

Administrator
Washington, DC 20201

December 21, 2021

Dawn Stehle
Deputy Director for Health & Medicaid
Arkansas Department of Human Services
P.O. Box 1437
Slot S201
Little Rock, AR 72203-1437

Dear Dawn Stehle:

The Centers for Medicare & Medicaid Services (CMS) is approving Arkansas's request for a new section 1115(a) demonstration titled, "Arkansas Health and Opportunity for Me" (ARHOME) (Project Number 11-W-00379/6) (the "demonstration"), in accordance with section 1115(a) of the Social Security Act (the Act). Approval of this demonstration will enable Arkansas ("the state") to provide premium assistance to Medicaid beneficiaries with incomes up to and including 133 percent of the federal poverty level (FPL), who are eligible under the new adult group, to assist beneficiaries in the purchase of coverage from qualified health plans (QHPs) offered in the individual market through the Federally Facilitated Marketplace. Furthermore, under this demonstration, the state will have a waiver of retroactive eligibility, allowing the state to limit retroactive coverage to 30 days prior to an application rather than the 90 days required under the Medicaid statute. The premium assistance authority and the waiver of retroactive eligibility were both approved and implemented in Arkansas under previous section 1115 demonstration authority.

In addition, this ARHOME demonstration will provide Arkansas a time-limited authority, through December 31, 2022, to allow the state to charge monthly premiums of up to two percent of household income for beneficiaries with incomes above 100 percent of the FPL. Premiums and cost-sharing will be subject to an aggregate cap of no more than five percent of family monthly or quarterly income. Cost-sharing limitations described in 42 CFR 447.56(a) will be applied to all program beneficiaries. Copayment and coinsurance amounts will be consistent with federal requirements regarding Medicaid cost-sharing and with the state's approved state plan.

CMS has concluded that the approval of this demonstration with the authorities described above is likely to support the state in its continued Medicaid expansion efforts. Accordingly, we have determined that ARHOME as approved is likely to advance the objectives of Medicaid. The state will comprehensively monitor and evaluate the effectiveness of each ARHOME demonstration component per expectations detailed in the special terms and conditions (STCs), and as outlined further below.

Arkansas had received approval to implement premium requirements under its previous section 1115 demonstration, Arkansas Works (Project Number 11-W-00287/6). However, CMS has since determined that premiums can present a barrier to coverage, and therefore, charging beneficiaries premiums beyond those specifically permitted under the Medicaid statute are not likely to promote the objectives of Medicaid. This policy determination is informed by findings in recent research across different states with section 1115 demonstrations, which show that charging beneficiaries premiums beyond those authorized under the state plan resulted in shorter enrollment spells, and were associated with lower initial enrollment rates and increased obstacles to accessing care in several states. In Arkansas, findings from the state's evaluation of its expiring Arkansas Works demonstration indicate that after the demonstration was implemented in 2017, beneficiaries had shorter, but more frequent gaps in coverage —a finding that is consistent with premium policy research in other states.

Further, premium requirements can exacerbate health disparities, as historically under-resourced populations may be disproportionately affected by these policies. For example, research from several states shows that premium policies led to decreased enrollment and shorter enrollment spells for Black beneficiaries compared to their White counterparts, and beneficiaries with lower incomes compared to those with higher incomes.⁴ In other states, beneficiaries also reported misperceptions about the affordability of Medicaid coverage and concerns about their ability to make monthly contributions under section 1115 demonstrations with premium policies.⁵ This

https://deepblue.lib.umich.edu/bitstream/handle/2027.42/154759/UM_HMP_Eval_Domain_VVI_Report_7-30_Appendix_Included_629937_7.pdf?sequence=1&isAllowed=y; and Cliff, B.Q., Miller, S., Kullgren, J.T., Ayanian, J.Z., & Hirth, R. (2021). Adverse Selection in Medicaid: Evidence from Discontinuous Program Rules. National Bureau of Economic Research. Working Paper 28762. Retrieved from https://www.nber.org/papers/w28762.

Evaluation Domains V/VI. Retrieved from

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

² Bradley, K., Niedzwiecki, M., Maurer, K., Chao, S., Natzke, B., & Samra, M. (2020). Medicaid Section 1115

Demonstrations Summative Evaluation Report: Premium Assistance, Monthly Payments, and Beneficiary Engagement.

Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/alt-medicaid-exp-summ-eval-report.pdf; Social & Scientific Systems, Inc. and the Urban Institute. (2020). Federal Evaluation of Indiana's Healthy Indiana Plan — HIP 2.0. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-indiana-2020.pdf; University of Michigan Institute for Healthcare Policy & Innovation. (2018). Report on the Impact of Cost Sharing in the Healthy Michigan Plan: Healthy Michigan Plan

³ **Arkansas Department of Human Services.** (2021). Arkansas Works Interim Evaluation Report. Under CMS review.

⁴ University of Wisconsin-Madison Institute for Research on Poverty. (2019). Evaluation of Wisconsin's BadgerCare Plus Health Coverage for Parents & Caretaker Adults and for Childless Adults 2014 Waiver Provisions. Retrieved from https://www.irp.wisc.edu/wp/wp-content/uploads/2019/11/BC-2014-Waiver-Provisions-Final-Report-08302019.pdf; Finkelstein, A., Hendren, N., & Shepard, M. (2019). Subsidizing Health Insurance for Low-Income Adults: Evidence from Massachusetts. American Economic Review. 109(4): 1530-67. Retrieved from https://www.aeaweb.org/articles?id=10.1257/aer.20171455; and The Lewin Group, Inc. (2020). Healthy Indiana Plan Interim Evaluation Report Final.pdf. University of Michigan Institute for Healthcare Policy & Innovation. (2018). Report on the Healthy Michigan Voices 2016-17 Survey of Individuals No Longer Enrolled in the Healthy Michigan Plan. Retrieved from https://www.michigan.gov/documents/mdhhs/Domain_IV 2018 Eligible But Unenrolled Report 652005 7.pdf; and The Lewin Group Inc. (2017). Health Indiana Plan 2.0: POWER Account Contribution Assessment. Retrieved from <a href="https://www.medicaid.gov/sites/default/files/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-POWER-acct-cont-assesmnt-03312017.pdf.

beneficiary concern and confusion could contribute to lower initial and overall enrollment rates, and higher disenrollment rates.

