



February 13, 2024

Vivian Levy
Interim Medicaid Director
Oregon Health Authority
500 Summer Street NE E35
Salem, OR 97301

Dear Director Levy:

The Centers for Medicare & Medicaid Services (CMS) is approving Oregon's (the state) application for a five-year section 1115(a) demonstration, titled "Oregon Project Independence-Medicaid" ("OPI-M" or the "demonstration") (Project Number 11-W-00380/10), effective February 13, 2024, through January 31, 2029. Approval of this demonstration will enable the state to receive federal financial participation (FFP) to provide a limited set of home and community-based services (HCBS) to qualifying individuals ages 18 or older, who are older adults or adults with disabilities, to avoid or delay entry into Medicaid through an institutional level of care. This demonstration is likely to assist in promoting the objectives of title XIX of the Social Security Act (Act) as further specified in this approval letter.

CMS' approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authority, waiver authorities, special terms and conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this demonstration project. The state may deviate from the Medicaid state plan requirements only to the extent that those requirements have been specifically identified as not applicable under the demonstration.

The OPI-M demonstration will enable beneficiaries to coordinate with case managers to create a limited service plan to maintain a beneficiary's level of independence and quality of life in their home. The demonstration also provides supports to beneficiaries' unpaid caregivers, to meet the beneficiaries' health needs while also sustaining the needs of their caregiver. The goals of the demonstration are to:

- Provide limited HCBS for older adults and adults with disabilities at risk of needing Medicaid long-term services and supports (LTSS),
- Expand HCBS to individuals who need assistance with activities of daily living but do not meet the current Medicaid nursing facility level of care, and
- Provide support to unpaid family caregivers who care for demonstration beneficiaries.

The OPI-M demonstration will permit individuals who are otherwise eligible for Oregon's Medicaid state plan, but meet the demonstration eligibility requirements, to "opt into" the demonstration to receive the targeted benefit package through OPI-M. Beneficiaries who are otherwise eligible for Oregon's Medicaid state plan will have access to the mandatory state plan

medical services provided, however, they will not have access to Medicaid optional state plan services, LTSS under the Medicaid state plan or any of Oregon's other Medicaid waivers (other than Medicare buy-in benefits), unless they choose to disenroll from the demonstration to access Medicaid LTSS.

Subject to certain exceptions specified in the STCs, this demonstration also permits the state to provide continuous eligibility for beneficiaries enrolled in the demonstration for up to 24 months, regardless of certain changes in circumstances that would otherwise cause a loss of eligibility. CMS is authorizing this continuous eligibility to align this demonstration with the Oregon Health Plan and Oregon Contraceptive Care demonstrations,^{1,2} and to support consistent coverage and continuity of care by keeping beneficiaries enrolled for 24 months, regardless of income fluctuations or other similar changes that otherwise would affect eligibility, except for such circumstances specifically excepted, which would result in the individual's eligibility being redetermined or terminated, as specified in the STCs (for example, the individual ceasing to be a resident of the state).

CMS has determined that this demonstration is likely to assist in promoting the objectives of Medicaid under title XIX of the Act because it will expand Medicaid services to individuals at risk of needing Medicaid LTSS and provide supports to unpaid family caregivers who care for demonstration beneficiaries. Continuous eligibility is also likely to assist in promoting the objectives of Medicaid as it is expected to minimize coverage gaps and help maintain continuity of access to program benefits, thereby helping improve health outcomes of beneficiaries.

Budget Neutrality

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstration is likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs in that state likely would have been without the demonstration.

In requiring demonstrations to be budget neutral, CMS strives to achieve a balance between its interests in preserving the fiscal integrity of the Medicaid program and facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" (WOW) costs).

In this new demonstration, CMS is including STCs, as applicable, that reflect these efforts to achieve the aforementioned balance between fiscal integrity and state innovation. Specifically,

¹ Oregon Health Plan section 1115 demonstration approval. <https://www.medicaid.gov/sites/default/files/2023-02/or-health-plan-ca-10282022.pdf>

² Oregon Contraceptive Care section 1115 demonstration approval. <https://www.medicaid.gov/sites/default/files/2023-12/or-contraceptive-care-appvl-12072023.pdf>

CMS is revising the approach to adjusting the budget neutrality calculation in the middle of a demonstration approval period. Historically, CMS has limited its review of state requests for “mid-course” budget neutrality adjustments to situations that necessitate a corrective action plan, in which projected expenditure data indicate a state is likely to exceed its budget neutrality expenditure limit. CMS has updated its approach to midcourse corrections in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state’s baseline may be adjusted based on (1) actual expenditure data to accommodate circumstances that are out of the state’s control (e.g., expensive new drugs enter the market and the state is required to cover them); and/or (2) the effect is not a condition or consequence of the demonstration (e.g., unexpected costs due to a public health emergency); or (3) the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (e.g., a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

Monitoring and Evaluation

Consistent with CMS requirements for section 1115 demonstrations (*see, e.g.*, 42 CFR 431.424 and 42 CFR 431.428), and as outlined in the demonstration’s STCs, the state is required to conduct systematic monitoring and robust evaluation of the demonstration in accordance with the STCs. The demonstration’s monitoring activities must support tracking the state’s progress toward meeting the demonstration goals. The state must report on metrics that relate to the demonstration’s continuous eligibility and benefits provisions and must cover categories including but not limited to: enrollment and renewal, including the percent of renewals completed *ex-parte* (administratively); access to providers; utilization of services; grievances and appeals; and quality of care and health outcomes. The state’s selection of the quality of care and health outcomes metrics must be aligned with the demonstration’s policy composition and objectives, to be reported for all demonstration populations. As appropriate, the state must leverage measures from the HCBS Quality Measure Set³ and CMS’ draft Disparities Sensitive Measure Set.

Furthermore, in accordance with the STCs, Oregon must develop for the demonstration period a rigorous evaluation design using robust data sources and sound analytic approaches that support a comprehensive independent evaluation of the demonstration to assess whether the demonstration initiatives are effective in producing the desired outcomes for beneficiaries and the state’s overall Medicaid program. The demonstration evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components, including the continuous eligibility policy, that support understanding the demonstration’s impact on beneficiary coverage, access to and quality of care, and health outcomes, as well as the demonstration’s effectiveness achieving the policy goals and objectives.

