



December 2, 2024

Brian Meyer
Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive, Mail Stop 8
Tallahassee, FL 32308

Dear Deputy Secretary Meyer:

The Centers for Medicare & Medicaid Services (CMS) is approving Florida's section 1115(a) demonstration titled, "Florida Children's Health Insurance Program Eligibility Extension" (Project Number 21-W-00076/4). Approval of this demonstration will allow the state to increase the income eligibility threshold of its separate title XXI Children's Health Insurance Program (CHIP) (known in the state as the Florida KidCare Program or KidCare) from 210 percent of the federal poverty level (FPL) to up to, and including, 300 percent of the FPL. This threshold increase specifically applies to children aged 1 through 18 who qualify for these components of Florida's separate CHIP: MediKids, Florida Healthy Kids, and Children's Medical Services. The demonstration is effective as of the date of this letter and will expire on September 30, 2029.

Extent and Scope of the Demonstration

With this approval, Florida will have the authority to raise the CHIP income eligibility threshold, therefore expanding eligibility under the Florida KidCare Program to children aged 1 through 18 with family incomes above 210 percent of the FPL and up to, and including, 300 percent of the FPL. Any reduction in the eligibility limit would require submission of a formal amendment as described in the special terms and conditions (STCs).

The state will also have the authority to require enrollees in the CHIP expansion population (i.e., children aged 1 through 18 with a household income ranging above 210 percent of the FPL and up to, and including, 300 percent of the FPL) to pay a monthly premium, consistent with what is allowable under the CHIP state plan. CMS is approving Florida's request to charge premiums to the CHIP expansion population that vary depending on a household's income. Table 1 shows the premium tiers by household FPL level in the first year of the demonstration period. The premiums for the CHIP expansion population must comply with the statutory requirements related to maintenance of effort under section 2105(d)(3)(A) of the Social Security Act ("the Act").

Table 1. CHIP Monthly Premiums for the Florida KidCare Expansion Population

210.01 – 235.00% FPL	235.01 – 255.00% FPL	255.01 – 275.00% FPL	275.01 – 300.00% FPL
\$60	\$95	\$145	\$195; \$145 for a household size of 1*

*Individuals with income between 275.01 – 300.00 percent of the FPL and with a household size of 1 are subject to a lower premium to ensure the 5 percent cost sharing cap will not be exceeded.

In addition, the premiums and cost sharing amounts combined cannot exceed five (5) percent of a household's income.¹ Consistent with CHIP state plan requirements, Florida will have the authority to increase these CHIP premiums annually by applying inflation adjustments that are based on (and no more than) the percentage increase in the Consumer Price Index (CPI) trended forward using the applicable CPI: Medical care inflation rate (or another state specific index submitted by the state and approved by CMS). After applying inflation adjustments, the premiums and cost sharing amounts combined still cannot exceed five (5) percent of a household's income. Florida must submit a CHIP state plan amendment to revise the premiums for households with income above 133 percent of the FPL and up to, and including, 210 percent of the FPL.

Beginning January 1, 2024, pursuant to the Consolidated Appropriations Act, 2023 (CAA, 2023) (P.L. 117- 328)A, states are required to provide twelve (12) months of continuous eligibility for Medicaid and CHIP coverage to children under age 19.² The CHIP expansion population in this demonstration is also subject to 12 months of continuous eligibility. The CAA, 2023 prohibits disenrollment of the expansion population for nonpayment of premiums during the 12-month continuous eligibility period.³ Even if the CAA, 2023 did not prohibit disenrollment for failure to pay premiums, CMS would impose the same condition in this demonstration as a matter of policy in order to promote access to care and continuity of coverage. It has been found that individuals with continuous health coverage are more likely to be in better health, less likely to

¹ Section 2103(e)(3)(B) of the Social Security Act.

² Section 5112 of the CAA, 2023 amended sections 1902(e)(12) and 2107(e)(1) of the Social Security Act to add this requirement.