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

This demonstration is effective upon approval, with an implementation date of January 1, 2022, through December 31, 2026, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached waiver and expenditure authorities, STCs, and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived under the demonstration.

Consistent with CMS requirements for section 1115 demonstrations, and as outlined in the ARHOME demonstration STCs, the state is required to conduct systematic monitoring of the various demonstration components, per applicable CMS guidance and technical assistance. Such monitoring will support tracking the state's progress on the demonstration components towards their corresponding milestones and/or goals.

Furthermore, in alignment with CMS guidance and STC requirements, Arkansas will develop, for the new demonstration, a rigorous Evaluation Design using robust data sources and analytic approaches that will support a comprehensive evaluation of the demonstration to assess whether the demonstration components are effective in producing the desired outcomes for its beneficiaries and providers, as well as for the state's overall Medicaid program. The demonstration evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact on beneficiary coverage, access to and quality of care, and health outcomes, as well as its effectiveness in achieving the policy goals and objectives.

The state must collect necessary data to accommodate CMS's enhanced monitoring and evaluation expectations to rigorously assess the effects of the waiver of retroactive eligibility on beneficiaries and providers. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. CMS underscores the importance

of the state undertaking a well-designed beneficiary survey to assess, for instance, beneficiary understanding of the various demonstration policy components, including the waiver of retroactive eligibility, beneficiary experiences with access to and quality of care, as well as changes in incidence of beneficiary medical debt.

The evaluation must also provide an assessment of the progression towards unwinding the state's premium requirement, and any potential lessons thereof. For the demonstration component authorizing premium assistance and cost-sharing reduction payments for beneficiaries in QHPs, the state will study outcomes such as beneficiary enrollment, take-up rates, access and health outcomes, and unmet need for care. In addition, the state must investigate cost outcomes for the demonstration as a whole, including but not limited to, provider uncompensated care costs.

Finally, the state's monitoring and evaluation should accommodate data collection and analyses stratified by key subpopulations of interest to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

Components of the Proposal Still Under Review

The ARHOME demonstration application included additional components still under review by CMS. CMS will continue to work on these items with the state, including state efforts to address social determinants of health and health equity through the proposed Life360 HOMEs.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, services, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

Sections 1115(d)(2)(A) and (C) of the Act further specify that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not necessarily provide written responses to all public comments (42 CFR 431.416(d)(2)).

The federal comment period was open from September 24, 2021 through October 24, 2021. A total of 13 comments were submitted, which CMS analyzed. Eleven of the 13 comments expressed concerns about cost sharing and the barriers that premiums and copayments may present for certain populations. CMS has taken into consideration such public comments and the body of available evidence on premium policies in section 1115 demonstrations in determining to approve a phase-out period for the authority to require beneficiaries to pay a share of the premium in the ARHOME demonstration by the end of the first year of the demonstration

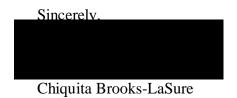
approval period. This timeline will allow the state to ensure adequate stakeholder communication and necessary system updates associated with the policy change. Eleven comments also voiced opposition to the state's proposal to reduce the period of retroactive coverage from 90 to 30 days. As indicated above, CMS will work with the state to continue collecting robust data to measure the effects of the waiver of retroactive eligibility on beneficiaries and providers. CMS continues its assessment of the merits of additional proposed policies within the ARHOME demonstration application.

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

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

Email: April.Wiley@cms.hhs.gov

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



Enclosures

cc: Michala Walker, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE AND MEDICAID SERVICES EXPENDITURE AUTHORITY

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me Section 1115

Demonstration

AWARDEE: Arkansas Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditure under section 1903 shall, for the period of this demonstration, January 1, 2022 through December 31, 2026, be regarded as expenditures under the state's Title XIX plan but are further limited by the special terms and conditions (STCs) for the Arkansas Health and Opportunity for Me (ARHOME) section 1115 demonstration.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the ARHOME section 1115 demonstration, including the granting of the waiver and expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Social Security Act.

The following expenditure authorities shall enable Arkansas to implement the ARHOME section 1115 demonstration:

 Premium Assistance and Cost Sharing Reduction Payments. Expenditures for part or all of the cost of private insurance premiums in the individual market, and for payments to reduce cost sharing under such coverage for certain beneficiaries as described in these STCs.

Requirements Not Applicable to the Expenditure Authority:

1. Cost Effectiveness

Section 1902(a)(4) and 42 CFR 435.1015(a)(4)

To the extent necessary to permit the state to offer, with respect to beneficiaries through qualified health plans, premium assistance and cost sharing reduction payments that are determined to be cost effective using state developed tests of cost effectiveness that differ from otherwise permissible tests for cost effectiveness as described in these STCs.

CENTERS FOR MEDICARE & MEDICAID SERVICES WAIVER LIST

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me Section 1115

Demonstration

AWARDEE: Arkansas Department of Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities, shall apply to the demonstration project effective January 1, 2022 through December 31, 2026. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of state plan requirements contained in section 1902 of the Act are granted for the ARHOME Section 1115 demonstration, subject to the STCs.

1. Freedom of Choice

Section 1902(a)(23)(A)

To the extent necessary to enable Arkansas to limit beneficiaries' freedom of choice among providers to the providers participating in the network of the beneficiary's Qualified Health Plan. No waiver of freedom of choice is authorized for family planning providers.

2. Payment to Providers

Section 1902(a)(13) and Section 1902(a)(30)

To the extent necessary to permit Arkansas to provide for payment to providers equal to the market-based rates determined by the Qualified Health Plan.

3. Prior Authorization

Section 1902(a)(54) insofar as it incorporates Section 1927(d)(5)

To permit Arkansas to require that requests for prior authorization for drugs be addressed within 72 hours, and for expedited review in exigent circumstances within 24 hours, rather than 24 hours for all circumstances as is currently required in their state policy. A 72- hour supply of the requested medication will be provided in the event of an emergency.

4. Premiums

Section 1902(a)(14) insofar as it incorporates Sections 1916 and 1916A

To the extent necessary to enable Arkansas to collect monthly premium payments, for beneficiaries with incomes above 100 up to and including 133 percent of the federal poverty

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level (FPL) as described in these STCs. This waiver authority will sunset on December 31, 2022.