³ The HCBS Quality Measure Set can be accessed on Medicaid.gov at the following link: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

Specifically, evaluation hypotheses must focus on the impact of the demonstration in helping eligible beneficiaries access HCBS, coordinate with case managers, and pursue support for unpaid family caregivers. The evaluation must also examine beneficiary and caregiver perspectives on the usefulness of the services and supports received. Hypotheses must include, but not be limited to, outcomes such as beneficiaries' quality of life at home and their increased independence. In addition, the evaluation must assess how the demonstration helps to prevent or delay escalation of beneficiary health outcomes, disability, and need for institutional levels of care, and thereby may support any cost savings in the long run. For the continuous eligibility policy, the state must evaluate how the policy affects coverage, enrollment, and churn (i.e., temporary loss of coverage during which beneficiaries are disenrolled but re-enroll within 12 months), as well as appropriate measures of HCBS utilization and health outcomes. In addition, the state must conduct a demonstration cost assessment.

The state is strongly encouraged to conduct an implementation evaluation and undertake a well-designed beneficiary survey, both of which will significantly strengthen the demonstration's evaluation. Finally, to the extent feasible, the state must collect data to support its monitoring and evaluation efforts stratified by key subpopulations of interest (*e.g.*, by sex, age, race, ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing shortcomings or disparities in access to and quality of care and health outcomes, as well as help inform how the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

Consideration of Public Comments

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

Section 1115(d)(2)(A) and (C) of the Act further specifies that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute does not impose additional requirements on the states or the Secretary to provide individualized responses to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations at 42 CFR part 431, subpart G, specifically 42 CFR 431.416(d)(2) provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments.

The federal comment period was open from November 16, 2021 through December 16, 2021. CMS received 19 comments during the federal comment period. Two comments were unrelated to the demonstration request, and two comments misunderstood the intent of the demonstration request because commenters thought the demonstration would impact beneficiaries who are

disabled and currently receiving Medicaid state plan benefits. Overall, the comments indicated strong support for the demonstration.

Several commenters expressed support for expanding coverage for older adults, and praised supporting family members who assume care taking responsibilities for individuals in need. Commenters emphasized that the demonstration will provide services beyond what the state-funded program can offer due to limited funding. Lastly, commenters asserted that the demonstration will help prolong qualifying individuals' independence by delivering care that can be received in-home rather than in an institutional setting.

Other Information

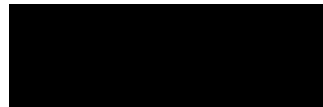
CMS' approval of this demonstration project is contingent upon the state's compliance with the enclosed expenditure authority, waiver authority, and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to CMS receiving your 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. Valisha Andrus. She is available to answer any questions concerning your section 1115 demonstration. Ms. Andrus's contact information is as follows:

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

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

Sincerely,

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

Chiquita Brooks-LaSure

Enclosure

cc: Nikki Lemmon, State Monitoring Lead, Medicaid, and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W-00380/10

TITLE: Oregon Project Independence-Medicaid (OPI-M)

AWARDEE: Oregon Health Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Oregon (the “state”) for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period beginning February 13, 2024, through January 31, 2029, unless otherwise specified, be regarded as matchable expenditures under the state's Medicaid state plan under title XIX of the Act.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable the state to operate its section 1115(a) Medicaid demonstration:

1. Oregon Project Independence-Medicaid (OPI-M) Program

Expenditures for limited home and community-based services (HCBS) for beneficiaries eligible for OPI-M, as described in Section IV.

2. Continuous Eligibility

Expenditures for continued benefits for individuals who have been determined eligible who would otherwise lose coverage during an eligibility redetermination, except as noted in STC 16.d.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY**

NUMBER: 11–W–00380/10

TITLE: Oregon Project Independence–Medicaid (OPI–M)

AWARDEE: Oregon Health Authority

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration project beginning February 13, 2024 through January 31, 2029, unless otherwise specified. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of state plan requirements contained in section 1902 of the Act are granted in order to enable Oregon (state) to carry out the Oregon Project Independence–Medicaid (OPI–M) section 1115 demonstration.

1. Medicare Savings Program (MSP) Beneficiaries **Section 1902(a)(10)(E)(iv)**

To the extent necessary to enable Qualifying Individuals (QI) in the Medicare Savings Program, not otherwise eligible for medical assistance under the state plan, to receive coverage through OPI–M demonstration.

2. Amount, Duration, Scope of Services, and Comparability **Section 1902(a)(10)(B)**

To the extent necessary to permit the state to provide benefits not available in the standard Medicaid benefit package to individuals who have elected and enrolled to receive OPI–M benefits.

**CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11–W–00380/10

TITLE: Oregon Project Independence–Medicaid (OPI–M)

AWARDEE: Oregon Health Authority

I. PREFACE

The following are the Special Terms and Conditions (STC) for the Oregon Project Independence– Medicaid (OPI–M) section 1115(a) Medicaid demonstration (hereafter “OPI–M” or “demonstration”) to enable the state of Oregon (hereafter “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of certain Medicaid requirements, and has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration, the state’s implementation of the expenditure authorities and the state’s obligations to CMS during the demonstration period. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The effective date of the demonstration is February 13, 2024, through January 31, 2029.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Demonstration Eligibility
- V. Benefits
- VI. HCBS Quality Assurance and Reporting Requirements
- VII. Cost Sharing
- VIII. Delivery System
- IX. Monitoring and Reporting Requirements
- X. General Financial Requirements
- XI. Monitoring Budget Neutrality
- XII. Evaluation of the Demonstration
- XIII. Schedule of State Deliverables for the Demonstration Period

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports

Attachment C: Evaluation Design

Attachment D: Service Definitions & Provider Qualifications

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Oregon Project Independence–Medicaid (OPI–M) demonstration provides services to individuals ages 18 and older who are older adults or adults with physical disabilities and enables beneficiaries to coordinate with case managers to create a limited service plan to maintain a beneficiary’s level of independence and quality of life in their home. The demonstration also provides supports to beneficiaries’ unpaid caregivers, in order to meet the beneficiaries’ health needs while also sustaining the needs of the caregivers. The demonstration likely will further the objectives of the Medicaid program by enabling individuals to remain independent so they can delay or avoid entry into Medicaid through an institutional level of care or community long term care setting.

