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

March 19, 2025

Theresa C. Arriola, Director
Bureau of Health Care Financing Administration—Medicaid Program
Guam Department of Public Health and Social Services
123 Chalan Kareta
Mangilao, GU 96913-6304

Dear Director Arriola:

The Centers for Medicare & Medicaid Services (CMS) completed its review of Guam's Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC #33 "Draft Evaluation Design" of the territory's section 1115 demonstration, "Guam Alternative Drug Coverage Program Demonstration" (Project No: 11-W-00427/9), effective through March 31, 2028. CMS has determined that the Evaluation Design, which was submitted on December 1, 2023, and July 1, 2024, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the territory's Evaluation Design.

CMS has added the approved Evaluation Design to the demonstration's STCs as Attachment C. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the territory's Medicaid website within 30 days. CMS will also post the approved Evaluation Design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an Interim Evaluation Report, consistent with the approved Evaluation Design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the territory chooses to extend the demonstration. Likewise, a Summative Evaluation Report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

We appreciate our continued partnership with Guam on the Alternative Drug Coverage Program Demonstration section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S

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Date: 2025.03.19 14:40:50 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00427/9**

TITLE: **Guam Alternative Drug Coverage Program Demonstration**

AWARDEE: **Guam Department of Public Health and Social Services**

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by the territory for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from April 7, 2023 through March 31, 2028, unless otherwise specified, be regarded as expenditures under the territory's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable Guam to operate the above-identified section 1115(a) demonstration.

1. Pharmaceutical Drug Package

Expenditures for Medicaid coverage of prescribed drugs not covered under the State plan.

CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00427/9**

TITLE: **Guam Medicaid Alternative Drug Coverage Program Demonstration**

AWARDEE: **Guam Department of Public Health and Social Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Guam Medicaid Alternative Drug Coverage Program section 1115(a) Medicaid demonstration (hereinafter demonstration) to enable the Guam Department of Public Health and Social Services (territory) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are enumerated above. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the territory's obligations to CMS during the life of the demonstration.

These STCs are effective April 7, 2023 through March 31, 2028, unless otherwise stated.

The STCs have been arranged into the following subject areas:

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

Attachment A Developing the Evaluation Design
Attachment B Preparing the Interim and Summative Evaluation Report
Attachment C Evaluation Design (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Guam Alternative Drug Coverage Program Demonstration will allow the territory to provide prescribed drug coverage without complying with the requirements at sections 1902(a)(54) and 1927 of the Social Security Act (the Act) that would apply if the coverage was provided under the State plan

option provided for in those provisions, and maintain their current prescribed drug delivery system. Guam is seeking this demonstration because participation in the MDRP would contribute pressure to the territory. Sections 1902(a)(54) and 1927 of the Act require states to ensure coverage and payment is available for all the covered outpatient drugs (CODs) of a manufacturer with a Medicaid drug rebate agreement in effect and comply with additional reporting requirements in order to collect applicable rebates, and Guam will not be seeking rebates. The territory's pharmacy providers already face barriers in inventory due to the remoteness of the island and the relatively insignificant purchasing amounts that make it difficult to negotiate favorable shipping terms. Purchasing greater volumes of drugs would further burden Guam's constrained budget. In addition, establishing a MDRP system would create a large burden for the territory. Guam proposes that the demonstration is necessary to ensure the territory maintains the appropriate number of pharmacy providers required to meet the demand of program participants.

Through this demonstration period, the territory seeks to meet several demonstration objectives, which include, but are not limited to, the following:

- Maintain the existing network capacity of on-island providers in order to provide adequate access to pharmacy services for program beneficiaries, and
- Allow time to properly assess potential benefits and adverse effects of providing coverage of prescribed drugs consistent with sections 1902(a)(54) and 1927 of the Act on Guam's pharmacy providers and program beneficiaries.

III. GENERAL PROGRAM REQUIREMENTS

1. Compliance with Federal Non-Discrimination Laws. The territory must comply with all applicable federal statues 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 Affordable Care Act (Section 1557).

2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs, expressed in federal law, regulation, and written policy, 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 territory must, within the timeframes specified in federal law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or written policy affecting the Medicaid and/or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the territory to submit an amendment to the demonstration under STC 7. CMS will notify the territory 30 calendar days in advance of the expected approval date of the amended STCs to allow the territory to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The territory 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 written policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the territory must adopt, subject to CMS approval, a modified budget neutrality agreement and/or a modified allotment neutrality worksheet for the demonstration as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the territory may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
    b. If mandated changes in the federal law, regulation, or policy require territory legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such territory legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

5. **State Plan Amendments.** The territory will not be required to submit title XIX or title 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 may be required, except as otherwise noted in these STCs. In all such instances, 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, evaluation design, sources of non-federal share of funding, budget neutrality, and other comparable program elements authorized through these STCs 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 territory must not implement or begin operational changes to these demonstration elements without prior approval. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for amendments to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3 or otherwise specified in the STCs.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the territory to submit required elements of a complete amendment request as described in this STC, and failure by the territory to submit reports and other deliverables 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 territory, consistent with the requirements of STC 13. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the territory 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 worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed

level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

d. An up-to-date CHIP allotment neutrality worksheet, if necessary;
e. The territory 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. Territories that intend to request an extension of the demonstration extension must submit an application to CMS from the Governor of the territory in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). Territories that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.