5. Comparability

Section 1902(a)(10)(B)

To the extent necessary to enable the state to impose targeted cost sharing on beneficiaries as described in these STCs.

6. Retroactive Eligibility

Section 1902(a)(34)

To enable the state to not provide beneficiaries in table 1 retroactive eligibility but for 30 days prior to the date of the application for coverage under the demonstration.

CENTERS FOR MEDICARE AND MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me

AWARDEE: Arkansas Department of Human Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the ARHOME section 1115(a) Medicaid demonstration (hereinafter demonstration) to enable the Arkansas Department of Human Services (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. Enrollment into the demonstration is statewide and is approved through December 31, 2026.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. ARHOME Program Populations Affected
- V. ARHOME Premium Assistance Enrollment
- VI. Premium Assistance Delivery System
- VII. Benefits
- VIII. Premiums & Cost Sharing
- IX. Appeals
- X. General Reporting Requirements
- XI. General Financial Requirements
- XII. Monitoring Budget Neutrality
- XIII. Evaluation of the Demonstration

Attachments

Attachment A: Copayment Amounts

Attachment B: Developing the Evaluation Design

Attachment C: Preparing the Interim and Summative Evaluation Reports

Attachment D: Approved Implementation Plan (reserved) Attachment E: Approved Monitoring Protocol (reserved)

Attachment F: Approved Evaluation Design (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

Under the prior demonstration project in place in Arkansas, known as Arkansas Works, the state provided premium assistance to support the purchase by beneficiaries eligible under the adult group under the state plan of coverage from qualified health plans (QHPs) offered in the individual market through the Marketplace. Enrollment activities for the adult population began on October 1, 2013 for QHPs with eligibility effective January 1, 2014. Beginning in 2014, individuals eligible for coverage under the adult group are described at Section 1902(a)(10)(A)(i)(VIII) of the Social Security Act and were further specified in the state plan. The Arkansas Works demonstration terminated on December 31, 2021.

Effective January 1, 2022, the ARHOME demonstration will provide the premium assistance for the adult group.

Over the demonstration period, the state seeks to demonstrate several demonstration goals. The state's goals will inform the state's evaluation design hypotheses, subject to CMS approval, as described in these STCs. The state's goals include, and are not limited to the following:

- Providing continuity of coverage for individuals,
- Improving access to providers,
- Improving continuity of care across the continuum of coverage, and
- Furthering quality improvement and delivery system reform initiatives that are successful across population groups.

Arkansas proposes that the demonstration will provide integrated coverage for low-income Arkansans, leveraging the efficiencies and experience of the private market to improve continuity, access, and quality for ARHOME beneficiaries that should ultimately result in lowering the rate of growth in premiums across population groups. The state proposes that the demonstration will also drive structural health care system reform and more competitive premium pricing for all individuals purchasing coverage through the Marketplace by at least doubling the size of the population enrolling in QHPs offered through the Marketplace. The state proposes to demonstrate the following key features:

Continuity of coverage and care - The demonstration will allow qualifying households to stay enrolled in the same plan regardless of whether their coverage is subsidized through Medicaid, or Advanced Premium Tax Credits (APTC).

Support equalization of provider reimbursement and improve provider access - The demonstration will support equalization of provider reimbursement across payers, toward the end of expanding provider access and eliminating the need for providers to cross-subsidize. Arkansas Medicaid provides rates of reimbursement lower than Medicare or commercial payers, causing some providers to forego participation in the program and others to "cross subsidize" their Medicaid patients by charging more to private insurers.

Integration, efficiency, quality improvement and delivery system reform - Arkansas is

proposing taking an integrated and market-based approach to covering uninsured Arkansans. It is anticipated that QHPs will bring the experience of successful private sector models that can improve access to high quality services and lead delivery system reform.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes. The state must comply with all applicable federal statutes relating to non-discrimination in services and benefits in its programs and activities. 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 program 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 state must, within the timeframes specified in law, regulation, or written policy, 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 of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.
- 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 state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet if applicable, to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

- 5. State Plan Amendments. The state will not be required to submit title XIX or 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 plan governs.
- 6. Changes Subject to the Amendment Process. If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit reports required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
 - a. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;
 - b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - c. An up-to-date CHIP allotment neutrality worksheet, if necessary;
 - d. An explanation of the public process used by the state consistent with the requirements of STC 13; and

- e. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.
- **8. Extension of the Demonstration.** States that intend to request demonstration extensions under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in the statute. Otherwise, no later than 12 months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.
- **Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
 - a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft 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 plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan Amendment, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
 - b. **Transition and Phase-out Plan Requirements**. The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the program for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will take to notify affected beneficiaries, including community resources that are available.
 - c. **Transition and Phase-out Plan Approval.** The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must begin no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

- d. **Transition Phase-out Procedures.** The state must comply with all fair hearing and notice requirements found in 42 CFR part 431 subpart E. If a demonstration participant requests a fair hearing before the date of action, the state must maintain benefits as required in 42 CFR Section 431.230. In addition, the state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as required in 42 CFR Section 435.916 prior to determining a beneficiary is ineligible and terminating coverage. For individuals determined ineligible for Medicaid or CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e) and 457.350.
- 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. **Federal Financial Participation (FFP).** FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling beneficiaries.
- **10. Expiring Demonstration Authority.** For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a transition plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:
 - a. **Expiration Requirements.** The state must include, at a minimum, in its demonstration expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.
 - b. **Expiration Procedures**. The state must comply with all fair hearing and notice requirements found in 42 CFR part 431 subpart E. If a demonstration beneficiary requests a fair hearing before the date of action, the state must maintain benefits as required in 42 CFR Section 431.230. In addition, the state must conduct redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility prior to determining an individual is ineligible and terminating coverage as required in 42 CFR Section 435.916. For individuals determined ineligible for Medicaid or CHIP, the state must determine potential eligibility for other insurance

- affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e) and 457.350.
- c. **Federal Public Notice.** CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR Section 431.416 in order to solicit public input on the state's demonstration expiration plan. CMS will consider comments received during the 30-day period during its review and approval of the state's demonstration expiration plan. The state must obtain CMS approval of the demonstration expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than 14 days after CMS approval of the plan.
- d. **Federal Financial Participation (FFP).** FFP shall be limited to normal closeout costs associated with the expiration of the demonstration including services and administrative costs of disenrolling beneficiaries.
- withdrawal of Demonstration Authority. CMS reserves the right to amend and withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of Title XIX or title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the amendment and withdrawal, together with the effective date, and afford the State an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.
- **12. Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
- 13. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The state must comply with the State Notice Procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994). The state must also comply with the tribal consultation requirements in section 1902(a)(73) of the Act as amended by section 5006(e) of the American Recovery and Reinvestment Act (ARRA) of 2009, the implementing regulations for the Review and Approval Process for Section 1115 demonstrations at 42 CFR Section 431.408, and the tribal consultation requirements contained in the state's approved state plan, when any program changes to the demonstration are proposed by the state.
 - a. In states 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 state's approved

- Medicaid state plan if that process is specifically applicable to consulting with tribal governments on waivers (42 CFR Section 431.408(b)(2)).
- b. In states with federally recognized Indian tribes, Indian health programs, and/or Urban Indian organizations, the state is required to submit evidence to CMS regarding the solicitation of advice from these entities prior to submission of any demonstration proposal, amendment and/or renewal of this demonstration (42 CFR Section 431.408(b)(3)).
- c. The state must also comply with the Public Notice Procedures set forth in 42 CFR Section 447.205 for changes in statewide methods and standards for setting payment rates.
- **14. Federal Financial Participation (FFP).** No federal matching for state 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 late, as expressly state 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 organizations (MCOs), and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 16. Common Rule Exemption. The state shall 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 procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ARKANSAS HEALTH AND OPPORTUNITY FOR ME PROGRAM POPULATIONS AFFECTED

The state will use this demonstration to ensure coverage for ARHOME eligible beneficiaries provided primarily through QHPs offered in the individual market instead of the fee-for-service (FFS) delivery system that serves the traditional Medicaid population. The state will provide premium assistance to aid ARHOME beneficiaries in enrolling in coverage through QHPs in the Marketplace.

17. Populations Affected by the ARHOME Demonstration. Except as described in STCs 18 and 19, the ARHOME demonstration affects adults aged 19 through 64 eligible under the state plan under section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR Section 435.119 (the adult group). Eligibility and coverage for ARHOME beneficiaries is subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan, except as expressly waived in this demonstration and as described in these STCs. Any Medicaid state plan amendments to the adult group will apply to this demonstration.

Table 1. Eligibility Groups

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Medicaid State Plan Mandatory Groups	Federal Poverty Level	Funding Stream	Expenditure and Eligibility Group Reporting		
Adult Group	Adults up to and including 133 percent of the FPL who meet the other criteria specified in Section 1902(a)(10)(A)(i)(VIII) of the Social Security Act	Title XIX	Adult Group		

- 18. Medically Frail Individuals. Arkansas has instituted a process to determine whether a beneficiary is medically frail. The process is described in the Alternative Benefit state plan. Beneficiaries excluded from enrolling in QHPs through the ARHOME as a result of a determination of medical frailty as defined in the ABP state plan amendment (SPA) will have the option of receiving direct coverage through the state of either the same ABP offered to the beneficiaries or an ABP that includes all benefits otherwise available under the approved Medicaid state plan (the standard Medicaid benefit package). Direct coverage will be provided through a FFS system or the PASSE program.
- Indian or Alaska Native (AI/AN) will not be required to enroll in QHPs in this demonstration, but can choose to opt into a QHP. New applicants will be subject to provisions of STC 17 and coverage will begin 30 days prior to the date an application is submitted for coverage. Beneficiaries who are AI/AN and who have not opted into a QHP will receive the ABP through a FFS system. An AI/AN beneficiary will be able to access covered benefits through Indian Health Service (IHS), Tribal or Urban Indian Organization (collectively, I/T/U) facilities funded through the IHS. Under the Indian Health Care Improvement Act (IHCIA), I/T/U facilities are entitled to payment notwithstanding network restrictions.
- **20. Retroactive Eligibility.** The state will only provide coverage effective thirty (30) days prior to the date a beneficiary submits an application. All other regulations governing retroactive eligibility are otherwise consistent with the requirements of 42 CFR 435.915, for coverage for beneficiaries in table 1.

V. ARKANSAS HEALTH AND OPPORTUNITY FOR ME PREMIUM ASSISTANCE ENROLLMENT

- **21. ARHOME.** For ARHOME beneficiaries, except as noted in STCs 18 and 19 enrollment in a QHP is a condition of receiving benefits.
- **QHP Selection.** The QHPs in which ARHOME beneficiaries enroll are certified through the Arkansas Insurance Department's QHP certification process. The QHPs available for selection by the beneficiary are determined by the Medicaid agency.
- **23. Auto-assignment.** In the event that a beneficiary is determined eligible for coverage through the ARHOME QHP premium assistance program, but does not select a plan, the state will auto-assign the beneficiary to one of the available QHPs in the beneficiary's rating area. Beneficiaries who are auto-assigned will be notified of their assignment, and the effective date of QHP enrollment, and will be given a thirty-day period from the date of enrollment to request enrollment in another plan.
- **24. Distribution of Members Auto-assigned.** ARHOME QHP auto-assignments will be distributed among QHP issuers in good standing with the Arkansas Insurance Department offering certified silver-level QHPs certified by the Arkansas Insurance Department.
- **25. Changes to Auto-assignment Methodology.** The state will advise CMS prior to implementing a change to the auto-assignment methodology.
- **26. Disenrollment.** Beneficiaries may be disenrolled from the demonstration if they are determined to be medically frail after they were previously determined eligible.