Over the five–year demonstration period, Oregon will strive to promote the objectives of title XIX by:

- Providing limited home and community–based services (HCBS) for older adults and adults with disabilities at risk of needing Medicaid long–term services and supports (LTSS),
- Expanding HCBS to individuals who need assistance with Activities of Daily Living but do not meet the current Medicaid nursing facility level of care, and
- Providing support to unpaid family caregivers who care for demonstration beneficiaries.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non–Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non–discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid programs expressed in law, regulation, and policy statement not expressly waived or identified as not applicable in the expenditure authority document (which is a part of these terms and conditions), must apply to the demonstration.
- 3. Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance any 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 or other changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 5. State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS in writing for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with 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 STC, and failure by the state to submit required reports and other deliverables in a timely fashion 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 12. Such explanation must include a summary of any public feedback received

- and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
- b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - d. An up-to-date CHIP allotment neutrality worksheet, if necessary; and
 - e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- 8. Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS at least 12 months in advance from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.
- 9. Demonstration Phase Out.** The state may only suspend or terminate this demonstration, in whole or in part, at any time prior to the date of expiration 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 12, 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 administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities, including community resources that are available.

- c. Phase-out Plan Approval: The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights are afforded to demonstration participants as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as found in 42 CFR 435.916.
- e. Exemption from Public Notice Procedures 42 CFR 431.416(g): CMS may expedite federal and state public notice requirements in accordance with the 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 eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and 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.

- 11. Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems applicable to the demonstration; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
- 12. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

A state with Federally-recognized Indian Tribes, Indian Health Programs, or Urban Indian Health Organizations must comply with the tribal consultation requirements set forth in section 1902(a)(73) of the Act and implemented in regulation at 42 CFR 431.408(b) or the tribal consultation requirements contained in the state's approved Medicaid state plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

- 13. Federal Financial Participation (FFP).** No federal matching funds for administrative or medical assistance payments for services provided under this demonstration will take effect until the effective date identified in the CMS demonstration approval documents. Expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter associated with these STCs.
- 14. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid agency must maintain authority, accountability, and oversight of the program. The State Medicaid agency must exercise oversight of all delegated functions to operating agencies, managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and any other contracted entities. The Single State Medicaid agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 15. Common Rule Exemption.** The state must ensure the only involvement of human subjects in research activities authorized or required by this demonstration is for projects conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program—including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration, as represented in these approved STCs, meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

IV. DEMONSTRATION ELIGIBILITY

16. OPI–M Eligibility Overview. The OPI–M demonstration provides HCBS to individuals who are “at risk” of becoming eligible for Medicaid to access LTSS. Individuals eligible for OPI–M must meet the following eligibility criteria:

- a. Be age 18 or older;
 - i. Individuals ages 59 or younger with a physical disability must apply and be determined eligible for Social Security Disability Insurance (SSDI) or Social Security Income (SSI) based on disability or complete the state’s presumptive Medicaid disability determination team (PMDDT) process.
 - ii. Individuals ages 60 and above are exempt from having to meet SSDI/SSI and PMDDT eligibility determination requirements.
- b. Have income up to and including 400 percent of the federal poverty level (FPL);
 - i. **Countable Resource Limit:** The individual’s separate non–excluded resources are at or below the current monthly Medicaid nursing facility rate multiplied by six months, or, for a married couple, that non–excluded resources (calculated as of the first point at which the individual is deemed to have the status of an “institutionalized spouse”) are at or below a combination of the current monthly Medicaid nursing facility rate multiplied by six months plus the current state Community Spouse Resource Allowance, based on verified household resources. This amount will be adjusted annually on July 1st if there are changes to Oregon’s monthly Medicaid pay rate for nursing facilities.
 - ii. No post–eligibility treatment of income will apply, and eligibility will be determined using only the applicant’s income.
- c. Meet the Service Priority Level (SPL) functional needs criteria within level one through 18. The SPL system is used to determine an individual’s level of needed assistance with Activities of Daily Living.
- d. **Continuous Eligibility:** For an individual found to be income–eligible for this demonstration upon initial application or annual redetermination, the state will provide twenty–four (24) months continuous eligibility during which the state will not terminate coverage based on a change in circumstance. The continuous eligibility period begins on the effective date of the individual’s eligibility determination or the effective date of the most recent renewal of eligibility. Given individuals are continuously eligible regardless of changes in circumstances (except as provided under STC 16.d.i), the state will conduct renewals of eligibility at the end of the individual’s continuous eligibility period. The state will continue to redetermine eligibility during a period of continuous eligibility in limited circumstances, if appropriate, as described in STC 16.d.i.

- i. Continuous Eligibility Exceptions. Notwithstanding STC 16.d, if any of the following circumstances occur during an individual’s designated continuous eligibility period, the individual’s eligibility for this demonstration shall be redetermined or terminated:
 1. The individual becomes pregnant or otherwise eligible for Medicaid or CHIP;
 2. The individual is no longer an Oregon resident;
 3. The individual requests termination of eligibility;
 4. The individual dies; or
 5. The agency determines that eligibility was erroneously granted at the most recent determination, redetermination or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the individual.

17. Optional Choice for Medicaid State Plan Eligible Individuals. Individuals who are eligible for, but have chosen not to receive, Medicaid-funded LTSS will be eligible to receive service through OPI-M if they meet OPI-M eligibility requirements. These individuals do not constitute a separate Medicaid eligibility group (MEG) in the demonstration. The demonstration allows them a benefits choice that will enable them to remain in their homes for a longer period. Individuals may apply to change their coverage to Medicaid state plan coverage (foregoing their demonstration coverage) at any time.

- a. Beneficiaries receiving OPI-M services who are otherwise Medicaid eligible may receive mandatory medical services covered by the Medicaid state plan, but are not eligible other Medicaid optional state plan services, 1915(k), 1915(i), or 1915(c) LTSS benefits at the same time. If an eligible individual chooses to access 1915(i), 1915(k) or 1915(c) LTSS benefits, they will no longer be eligible to receive OPI-M services. Services offered under this demonstration will not duplicate services covered under the state plan, Medicare or private insurance, or through other federal or state programs.

18. Estate Recovery. Beneficiaries receiving services through OPI-M are exempted from Medicaid estate recovery requirements for all services provided.

19. Medicare Savings Program (MSP) Beneficiaries. Qualifying Individuals (QI) in the Medicare Savings Program, not otherwise eligible for medical assistance under the state plan, are eligible to receive coverage through the OPI-M demonstration if they meet the demonstration eligibility requirements outlined in STC 16.