³ After enactment of the CAA, 2023, the Medicaid statute's continuous eligibility requirement applies to CHIP "in the same manner" as it applies to Medicaid, where states are not permitted to terminate coverage based on nonpayment of premiums during the continuous eligibility period. *See* Section 5112(a) of the CAA, 2023 (amending the Medicaid statute to require that a "State plan . . . shall provide" that children "determined to be eligible for benefits under a State plan" generally "shall remain eligible for such benefits" for a 12-month period); 42 C.F.R. § 435.930(b) (providing that states "must . . . [c]ontinue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible); 42 C.F.R. § 435.926(d) (providing that a "child's eligibility" for Medicaid "may not be terminated during a continuous eligibility period" unless one of five exceptions is met); Section 5112(b) of the CAA, 2023 (amending the CHIP statute to provide that, with one exception, the continuing eligibility requirement in section 1902(e)(12) of the Medicaid statute, as amended by the CAA, 2023, "shall apply to States under this title [i.e., CHIP] in the same manner as they apply to a State under title XIX [i.e., Medicaid]"). CMS has published a final rule explaining this requirement. *See* CMS, Department of Health & Human Services, *Medicare and Medicaid Programs: ...Medicaid and CHIP Continuous Eligibility (Nov. 1, 2024)*, <https://www.federalregister.gov/public-inspection/2024-25521/medicare-and-medicare-progrf...jal-outpatient-prospective-payment-and-ambulatory-surgical>

forgo needed medical care, and more likely to develop patient-provider relationships.⁴ This condition is reflected in the STCs.

CMS has determined that this demonstration as approved is likely to assist in promoting the objectives of CHIP, as it will provide access to comprehensive health coverage for low-income children who would otherwise not be covered under the state's CHIP. Florida estimates that an additional 41,874 children will be eligible for KidCare with this expansion by demonstration year (DY) 5.

CHIP Allotment

Under this demonstration, the state will be subject to a limit on the amount of federal title XXI funding that the state may receive on allowable demonstration expenditures during the demonstration period. CMS has long required, as a condition of demonstration approval, that demonstrations be "allotment neutral," meaning the federal title XXI funds for the state's CHIP are restricted to the state's available allotment and reallocated funds. The state is eligible to receive title XXI funds for the demonstration population as described in STC 4.1, up to the amount of its title XXI allotment. Title XXI funds must be first used to fully fund costs associated with CHIP state plan populations. The demonstration expenditures are limited to remaining funds. The state is required to comply with all existing rules for operating within the available CHIP allotment and, as necessary, requesting an increase in allotment. In requiring demonstrations to be allotment neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of CHIP and its interest in facilitating state innovation and coverage through section 1115 demonstration approvals.

Monitoring and Evaluation

The state is required to conduct systematic monitoring and robust independent evaluation of the demonstration in alignment with the STCs. Throughout the life cycle of the demonstration approval period, monitoring will help track the state's progress towards its demonstration goals. The state must develop a comprehensive Evaluation Design to assess whether the demonstration is effective in producing the desired outcomes for its beneficiaries as well as the state's Medicaid and CHIP programs overall. Evaluation of the demonstration must assess the impact of expanding eligibility for CHIP, including the premium requirement, on beneficiary enrollment, access, and health outcomes. The state's monitoring and evaluation efforts must facilitate understanding the extent to which the demonstration might support reducing existing health disparities.

Consideration of Public Comments

⁴ Brantley, E., & Ku, L. (2022). Continuous eligibility for Medicaid associated with improved child health outcomes. *Medical Care Research and Review*, 79(3), 404-413.; Brooks T, Gardner A. (2021). Continuous Coverage in Medicaid and CHIP. Georgetown University Health Policy Institute. <https://ccf.georgetown.edu/wp-content/uploads/2012/03/CE-program-snapshot.pdf>; Fox, J. B., & Richards, C. L. (2010). Vital Signs: Health Insurance Coverage and Health Care Utilization--United States, 2006-2009 and January-March 2010. *MMWR: Morbidity & Mortality Weekly Report*, 59(44).; Smith, D. A., Akira, A., Hudson, K., Hudson, A., Hudson, M., Mitchell, M., & Crook, E. (2017). The effect of health insurance coverage and the doctor-patient relationship on health care utilization in high poverty neighborhoods. *Preventive Medicine Reports*, 7, 158-161.

