Department of Health & Human Services Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-26-12 Baltimore, Maryland 21244-1850



December 18, 2024

Cora Steinmetz
Director of Medicaid
Indiana Medicaid
State of Indiana, Family and Social Services Administration
402 West Washington Street, Room W461, MS 25
Indianapolis, IN 46204

### Dear Director Steinmetz:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) has approved a temporary extension and amendment of Indiana's section 1115 demonstration, titled "Workforce Bridge Account Program" (Project Number #11-W-00237/5), formerly entitled "End Stage Renal Disease (ESRD)" in order to allow Indiana and CMS to continue negotiations of the demonstration. This demonstration will now expire December 31, 2025.

The temporary extension and amendment only apply to existing title XIX expenditure authority for the not yet implemented Workforce Bridge Account Program. This program would, when implemented, allow certain Medicaid beneficiaries, who lose Medicaid eligibility due to an increase in income, to be eligible for up to \$1,000 for the purpose of temporarily paying for costs that would include premiums and copayments for health insurance coverage, or the direct costs of health care services that would be covered by Medicaid for state plan eligible individuals.

The temporary extension and amendment will not include a continuation of existing title XIX authority for coverage of low-income individuals with a diagnosis of End Stage Renal Disease (ESRD) because Indiana requested to phase-out these authorities. The ESRD population in the demonstration was added in May 2014 to support Medicare beneficiaries in need of supplemental health care coverage. These beneficiaries were able to access kidney transplant and related services that they might not otherwise be able to afford without the additional supplemental benefits. However, the state has requested to phase out this authority for two reasons. First, they report a decline in the number of beneficiaries with unique dialysis claims and an increase in the number of beneficiaries receiving kidney transplants. Second, there is a new Medicare Advantage enrollment option created by the 21st Century Cures Act<sup>1</sup> allowing ESRD patients to enroll in Medicare Advantage which, unlike traditional Medicare Part A and Part B, acts as an "all in one" plan that includes prescription (Part D) coverage and in some cases additional benefits such as vision, hearing, and dental. This authority will expire on December 31, 2024, consistent with the current special terms and conditions (STCs).

<sup>&</sup>lt;sup>1</sup> Sec. 17006. Allowing End-Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan.

# **Budget Neutrality** <sup>2</sup>

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 likely would have been in that state absent the demonstration. The demonstration temporary extension and amendment is projected to be budget neutral to the federal government. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in 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). The state will be held to the budget neutrality monitoring and reporting requirements as outlined in the STCs.

## Hypothetical Budget Neutrality Treatment

In the previous demonstration approval, the Workforce Bridge Account Program relied on savings. For this amendment, CMS will rely on a hypothetical model of budget neutrality, reflecting CMS practice for premium assistance demonstration programs and because the Workforce Bridge Account Program expenditures are for otherwise coverable Medicaid services and populations. Under its current approach to budget neutrality, CMS generally treats expenditures for populations or services which could have otherwise been covered via the Medicaid state plan, or other title XIX authority, such as a section 1915 waiver, as "hypothetical" for the purposes of budget neutrality. In these cases, CMS adjusts budget neutrality in the manner discussed below to account for the spending which the state could have hypothetically provided through the Medicaid state plan or other title XIX authority. CMS does not, however, currently allow for budget neutrality savings accrual as a result of including hypothetical populations or services in section 1115 demonstration projects. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent budget neutrality "supplemental test" for hypothetical expenditures. These supplemental budget neutrality tests subject the hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's "with waiver" (WW) hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending with savings elsewhere in the demonstration or to refund the federal financial participation (FFP) to CMS. For the Medicaid expenditure group (MEG) included in this approval, CMS calculated the WOW baseline (which refers to the projected expenditures that could have occurred absent the demonstration and which is the basis for the budget neutrality expenditure limit for each approval period). The revised budget neutrality agreement will apply as described in the STCs until December 31, 2025, or until the demonstration is extended, whichever is sooner.