V. BENEFITS

20. OPI-M Benefit Package. The OPI-M benefit package will be offered through a person-centered planning process identified in a beneficiary’s plan of care. Except for services authorized under presumptive eligibility, services offered under this program will not duplicate services covered under the Medicaid state plan, Medicare or private insurance, or through other federal or state programs. The following are the OPI-M benefits with

corresponding descriptions included in Attachment D:: Service Definitions & Provider Qualification s:

- a. Adult Day Services Program
- b. Assistive Technology– linked to an assessed need or goal in the individual’s person–centered service plan that increases an individual’s independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance. The monetary limit for assistive technology services is \$5,000.
- c. Assisted Transportation (only in conjunction with the delivery of a service authorized for this specific program)
- d. Caregiver Education and Training
- e. Case Management and Service Coordination
- f. Chore Services
- g. Community Caregiver Support Services
- h. Evidence–Based Health Promotion
- i. Emergency Response Systems
- j. Home Delivered Meals
- k. Home Modifications – linked to an assessed need or goal in the individual’s person–centered service plan that increases an individual’s independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance. A monetary limit of \$5,000 will be set for home modifications, unless an exception is otherwise provided.
- l. In–Home Support and Personal Care Services
- m. Long Term Care Community Nursing Services
- n. Options Counseling
- o. Special Medical Equipment and Supplies, and
- p. Supports for Consumer Direction and Advocacy

VI. HCBS QUALITY ASSURANCE AND REPORTING REQUIREMENTS

- 21. Electronic Visit Verification System Requirements.** The state will demonstrate compliance with the Electronic Visit Verification System (EVV) requirements for personal care services (PCS) by January 1, 2021 and home health services by January 1, 2023 in accordance with section 12006 of the 21st Century CURES Act.
- 22. Person Centered Service Planning.** The state assures there is a person–centered service plan for each beneficiary determined to be eligible for HCBS. The person–centered service plan is developed using a person–centered service planning process in accordance with 42 CFR 441.301(c)(1) and the written person–centered service plan meets federal requirements at 42 CFR 441.301(c)(2) The person–centered service plan is reviewed, and revised upon reassessment of functional need as required by 42 CFR 441.365(e), at least every 12 months, when the individual’s circumstances or needs change significantly, or at the request of the beneficiary.
- 23. For LTSS: Quality Strategy for 1915(c) or 1915(i) approvable HCBS Services.** For services that could have been authorized to individuals under a 1915(c) HCBS waiver or

under a 1915(i) HCBS state plan amendment, the state must have an approved Quality Strategy that reflects how the state will assess and improve performance to demonstrate compliance with applicable federal requirements at 42 CFR 441.745(b) as follows, and is required to develop performance measures to address the following requirements:

- a. **Administrative Authority.** A performance measure should be developed and tracked for any authority that the State Medicaid Agency (SMA) delegates to another agency, unless already captured in another performance measure.
- b. **Eligibility based on Section 1115 Requirements.** Performance measures are required for the following: applicants with a reasonable likelihood of needing services receive an evaluation for HCBS eligibility, and the processes for determining eligibility for HCBS are followed as documented. While a performance measure for annual eligibility is not required to be reported, the state is expected to ensure that annual eligibility is determined.
- c. **Qualified Providers.** The state must have performance measures that track that providers meet applicable licensure/certification standards, that non-licensed/non-certified providers are monitored to assure adherence to demonstration requirements, and that the state verifies that training is given to providers in accordance with the demonstration.
- d. **Service Plan.** The state must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants, including compliance with STC 22. Performance measures are required for ensuring that service plans reflect the choice of waiver services and providers, that service plans address all assessed needs and personal goals, and that services are delivered in accordance with the service plan including the type, scope, amount, duration, and frequency specified in the service plan.
- e. **Health and Welfare.** The state must demonstrate it has designed and implemented an effective system for assuring HCBS participants' health and welfare. The state must have performance measures that track that, on an ongoing basis, it identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; that an incident management system is in place that effectively resolves incidents and prevents further singular incidents to the extent possible; that state policies and procedures for the use or prohibition of restrictive interventions are followed; and, that the state establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved demonstration.
- f. **Financial Accountability.** The state must demonstrate that it has designed and implemented an adequate system for ensuring financial accountability of the HCBS program in accordance with 42 CFR 441.745(a)(2)(iii).

- g. **HCBS Settings Requirements.** The state must assure compliance with the characteristics of HCBS settings as described in 42 CFR 441.301(c)(4) regulations in accordance with implementation/effective dates as published in the Federal Register.
- h. **Quality Improvement Strategy (QIS).** The state must submit the Quality Improvement Strategy (QIS) and performance measures to CMS for review and approval within 90 days following approval of the demonstration.
- i. **Enrollment.** The state must annually report to CMS the actual number of unduplicated individuals served by this demonstration, and the estimated number of individuals to be served for the following year, no later than 90 days post the end of each Demonstration Year.
- j. **Reporting.** The state must report annually on the deficiencies found during the monitoring and evaluation of the HCBS demonstration assurances and measures, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not reoccur. The state must also report on the number of substantiated instances of abuse, neglect, exploitation or death, the actions taken regarding the incidents and how they were resolved. This report is to be submitted no later than 6 months after the end of each Demonstration year.

24. HCBS Reporting Requirements. The state will submit a report to CMS, following receipt of an Evidence Request letter and report template from the Division of HCBS Operations and Oversight (DHCBSO), no later than 21 months prior to the end of the approved demonstration period, which includes evidence on the status of the HCBS quality requirements and measures that adheres to the requirements outlined in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in §1915(c) Home and Community–Based Waivers, as described in Attachment E. Following receipt of the state’s evidence report, the DHCBSO will issue a draft report to the state and the state will have 90 days to respond. The DHCBSO will review and assess each evidentiary report to determine whether the assurances have been met and will issue a final report to the state 60 days following receipt of the state’s response to the draft report.

25. HCBS Beneficiary Protections.

- a. **Person–centered planning.** The state assures there is a person–centered service plan for each individual determined to be eligible for HCBS that meets the requirements set forth at 42 CFR 441.301(c)(1)–(3).
- b. **Conflict of Interest.** The state agrees that the entity that authorizes the services is external to the agency or agencies that provide the HCBS services. The state also agrees that appropriate separation of assessment, treatment planning and service provision functions are incorporated into the state’s conflict of interest policies.
- c. **Community Participation.** The state must ensure that participants’ engagement and community participation is supported to the fullest extent desired by each participant.

VII. COST SHARING

26. **Cost Sharing.** All cost sharing must comply with Medicaid requirements that are set forth in federal statute, regulation, the state plan, and policies, except as modified by the waivers and STCs granted for this demonstration. There are no additional cost sharing requirements for beneficiaries receiving services.