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

a. Notification of Suspension or Termination. The territory must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The territory must submit a notification letter and a draft transition and phase-out plan to CMS no less than six (6) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the territory must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the territory must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the territory must provide a summary of the issues raised by the public during the comment period and how the territory considered the comments received when developing the revised transition and phase-out plan.
b. Transition and Phase-out Plan Requirements. The territory must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the territory will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the territory will undertake to notify affected beneficiaries, including community resources that are available.
c. Transition and Phase-out Plan Approval. The territory 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 begin no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
d. Transition and Phase-out Procedures. The territory must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different 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, the territory must determine potential eligibility for other insurance affordability programs and

comply with the procedures set forth in 42 CFR 435.1200(e). The territory must comply with all applicable notice requirements for Medicaid found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214 or for CHIP found at 42 CFR 457.340(e), including information about a right to a review consistent with 42 CFR 457.1180. In addition, the territory must assure all applicable Medicaid appeal and hearing rights are afforded to Medicaid 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 territory must maintain benefits as required in 42 CFR 431.230.

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

f. Enrollment Limitation during Demonstration Phase-Out. If the territory elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the territory'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 territory, FFP must be limited to normal closeout costs associated with termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling participants.

10. 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 territory has materially failed to comply with the terms of the project. CMS must promptly notify the territory in writing of the determination and the reasons for the suspension or termination, together with the effective date.

11. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX or title XXI. CMS will promptly notify the territory in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the territory an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

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

13. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The territory must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the territory must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to

submitting such request. The territory must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in territory-wide methods and standards for setting payment rates.

In states and territories with federally recognized Indian tribes, consultation must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the consultation process in the territory's approved Medicaid state plan if that process is specifically applicable to consulting with tribal governments on waivers in accordance with 42 CFR §431.408(b)(2).

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

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

16. Common Rule Exemption. The territory 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 and CHIP benefits or services under those programs. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

IV. ELIGIBILITY

17. Populations Affected by the Guam Alternative Drug Coverage Program Demonstration. This demonstration does not modify the manner in which any beneficiaries interact with the Guam pharmacy delivery system or pharmacy providers.

18. Fair Hearings. The territory will afford beneficiaries in the demonstration fair hearing rights in accordance with 42 CFR part 431 subpart E. No waiver will be granted related to fair hearings. The territory must ensure compliance with all federal and territory requirements related to beneficiary fair hearing rights, including compliance with the approved state plan.

V. BENEFITS

19. Benefits. There are no changes to benefits under this demonstration.

VI. DELIVERY SYSTEM

20. Medicaid Drug Rebate Program. Because the drug coverage under this demonstration would be provided using expenditure authority under section 1115(a)(2) of the Act, and not under the State plan optional benefit of prescribed drugs at section 1905(a)(12) of the Act, compliance with sections 1902(a)(54) and 1927 would not be required.

VII. PREMIUMS AND COST SHARING

21. Premiums. There are no changes to premiums under this demonstration.

22. Cost Sharing. There are no changes to cost sharing under this demonstration.

VIII. MONITORING AND REPORTING REQUIREMENTS

23. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or are found to be inconsistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration. The territory does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the territory materially failed to comply with the terms of this agreement.

In the event that either (1) the territory has not submitted a written request to CMS for approval of an extension, as described below, within 30 calendar days after a deliverable was due, or (2) the territory has not submitted a revised submission or a plan for corrective action to CMS within 30 calendar days after CMS has notified the territory in writing that a deliverable was not accepted for being inconsistent with the requirements of this agreement including the information needed to bring the deliverable into alignment with CMS requirements; the following process is triggered:

a. CMS will issue a written notification to the territory providing advance notification of a pending deferral for late or non-compliant submission of required deliverable(s). For each deliverable, the territory 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 territory's anticipated date of submission. Should CMS agree to the territory's request, a corresponding extension of the deferral process can be provided.
b. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the territory's written extension request.
c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the territory fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the territory.
d. If the CMS deferral process has been initiated for the territory's non-compliance with the terms of this agreement for submitting deliverable(s), and the territory 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, the territory'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.

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

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

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all section 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the territory; and
c. Submit deliverables to the appropriate system as directed by CMS.