<sup>&</sup>lt;sup>2</sup> For more information on CMS's current approach to budget neutrality, see <a href="https://www.medicaid.gov/medicaid/section-1115-demonstrations/budget-neutrality/index.html">https://www.medicaid.gov/medicaid/section-1115-demonstrations/budget-neutrality/index.html</a>

CMS has updated its approach to mid-course corrections to budget neutrality calculations 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 actual expenditure data to accommodate circumstances that are either out of the state's control (for example, if expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (for example, unexpected costs due to a public health emergency); and/or 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 (for example, 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**

Indiana submitted an Interim Evaluation Report covering the ESRD portion of the demonstration through 2020. Descriptive trends show that between 2014 and 2020, there were a total of 760 unique individuals enrolled in the program. Over this time period, the total number and percent of members with a kidney transplant claim increased, while the total number and percent of members with a dialysis claim decreased, in line with the demonstration's goal of increasing transplants and, as a result, decreasing the need for dialysis in the demonstration population and ultimately decreasing the number of members in the demonstration. CMS looks forward to receiving the Final "Summative" Evaluation Report 18 months after the end of the ESRD portion of the demonstration.<sup>3</sup>

For the temporary extension period for the Workforce Bridge Account Program authority, the state must when implemented monitor its demonstration as stipulated in the current STCs. In addition, the state is required to include this and the prior temporary extension periods in its demonstration's evaluation. The state may choose to include this and prior temporary extensions within its summative evaluation for the demonstration approval period beginning July 28, 2016 discussed above. Alternatively, if CMS approves an extension beyond December 31, 2025, the state may choose to include the temporary extension periods in the Evaluation Design and activities of the next full demonstration approval period.

### **Other Information**

The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer for this demonstration is Alicia Bazell, who is available to answer any questions concerning your section 1115 demonstration and her contact information is as follows:

<sup>&</sup>lt;sup>3</sup> The demonstration's STCs approved on July 28, 2016 require the state to complete a Final Evaluation Report, which CMS has since referred to in more recent demonstration approvals as a Summative Evaluation Report. For alignment with Indiana's ESRD demonstration STCs, we refer to this report as the Final Evaluation Report.

# Page 4 – Cora Steinmetz, Director

Centers for Medicare & Medicaid Services Center for Medicaid and CHIP Services Mail Stop: S2-25-26

7500 Security Boulevard Baltimore, MD 21244-1850

Email: Alicia.Bazell@cms.hhs.gov

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

Sincerely,



Daniel Tsai Deputy Administrator and Director

cc: Rhonda Gray, State Monitoring Lead, Medicaid and CHIP Operations Group

# CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00237/5

TITLE: Workforce Bridge Account Program

**AWARDEE:** Indiana Family and Social Services Administration

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period of this demonstration, be regarded as expenditures under the state's Medicaid title XIX state plan. The expenditure authority period of this demonstration is from the effective date identified in the demonstration approval letter, or as otherwise indicated herein or in the Special Terms and Conditions (STCs), through December 31, 2025.

The following expenditure authorities shall enable Indiana to implement the Workforce Bridge Account Program Medicaid section 1115 demonstration.

1. **Demonstration Population 1:** Expenditures only for health insurance premiums and/or cost sharing, and/or for payment for services that otherwise would be covered by Medicaid, not to exceed \$1000 per individual for the period from the approval date of this expenditure authority through December 31, 2025, for individuals age 19-64 who were, but due to an increase in verified income are no longer, eligible for Medicaid under section 1902(a)(10)(A)(i)(VIII) of the Act and who are otherwise not eligible for Medicaid.

# CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00237/5

TITLE: Workforce Bridge Account Program

**AWARDEE:** Indiana Family and Social Services Administration

### I. PREFACE

The following are the Special Terms and Conditions (STCs) for Indiana's Workforce Bridge Account Program section 1115(a) Medicaid demonstration (hereinafter referred to as "demonstration"). The parties to this agreement are the Indiana Family and Social Services Administration (hereinafter referred to as "state") and the Centers for Medicare & Medicaid Services (CMS). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. This demonstration is approved through December 31, 2025.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Affected Populations and Populations Made Eligible under the Demonstration
- V. Workforce Bridge Account Program
- VI. Cost Sharing
- VII. Delivery System
- VIII. General Reporting Requirements
- IX. General Financial Requirements
- X. Monitoring Budget Neutrality for the Demonstration
- XI. Evaluation of the Demonstration
- XII. Schedule of State Deliverables During the Demonstration

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

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports

## II. PROGRAM DESCRIPTION AND OBJECTIVES

This demonstration, originally titled as Indiana's HIP 1.0 demonstration, began in 1994 to supplement state plan benefits for Medicaid eligible children and otherwise eligible adults who

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Demonstration Approval Period: July 28, 2016 through December 31, 2020

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are not aged, blind or disabled. HIP 1.0 utilized an account similar to a health savings account called a Personal Wellness and Responsibility (POWER) account to cover uninsured parents as well as childless adults whose incomes are below 200 percent of the federal poverty level (FPL). HIP 1.0 was scheduled to expire at the end of 2013 but was extended for an additional year through December 31, 2014.

In May 2014, CMS approved an amendment to the HIP 1.0 demonstration to include former spend down enrollees diagnosed with End Stage Renal Disease (ESRD) as a new HIP 1.0 demonstration population. The ESRD enrollees at issue were Medicare beneficiaries in need of supplemental health care coverage. By providing coverage through HIP, these beneficiaries were able to access kidney transplant and related services that they might not otherwise be able to afford without the additional supplemental benefits.

In January 2015, CMS approved the Healthy Indiana Plan 2.0 (HIP 2.0) demonstration, which provided health care coverage for adults through a managed care plan and a POWER account. The demonstration included POWER account contributions, implemented healthy behavior incentives, and a premium assistance program for individuals with employer sponsored insurance. HIP 1.0 enrollees who originally were part of this demonstration were transitioned from this demonstration to the new HIP 2.0 demonstration, and as a result the ESRD enrollees became the only population remaining in the original HIP 1.0 demonstration. Since the ESRD population was the only one receiving benefits under this demonstration, it was renamed the End Stage Renal Disease (ESRD) demonstration. This demonstration would continue to provide coverage for individuals with ESRD that were not eligible under the Medicaid state plan. The ESRD demonstration was set to expire at the end of 2020.

In an amendment to this ESRD demonstration dated June 1, 2020, the state received authority to create a Workforce Bridge Account Program, under which certain Medicaid beneficiaries would be informed that, if they lost their Medicaid eligibility due to an increase in income, they would be eligible for up to \$1,000 for the purpose of temporarily paying for costs that include premiums and copayments for health insurance coverage, or the direct costs of health care services that would be covered by Medicaid. While reimbursement for health insurance premiums would be paid to the individual or at the request of the individual enrolled in a Marketplace health plan, the state would pay for the premiums directly to the plan. Coverage of plan cost-sharing, or of direct services, would be paid for with a card that would be issued to beneficiaries. The card could only be used for Medicaid covered services received by a Medicaid enrolled provider. Thus, if a beneficiary who purchased health insurance wanted to have cost-sharing covered, he or she must use a Medicaid enrolled provider. This approval included an 8,000-person enrollment cap for the Workforce Bridge Account Program.

CMS subsequently approved four temporary extensions of the ESRD demonstration on December 21, 2020, December 17, 2021, November 28, 2022, and June 23, 2023. In the December 17, 2021 temporary extension approval, CMS also amended the demonstration to remove the enrollment cap for the Workforce Bridge Account Program.

On December 18, 2024, CMS approved the ending of the authority for the ESRD part of the demonstration. That authority will expire on December 31, 2024. The state has established a

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transition process for currently enrolled and newly enrolling eligible beneficiaries, and the authority is being phased out.