VIII. DELIVERY SYSTEM

27. **Delivery System.** The demonstration will utilize the current fee for service (FFS) delivery system and payment rates currently constituted in Oregon’s state plan and relevant Medicaid waivers. FFS rates for services not otherwise covered in the state plan must be within the ranges published by the state for each service. Payment will not exceed the prevailing charges in the locality for comparable services under comparable circumstances, or the rates charged by Oregon’s Area Agencies on Aging (AAA) for comparable services funded by other sources.

IX. MONITORING AND REPORTING REQUIREMENTS

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

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable. The extension request must explain the reason why the required deliverable was not submitted, the steps the state has taken to address such issue, 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 as an interim step before

applying the deferral, if corrective action is proposed in the state’s written extension request.

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

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

- 29. Submission of Post-Approval Deliverables.** The state shall submit all required analyses, reports, design documents, presentations, and other items specified in these STCs (“deliverables”). The state shall use the processes as stipulated by CMS and within the timeframes outlined within these STCs.
- 30. 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, 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.
- 31. 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, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. **Performance Metrics.** The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's 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, as applicable. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

The state and CMS will work collaboratively to finalize the list of metrics to be reported on in demonstration Monitoring Reports. The demonstration's monitoring metrics must cover categories to include, but not limited to, enrollment and renewal, including the percent of renewals completed ex-parte (administratively), access to providers, utilization of services, and grievances and appeals. In addition, the state must undertake robust reporting of quality of care and health outcomes metrics aligned with the demonstration's policies and objectives, to be reported for all demonstration populations. As appropriate, the state must leverage measures from the Home and Community-Based Services (HCBS) Quality Measure Set¹ and CMS's draft Disparities Sensitive Measure Set. The reporting of these monitoring metrics must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race, ethnicity, and geography) and by demonstration components, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes, and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

¹ The HCBS Quality Measure Set can be accessed on Medicaid.gov at the following link: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

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

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

32. Corrective Action Plan Related to Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state’s demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

33. 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 or Summative Evaluation Reports stipulated in STCs 66 and 67, 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 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 28.

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

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

35. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) 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 thirty (30) calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

X. GENERAL FINANCIAL REQUIREMENTS

36. 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.

37. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS–37

and CMS–64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS–37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state’s estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS–64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS–64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

38. Sources of Non–Federal Share. As a condition of demonstration approval, the state certifies that its funds that make up the non–federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non–federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non–federal share or associated funding mechanisms and all sources of non–federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non–federal share are impermissible.

- a. If requested, the state must submit for CMS review and approval documentation of any sources of non–federal share that would be used to support payments under the demonstration.
- b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS’s concerns within the time frames allotted by CMS.
- c. Without limitation, CMS may request information about the non–federal share sources for any amendments that CMS determines may financially impact the demonstration.

39. State Certification of Funding Conditions. As a condition of demonstration approval, the state certifies that the following conditions for non–federal share financing of demonstration expenditures have been met:

- a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non–federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non–federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding

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

- c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non–federal share of expenditures under the demonstration must be made in an amount not to exceed the non–federal share of the expenditures under the demonstration.
- d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre–arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider–related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
- e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state’s share of the allowable expenditures reported on the CMS–64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

40. Requirements for Health Care–Related Taxes and Provider Donations. As a condition of demonstration approval, the state attests to the following, as applicable:

- a. Except as provided in paragraph (c) of this STC, all health care–related taxes as defined by section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad–based as defined by section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).
- b. Except as provided in paragraph (c) of this STC, all health care–related taxes are uniform as defined by section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).
- c. If the health care–related tax is either not broad–based or not uniform, the state has

applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.

- d. The tax does not contain a hold harmless arrangement as described by section 1903(w)(4) of the Act and 42 CFR 433.68(f).
- e. All provider related-donations as defined by 42 CFR 433.52 are bona fide as defined by section 1903(w)(2)(B) of the Act, 42 CFR 433.66, and 42 CFR 433.54.

41. State Monitoring of Non-federal Share. If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 28. This report must include:

- a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state or other entities relating to each locality tax or payments received that are funded by the locality tax;
- b. Number of providers in each locality of the taxing entities for each locality tax;
- c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
- d. The assessment rate that the providers will be paying for each locality tax;
- e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
- f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
- g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
- h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

42. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in STC 56:

- a. Administrative costs, including those associated with the administration of the demonstration;

- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.

- 43. Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- 44. Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. Table 7 provides a master list of MEGs defined for this demonstration.

Table 1. Master MEG Chart					
MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
OPI-M	Hypo	X		X	Limited HCBS
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

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

- 45. Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00415/10). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service

associated with the expenditure. All MEGs identified in Table 7 as WW must be reported for expenditures, as further detailed in Table 8. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS–64.9P WAIVER) for the summary sheet line 10b (in lieu of lines 9 or 10c), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS–64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS–64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. **Pharmacy Rebates.** Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS–64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS–64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate–eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
- d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS–64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on Table 2 or in STC 45, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in STC 31, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in Table 1. The

term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

- f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS–64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 2. MEG Detail for Expenditure and Member Month Reporting							
MEG (Waiver Name)	Detailed Description	CMS–64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
OPI–M	Expenditures authorized under the demonstration for beneficiaries receiving limited HCBS.	Follow CMS 64.9 Base Category of Service Definition	Date of service	MAP	Y	02/13 /2024	01/31 /2029
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality	Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	02/13 /2024	01/31 /2029

ADM – administration; DY – demonstration year; MAP – medical assistance payments;

MEG – Medicaid expenditure group.

- 46. Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in Table 3.

Table 3. Demonstration Years		
Demonstration Year 1	February X, 2024 to January 31, 2025	12 months
Demonstration Year 2	February 1, 2025 to January 31, 2026	12 months
Demonstration Year 3	February 1, 2026 to January 31, 2027	12 months
Demonstration Year 4	February 1, 2027 to January 31, 2028	12 months
Demonstration Year 5	February 1, 2028 to January 31, 2029	12 months

- 47. Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing the demonstration’s actual expenditures to the budget neutrality expenditure limits described in STC 51. CMS will provide technical assistance, upon request.²
- 48. Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.
- 49. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
- a. To be consistent with enforcement of laws and policy statements, including regulations

² Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS’s current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

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

- a. **Contents of Request and Process.** In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 50.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration, are outside of the state's control, and/or that result from a new expenditure that is not a new demonstration–covered service or population and that is

likely to further strengthen access to care.