The federal comment period was open from March 29, 2024, through April 28, 2024, and received 13 comments. One comment was unrelated to Florida's demonstration request. The majority of the comments explicitly expressed support for expanding the CHIP eligibility threshold, but many commenters expressed concerns that the premiums for the CHIP expansion population were too costly to be affordable and would create a financial burden for families. Some specifically opposed the premium structure for those at or below 150 percent of the FPL, expressing that they were too expensive. However, CHIP enrollees at or below 150 percent of the FPL are covered by Florida's non-demonstration CHIP state plan and are not impacted by this demonstration. The premiums for the CHIP expansion population align with what is allowable under the CHIP state plan, and the premiums and cost sharing amounts combined cannot exceed 5 percent of a family's income.

Other commenters had concerns that Florida's demonstration conflicted with the CAA, 2023, which they stated prohibits termination from CHIP for non-payment of premiums during the 12-month continuous eligibility period. Commenters said that termination of coverage due to non-payment of premiums could create barriers to accessing care and disruptions in treatment, and that there was insufficient monitoring and evaluation related to disenrollments. CMS believes continuous eligibility is a valuable tool that has the potential to advance access to care and improve health outcomes. Therefore, CMS is not allowing the state to disenroll individuals for non-payment of CHIP premiums during the 12-month continuous eligibility period based on research cited above supporting the importance maintaining continuous eligibility has on health outcomes and ongoing access to care.

One comment noted that the CHIP premiums should consider the number of children in a household so families with one child can pay less than families with multiple children. Another comment suggested removing the income threshold to qualify for the Children's Medical Services program, which is a component of KidCare that is tailored to children with special health care needs, so children with disabilities can have access to better and more affordable insurance options. We thank the commenters for these recommendations, but these decisions are outside the scope of this demonstration review.

After careful review of the information received from the state and the comments submitted during the federal comment period, CMS has concluded that the demonstration is likely to advance the objectives of CHIP.

Other Information

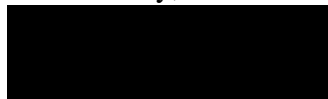
CMS's approval of this section 1115(a) demonstration project is contingent upon compliance with the enclosed expenditure authority, STCs, and any supplemental attachments defining the nature, character, and extent of anticipated federal involvement in this demonstration project. The state may deviate from CHIP state plan requirements only to the extent those requirements have been specifically listed as not applicable under the demonstration. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

The project officer for this demonstration is Ms. Jamie John. She is available to answer any questions concerning implementation of the state's section 1115(a) demonstration and her contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Email: Jamie.John@cms.hhs.gov

We look forward to our continued partnership on the Florida Children's Health Insurance Program Eligibility Extension demonstration. If you have any questions regarding this approval, please contact Jacey Cooper, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

A solid black rectangular box used to redact the signature of Chiquita Brooks-LaSure.

Chiquita Brooks-LaSure
Administrator

Enclosures

cc: Jason Weida, Secretary, Florida Agency for Health Care Administration
Austin Noll, Deputy Secretary for Medicaid Policy, Quality, and Operations, Florida Agency
for Health Care Administration
Kia Carter-Anderson, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 21-W-00076/4

TITLE: Florida Children’s Health Insurance Program Eligibility Extension

AWARDEE: Florida Agency for Health Care Administration

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Florida (referred to herein as the state) for the item identified below, which is not otherwise included as expenditures under section 2105 of the Act, shall for the period from December 2, 2024, through September 30, 2029, unless otherwise specified, be regarded as expenditures under the state's title XXI plan.

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

All requirements of CHIP expressed in law, regulation, and policy statements, not expressly waived or identified as not applicable to the below expenditure authority, shall apply to the Florida CHIP Eligibility Extension demonstration for the period of this approved demonstration.

Title XXI Costs Not Otherwise Matchable

Under the authority of section 1115(a)(2) of the Act as incorporated into title XXI by section 2107(e)(2)(A), state expenditures described below, shall, for the period of this demonstration, through September 30, 2029, and to the extent of the state’s available allotment under section 2104 of the Act, be regarded as matchable expenditures under the state’s title XXI plan. All requirements of title XXI will be applicable to such expenditures for the beneficiaries described in demonstration expenditure authority 1.