However, this temporary extension and amendment is continuing authority for the Workforce Bridge Account Program.

## 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 (ADA), title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid Law, Regulation, and Policy. All requirements of the Medicaid and CHIP program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part) apply to the demonstration.
- 3. Changes in Medicaid Law, Regulation, and Policy. The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable.

In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration per STC 7. CMS will notify the state thirty (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. The modified agreement would be effective upon implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day

- such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 5. State Plan Amendments. The state shall not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan may be required, except as otherwise noted in these STCs. In all such cases, the Medicaid 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 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 for approval no later than one-hundred and twenty (120) days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with STCs, including but not limited to failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
  - a. An explanation of the public process used by the state, consistent with the requirements of STC 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 shall include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

- d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- **8. Extension of the Demonstration**. States that intend to request demonstration extensions must submit an application to CMS from the Governor 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 a phase-out plan consistent with the requirements of STC 9.
- **9. Demonstration Phase-Out.** The state may suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
  - a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the effective date and reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. At least six (6) months before the effective date of the demonstration's suspension or termination, the state must submit to CMS its proposed transition and phase-out plan, together with intended notifications to demonstration enrollees. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the thirty (30) day public comment period has ended, the state must provide a summary of public comments received, the state's response to the comments received, and how the state incorporated the received comments into the transition and phase-out plan submitted to CMS.
  - b. <u>Phase-out Plan Requirements:</u> The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities including community resources that are available.
  - c. <u>Transition and Phase-Out Plan Approval:</u> The state must obtain CMS' approval of the transition and phase-out plan prior to the implementation of the transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) days after CMS approval of the phase-out plan.
  - d. <u>Transition and Phase-out Procedures:</u> The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1). For individuals determine ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR

- 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to demonstration participants as outlined in 42 CFR subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR section 431.230.
- e. Exemption from Public Notice Procedures 42 CFR 431.416(g): CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g)
- f. Enrollment Limitation during Demonstration Phase-Out: If the state elects to suspend, terminate, or not extend this demonstration, during the last six (6) 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. <u>Federal Financial Participation (FFP):</u> If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling participants.
- 10. Withdrawal of Waiver/Expenditure Authority. CMS reserves the right to amend or withdraw waiver and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the amendment or withdrawal., together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn or amended, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals and administrative costs of disenrolling participants.
- **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 section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59

Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with public notice procedures set forth in 42 CFR section 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with the tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved 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 expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- 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), and any contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies of the demonstration.
- 15. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program including public benefit or service programs, procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid 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. AFFECTED POPULATIONS AND POPULATIONS MADE ELIGIBLE UNDER THE DEMONSTRATION

**16. Populations.** This demonstration includes one population and benefits made eligible under the demonstration; no state plan populations are affected by the demonstration. Population 1 is the Workforce Bridge Account Program which includes individuals who are no longer eligible for Medicaid under section 1902(a)(10)(A)(i)(VIII) due to a verified increase in income.

## V. WORKFORCE BRIDGE ACCOUNT PROGRAM

**17. Workforce Bridge Account Program.** This program provides up to \$1,000 for eligible individuals for the purpose of paying health insurance premiums, cost-sharing, or the

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direct costs of prescription drugs and services otherwise coverable as described in STC 21. The state may claim as allowable expenditures under the demonstration funds as described below.