- b. **Types of Allowable Changes.** Adjustments will only be made for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:
 - i. Provider rate increases that are anticipated to further strengthen access to care;
 - ii. CMS or state technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors (such as not aging data correctly) or unintended omission of certain applicable costs of services for individual MEGs;
 - iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
 - iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
 - v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
 - vi. High cost innovative medical treatments that states are required to cover; or,
 - vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.
- c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:
 - i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,
 - ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

XI. MONITORING BUDGET NEUTRALITY

- 51. Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of a

Main Budget Neutrality Test, three Hypothetical Budget Neutrality Tests, and a Capped Hypothetical Budget Neutrality Test, as described below. CMS’s assessment of the state’s compliance with these tests will be based on the Schedule C CMS–64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS–64 that pertain to the demonstration.

- 52. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 4. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- 53. Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual or CE calculated number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 54. Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality test must be returned to CMS.
- 55. Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be “hypothetical,” such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non–

hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state’s WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

56. Hypothetical Budget Neutrality Test. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.” MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 4. Hypothetical Budget Neutrality Test

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY1	DY2	DY3	DY4	DY5
OPI-M	PC	Both	4.7%	\$2,640.00	\$2,764.08	\$2,893.99	\$3,030.01	\$3,172.42

57. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

58. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from February 13, 2024 to January 31, 2029. If at the end of the demonstration approval period the Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior

to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

- 59. Corrective Action Plan.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in Table 13 as a guide for determining when corrective action is required.

Table 5. Budget Neutrality Test Corrective Action Plan Calculation		
Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XII. EVALUATION OF THE DEMONSTRATION

- 60. Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state’s participation – including representation from the state’s contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable – in a federal learning collaborative aimed at cross–state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and evaluation. The 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 28.

- 61. 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 draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- 62. 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. In addition to these requirements, if determined culturally appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic) – as these implementation strategies help create strong comparison groups and facilitate robust evaluation.

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 66 and 67.

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 (as applicable) and Summative Evaluation Reports, described below.

- 63. Evaluation Design Approval and Updates.** The state must submit 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 Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Quarterly and 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.

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

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of HCBS services. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include the Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, the HCBS Quality Measure Set, the Behavioral Risk Factor Surveillance System (BRFSS) survey, or measures endorsed by National Quality Forum (NQF).

Specifically, evaluation hypotheses must focus on the impact of the demonstration in improving eligible beneficiaries' access to HCBS, coordination with case managers, and support for unpaid family caregivers. Hypotheses must include, but not be limited to, outcomes such as beneficiaries' quality of life at home and their increased independence. In addition, the evaluation must assess how the demonstration helps to prevent or delay escalation of beneficiary health outcomes, disability, and need for institutional levels of care, and thereby may support any cost savings in the long run. For the continuous eligibility policy, the state must evaluate how the policy affects coverage, enrollment, and churn (i.e., temporary loss of coverage during which beneficiaries are disenrolled but re-enroll within 12 months), as well as appropriate measures of HCBS utilization and health outcomes. The state must also evaluate the effectiveness of the continuous eligibility authority. For example, the state may conduct a comprehensive qualitative assessment involving beneficiary focus groups and interviews with key stakeholders to assess the merits of such policies.

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 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 program.

CMS underscores the importance of the state undertaking a well–designed beneficiary survey or interviews to assess, for instance, beneficiary understanding of the demonstration policy components and beneficiary experiences with access to and quality of care. 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—and barriers to—implementation, the state is strongly encouraged to undertake a robust process/implementation evaluation. 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 collect data to support analyses stratified by key subpopulations of interest (e.g., by sex, age, race, ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes, as well as help inform how the demonstration’s various policies might support reducing such disparities.

- 65. Evaluation Budget.** A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations 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 designs are not sufficiently developed, or if the estimates appear to be excessive.
- 66. 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 an extension of the demonstration, the Interim Evaluation Report should be posted to the state’s website with the application for public comment.
 - a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.
 - b. For demonstration authority 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 extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.

- d. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
 - e. The Interim Evaluation Report must comply with Attachment B of these STCs.
- 67. Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs, and in alignment with the approved Evaluation Design.
- a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS of the draft.
 - b. Once approved by CMS, the state must post the final Summative Report to the state's Medicaid website within 30 calendar days.
- 68. Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- 69. 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, and the Summative Evaluation.
- 70. Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.
- 71. 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. 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.

XIII. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION

Deliverable	Timeline	STC Reference
State Acceptance of the demonstration waiver authorities, expenditure authorities, and STCs	30 calendar days after approval.	Approval Letter
HCBS Quality Improvement Strategy Report	The state must submit the Quality Improvement Strategy (QIS) to CMS for review and approval within 90 days following approval of the demonstration.	STC 23.h
HCBS Performance Measure Report	The state must submit the performance measures to CMS for review and approval within 90 days following approval of the demonstration.	STC 23.h
HCBS Evidentiary Report	21 months prior to the end of the approved demonstration period	STC 24
Evaluation Design	No later than 180 days after approval. Revised no later than 60 days following receipt of CMS comments on Draft Evaluation Design.	STC 62
Interim Evaluation Report	One year prior to current expiration date, January 31, 2028 or when the extension application is submitted, whichever is sooner. Revised no later than 60 days after receipt of CMS comments.	STC 66
Summative Evaluation Report	No later than 18 months after the end of the demonstration period (01/31/2029).	STC 67

Deliverable	Timeline	STC Reference
	Revised no later than 60 days after receipt of CMS comments.	
<i>Annually</i>		
HCBS Deficiency, Remediation and A/N/E Incident Report	Annually, 6 months post the end of each demonstration year	STC 23.i
HCBS Actual and Estimated Enrollment Number Report	Annually, 90 days post the end of each demonstration year	STC 23.j
Annual Monitoring Reports	No later than 90 days after the end of each demonstration year.	STC 31
Post Award Forum	No later than 6 months after the demonstration’s implementation and annually thereafter.	STC 35
<i>Quarterly</i>		
Quarterly Monitoring Reports	No later than 60 days after the end of each demonstration quarter.	STC 31
CMS–64 Budget Neutrality Expenditure Reports	Quarterly	STC 31.c.