26. Annual Monitoring Reports. The territory must submit one Annual Monitoring Report each demonstration year (DY) and is due no later than 90 calendar days following the end of the DY. The territory must submit a revised Annual Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Annual Monitoring Reports must follow the framework to be 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 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, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
b. Performance Metrics. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration on beneficiaries' outcomes of care, quality and cost of care, and access to care, as applicable. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

The territory and CMS will work collaboratively to finalize the list of metrics to be reported on in Annual Monitoring Reports. The demonstration's monitoring metrics may include, but not be limited to: number of enrolled Medicaid beneficiaries, number of pharmaceutical providers, and number of pharmacy prescriptions filled. The territory is furthermore strongly encouraged

to report on at least two pharmacy-focused established quality measures suitable for Medicaid beneficiary populations (e.g., the territory may consult the Pharmacy Quality Alliance Measures, available here: https://www.pqaalliance.org/assets/Measures/PQA_Measures_Overview.pdf).

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the CMS framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Consistent with the August 22, 2018 State Health Official Letter #18-009, CMS has determined that this demonstration is budget neutral based on its assessment that the authority granted for the demonstration is unlikely to result in any increase in federal Medicaid expenditures for medical assistance. The territory will not be allowed to obtain budget neutrality "savings" from this demonstration. The demonstration will not include a budget or allotment neutrality expenditure limit and no further test of budget or allotment neutrality will be required. CMS reserves the right to request budget or allotment neutrality worksheets or analyses from the territory should the territory ever seek changes to the demonstration, pers STC 7. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The territory must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.

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

27. 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 territory to submit a corrective action plan to CMS for approval. A territory 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 pharmaceuticals. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS will withdraw an authority, as described in STC 11, when metrics indicate substantial and sustained directional change inconsistent with the territory's demonstration goals, and the territory 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.

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

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

b. In consultation with CMS, and per guidance from CMS, the territory 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 101 and 102, respectively.

c. The territory will present to and participate in a discussion with CMS on the Close-Out report.
d. The territory 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 30 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 territory to penalties described in STC 23.

29. Monitoring Calls. CMS will convene periodic conference calls with the territory.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The territory and CMS will jointly develop the agenda for the calls.

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

IX. EVALUATION OF THE DEMONSTRATION

31. Cooperation with Federal Evaluators and Learning Collaboration. As required under 42 CFR 431.420(f), the territory shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The territory shall include in its contracts with entities that collect, produce, or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the territory's participation—including representation from the territory's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable—in a federal learning collaborative aimed at cross-state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and evaluation. The territory may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 23.

32. Independent Evaluator. The territory 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 is to 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 territory may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

33. Draft Evaluation Design. The territory must submit, for CMS comment and approval, a draft Evaluation Design no later than 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 also 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 territory 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 37 and 38.

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

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

35. Evaluation Questions and Hypotheses. Consistent with attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the territory 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 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. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality Forum (NQF). Specifically, the evaluation must study outcomes, such as the status of pharmaceutical supply chains, beneficiary access to and utilization of pharmaceuticals (e.g., ability of beneficiaries to fill a prescription), expenditures on pharmaceuticals (utilizing applicable data elements from pharmacy claims, such as relevant National Drug Codes [NDCs], Medicaid paid amount, quantity dispensed, as well as dispensing pharmacy, as needed), and consider challenges encountered by pharmacies.

36. 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.

37. Interim Evaluation Report. The territory 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 renewal, the Interim Evaluation Report should be posted to the territory's website with the application for public comment.

a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.
b. For demonstration authority or any component within the demonstration that expires prior to the overall demonstration's expiration date, and depending on the timeline of the expiration/phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the territory.
c. If the territory is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the territory is not requesting an extension for a demonstration, an Interim Evaluation report is due one year prior to the end of the demonstration.
d. The territory must submit a revised Interim Evaluation Report within 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report. Once approved by CMS, the territory must post the final Evaluation Report to the territory's Medicaid website within 30 calendar days.
e. The Interim Evaluation Report must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

38. Summative Evaluation Report. The territory must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period

represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs, and in alignment with the approved Evaluation Design.

a. The territory must submit a revised Summative Evaluation Report 60 calendar days after receiving CMS's comments on the draft.
b. Once approved by CMS, the territory must post the final Summative Evaluation Report to the territory's Medicaid website within 30 calendar days.

39. 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 territory to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the territory's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

40. Territory Presentations for CMS. CMS reserves the right to request that the territory present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

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

42. Additional Publications and Presentations. For a period of 6 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 territory, contractor, or any other third party directly connected to the demonstration over which the territory 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 business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to territory or local government officials.

X. GENERAL FINANCIAL REQUIREMENTS

43. 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.

44. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The territory 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 2115 of the Territory Medicaid Manual. The territory will estimate matchable demonstration expenditures (total computable and federal share) and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and territory and local administration costs (ADM). CMS shall make federal funds available based upon the territory's estimate, as approved by CMS. Within 30 days after the end of each quarter, the territory 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 territory, and include the reconciling adjustment in the finalization of the grant award to the territory.