- 18. Eligibility. Individuals who qualify for this program are those who are no longer eligible under section 1902(a)(10)(A)(i)(VIII) of the Act or any other Medicaid eligibility category due to increased income. Individuals who are not eligible for Medicaid based on a failure to meet conditions for eligibility will not qualify for the Workforce Bridge Account Program. Multiple individuals in the same household, if they meet the eligibility requirements, will have access to their own account. These qualified individuals will be notified of their eligibility and opt in opportunity consecutive with their notice of disenrollment. Accounts may be closed if an individual moves out of state, voluntarily withdraws, ages out, becomes incarcerated, enrolls in Medicare, or regains Medicaid or Presumptive Medicaid eligibility. Eligibility for the Workforce Bridge Account Program is for one 12-month period and is not eligible to be renewed.
- **19. Enrollment.** The state will send notification to individuals who are eligible for the Workforce Bridge Account Program due to a loss in Medicaid eligibility based on an increase in income. Individuals will have 30 days from receipt of the notice informing them of eligibility to opt-in to this program to activate the account.
- 20. Benefits. The state will provide funds to the account of no more than \$1,000 to those eligible individuals who opt-in to the account. As part of the opt-in process, individuals will have the option to be referred to Navigators who will inform individuals of their health insurance options, and the benefits of purchasing Affordable Care Act (ACA) compliant coverage. The funds are limited to payments for premiums, payments for costsharing, such as copayments, coinsurance and deductibles, or payments for the direct costs for otherwise Medicaid-eligible services rendered by a Medicaid provider, with the exception of long term care, hospice, waiver and 1915(i) services, Medicaid Rehabilitation Option (MRO), NEMT, and some specialty services that are not covered under the HIP 2.0 program. Individuals enrolled in short-term, limited-duration insurance (as defined in 45 CFR 144.103) or a plan or coverage that consists solely of excepted benefits but for limited scope benefits (as defined in 45 CFR 146.145(b) and 148.220) must not use the funds to pay for premiums. Reimbursement for health insurance premiums will be paid to the individual or paid directly on behalf of the individual. Individuals will be issued a card that provides details for providers to bill the Workforce Bridge Account Program for cost sharing or direct costs of covered services via standard fee for service methodology. The funds in the account will be available to individuals for 12 months or until the full amount has been expended, whichever comes first, after the individual opts-in to the account. Individuals will only be allowed to use the funds for expenses incurred or services received within 12 months and once the 12 months is complete, the individual will not be able to access the account. If a former or current Workforce Bridge Account Program recipient reenrolls in Medicaid, they again could be found subsequently eligible for a Workforce Bridge Account Program if they meet the qualifying criteria.

- **21. Delivery System.** Claims received under the Workforce Bridge Account Program will be processed through the fee-for-service (FFS) arrangement.
- 22. Minimum Essential Coverage (MEC). The Workforce Bridge Account Program is limited to the provision of services described in STC 20, and consequently, is not recognized as Minimum Essential Coverage (MEC) as outlined in section 5000A(f)(1)(A)(ii) of the Internal Revenue Code of 1986. The state shall adhere to all applicable Internal Revenue Service (IRS) reporting requirements with respect to MEC for demonstration enrollees.
- **23. Reporting.** The state must provide data regarding the operation of this program in the quarterly and annual monitoring reports per STCs 30 and 31. This data must, at a minimum, include:
  - a. Number of beneficiaries under 1902(a)(10)(A)(i)(VIII) who lost Medicaid eligibility due to mid-year change in circumstance
    - i. Number of beneficiaries extended an opt-in offer for the Workforce Bridge Account Program.
  - b. The number of individuals served by the program monthly, reflecting counts of beneficiaries both new and continuing on a monthly basis;
  - c. Amount paid per beneficiary (average) from the Bridge Account cap of \$1000 and the average number of months for beneficiaries to reach the cap of \$1000;
  - d. Percent of claims paid as primary insurance and as third-party liability (TPL) from the Bridge Account.

## VI. COST SHARING

**24. Allowable Cost Sharing.** No additional cost sharing will be imposed on individuals enrolled in the Workforce Bridge Account Program.

#### VII. DELIVERY SYSTEM

**25. Fee for Service.** The participants in the demonstration will receive services through a fee-for-service delivery system.