1. **Expenditures for Florida KidCare Expansion.** Expenditures for all state plan services under the demonstration for individuals ages 1 through 18 who meet all eligibility criteria for CHIP with incomes above 210 percent up to, and including, 300 percent of the federal poverty level (FPL) as described in STC 3.6 and 4.1 who are not otherwise eligible for CHIP coverage as of December 2, 2024.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 21-W-00076/4

TITLE: Florida Children’s Health Insurance Program Eligibility Extension

AWARDEE: Florida Agency for Health Care Administration

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the Florida Children’s Health Insurance Program (CHIP) Eligibility Extension section 1115(a) CHIP demonstration (hereafter “demonstration”) to enable Florida (hereafter “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority under section 2105 of the Social Security Act (Act) authorizing federal matching of demonstration costs not otherwise matchable, and which is separately enumerated. These STCs set forth conditions and limitations on the expenditure authority, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the program for those populations affected by the demonstration are effective from December 2, 2024 through September 30, 2029, unless otherwise specified.

The STCs have been arranged into the following subject areas:

1	Preface
2	Program Description and Objectives
3	General Program Requirements
4	Eligibility for the Demonstration
5	Benefits, Cost-sharing, and Delivery System
6	General Financial Requirements
7	Monitoring Allotment Neutrality
8	Monitoring and Reporting Requirements
9	Evaluation of the Demonstration
10	Schedule of State Deliverables for the Demonstration Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A	Developing the Evaluation Design
Attachment B	Preparing the Interim and Summative Evaluation Reports
Attachment C	Evaluation Design [Reserved]

Florida CHIP Eligibility Extension Section 1115(a) Demonstration
Approval Period: December 2, 2024 through September 30, 2029

2. PROGRAM DESCRIPTION AND OBJECTIVES

The Florida CHIP Eligibility Expansion section 1115 demonstration provides title XXI expenditure authority to allow the state to increase the income eligibility threshold in Florida KidCare, the state's CHIP program, from 210 percent of the federal poverty level (FPL) up to, and including, 300 percent of the FPL, as described in STC 4.1. This threshold increase specifically applies to children aged 1 through 18 who qualify for these components of Florida's separate CHIP: MediKids, Florida Healthy Kids, and Children's Medical Services.

During the demonstration period, the state seeks to achieve the following goals:

- Increase enrollment and access to CHIP coverage; and
- Improve or maintain the rate of uninsured children under age 19 in the state.

3. GENERAL PROGRAM REQUIREMENTS

- 3.1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 3.2. **Compliance with Medicaid and Children’s Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3.3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 3.4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified allotment neutrality worksheet for the demonstration as necessary to comply with such change. The modified allotment neutrality agreement will be effective upon the implementation of the change.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 3.5. **State Plan Amendments.** The state will not be required to submit title XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the CHIP state plan governs.

- 3.6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. Any reduction in the CHIP eligibility threshold below the most recently approved threshold will require submission of a formal amendment, as described in STC 3.7. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 3.7 below, except as provided in STC 3.3.
- 3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STCs, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
- a. An explanation of the public process used by the state, consistent with the requirements of STC 3.13. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
 - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. An up-to-date CHIP allotment worksheet, that reflects the associated costs of implementing the amendment as proposed by the state;
 - d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- 3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS at least 12 months in advance from the Governor of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 3.9.

Florida CHIP Eligibility Extension Section 1115(a) Demonstration
Approval Period: December 2, 2024 through September 30, 2029

- 3.9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration, in whole or in part, consistent with the following requirements:
- a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 3.13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
 - b. **Transition and Phase-Out Plan Requirements.** The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
 - c. **Transition and Phase-Out Plan Approval.** The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
 - d. **Transition and Phase-Out Procedures.** The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(d)(1) or for children in CHIP consider eligibility for other insurance affordability programs under 42 CFR 457.350. 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 42 CFR 457.350, respectively. The state must comply with all applicable notice requirements for Medicaid found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214 or for CHIP found at 42 CFR 457.340(e), including information about a right to a review consistent with 42 CFR 457.1180. In addition, the state must assure all applicable appeal and

hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221 for Medicaid or 42 CFR 457.1120 through 457.1190 for CHIP. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230 for Medicaid or must ensure the opportunity for continuation of enrollment and benefits in CHIP consistent with 42 CFR 457.1170.

- e. **Exemption from Public Notice Procedures 42 CFR Section 431.416(g).** CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. **Enrollment Limitation during Demonstration Phase-Out.** If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid or CHIP eligibility in accordance with the approved Medicaid or CHIP state plan.
- g. **Federal Financial Participation (FFP).** If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

3.11. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS's 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.

3.12. **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.