45. Sources of Non-Federal Share. As a condition of demonstration approval, the territory certifies that its funds that make up the non-federal share are obtained from permissible territory and/or local funds that, unless permitted by law, are not other federal funds. The territory 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 territory 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 territory 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.

46. Territory Certification of Funding Conditions. As a condition of demonstration approval, the territory certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

a. If units of territory or local government, including health care providers that are units of territory or local government, supply any funds used as non-federal share for expenditures under the demonstration, the territory must certify that territory 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 territory utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the territory 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 territory 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 territory 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 territory 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 territory. 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 territory and/or local governments, or third parties to return and/or redirect to the territory 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 Territory Medicaid Director or his/her designee certifies that all territory and/or local funds used as the territory'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.

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

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

48. Requirements for Health Care-Related Taxes and Provider Donations. As a condition of demonstration approval, the territory 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 territory 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 Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.

49. Territory Monitoring of Non-federal Share. If any payments under the demonstration are funded in whole or in part by a locality tax, then the territory must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 23. 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 territory, 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 territory will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

50. 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:

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.

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

52. Medicaid Expenditure Groups. Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to allotment neutrality, components of allotment 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	**Brief Description**
Prescribed Drug Coverage	Expenditures for prescribed drug coverage

53. Reporting Expenditures. The territory must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to allotment 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-00209/9). 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 must be reported for expenditures, as further detailed in the MEG Detail for Expenditure Reporting table below.

a. **Cost Settlements**. The territory 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 Territory.** The territory will report any premium contributions collected by the territory 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. In the annual calculation of expenditures subject to the allotment neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the territory's compliance with the budget neutrality limits.

c. **Administrative Costs.** The territory 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.

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

Table 3: Demonstration Years		
Demonstration Year 1	April 7, 2023 to March 31, 2024	12 months
Demonstration Year 2	April 1, 2024 to March 31, 2025	12 months
Demonstration Year 3	April 1, 2025 to March 31, 2026	12 months
Demonstration Year 4	April 1, 2026 to March 31, 2027	12 months
Demonstration Year 5	April 1, 2027 to March 31, 2028	12 months

XI. SCHEDULE OF DELIVERABLES

The territory is held to all reporting requirements as outlined in the STCs; this schedule of deliverables should serve only as a tool for informational purposes only.

Date – Specific	Deliverable	Section Reference
No later than 180 calendar days from approval date	Draft Evaluation Design	STC 33
No later than 60 days of receiving CMS comments	Revised Evaluation Design	STC 34

Date – Specific	Deliverable	Section Reference
One year prior to demonstration expiration or with extension application	Draft Interim Evaluation Report	STC 37(c)
No later than 60 days of receiving CMS comments	Revised Interim Evaluation Report	STC 37(d)
No later than 18 months after the expiration of this demonstration period	Draft Summative Evaluation Report	STC 38
No later than 60 days of receiving CMS comments	Revised Summative Evaluation Report	STC 38(a)
No later than 120 days after the end of the demonstration, and if no extension	Draft Close-Out Report	STC 28
No later than 30 days after receiving CMS comments	Revised Close-Out Report	STC 28(e)
Annually		
90 days after the end of each DY	Annual Monitoring Report (including Q4 monitoring information and budget neutrality)	STC 26
No later than 60 days of receiving CMS comments	Revised Annual Monitoring Report	STC 26

Attachment A
Developing the Evaluation Design

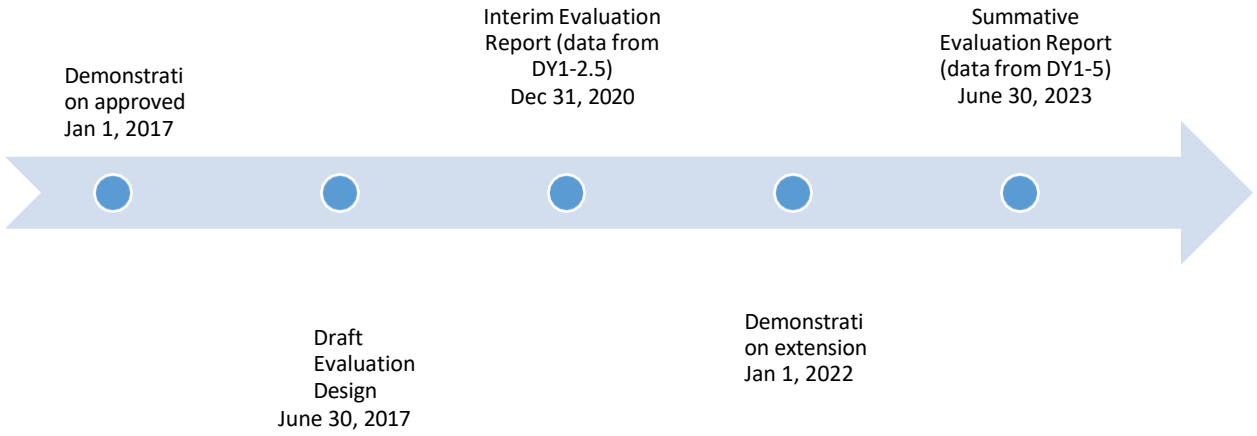
Introduction

Both territory and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states and territories that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future.