ATTACHMENT A

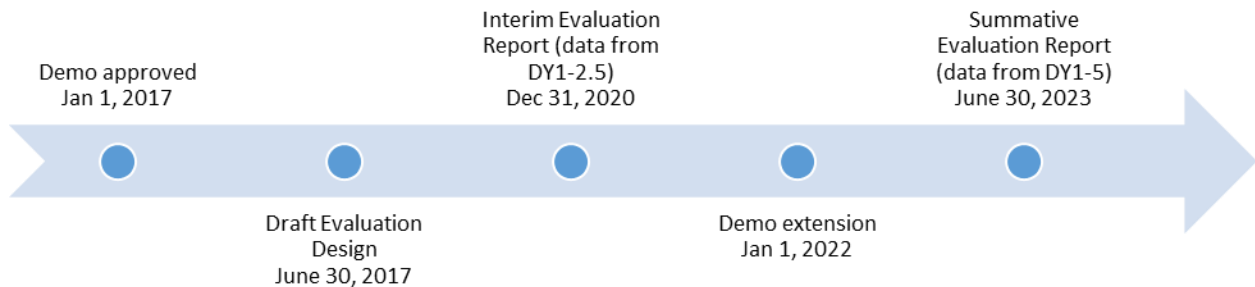
Developing the Evaluation Design

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 programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the 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:

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:
 - a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-in-differences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.

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

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

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

E. Attachments

1. **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a “No Conflict of Interest” statement signed by the independent evaluator.

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

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

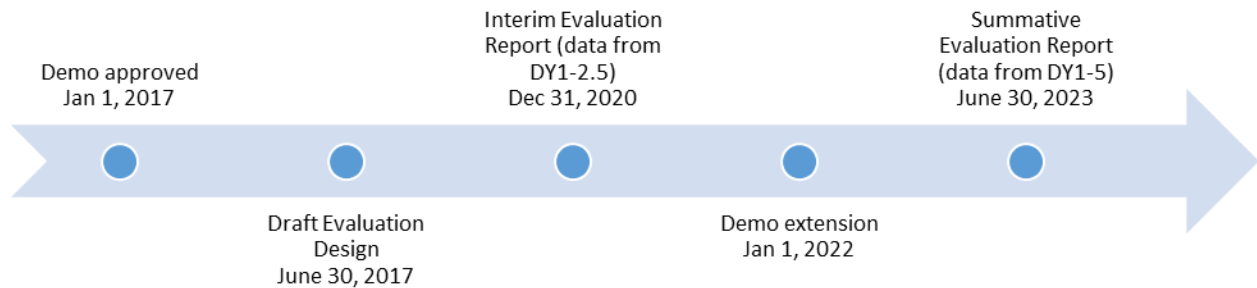
ATTACHMENT B Preparing the Interim and Summative Evaluation Reports

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 programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the 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 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 policy.

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

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

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

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

1. The 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 context and long-range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretations of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.
- I. **Lessons Learned and Recommendations** – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the 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)

ATTACHMENT D
Service Definitions and Provider Qualifications

Service Definitions	Provider Qualifications
<p>“Adult Day Services (ADS) Program” means a community–based group program designed to meet the needs of adults needing assistance with ADLs. All ADS programs meet HCBS requirements.</p>	<p>ADS Programs are certified under OAR chapter 411, division 066.</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-066.pdf</p> <p>OAR 411-066-0015(2)</p>
<p>"Assistive Technology" means any item, piece of equipment, technology, system, whether acquired commercially, modified, or customized, that is linked to an assessed need or goal in the individual’s person–centered service plan, and used to increase, maintain, or improve the functional capabilities of an individual, that provides additional security and support to an individual, replaces the need for human interventions or enables an individual to self–direct their care and maximize their independence. Training on using the technology is available if requested by the recipient, representative, caregivers, and/or family.</p>	<p>Assistive Technology Providers must meet the requirements in OAR chapter 411, division 35.</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-035.pdf</p> <p>OAR 411-035-0035</p>

Service Definitions	Provider Qualifications
<p>"Assisted Transportation" means escort services that assists an individual who has difficulties (physical or cognitive) using regular vehicular transportation and includes those services and supports provided so that the individual may access their local community to engage in services necessary to meet their Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL). These services also include "community transportation," which is non-medical transportation provided by a service provider with a Medicaid provider number and prior authorized as part of an OPI-M service plan by a Service Plan Case Manager.</p>	<p>Assistive transportation is offered through contracted transportation providers, public transportation, homecare workers or in-home care agencies who have a valid Medicaid provider number.</p>
<p>"Caregiver Education and Training" means education and training programs and services to increase an unpaid caregiver's skills in providing care and supports unique to the consumer receiving unpaid caregiver services.</p>	<p>Caregiver Education and Training providers are contracted entities that provide one to one training or those that are contracted to provide classroom type trainings.</p> <p>Providers must at a minimum meet the following requirements:</p> <ul style="list-style-type: none"> • Be over the age 18; • Have a high school diploma or GED. • Pass a criminal background check; • Be willing and able to enroll as a Medicaid provider; and • Meet the specific requirements for the subject matter content on which they are teaching or training.

Service Definitions	Provider Qualifications
<p>"Case Management and Service Coordination" means a service designed to individualize and integrate social and health care options with an individual being served. The goal of service coordination is to provide access to an array of service options to assure appropriate levels of service and to maximize coordination in the service delivery system.</p>	<p>Case managers must meet the qualifications in OAR chapter 411, division 028 and pass a background check</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-028.pdf</p> <p>OAR 411-028-0040</p>
<p>"Chore Services" means assistance such as heavy housework, yard work, or sidewalk maintenance provided on an intermittent or one-time basis to assure health and safety.</p>	<p>Chore services providers must meet the qualifications in chapter 411, division 035:</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-035.pdf</p> <p>411-035-0050 (1)</p>
<p>"Community Caregiver Support Services" means supports and services that assist the individual and their unpaid caregivers to sustain their caregiving relationship and natural support systems. These supportive services directly benefit the individual by sustaining the caregiver's health, improving caregiver wellbeing, and reducing stress. This may help prevent abuse, neglect and transitions to more intensive levels of care. Services include: paid wellness services, group-based activities, training, gaining skills and knowledge to sustain a care receiver to remain at home or a caregiver to remain in their role, peer supports and facilitated support groups.</p>	<p>Community Caregiver Support Services providers are contracted entities that provide group-based support groups and other direct services to the caregiver.</p> <p>Providers must at a minimum meet the following requirements:</p> <ul style="list-style-type: none"> • Be over the age 18; • Have a high school diploma or GED. • Pass a criminal background check; • Be willing and able to enroll as a Medicaid provider; and • Meet the requirements for the specific program being offered.