- 3.13. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved CHIP State Plan consistent with section 2107(e)(1)(F) of the Act, when any program changes to the demonstration, either through amendment as set out in STC 3.7 or extension, are proposed by the state.

- 3.14. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- 3.15. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 3.16. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

4. ELIGIBILITY FOR THE DEMONSTRATION

4.1. **Florida KidCare Eligibility Expansion.** This demonstration increases the CHIP eligibility threshold from 210 percent of the FPL up to, and including, 300 percent of the FPL. The beneficiaries in the Florida KidCare eligibility expansion population, described in expenditure authority 1, will include individuals ages 1 through 18 with a household income ranging from above 210 percent of the FPL up to, and including, 300 percent of the FPL and who meet all other non-financial eligibility criteria for these components of Florida’s separate CHIP: MediKids, Florida Healthy Kids, and Children’s Medical Services. The expansion population is made eligible by virtue of the expenditure authority expressly granted in this demonstration and is subject to the CHIP laws or regulations except as specified in the STCs and expenditure authority for this demonstration. These cited documents generally provide that all requirements of CHIP laws and regulations do apply, except to the extent waived or specified as not applicable. The criteria for the Florida KidCare Eligibility Expansion population are as follows (Table 1):

Table 1. Expansion Population Affected by the Demonstration

Description	Program	Social Security Act Citation	42 CFR Citation
KidCare Expansion Group – individuals ages 1 through 18 with income above 210 percent up to, and including, 300 percent of the FPL who meet all other CHIP eligibility criteria.	CHIP	2110(b)	457.310

5. BENEFITS, COST SHARING, AND DELIVERY SYSTEM

- 5.1. **Demonstration Benefits.** Individuals enrolled in this demonstration will receive comprehensive benefits as provided under the CHIP state plan for the separate title XXI program that the individual is enrolled in, whether MediKids, Florida Healthy Kids, or Children’s Medical Services.
- 5.2. **Cost Sharing.** Individuals enrolled in this demonstration will be subject to cost sharing responsibilities, such as monthly premiums and co-pays, to the extent allowable under Title XXI requirements, except as specified in this STC. Premiums will be dependent on a household’s FPL and will range from \$60 to \$195 in demonstration year 1 (see Table 2). The state can increase premiums annually to account for inflation, using the Consumer Price Index (CPI): Medical Care inflation rate or another state-specific index submitted by the state and approved by CMS. Individuals may not be disenrolled from this demonstration for failure to pay the monthly premium during the individual’s 12-month continuous eligibility period. The state must notify CMS if the copayment amounts charged under this demonstration will differ from the amounts charged for individuals with income below 210 percent of the FPL under the CHIP state plan, and premiums for the demonstration population must be consistent with what is allowable under the CHIP regulations. The premiums and cost sharing amounts combined cannot exceed an individual’s 5 percent cost sharing cap.

Table 2. CHIP Monthly Premiums for the Florida KidCare Expansion Population¹

210.01 – 235.00% FPL	235.01 – 255.00% FPL	255.01 – 275.00% FPL	275.01 – 300.00% FPL
\$60	\$95	\$145	\$195; \$145 for a household size of 1 ²

¹Florida can increase premiums annually by inflation only. The inflation adjustment must be based on (and no more than) the percentage increase in the Consumer Price Index (CPI) trended forward using the applicable CPI: Medical care inflation rate (or another state-specific index submitted by the state and approved by CMS).

² Individuals with income between 275.01 – 300.00 percent of the FPL and with a household size of 1 are subject to a lower premium to ensure the 5 percent cost sharing cap will not be exceeded.

- 5.3. **Delivery System.** Individuals enrolled in this demonstration will receive all applicable CHIP state plan services through a fee-for-service or a managed care delivery system, as described in the CHIP state plan. The managed care delivery system is authorized under other managed care authorities, including the Florida Managed Medical Assistance section 1115 demonstration.

6. GENERAL FINANCIAL REQUIREMENTS

- 6.1. **Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.
- 6.2. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act [cross referenced at section 2107(e)(1)(Q) for CHIP] and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.
- a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
 - b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
 - c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.
- 6.3. **State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:
- a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act [cross referenced at section 2107(e)(1)(Q) for CHIP] and applicable implementing regulations.
 - b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology.