VI. PREMIUM ASSISTANCE DELIVERY SYSTEM

- 27. Memorandum of Understanding for QHP Premium Assistance. The Arkansas Department of Human Services and the Arkansas Insurance Department have entered into a memorandum of understanding (MOU) with each QHP that enrolls beneficiaries. Areas to be addressed in the MOU include, but are not limited to:
 - a. Enrollment of beneficiaries in populations covered by the demonstration;
 - b. Payment of premiums and cost sharing reductions, including the process for collecting and tracking beneficiary premiums and cost sharing, and ceasing premium collections;
 - c. Reporting and data requirements necessary to monitor and evaluate the ARHOME including those referenced in STCs 78 and 79, ensuring beneficiary access to EPSDT and other covered benefits through the QHP;

- d. Requirement for QHPs to provide, consistent with federal and state laws, claims and other data as requested to support state and federal evaluations, including any corresponding state arrangements needed to disclose and share data, as required by 42 CFR 431.420(f)(2), to CMS or CMS' evaluation contractors.
- e. Noticing requirements; and
- f. Audit rights.
- **28. Qualified Health Plans.** The state will use premium assistance to support the purchase of coverage for ARHOME beneficiaries through Marketplace QHPs.
- **29. Choice of QHPs.** Each ARHOME beneficiary required to enroll in a QHP will have the option to choose between at least two silver plans covering only Essential Health Benefits that are offered in the individual market through the Marketplace. The state will pay the full cost of QHP premiums, less the cost of the premium paid by the beneficiary in accordance with these STCs.
 - a. ARHOME beneficiaries will be able to choose from at least two silver plans covering only Essential Health Benefits that are in each rating area of the State.
 - b. ARHOME beneficiaries will be permitted to choose among all silver plans covering only Essential Health Benefits that are offered in their geographic area and that meet the purchasing guidelines established by the State in that year, and thus all ARHOME beneficiaries will have a choice of at least two OHPs.
 - c. The state will comply with Essential Community Provider network requirements, as part of the QHP certification process.
 - d. ARHOME beneficiaries will have access to the same networks as other beneficiaries enrolling in QHPs through the individual Marketplace.
- **30.** Coverage Prior to Enrollment in a QHP. The state will provide coverage through FFS Medicaid from the date a beneficiary is determined eligible until the beneficiary's enrollment in the QHP becomes effective.
 - a. For beneficiaries who enroll in a QHP (whether by selecting the QHP or through auto-assignment) between the first and fifteenth day of a month, QHP coverage will become effective as of the first day of the month following QHP enrollment.
 - b. For beneficiaries who enroll in a QHP (whether by selecting the QHP or through auto-assignment) between the sixteenth and last day of a month,

QHP coverage will become effective as of the first day of the second month following QHP selection (or auto-assignment).

- **31. Family Planning.** If family planning services are accessed at a facility that the QHP considers to be an out-of-network provider, the state's FFS Medicaid program will cover those services.
- **32. Non-Emergency Medical Transportation (NEMT).** Non-emergency medical transport services will be provided through the state's FFS Medicaid program. See STC 39 for further discussion of non-emergency medical transport services.
- **33.** Access to Federally Qualified Health Centers and Rural Health Centers. ARHOME beneficiaries will have access to at least one QHP in each service area that contracts with at least one FQHC and RHC.

VII. BENEFITS

- **34. ARHOME Benefits.** Beneficiaries affected by this demonstration will receive benefits as set forth in section 1905(y)(2)(B) of the Act and codified at 42 CFR Section 433.204(a)(2). These benefits are described in the Medicaid state plan.
- **35. Alternative Benefit Plan.** The benefits provided under an alternative benefit plan for the adult group are reflected in the State ABP state plan.
- **Medicaid Wrap Benefits.** The State will provide through its fee-for-service system wrap-around benefits that are required for the ABP but not covered by QHPs. These benefits include NEMT and Early Periodic Screening Diagnosis and Treatment (EPSDT) services for beneficiaries participating in the demonstration who are under age 21.
- 37. Access to Wrap Around Benefits. In addition to receiving an insurance card from the applicable QHP issuer, ARHOME beneficiaries will have a Medicaid CIN through which providers may bill Medicaid for wrap-around benefits. The notice containing the CIN will include information about which services ARHOME beneficiaries may receive through FFS Medicaid and how to access those services. This information is also posted on Arkansas Department of Human Service's Medicaid website and will be provided through information at the Department of Human Service's call centers and through QHP issuers.
- **38.** Early and Periodic Screening, Diagnosis, and Treatment. The State must fulfill its responsibilities for coverage, outreach, and assistance with respect to EPSDT services that are described in the requirements of sections 1905(a)(4)(b) (services), 1902(a)(43) (administrative requirements), and 1905(r) (definitions).

39. Access to Non-Emergency Medical Transportation. The state will establish prior authorization for NEMT in the ABP. Beneficiaries served by IHS or Tribal facilities and medically frail beneficiaries will be exempt from such requirements.

VIII. PREMIUMS & COST SHARING

- **40. Premiums & Cost Sharing.** Cost sharing for ARHOME beneficiaries must be in compliance with federal requirements that are set forth in statute, regulation and policies, including requirements and limitations from cost sharing set forth in 42 CFR Section 447.50-57. Waiver authority for premiums will sunset on December 31, 2022.
- **41. Premiums & Cost Sharing Parameters for the ARHOME Program.** With the approval of this demonstration:
 - a. Beneficiaries up to and including 100 percent of the FPL will have no cost sharing.
 - b. Beneficiaries above 100 percent of the FPL will have cost sharing consistent with Medicaid requirements.
 - c. Beneficiaries above 100 percent of the FPL will be required to pay monthly premiums of up to 2 percent of household income.
 - d. Premiums and cost sharing will be subject to an aggregate cap of no more than 5 percent of family quarterly income.
 - e. Cost sharing requirements and/or limitations described in 42 CFR 447.50-57 will be applied to all program beneficiaries.
 - f. Copayment and coinsurance amounts will be consistent with federal requirements regarding Medicaid cost sharing and with the state's approved state plan; copayment and coinsurance amounts are listed in Attachment A.
- 42. Payment Process for Payment of Cost Sharing Reduction to QHPs. Agreements with QHP issuers may provide for advance monthly cost-sharing reduction (CSR) payments to cover the costs associated with the reduced cost sharing for ARHOME beneficiaries. Such payments will be subject to reconciliation at the conclusion of the benefit year based on actual expenditures by the QHP for cost sharing reduction. If a QHP issuer's actuary determines during the benefit year that the estimated advance CSR payments are significantly different than the CSR payments the QHP issuer will be entitled to during reconciliation, the QHP issuer may ask Arkansas' Department of Human Services to adjust the advance payments. Arkansas' reconciliation process will follow 45 CFR Section 156.430 to the extent applicable.