While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the territory's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5- year demonstration. In addition, the territory should be aware that section 1115 evaluation documents are public records. The territory is required to publish the Evaluation Design to the territory's website within 30 calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



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

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

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

The format for the Evaluation Design is as follows:

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

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

1. The issue/s that the territory is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the territory selected this course of action to address the issue/s (e.g., a narrative on why the territory submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

1. Identify the territory's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. Describe how the territory's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.
4. Include a Logic Model or Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the goal, the primary drivers that contribute directly to achieving the goal, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.
5. Include implementation evaluation questions to inform the territory's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

C. Methodology – In this section, the territory is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate. The evaluation approach should also consider principles of equitable evaluations, and involve partners—such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context—in developing an evaluation approach.

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

Specifically, this section establishes:

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

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

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

4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. The territory also should include information about how it will define the numerators and denominators. Furthermore, the territory should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the territory shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The territory also should incorporate benchmarking and comparisons to national and territory standards, where appropriate.

   Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality Forum. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

5. *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the territory plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.

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

7. *Other Additions* – The territory may provide any other information pertinent to the Evaluation Design for the demonstration.

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

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

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

CMS also recognizes that there may be certain instances where a territory cannot meet the rigor of an evaluation as expected by CMS. In these instances, the territory should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. For example, if a demonstration is long- standing, it may be difficult for the territory to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

1. When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).

2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes;
    b. No or minimal appeals and grievances;
    c. No territory issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans for the demonstration.

E. Attachments

1. **Independent Evaluator.** This includes a discussion of the territory'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 territory will assure no conflict of interest. Explain how the territory will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement signed by the independent evaluator.

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

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

Attachment B
Preparing the Interim and Summative Evaluation Reports

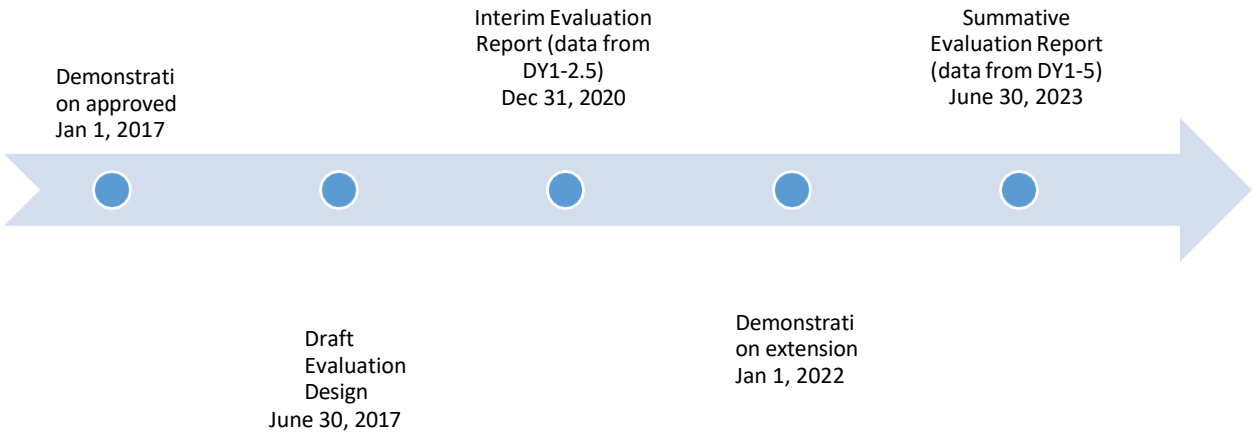
Introduction

Both territory and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for territories that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future.

While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the territory's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the territory 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 territory is required to publish the Interim and Summative Evaluation Reports to the territory's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports
All territories with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). The already-approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. However, the territory may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When submitting an application for extension, the Interim Evaluation Report should be posted on the territory's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.

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

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

Required Core Components of Interim and Summative Evaluation Reports
The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the territory would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. The format for the Interim and Summative Evaluation reports is as follows:

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

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

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

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

1. The issue/s that the territory is trying to address with its section 1115 demonstration and/or expenditure authorities, how the territory became aware of the issue, the potential magnitude of the issue, and why the territory selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, or expansion of, the demonstration.
5. For extensions, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the territory and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the territory should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

1. Identify the territory's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.
3. Describe how the territory's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
4. The inclusion of a Logic Model or Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

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

reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The territory also should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what was measured and how, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

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

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
    a. If the territory did not fully achieve its intended goals, why not?
    b. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

section, the territory 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 territory'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 territory with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the territory and national levels. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

I. Lessons Learned and Recommendations – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the territory should address the following questions:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other territories which may be interested in implementing a similar approach?