This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 [cross referenced at 42 CFR 457.628(a) for CHIP] it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c) [cross referenced at 42 CFR 457.628(a) for CHIP].

- c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 [cross referenced at 42 CFR 457.628(a) for CHIP] and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.
- d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of CHIP payments in a manner inconsistent with the requirements in section 1903(w) of the Act [cross referenced at section 2107(e)(1)(Q) for CHIP] and its implementing regulations. This confirmation of CHIP payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to CHIP and in which there is no connection to CHIP payments, are not considered returning and/or redirecting a CHIP payment.
- e. The State Medicaid Director/CHIP Director or his/her designee certifies that all state and/or local funds used as the state’s share of the allowable expenditures reported on the CMS-21 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

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

Table 3. Demonstration Years

Demonstration Year (DY)	Dates	Duration
DY 1	December 2, 2024 to September 30, 2025	10 months
DY 2	October 1, 2025 to September 30, 2026	12 months

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Demonstration Year (DY)	Dates	Duration
DY 3	October 1, 2026 to September 30, 2027	12 months
DY 4	October 1, 2027 to September 30, 2028	12 months
DY 5	October 1, 2028 to September 30, 2029	12 months

7. MONITORING ALLOTMENT NEUTRALITY

7.1. **Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement.** The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

- a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 reporting instructions outlined in section 2115 of the State Medicaid Manual.
- b. **Use of Waiver Forms.** Title XXI demonstration expenditures will be reported on the following separate forms designated for CHIP (i.e., Forms CMS-21 Waiver and/or CMS-21P Waiver), identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The state must submit separate CMS-21 waiver forms for each title XXI demonstration population.
- c. **Premiums.** Any premium contributions collected under the demonstration shall be reported to CMS on the CMS-21 Waiver form (specifically lines 1A through 1D as applicable) for each title XXI demonstration population that is subject to premiums, in order to assure that the demonstration is properly credited with the premium collections.
- d. **Claiming Period.** All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the Form CMS-21 Waiver, net expenditures related to dates of service during the operation of the demonstration.

7.2. **Standard CHIP Funding Process.** The standard CHIP funding process will be used during the demonstration. The state will continue to estimate matchable CHIP expenditures on the quarterly Forms CMS-21B for CHIP. On these forms estimating expenditures for the title XXI funded demonstration populations, the state shall separately identify estimates of expenditures for each applicable title XXI demonstration population.

- a. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must report demonstration expenditures through Form CMS-21W and/or CMS-21P Waiver for the CHIP population. Expenditures reported on the waiver forms must be identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). CMS will reconcile expenditures reported on the CMS-21W/CMS-21P Waiver form with federal funding previously made available to the state and include the reconciling adjustment in the finalization of the grant award to the state.

- 7.3. **Title XXI Administrative Costs.** All administrative costs (i.e., costs associated with the title XXI state plan and the title XXI funded demonstration populations identified in these STCs) are subject to the title XXI ten (10) percent administrative cap described in section 2105(c)(2)(A) of the Act.
- 7.4. **Limit on Title XXI Funding.** The state will be subject to a limit on the amount of federal title XXI funding that the state may receive on eligible CHIP state plan populations and the CHIP demonstration population described in STC 4.1 during the demonstration period. Federal title XXI funds for the state’s CHIP program (i.e., the approved title XXI state plan and the demonstration populations identified in these STCs) are restricted to the state’s available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.
- 7.5. **Exhaustion of Title XXI Funds for CHIP Population.** If the state exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the state must continue to provide coverage to the approved title XXI separate state plan population.

8. MONITORING AND REPORTING REQUIREMENTS

- 8.1. **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 demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay, and the state’s anticipated date of submission. Should CMS agree in writing to the state’s request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state’s written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b) above, and the state fails to comply with the corrective action plan or, still fails to submit the overdue deliverable(s) that meet the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

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

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

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

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

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

- a. **Operational Updates.** Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operational and other challenges, underlying causes of challenges, 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. **Performance Metrics.** The performance metrics will provide data to demonstrate how the state is progressing toward meeting the goals. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration on beneficiaries' outcomes of care, quality and cost of care, and access to care. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

Additionally, the demonstration's metrics reporting must cover categories to include, but not limited to: enrollment and renewal, disenrollments, the number of individuals eligible for the demonstration, the number of individuals subject to premiums, and the number of individuals who pay monthly premium payments including at enrollment and renewal.