43. Grace Period/Debt Collection. The grace period/debt collection process will be consistent with federal requirements regarding Medicaid cost sharing, including requirements at 42 CFR 447.55(b). ARHOME beneficiaries will have two months from the date of the payment invoice to make the required monthly premium contribution. Arkansas and/or its vendor may attempt to collect unpaid premiums and the related debt from beneficiaries, but may not report the debt to credit reporting agencies, place a lien on an individual's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the individual's earnings for beneficiaries at any income level. The state and/or its vendor may not "sell" the debt for collection by a third party. The waiver authorizing this policy will sunset on December 31, 2022.

IX. FAIR HEARINGS

44. The state 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 state must ensure compliance with all federal and state requirements related to beneficiary fair hearing rights, including compliance with the approved state plan.

X. GENERAL REPORTING REQUIREMENTS

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

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an

- interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

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

- **47. Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than one hundred fifty (150) calendar days after the effective date of the demonstration. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments, if any. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS's template. Any proposed deviations from CMS's template should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as described in STC 48b below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and metrics calculations covering reporting topics, including but not limited to, enrollment, access to care, quality of care and health outcomes, enrollment by premium payment status, and unpaid medical bills at application. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 48a below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.
- **48. Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would

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

- a. Operational Updates Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. <u>Performance Metrics</u> Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress with the demonstration components towards their corresponding milestones and/or goals, and must cover all key policies under this demonstration. For example, these metrics will cover measures of enrollment, unpaid medical bills at application, and policy-specific measures of access to care, utilization of services, quality of care and health outcomes.

Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals.

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

c. <u>Budget Neutrality and Financial Reporting Requirements</u> – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality

- workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
- d. <u>Evaluation Activities and Interim Findings</u> Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
- demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS will withdraw an authority, as described in STC 11, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- **Close-Out Report**. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.
 - a. The draft Close-Out Report must comply with the most current guidance from CMS.
 - b. The state will present to and participate in a discussion with CMS on the Close-Out report.
 - c. The state must take into consideration CMS's comments for incorporation into the final Close-Out report.
 - d. The final Close-Out report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.
 - e. A delay in submitting the draft or final version of the Close-Out report may subject the state to penalties described in STC 45.

- 51. Monitoring Calls. CMS will convene periodic conference calls with the state.
 - a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
 - b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
 - c. The state and CMS will jointly develop the agenda for the calls.
- **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Annual Monitoring Report associated with the year in which the forum was held.
- **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined in these STCs.
- **54. Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate 1115 waiver reporting and analytics functions, the state will work with CMS to:
 - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to are provided; and
 - c. Submit deliverables to the appropriate system as directed by CMS.

XI. GENERAL FINANCIAL REQUIREMENTS

This project is approved for Title XIX expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

55. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered 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.¹
- **56. Unallowable Expenditures.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any room and board costs for home and community-based services.
- **57. Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- **58. Quarterly Expenditure Reports.** The state must provide quarterly Title XIX expenditure reports using Form CMS-64, to separately report total Title XIX expenditures for services provided through this demonstration under section 1115 authority. CMS shall provide Title XIX FFP for allowable demonstration expenditures, only as long as they do not exceed the pre-defined limits on the costs incurred, as specified in section XII of the STCs.
- **59. Reporting Expenditures under the Demonstration.** The following describes the reporting of expenditures subject to the budget neutrality agreement:
 - **Tracking Expenditures.** In order to track expenditures under this a. demonstration, the State will report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 and Section 2115 of the SMM. All demonstration expenditures subject to the budget neutrality limit must be reported each quarter on separate forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made). For monitoring purposes, and consistent with annual CSR reconciliation, cost settlements must be recorded on the appropriate prior period adjustment schedules (forms CMS-64.9 Waiver) for the summary line 10B, in lieu of lines 9 or lOC. For any other cost settlements (i.e., those not attributable to this demonstration), the adjustments should be reported on lines 9 or 10C, as instructed in the SMM. The term, "expenditures subject to the budget neutrality limit," is defined below in STC 67.

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¹ For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

- b. **Cost Settlements.** For monitoring purposes, and consistent with annual CSR reconciliation, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (forms CMS-64.9P Waiver) for the summary sheet sine 10B, in lieu of lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the SMM.
- c. **Premium and Cost Sharing Contributions.** Premiums and other applicable cost sharing contributions from beneficiaries that are collected by the state from beneficiaries under the demonstration must be reported to CMS each quarter on Form CMS-64 summary sheet line 9.D, columns A and B. In order to assure that these collections are properly credited to the demonstration, premium and cost-sharing collections (both total computable and federal share) should also be reported separately by DY on the form CMS-64 narrative. In the calculation of expenditures subject to the budget neutrality expenditure limit, premium collections applicable to demonstration populations will be offset against expenditures. These section 1115 premium collections will be included as a manual adjustment (decrease) to the demonstration's actual expenditures on a quarterly basis.
- d. **Pharmacy Rebates.** Pharmacy rebates are not considered here as this program is not eligible.
- e. **Use of Waiver Forms for Medicaid.** For each DY, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver shall be submitted reporting expenditures for individuals enrolled in the demonstration, subject to the budget neutrality limit (Section XII of these STCs). The State must complete separate waiver forms for the following eligibility groups/waiver names:
 - i. "Adult Group"
- f. The first Demonstration Year (DY1) will begin on January 1, 2022. Subsequent DYs will be defined as follows:

Table 2 Demonstration Populations

Demonstration Year 1 (DY1)	January 1, 2022	12 months
Demonstration Year 2 (DY2)	January 1, 2023	12 months
Demonstration Year 3 (DY3)	January 1, 2024	12 months
Demonstration Year 4 (DY4)	January 1, 2025	12 months
Demonstration Year 5 (DY5)	January 1, 2026	12 months