Department of Public Health and Social Services

Guam Alternative Drug Coverage Program Demonstration

Project No. 11-W-00427/9

Evaluation Design

Version 2.0

July 1, 2024

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A. General Background Information

On April 7, 2023, the Centers for Medicare & Medicaid Services (CMS) approved Guam's request for a new demonstration titled, "Guam Alternative Drug Coverage Program Demonstration" (Project Number 11-W-00427/9) (the "demonstration"), under which the territory would elect not to provide optional prescribed drug coverage consistent with section 1902(a)(54) of the Social Security Act (the Act), which requires compliance with requirements in section 1927, and instead cover prescribed drugs in the manner it is now under the state plan, using expenditure authority in section 1115(a)(2).

The Medicaid Drug Rebate Program (MDRP) helps offset the federal and state costs of most outpatient drugs prescribed to Medicaid patients by requiring drug manufacturers to enter into a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) and pay applicable rebates in exchange for state Medicaid payment and coverage of a manufacturer's covered outpatient drugs (CODs). Drug manufacturers are required under section 1927(b)(1)(A) of the Act and their rebate agreements to pay a rebate to states on CODs for which Medicaid payment was made under the state plan on a quarterly basis. All fifty states and the District of Columbia provide optional coverage of prescribed drugs (see section 1905(a)(12) of the Act), consistent with section 1902(a)(54), which requires such state plan coverage to be compliant with section 1927 of the Act.

On February 1, 2016, CMS published the "Medicaid Program; Covered Outpatient Drug" Final Rule (CMS- 2345-FC), in which CMS amended the regulatory definitions of "States" and "United States" to include the U.S. territories beginning April 1, 2017. This inclusion requires territories electing to provide optional prescribed drug coverage under their Medicaid state plan, as provided under section 1902(a)(54) to do so, in compliance with section 1927 of the Act. However, Guam may elect not to cover prescribed drugs under their State plan, and instead provide drug coverage under a demonstration project under section 1115, using expenditure authority in section 1115(a)(2).

On November 15, 2016, CMS published an interim final rule with comment period to delay the inclusion of the U.S. territories in the regulatory definitions of "States" and "United States" until April 1, 2020 (81 FR 80003) because interested territories would not be ready to implement the MDRP by April 2017. On November 21, 2019, this inclusion was delayed again until April 1, 2022, to provide interested territories more time when CMS issued the "Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in the Definitions of States and United States" Interim Final Rule with Comment Period (84 FR 64783). Finally, on November 19, 2021, the inclusion was delayed again until January 1, 2023 due to natural disasters and the COVID-19 public health emergency (86 FR 64819).

Effective January 1, 2023, Guam was thus required to provide optional prescribed drug coverage consistent with sections 1902(a)(54) and 1927 of the Act. Guam has elected to not provide coverage of prescribed drugs consistent with sections 1902(a)(54) and 1927 of the Act, and instead, has applied to use section 1115 demonstration expenditure authority to provide coverage of prescribed drugs. While Guam and CMS had a goal of approving the section 1115 demonstration application by January 1, 2023, which was the date by which the territories are

included as "states" for the purposes of the MDRP under requirements in sections 1902(a)(54) and 1927 of the Act, we were not able to approve the state's section 1115 demonstration application by that date. On December 28, 2022, CMS sent Guam a letter to indicate that CMS temporarily would not initiate any action under section 1904 of the Act for noncompliance with sections 1902(a)(54) and 1927 of the Act, nor would the agency take enforcement action for failure to comply with any of the regulations found at 42 CFR 447, Subpart I. This enforcement discretion is applicable only until the demonstration is approved, and Guam will no longer be required to comply with sections 1902(a)(54) and 1927 of the Act. This enforcement discretion extends only to Guam's participation in the MDRP and other coverage requirements of sections 1902(a)(54) and 1927.

The Guam Alternative Drug Coverage Program Demonstration will allow the territory to continue to provide prescribed drug coverage as it currently does under the state plan, instead of having to come into compliance with sections 1902(a)(54) and 1927 of the Act. Guam is seeking this waiver because participation in the MDRP, at this time, would contribute pressure to the territory's already burdened pharmacy providers.

Through this demonstration's period, Guam seeks to exhibit several demonstration goals that will inform the territory's Evaluation Design hypotheses, subject to CMS approval, as described in the STCs. The demonstration's goals include, but are not limited to, the following:

- Maintain the existing network capacity of on-island providers in order to provide adequate access to pharmacy services for program beneficiaries, and
- Allow time to properly assess potential benefits and adverse effects of providing coverage of prescribed drugs consistent with sections 1902(a)(54) and 1927 of the Act on Guam's pharmacy

As part of the demonstration's Monitoring and Evaluation Requirements, CMS requires Guam to conduct systematic monitoring and comprehensive evaluation of the demonstration per applicable CMS guidance and technical assistance.