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

- c. **Allotment Neutrality and Financial Reporting Requirements.** Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64 or CMS-21, as applicable. Administrative costs for this demonstration should be reported separately on the Form CMS-64 or CMS-21, as applicable.
- d. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

- 8.5. **Compliance with Managed Care, Network Adequacy, Quality Strategy and EQR Reporting Requirements.** The state must comply with all managed care reporting regulations of 42 CFR Part 438, and 42 CFR Part 457 subpart L except as expressly identified as not applicable in the expenditure authorities incorporated into these STCs.

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8.6. **Corrective Action Plan Related to Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid or CHIP, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing preventive services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.11. CMS will withdraw an authority, as described in STC 3.11, 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.

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

- a. The Close-Out Report must comply with the most current guidance from CMS.
- b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 9.7 and 9.8, respectively.
- c. The state will present to and participate in a discussion with CMS on the Close-Out report.
- d. The state must take into consideration CMS's comments for incorporation into the final Close-Out Report.
- e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.
- f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

8.8. **Monitoring Calls.** CMS will convene periodic conference calls with the state.

- a. The purpose of these calls is to discuss ongoing demonstration operations, 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, allotment neutrality, enrollment and access, 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.
- 8.9. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its Medicaid or CHIP website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

9. EVALUATION OF THE DEMONSTRATION

- 9.1. **Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.1.
- 9.2. **Independent Evaluator.** The state must use an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- 9.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs, and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 9.7 and 9.8.

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

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

- 9.4. **Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the 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.
- 9.5. **Evaluation Design Approval and Updates.** The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's Medicaid or CHIP website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Annual Monitoring Reports. 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.
- 9.6. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as enrollment and enrollment continuity, reasons for nonpayment of premiums, 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. Specifically, evaluation hypotheses must assess the impact of the premium requirement on the outcomes of interest. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of preventive services. Proposed measures should be selected from nationally-recognized sources and national measure sets, where

possible. Measures sets could include CMS’s Core Set of Children’s Health Care Quality Measures for Medicaid and CHIP (Child Core Set); Consumer Assessment of Health Care Providers and Systems (CAHPS); and/or measures endorsed by National Quality Forum (NQF).

As part of its evaluation efforts, the state must also conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation, as well as Medicaid or CHIP health services expenditures. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration’s effects on the fiscal sustainability of the state’s Medicaid or CHIP program.

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

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

- 9.7. **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 of the demonstration, the Interim Evaluation Report should be posted to the state’s Medicaid or CHIP website with the application for public comment.
- a. The Interim Evaluation Report, in alignment with the CMS-approved Evaluation Design, will discuss evaluation progress and present findings to date.
 - b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration’s expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report may include an evaluation of the authority, to be collaboratively determined by CMS and the state.

- c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for the extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting an extension for a demonstration, the draft Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Interim Evaluation Report within 60 calendar days of receiving comments from CMS on the draft Interim Evaluation Report, if any.
- e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid or CHIP website within 30 calendar days.
- f. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs.

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

- a. The Summative Evaluation Report, in alignment with the Evaluation Design, must evaluate the entirety of the demonstration period.
- b. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.
- c. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid or CHIP website within 30 calendar days.
- d. The Summative Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs.

9.9. **Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid or CHIP, 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 initiatives, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals,

such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.11. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

- 9.10. **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.
- 9.11. **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 or CHIP website within 30 calendar days of approval by CMS.
- 9.12. **Additional Publications and Presentations.** For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration, over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given 30 calendar days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

10. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION PERIOD

Due	Deliverable	STC
30 calendar days after demonstration approval date	State acceptance of demonstration STCs and associated Expenditure Authority	Approval letter
180 calendar days after demonstration approval date	Evaluation Design	9.3
September 30, 2028, or with extension application	Interim Evaluation Report	9.7.c
Within 18 months of the end of the demonstration approval period represented by these STCs	Summative Evaluation Report	9.8
Annual deliverable – due 90 calendar days after end of each demonstration year	Annual Monitoring Reports	8.4
Quarterly deliverable – due 60 calendar days after end of each demonstration quarter	Quarterly Monitoring Reports	8.4
Annual deliverable – due 90 calendar days after end of each demonstration year as part of the annual monitoring report	Allotment Neutrality Reports	8.4
Close-out Report due 120 days after the end of the demonstration	Close-out Report	8.7