<p>"Evidence-Based Health Promotion" means individual or group programs that meet the requirements for ACL's Evidence-Based Definition or is considered to be an "evidence-based program" by any operating division of the U.S. Department of Health and Human Services (HHS) and is shown to be effective and appropriate for older adults.</p> <p>These services include:</p> <ul style="list-style-type: none"> • Program to Encourage Active, Rewarding Lives for Seniors (PEARLS) • Healthy IDEAS (Identifying Depression Empowering Activities for Seniors) • The suite of Chronic Disease Self-Management Education (CDSME) programs • Fit & Strong! • A Matter of Balance • The Otago Exercise Program (OEP) • Tai Chi – Moving for Better Balance • SHARE for Dementia (Support, Health, Activities, Resources, Education) <p>Information of these services can be found on the Administration for Community Living's Aging and Disabilities Evidence-Based Programs and Practices website.</p> <p>ACL Definition of Evidence-Based Programs</p> <ul style="list-style-type: none"> • Demonstrated through evaluation to be effective for improving the health and well-being or reducing disease, disability and/or injury among older adults; and 	<p>Providers must enroll as a Medicaid provider and must meet the provider qualifications specified in the specific health promotion activity.</p> <p>https://acl.gov/programs/health-wellness/disease-prevention#future</p> <p>Providers must at a minimum meet the following requirements:</p> <ul style="list-style-type: none"> • Be over the age 18; • Have a high school diploma or GED. • Pass a criminal background check; • Be willing and able to enroll as a Medicaid provider; and • Meet the training and credential requirements for the specific Evidence-Based program or programs they are providing.
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Service Definitions	Provider Qualifications
<ul style="list-style-type: none"> • Proven effective with older adult population, using Experimental or Quasi-Experimental Design;* and • Research results published in a peer-review journal; and • Fully translated** in one or more community site(s); and • Includes developed dissemination products that are available to the public. 	
<p>“Emergency Response Systems” mean a type of electronic back-up system that: secures help for individuals in an emergency, ensures a consumer's safety in the community; and includes other reminders that help an individual with their activities of daily living and instrumental activities of daily living, including alert systems, a unit that is worn by the individual or is located in the individual's home for the purpose of generating notification that an emergency has or may occur.</p>	<p>Providers must enroll as a Medicaid provider and must meet the provider qualifications specified OAR chapter 411, division 035</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-035.pdf</p> <p>411-035-0035</p>
<p>“Home Delivered Meals” for the purpose of these rules means meals that are delivered to an eligible participant in their own home or apartment. This service does not constitute a full nutritional regimen.</p>	<p>Home Delivered Meal Providers must meet the qualifications in OAR chapter 41, division 40</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-040.pdf</p> <p>411-040-0030 (1) – (4)</p>

Service Definitions	Provider Qualifications
<p>"Home Modifications" means the changes made to adapt living spaces to meet specific service needs of eligible individuals with physical limitations to maintain their health, safety, and independence. All services are expected to be tied to an individual's ADLs, IADLs, or health-related needs identified in the person-centered service plans on and increases an individual's independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance.</p> <p>A monetary limit of \$5,000 will be set for home modifications, with an exception process in place with the state agency.</p>	<p>"Home Modifications" providers must meet the requirements in OAR Chapter 411, division 035.</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-035.pdf</p> <p>411-035-0065 Environmental Modification Provider Qualifications and Requirements</p>
<p>"In-Home Support and Personal Care Services" mean those services that meet an individual's assessed need related to activities of daily living and instrumental activities of daily living provided in the individual's home or family's home, and can include respite supports.</p> <p>*Note: This is the service that would be subject to the 40-hour per pay period limit, with an exceptions process for consumers who would need more hours. All other services are considered wrap-around services to this 40-hour limit to in-home services.</p>	<p>In-home support and personal care services providers must meet the qualifications for:</p> <ul style="list-style-type: none"> • Home care workers as defined in OAR chapter 411, division 31 – https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-031.pdf • In-home care agencies as defined in OAR chapter 411, division 33 – https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-033.pdf

Service Definitions	Provider Qualifications
<p>"Long Term Care Community Nursing Services" mean a distinct set of services that focus on an individual's chronic and ongoing health and activity of daily living needs. Long term care community nursing services include an assessment, monitoring, delegation, teaching, and coordination of services that addresses an individual's health and safety needs in a Nursing Service Plan that supports individual choice and autonomy. The requirements in these rules are provided in addition to any nursing related requirements stipulated in the licensing rules governing the individual's place of residence.</p>	<p>Long Term Care Community Nursing Services are provided by licensed RNs who meet the qualifications specified in</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-048.pdf</p> <p>411-048-0210 Qualifications for Enrolled Medicaid Provider</p>
<p>"Options Counseling" means counseling that supports informed long term care decision making through assistance provided to individuals and families to help them understand their strengths, needs, preferences, and unique situations and translate this knowledge into possible support strategies, plans, and tactics based on the choices available in the community, beyond the resources within the individual's service plan.</p> <p>Rate methodology: contracted service with the local Area Agencies on Aging. and Centers for Independent Living.</p>	<p>Options Counseling providers must meet the following requirements:</p> <ul style="list-style-type: none"> • Participate and pass competency requirements in state approved Person Centered Options Counselor training • Receive certification in national Information and assistance training such as AIRS.

Service Definitions	Provider Qualifications
<p>“Special Medical Equipment and Supplies” means mechanisms, and any specialized or durable medical equipment and medical supplies not covered by Medicare, Medicaid or other insurance, necessary to support the consumer’s health or well-being</p>	<p>Special Medical Equipment and Supplies providers must meet the requirements in OAR chapter 411, division 35.</p> <p>https://www.oregon.gov/DHS/SENIORS-DISABILITIES/SPPD/APDRules/411-035.pdf</p> <p>OAR 411-035-0035</p>
<p>"Supports for Consumer Direction and Advocacy" means activities to empower and inform individuals receiving in-home services regarding their rights, role, and responsibilities as employers of care providers and to empower the consumer to advocate for themselves in services and resources outside their service plan, such as health care and behavioral health services, housing, and transportation, and to help consumers manage their person-centered service plan, their personal goals and life experiences, ensuring the consumer’s health, safety, and overall wellbeing.</p>	<p>Supports for Consumer Direction and Advocacy Providers are Medicaid enrolled contractors who have demonstrated experience in assisting older adults and people with disabilities.</p> <p>Providers must at a minimum meet the following requirements:</p> <ul style="list-style-type: none"> • Be an organization with demonstrated expertise in empowering consumers to direct their own services with at least 2 years of experience; • The organization must: <ul style="list-style-type: none"> ○ Ensure that all staff are over the age 18 and have a high school diploma or GED. ○ Document that all staff have passed a criminal background check; ○ Be willing and able to enroll as a Medicaid provider.