- **Administrative Costs.** Administrative costs will not be included in the budget neutrality limit, but the State must separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name Local Administration Costs ("ADM").
- 61. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements resulting from annual reconciliation) must be made within 2 years after the calendar quarter in which the State made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the State must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 and Form CMS-21 in order to properly account for these expenditures in determining budget neutrality.
- **Reporting Member Months.** The following describes the reporting of member months for demonstration populations:
 - a. For the purpose of calculating the budget neutrality expenditure cap and for other purposes, the State must provide to CMS, as part of the quarterly report required under STC 48, the actual number of eligible member months for the demonstration populations defined in STC 17. The State must submit a statement accompanying the quarterly report, which certifies the accuracy of this information. To permit full recognition of "in-process" eligibility, reported counts of member months may be subject to revisions after the end of each quarter. Member month counts may be revised retrospectively as needed.
 - b. The term "eligible member months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months to the total, for a total of four eligible member months.
- 63. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure cap and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS will make federal funds available based upon the State's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the State must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. The CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

- **64. Extent of FFP for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined below, subject to the limits described in STC 59:
 - a. Administrative costs, including those associated with the administration of the demonstration.
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved State plan.
 - c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability or CMS payment adjustments.
- 65. Sources of Non-Federal Share. The state must certify that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds shall not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
 - a. CMS may review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
 - b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.
 - c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid State plan.
- **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
 - a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.
 - b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for Title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the State would

- identify those costs eligible under Title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the State utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of Title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the State as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes including health care provider-related taxes fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 67. Limit on Title XIX Funding. The state shall be subject to a limit on the amount of federal Title XIX funding that the State may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STC 62, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.
- **68. Risk.** The state will be at risk for the per capita cost (as determined by the method described below) for demonstration populations as defined in STC 64, but not at risk for the number of beneficiaries in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs of current eligibles, CMS assures that the

demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

- **69. Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.
- 70. Calculation of the Budget Neutrality Limit. For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, as described in STC 71 below. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by the Composite Federal Share, which is defined in STC 65 below.
- 71. Demonstration Populations Used to Calculate the Budget Neutrality Limit. For each DY, separate annual budget limits of demonstration service expenditures will be calculated as the product of the trended monthly per person cost times the actual number of eligible/member months as reported to CMS by the state under the guidelines set forth in STC 73. The trend rates and per capita cost estimates for each Mandatory Enrollment Group (MEG) for each year of the demonstration are listed in the table below.

Table 3 Per Capita Cost Estimate

MEG	TREND	DY 1 - PMPM	DY 2 - PMPM	DY 3 - PMPM	DY 4 - PMPM	DY 5 - PMPM
Adult Group	5.8%	\$717.25	\$758.85	\$802.86	\$849.43	\$898.69

- a. If the state's experience of the take up rate for the adult group and other factors that affect the costs of this population indicates that the PMPM limit described above in paragraph (a) may underestimate the actual costs of medical assistance for the adult group, the state may submit an adjustment to paragraph (a), along with detailed expenditure data to justify this, for CMS review without submitting an amendment pursuant to STC 7. Adjustments to the PMPM limit for a demonstration year must be submitted to CMS by no later than October 1 of the demonstration year for which the adjustment would take effect.
- b. The budget neutrality cap is calculated by taking the PMPM cost projection for the above group in each DY, times the number of eligible member months for that group and DY, and adding the products together across DYs. The federal share of the budget neutrality cap is obtained by multiplying total computable budget neutrality cap by the federal share.
- c. The state will not be allowed to obtain budget neutrality "savings" from this population.
- 72. Composite Federal Share Ratio. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported through the MBES/CBES and summarized on Schedule C (with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections) by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the extension approval period (see STC 9), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed upon method.
- **73. Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit:
 - a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
 - b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration.

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

- c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.
- **74. Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality over the life of the demonstration rather than on an annual basis. However, if the state's expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state must submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

Table 4 Cap Thresholds

Year	Cumulative target definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0%
DY 2	Cumulative budget neutrality limit plus:	1.5%
DY 3	Cumulative budget neutrality limit plus:	1.0%
DY 4	Cumulative budget neutrality limit plus:	0.5%
DY 5	Cumulative budget neutrality limit plus:	0.0%

75. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2022 to December 31, 2026. If at the end of the demonstration period the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

76. Impermissible DSH, Taxes or Donations. CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if CMS determines that any health care-related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is in violation of the provider donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

XIII. EVALUATION OF THE DEMONSTRATION

- 77. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 45.
- 78. Independent Evaluator. Upon approval of the demonstration, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- **79. Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design for ARHOME no later than one hundred eighty (180) days after the approval of the demonstration. The draft Evaluation Design also must include a timeline for key evaluation activities, including evaluation deliverables, as outlined in STCs 80 and 81.

The draft Evaluation Design must be developed in accordance with:

a. Attachment B (Developing the Evaluation Design) of these STCs;

- b. Any applicable CMS technical assistance on applying robust evaluation approaches, including establishing appropriate comparison groups and assuring casual inferences in demonstration evaluations; and
- c. All applicable Evaluation Design guidance, including guidance about the waiver of retroactive eligibility and overall demonstration sustainability.
- Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS's comments. Upon CMS approval of the Evaluation Design, the document will be included as Attachment F of these STCs. Per 42 CFR 431.424(c), the state will publish to its website the approved Evaluation Design within thirty (30) calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.
- 81. **Evaluation Questions and Hypotheses.** Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. For example, hypotheses for the demonstration's program component authorizing premium assistance and cost-sharing reduction payments for beneficiaries in QHPs must focus on outcomes such as beneficiary enrollment, takeup rates, access and health outcomes, and unmet need for care. Hypotheses for the waiver of retroactive eligibility must relate to (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, enrollment when people are healthy, and health status (as a result of greater enrollment continuity) and financial status. The state must also include descriptive research questions and hypotheses related to trends in enrollment, disenrollment, and reenrollment, beneficiary outreach, and challenges encountered during the premium policy phase out process. The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and uncompensated care costs. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses together to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program. The evaluation should accommodate data collection and analyses stratified by key subpopulations of interest to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF). CMS underscores the importance of the state undertaking a well-designed beneficiary survey to assess, for instance, beneficiary understanding of the various demonstration policy components, including the waiver of retroactive eligibility, beneficiary experiences with access to and quality of care, as well as changes in incidence of beneficiary medical debt.