## VIII. GENERAL REPORTING REQUIREMENTS

- **26. General Financial Requirements.** The state shall comply with all general financial requirements under title XIX set forth in these STCs.
- **27. Reporting Requirements Relating to Budget Neutrality.** The state shall comply with all reporting requirements for monitoring budget neutrality set forth in this agreement. The state must submit any corrected budget neutrality data upon request.

- **28. Monitoring Calls.** CMS will have monitoring calls with the state. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.
- **29. Quarterly Monitoring Reports.** The state must submit progress reports in accordance with the guidelines in Attachment A by no later than 60 days following the end of each quarter (March, June, September, and December of each year). The intent of these reports is to present the state's analysis and the status of the various operational program areas. These quarterly reports must include, but not be limited to:
  - a. An updated budget neutrality monitoring spreadsheet;
  - b. A discussion of events occurring during the quarter or anticipated to occur in the near future that affect health care delivery, including, but not limited to: approval and contracting with new plans, benefits, enrollment and disenrollment, grievances, quality of care, access, health plan contract compliance and financial performance that is relevant to the demonstration, pertinent legislative or litigation activity, and other operational issues;
  - c. Action plans for addressing any policy, administrative, or budget issues identified;
  - d. Quarterly enrollment reports for demonstration eligibles that include the member months for each demonstration population, as required to evaluate compliance with the budget neutrality agreement, and as specified in Section VIII, STC 28; and other statistical reports listed in Attachment A.

## **30. Annual Monitoring Report.**

- a. The state shall submit a draft annual monitoring report documenting accomplishments, project status, quantitative and case study findings, utilization data, interim evaluation findings, and policy and administrative difficulties and solutions in the operation of the demonstration.
- b. The state shall submit the draft annual report by no later than 120 days after the end of each demonstration year (DY) for CMS review. The state shall finalize and submit the final draft report within 60 days from receipt of CMS's comments.

## IX. GENERAL FINANCIAL REQUIRMENTS

**31. 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.

- **32. 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.
- 33. 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.
- **34. 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.
- **35. Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:
  - a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

- **36.** 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 Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.
- **37. 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 33. 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.
- **38. 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 the STCs in section IX:
  - 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.
- 39. 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.
- 40. 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. The Master MEG Chart table 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		
Workforce Bridge Account Program	Нуро	X		X	Individuals who are no longer eligible for Medicaid under section 1902(a)(10)(A)(i)(VIII) due to an increase in verified income.		

**41. 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,

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identified by the demonstration project number assigned by CMS (11- W-00237/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. 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 not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- 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 the MEG Charts and in the STCs in section IX, administrative costs are not counted in the budget neutrality test; however, these costs are subject to monitoring by CMS.
- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section VIII, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for

Expenditure and Member Month Reporting table below. 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	Exclusions	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
Workforce Bridge Account Program	Report all expenditures for individuals who are no longer eligible for Medicaid under section 1902(a)(10)( A)(i)(VIII) or other Medicaid coverage due to an increase in verified income.		Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	06/01/2020	12/31/2025

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group;

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

Table 3: Demonstration Years				
Demonstration Year 18	January 1, 2025 to December 31, 2025	12 months		

- 43. 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 section IX. CMS will provide technical assistance, upon request.<sup>1</sup>
- 44. 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.
- **45. 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 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

Indiana Workforce Bridge Account Program

Demonstration Approval Period: July 28, 2016 through December 31, 2020

<sup>&</sup>lt;sup>1</sup> 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.

- 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.
- **46. Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per 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 47c. 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 6. 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 and/or 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 be made only 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 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.

#### X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- **47. 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 Hypothetical Budget Neutrality Test, as described below. CMS's assessment of the state's compliance with this hypothetical test 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.
- **48. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 2, Master MEG Chart and Table 3, MEG Detail for Expenditure and Member Month Reporting. 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.