This Evaluation Design will guide the federally required Final Report and is organized as follows:

- Section A. General Background Information
- Section B. Evaluation Questions and Hypotheses
- Section C. Methodology
- Section D. Methodological Limitations
- Section E. Preparing the Final Report

B. Evaluation Questions and Hypotheses

Figure 1 outlines the hypotheses and research questions (RQs) designed to understand the impact and challenges related to implementing the demonstration.

Figure 1. Hypotheses and Research Questions

Research Question (RQ)	
Hypothesis 1 – Participating in the Medicaid Drug Rebate Program (MDRP) negatively impacts On-Island Pharmacies in Guam.	
RQ 1.1	How does the participation of Guam Medicaid in the MDRP impact the stocking practices of On-Island Pharmacies in terms of the complete catalog of a participating manufacturer's COD?
RQ 1.2	In what ways does the requirement to carry the complete catalog of a participating manufacturer's COD influence the financial sustainability of On-Island Pharmacies within the Medicaid program?
RQ 1.3	How do On-Island Pharmacies perceive the feasibility and practicality of the MDRP mandate in terms of their ability to continue as viable providers within the Guam Medicaid program?
RQ 1.4	What adjustments or strategies could On-Island Pharmacies implement to overcome the challenges posed by the MDRP mandate and ensure the maintenance of sufficient inventory levels while remaining active providers in the Medicaid program?
RQ 1.5	How do the experiences of On-Island Pharmacies in other regions or jurisdictions compare to those in Guam, particularly in relation to the impact of MDRP participation on inventory management and Medicaid provider viability?
Hypothesis 2 –Guam's participation in the Medicaid Drug Rebate Program (MDRP) will incur higher costs and require more labor-intensive processes.	
RQ 2.1	What specific labor-intensive processes are required for Guam to comply with the MDRP, and how do these processes contribute to the overall operational burden?
RQ 2.2	How does the magnitude of potential rebate savings from the MDRP compare to the actual incurred costs, taking into account both direct and indirect expenses?
RQ 2.3	How do the experiences of other U.S. territories or states that have participated in the MDRP compare to Guam's situation in terms of cost implications and labor requirements?
RQ 2.4	What strategies or interventions could be implemented to mitigate the financial and operational challenges posed by Guam's participation in the MDRP?

C. Methodology

This section provides details on the proposed methodology for the Evaluation Design, including anticipated data sources, analytic methods, and evaluation reporting periods

Section C.1 summarizes the types of data that will be used to prepare the Final Report.

Section C.2 outlines Guam's proposed analytic methods for the Evaluation.

Section C.3 includes analytic tables that detail the evaluation approach for each hypothesis. The analytic tables outline the planned research questions, outcome measures, data sources, and analytic approaches.

1. Data Sources

The territory will gather information for the evaluation from both qualitative and quantitative data sources. This includes conducting interviews with pharmacies, stakeholders, and staff, as well as analyzing data from the territory and administrative records.

Document Review

To compare information with other U.S. territories or states participating in the Medicaid Drug Rebate Program (MDRP), the territory will conduct a comprehensive review of pertinent documentation, including federal and local reports.

Pharmacy Interview

The territory will conduct On-Island Pharmacy interviews to evaluate if the demonstration facilitated attaining the objective of MDRP. Guam will identify On-Island Pharmacies interview based on current provider enrollment in the Medicaid program.

Reports

Guam will access its MMIS system (PH/Pro) to generate provider reports by Pharmacy for the purposes of identifying expenditures by fiscal year.

Guam's Claims Data

The territory will leverage regularly collected and validated claims cost data, overseen by Guam's independent evaluator, to estimate the unforeseen impact of participating in the Medicaid Drug Rebate Program (MDRP) on On-Island Pharmacies.

2. Analytic Methods

As a condition for the approval of the 1115 demonstration, CMS mandated Guam to create a "simplified" Evaluation Design. This design avoids evaluations that might be excessively burdensome or impractical for data collection and analysis. Instead, it emphasizes the use of qualitative methods and descriptive statistics to comprehend the impact of participating in the Medicaid Drug Rebate Program (MDRP) on Guam's Medicaid program and On-Island Pharmacies.

Qualitative Analysis

The state will collect qualitative data through methods such as stakeholders and staff interviews that involves examining non-numeric information, such as narratives, descriptions, and opinions, to gain insights into the program's impact, challenges, and experiences.

Descriptive Analyses

For research questions summarizing and presenting key characteristics of the program, focusing on quantitative data.

3. Analytic Table

Figure 2 outlines the hypotheses, research questions, outcome measures, data sources, and analytic approaches for this Evaluation Design.