- **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.
- 83. Interim Evaluation Report. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the Interim Evaluation Report should be posted to the state's website with the application for public comment.
 - a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design. In this report, the state must also describe its findings related unwinding the state's premium policies, and any potential lessons thereof.
 - b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. If the state made changes to the demonstration in its application for extension, the research questions, hypotheses and how the design was adapted should be included. If the state is not requesting an extension for the demonstration, an Interim Evaluation Report is due one (1) year prior

- to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit a revised Interim Evaluation Report sixty (60) days after receiving CMS's comments on the draft Interim Evaluation Report.
 Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website.
- e. The Interim Evaluation Report must comply with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs.
- **84. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.
 - a. Unless otherwise agreed upon in writing by CMS, the state must submit the revised Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
 - b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within thirty (30) calendar days.
- 85. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A 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.
- **86. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

- **Public Access.** The State shall post the final documents (e.g. Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the State's Medicaid website within thirty (30) calendar days of approval by CMS.
- 88. Additional Publications and Presentations. For a period of twelve (12) months following CMS's approval of deliverables, CMS will be notified prior to presentation of these reports or their findings, including in related publications (e.g., journal articles), by the state, contractor or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles and other documents, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

ATTACHMENT A Copayment Amounts²

Copayment	
	Cost Sharing for
	Beneficiaries with
	Incomes >100%
General Service Description	FPL
Behavioral Health - Inpatient	\$60
Behavioral Health - Outpatient	\$4
Behavioral Health -	\$4
Professional	
Durable Medical Equipment	\$4
Emergency Room Services	-
FQHC	\$8
Inpatient	\$60
Lab and Radiology	-
Skilled Nursing Facility	\$20
Other	\$4
Other Medical Professionals	\$4
Outpatient Facility	-
Primary Care Physician	\$8
Specialty Physician	\$10
Pharmacy - Generics	\$4
Pharmacy - Preferred Brand	\$4
Drugs	
Pharmacy - Non-Preferred	\$8
Brand Drugs, including	
specialty drugs	

No copayments for individuals at or below 100% FPL.

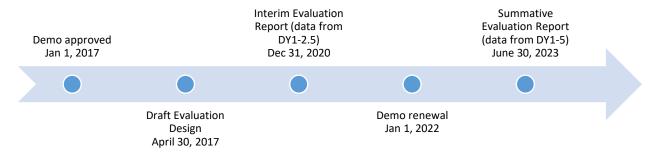
ATTACHMENT B Developing the Evaluation Design

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (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-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. The roadmap begins with the stated goals for the demonstration, followed by the measurable

evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

- A. General Background Information;
- **B.** Evaluation Questions and Hypotheses;
- **C.** Methodology;
- **D.** Methodological Limitations;
- **E.** Attachments.
- **A. General Background Information** In this section, the state should include basic information about the demonstration, such as:
 - 1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
 - 2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
 - 3. A description of the population groups impacted by the demonstration.
 - 4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
 - 5. For renewals, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

- 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
- 2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
- 3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.

- 4. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.
- **C. Methodology** In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate.

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

- 1. *Methodological Design* Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
- 2. Target and Comparison Populations Describe the characteristics of the target and comparison populations, incorporating the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally, discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3. Evaluation Period Describe the time periods for which data will be included.
- 4. Evaluation Measures List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate. The state also should include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning",

defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology.

- 5. Data Sources Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
- 6. *Analytic Methods* This section includes the details of the selected quantitative and/or qualitative analysis measures that will adequately assess the effectiveness of the demonstration. This section should:
 - a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-indifferences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.
- 7. *Other Additions* The state may provide any other information pertinent to the Evaluation Design for the demonstration.

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

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

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

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

1. When the demonstration is:

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

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

E. Attachments

- 1. **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement signed by the independent evaluator.
- 2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated costs, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.
- 3. **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The final Evaluation Design shall incorporate milestones for the development and submission of the Interim and Summative Evaluation Reports. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation Report is due.

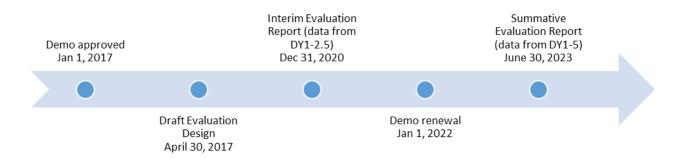
Attachment C: Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

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

the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

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

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

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

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

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

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results:
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and,
- J. Attachment(s).

- **A.** Executive Summary A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- **B.** General Background Information about the Demonstration In this section, the state should include basic information about the demonstration, such as:
 - 1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
 - 3. A description of the population groups impacted by the demonstration.
 - 4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration.
 - 5. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).
- **C.** Evaluation Questions and Hypotheses In this section, the state should:
 - 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
 - 2. Address how the research questions / hypotheses of this demonstration promote the objectives of titles XIX and XXI.
 - 3. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
 - 4. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
- **D. Methodology** In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration, consistent with the approved Evaluation Design. The Evaluation Design should also be included as an attachment to the

report. The focus is on showing that the evaluation builds upon other published research, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how, 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. *Target and Comparison Populations* Describe the target and comparison populations, describing inclusion and exclusion criteria.
- 3. Evaluation Period Describe the time periods for which data will be collected.
- 4. *Evaluation Measures* List the measures used to evaluate the demonstration and their respective measure stewards.
- 5. *Data Sources* Explain from where the data were obtained, and efforts to validate and clean the data.
- 6. *Analytic Methods* Identify specific statistical testing which was undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
- 7. *Other Additions* The state may provide any other information pertinent to the evaluation of the demonstration.
- **E. Methodological Limitations** This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.
- **F. Results** In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.

- **G.** Conclusions In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:
 - 1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
 - 2. If the state did not fully achieve its intended goals, why not?
 - 3. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?
- H. Interpretations, Policy Implications and Interactions with Other State Initiatives In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long-range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.
- I. Lessons Learned and Recommendations This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
 - 1. What lessons were learned as a result of the demonstration?
 - 2. What would you recommend to other states which may be interested in implementing a similar approach?

ATTACHMENT D: IMPLEMENTATION PLAN (RESERVED)

ATTACHMENT E: APPROVED MONITORING PROTOCOL (RESERVED))

ATTACHMENT F: APPROVED EVALUATION DESIGN (RESERVED)