ATTACHMENT A

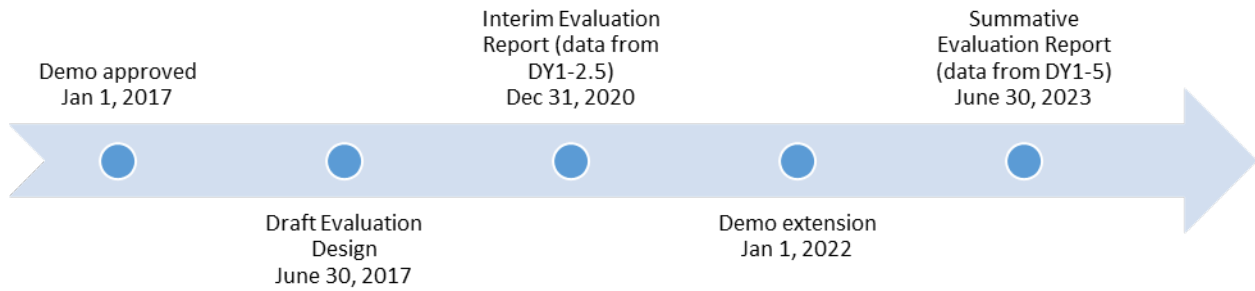
Developing the Evaluation Design

Introduction

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

Submission Timelines

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



Expectations for Evaluation Designs

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

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

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

1. Identify the state’s hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.

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

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

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:

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

Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating, securing, and submitting for endorsement, etc.). Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid–Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, 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 qualitative analysis measures that will adequately assess the effectiveness of the demonstration. This section should:
- Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
 - 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).
 - Include a discussion of how propensity score matching and difference-in-differences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - Consider the application of sensitivity analyses, as appropriate.
7. *Other Additions* – The state may provide any other information pertinent to the Evaluation Design for the demonstration.

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

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

D. Methodological Limitations – This section provides more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to

minimize these limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review.

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

1. When the demonstration is:
 - a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
 - b. Could now be considered standard Medicaid or CHIP policy (CMS published regulations or guidance).
2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
 - a. Operating smoothly without administrative changes;
 - b. No or minimal appeals and grievances;
 - c. No state issues with CMS-64 reporting or budget neutrality; and
 - d. No Corrective Action Plans for the demonstration.

E. Attachments

1. **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a “No Conflict of Interest” statement signed by the independent evaluator.
2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated costs, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.

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

ATTACHMENT B

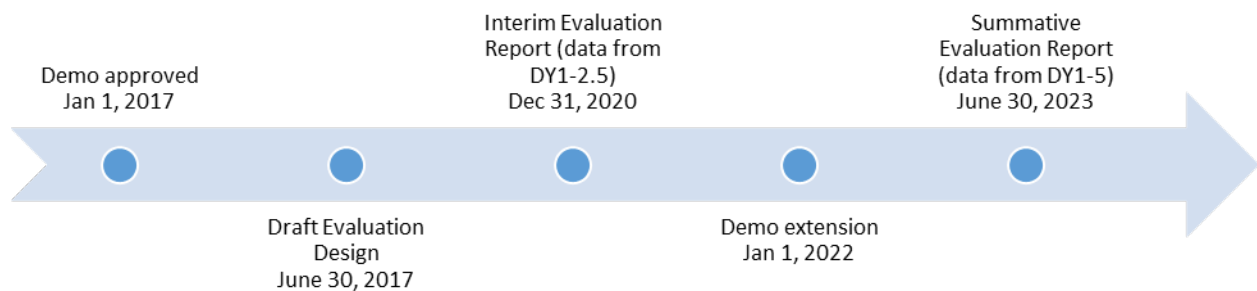
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

There is a specified timeline for the state’s submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5–year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Interim and Summative Evaluation Reports to the state’s website within 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 or CHIP 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-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

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

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

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

- D. **Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration, consistent with the approved Evaluation Design. The Evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published

research, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.

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

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
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 or CHIP context and long-range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid or CHIP program, interactions with other Medicaid or CHIP demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid or CHIP. This section provides the state with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

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

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

ATTACHMENT C
Evaluation Design [Reserved]