Figure 2. Analytic Table

Research Question	Outcome Measure(s)	Data Source(s)	Analytic Approach
Hypothesis 1 – Participating in the Medicaid Drug Rebate Program (MDRP) negatively impacts On-Island Pharmacies in Guam			
RQ 1.1: How does the participation of Guam Medicaid in the MDRP impact the stocking practices of On-Island Pharmacies in terms of the complete catalog of a participating manufacturer's COD?	Description of types of risk such as Inventory Turnover Rates, Product Availability, Inventory Costs, Ordering Patterns and Supply Chain Disruptions, as a result of MDRP participation.	Document Review	Qualitative Analysis
RQ 1.2: In what ways does the requirement to carry the complete catalog of a participating manufacturer's COD influence the financial sustainability of On- Island Pharmacies within the Medicaid program?	Financial sustainability in the program, as a result of MDRP participation.	Document Review	Quantitative/Qualitative Analysis
RQ 1.3: How do On-Island Pharmacies perceive the feasibility and practicality of the MDRP mandate in terms of their ability to continue as viable providers within the Guam Medicaid program?	Provider perception regarding the feasibility and practicality in the program, as a result of MDRP participation.	On-Island Pharmacies Interview	Qualitative analysis
RQ 1.4: What adjustments or strategies could On-Island Pharmacies implement to overcome the challenges posed by the MDRP mandate and ensure the maintenance of sufficient inventory levels while remaining active providers in the Medicaid program?	Description of the types of adjustments or strategies On-Island Pharmacies can implement to overcome the challenges, as a result of MDRP participation.	On-Island Pharmacies Interview	Qualitative analysis
RQ 1.5: How do the experiences of On-Island Pharmacies in other regions or jurisdictions compare to those in Guam, particularly in relation to the impact of MDRP participation on inventory management and Medicaid provider viability?	Cross-Regional comparative analysis conducting a comprehensive analysis to compare the experiences of On- Island Pharmacies in Guam with those in other regions or jurisdictions. Specifically, it focuses on the impact of MDRP participation on inventory management and Medicaid provider viability.	Pharmacies Interview and Document Review	Qualitative analysis
Hypothesis 2 –Guam's participation in the Medicaid Drug Rebate Program (MDRP) will incur higher costs and require more labor-intensive processes.			
RQ 2.1: What specific labor-intensive processes are required for Guam to comply with the MDRP, and how do these processes contribute to the overall operational burden?	Description to quantify and assess the specific labor-intensive processes required for Guam to comply with the Medicaid Drug Rebate Program (MDRP).	Guam Medicaid Staff Interview and Document Review	Qualitative/Quantitative Analysis
RQ 2.2: How does the magnitude of potential rebate savings from the MDRP compare to the actual incurred costs, taking into account both direct and indirect expenses?	New Cost Savings Margin to evaluate the net financial impact the Medicaid Drug Rebate Program (MDRP).	Document Review	Quantitative Analysis

RQ 2.3: How do the experiences of other U.S. territories or states that have participated in the MDRP compare to Guam's situation in terms of cost implications and labor requirements?	Description of cost implications and labor requirements with other U.S. territories or states that are participating in the Medicaid Drug Rebate Program (MDRP).	U.S. Territories and States Stakeholders Interviews and Document Review	Qualitative Analysis
RQ 2.4: What strategies or interventions could be implemented to mitigate the financial and operational challenges posed by Guam's participation in the MDRP?	Description of success of implemented strategies or interventions designed to mitigate the financial and operational challenges associated with Guam's participation in the Medicaid Drug Rebate Program (MDRP).	Guam Medicaid Staff Interview	Qualitative Analysis

D. Methodological Limitations

Given the simplified nature of this Evaluation Design, Guam does not anticipate encountering extensive methodological limitations. However, there are a few limitations the Guam may encounter, which are described below.

- **Qualitative Analysis.** The primary analytical approach employed in this Evaluation by Guam is qualitative analysis. While acknowledging some widely recognized limitations associated with qualitative analysis, such as challenges in demonstrating rigor, dependence on individual research skills, and potential bias, Guam is committed to mitigating these limitations. One strategy to address this is the creation of a scripted interview template to enhance consistency and structure in data collection.

- **Stakeholders Interviews.** The Territory intends to conduct interviews with pharmacies, stakeholders, and staff to assess Research Questions (RQs) 1.3 – 1.5 and RQs 2.1 – 2.4. The Territory will schedule interviews with On-Island Pharmacies that have been actively providing services for the Medicaid program.

E. Preparing the Final Report

Guam will submit to CMS a Final Report for this demonstration 18 months after either the expiration of the demonstration approval period or the end of the latest rating period covered under the state's approved expenditure authority, whichever comes later. The Final Report will include all applicable elements required by 42 CFR 431.428.