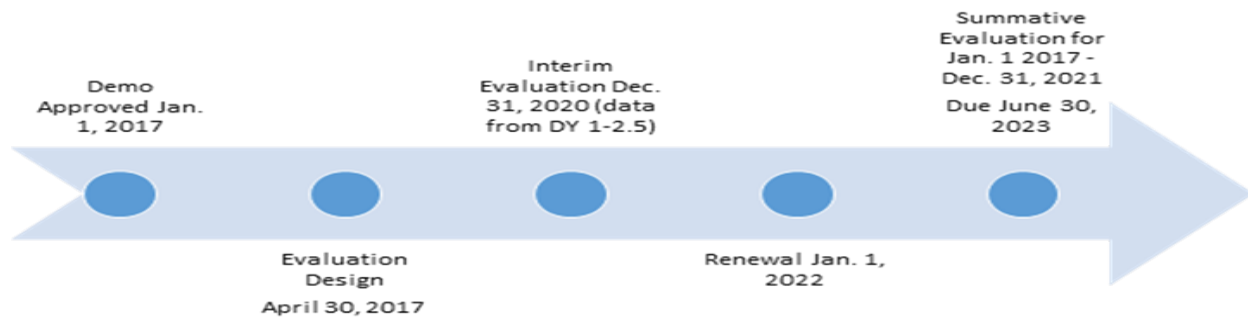
The format for the Interim and Summative Evaluation reports are as follows:

- 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)**