- 49. 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 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.
- **50. Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of a Hypothetical Budget Neutrality Test. Any excess spending under the Hypothetical Budget Neutrality Test must be returned to CMS.
- **51. 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.
- **52.** Hypothetical Budget Neutrality Test 1: Workforce Bridge Account Program. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. 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 1									
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 13	DY 14	DY 15	DY 16	DY 17	DY 18
Workforce Bridge Account Program	PC	Both	0.0%						\$83.33

<sup>\*</sup>PC = Per Capita, Agg = Aggregate

- 53. 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.
- **54. Exceeding Budget Neutrality**. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 01/01/2025 to 12/31/2025. 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.
- 55. 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 the tables below 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 18	Cumulative budget neutrality limit plus:	0.0 percent	

#### XI. EVALUATION OF THE DEMONSTRATION

- 56. Submission of Draft Evaluation Design. The state must submit to CMS for approval an updated draft evaluation design for an evaluation of the demonstration by no later than 120 days after the effective date of the demonstration. At a minimum, the state's evaluation hypotheses must include, but are not limited to, the following outcomes: percent of beneficiaries in the Workforce Bridge Account Program who maintained coverage through the end of the year, continuity of coverage when switching between Medicaid and Marketplace or other coverage; measures of access to care and health outcomes; take-up rates; and healthcare expenditures. The draft design must discuss the outcome measures that will be used in evaluating the impact of the demonstration during the period of approval. It shall discuss the data sources and sampling methodology for assessing these outcomes. The draft evaluation design must include a detailed analysis plan that describes how the effects of the demonstration must be isolated from other initiatives occurring in the state. The state must use the expertise of an independent evaluator in the implementation of the draft Evaluation design.
- 57. Interim Evaluation Report. In the event the state requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the state must submit an interim evaluation report as part of the state's request for each subsequent renewal.
- 58. Final Evaluation Design and Implementation. CMS shall provide comments on the draft evaluation design, and the state shall submit a final design within 60 days after receipt of CMS comments. The state must implement the evaluation design and submit its progress in each of the quarterly and annual progress reports. The state must submit to CMS a draft of the "summative" evaluation report within 18 months after the end of the demonstration period of performance, as well as at the end of a demonstration component, as applicable. CMS will provide comments after receipt of the report. Unless otherwise agreed upon in writing by CMS, the state must submit revised "summative" evaluation report within 60 days after receipt of CMS comments. The final "summative" evaluation report must be posted to the state's Medicaid website within 30 days of approval by CMS.
- **59.** Cooperation with Federal Evaluators. Should CMS undertake an independent evaluation of any component of the demonstration, the state shall cooperate fully with CMS or the independent evaluator selected by CMS. The state shall submit the required data to CMS or the contractor.

# XII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date Specific	Deliverable	STC Reference
180 days after date		
of demonstration		
approval letter	Draft Evaluation Design	STC 57
60 days after receipt		
of CMS comments	Final Evaluation Design	STC 59
As part of the		
state's extension		
request	Interim Evaluation Report	STC 58
18 months after the		
end of the		
demonstration		
period	Summative Evaluation Report	STC 59
	By May 1st - Draft Annual Monitoring	
Annual	Report	STC 31
Quarterly		
	Deliverable	STC Reference
	Quarterly Progress Reports	STC 30
60 days after the	Quarterly Expenditure Reports	STC 33
end of the quarter	Eligible Member Months	STC 42

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

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

CMS also recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including

comparison groups and baseline data analyses. For example, if a demonstration is long–standing, it may be difficult for the state to include baseline data because any pre–test data points may not be relevant or comparable. Other examples of considerations include:

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

### E. Attachments

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

#### ATTACHMENT B

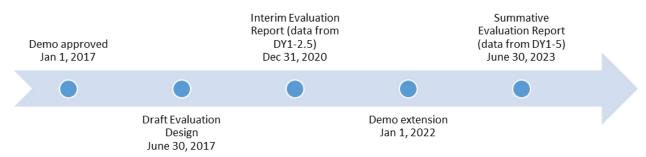
## **Preparing the Interim and Summative Evaluation Reports**

#### 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 (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-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?