DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 12 2019

Joshua Baker
Director
State of South Carolina, Department of Health & Human Services
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Dear Mr. Baker:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs, including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not "stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. As relevant here, section 1115(a)(1) of the Act allows the Secretary to waive compliance with the Medicaid program requirements of section 1902 of the Act, to the extent and for the period he finds necessary to carry out the demonstration project. In addition, section 1115(a)(2) of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving part of South Carolina's May 8, 2019, request to expand Medicaid coverage through a section 1115 demonstration project entitled, "Palmetto Pathways to Independence" (Project No. 11-W-00335/4), in accordance with section 1115(a) of the Act.

This approval for Palmetto Pathways to Independence is effective December 12, 2019 through November 30, 2024, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been listed as not applicable to expenditures under the demonstration.

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. Under section 1901 of the Act, the Medicaid program provides federal funding to

participating states "[f]or the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." Act § 1901. As this statutory text makes clear, two Medicaid objectives are to enable states to "furnish ... medical assistance" – i.e., healthcare services – to certain vulnerable populations and to furnish those populations with rehabilitation and other services to help them "attain or retain capability for independence or self-care." Section 1901 of the Act. Section 1115 demonstration projects also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better "enabling each [s]tate, as far as practicable under the conditions in such [s]tate" to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need.

We are committed to supporting states that seek to test measures that are likely to increase coverage and improve the health of beneficiaries and make them more financially independent, which in turn supports the fiscal sustainability of states' Medicaid programs. We expect that such demonstration policies will improve beneficiaries' physical and mental health, resulting in these beneficiaries consuming fewer health care services and resources while they are enrolled in Medicaid, which will preserve Medicaid program resources, make the Medicaid program more efficient, and potentially reduce the program's national average annual cost per beneficiary of $7590.[1] Moreover, we expect that the demonstration policies will increase beneficiaries' financial independence and assist them in gaining financial security, which will obviate their need for public assistance as they secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility. Such measures can promote the objectives of the Medicaid statute by enabling states to make improvements and investments "as far as practicable under the conditions in such state[s]," SSA Section 1901, in the broader Medicaid program. These measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.[2] By the same token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

The measures being testing with this demonstration approval may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may "result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing." Act § 1115(d)(1). But in the long term, these measures may create incentives and opportunities that

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[1] U.S. Department of Health and Human Services 2017 Actuarial Report on the Financial Outlook for Medicaid.

[2] States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state's program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure authority under section 1115(a)(2) of the Act. For example, recently, many states have been relying on this authority to expand the scope of services they offer to address substance use disorders beyond what the statute explicitly authorizes.

help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence and allow the state to more sustainably cover its vulnerable populations.

To create an effective incentive for beneficiaries to engage in behaviors that improve health and promote financial independence, it may be necessary for states to attach those incentives to eligibility for coverage, including by conditioning eligibility for Medicaid coverage on compliance with conditions designed to improve beneficiary health, promote financial independence, and safeguard the fiscal sustainability of the Medicaid program. This may mean that beneficiaries who fail to comply will not be eligible for Medicaid coverage, which is consistent with the consequences for failing to meet other conditions of eligibility. But, as we discuss more fully below, these measures have been designed to help maximize the number of eligible beneficiaries who, if they choose to opt into new Medicaid coverage, are successfully able to do so. In addition, section 1115 gives us the authority to offer states more flexibility in experimenting with different ways of improving health outcomes and strengthening the financial independence of beneficiaries.

The South Carolina demonstration is designed to extend medical assistance to beneficiaries as they move towards greater independence through community engagement. To help support this transition to independence and commercial coverage, the state has proposed to expand coverage to individuals who meet the community engagement requirements.

Background on Medicaid Coverage in South Carolina

As of August 2019, South Carolina's Medicaid program and Children's Health Insurance Program (CHIP) have enrolled over 1 million beneficiaries. In addition to the mandatory eligibility groups, the Medicaid program covers non-mandatory populations such as beneficiaries receiving family planning services only, optional targeted low income children, and working disabled beneficiaries. The state also covers several categories of non-mandatory services, including dental services, prescription drugs, and rehabilitative services in addition to mandatory services. Even though South Carolina covers some optional populations and services, the state, at this time, has elected not to participate in the Patient Protection and Affordable Care Act (ACA) expansion to provide Medicaid coverage to adults with incomes at or below 133 percent of the federal poverty level (FPL), also known as the New Adult group.

Extent and Scope of the Demonstration

New Coverage for Parents

With this approval, South Carolina will newly provide coverage to individuals ages 19 through 64 who meet the criteria for the parent/caretaker relative (P/CR) group but who have incomes above the Medicaid standard of 62 percent of the federal poverty level (FPL) up to 95 percent of the FPL (effectively 100 percent with the five percent income disregard) and who are not otherwise eligible for full Medicaid coverage, referred to as Population I in the STCs. As a condition of eligibility for choosing to opt into Medicaid and becoming newly enrolled, these individuals must, unless they are found to meet an exemption, engage in qualifying community engagement activities for at least 80 hours per month.

New Coverage for Targeted Adults

This approval also allows South Carolina to provide full Medicaid state plan benefits for 12 months to a Targeted Adult Group of individuals ages 19 through 64, who otherwise would not be eligible for Medicaid, and who meet defined criteria that include being chronically homeless, justice involved, or needing substance use disorder (SUD) treatment. Unless such individuals are found to meet an exemption, applicants to the Targeted Adult Group must also engage in qualifying community engagement activities for at least 80 hours per month, should they wish to opt into receiving Medicaid benefits. Beneficiaries in the Targeted Adult Group who are actively engaged in SUD treatment at the end of this 12 month period will have coverage extended for another 12 month period. Those beneficiaries who complete their 12 month period of eligibility and do not have coverage extended at the end of that 12 month period may reapply immediately and regain coverage under the Targeted Adult Group if the beneficiary meets the eligibility criteria, including the community engagement requirements, or is exempt from meeting the community engagement requirements, and if there is no waitlist for the Targeted Adult Group.

The state has also been given the flexibility to close enrollment in the Targeted Adult Group, if state appropriation is not adequate to cover the costs. When enrollment is closed, the state will continue to accept and review applications to determine whether applicants are eligible for Medicaid on any other basis. If the applicant is eligible for the Targeted Adult Group only, that applicant will be determined eligible but will be put into a suspended status until enrollment is re-opened. The state will maintain a waitlist to automatically enroll individuals the next time enrollment opens.

Community Engagement

To opt into receiving coverage, the state will notify non-exempt applicants to the expanded P/CR group (Population I) and the Targeted Adult Group at application that they must have completed a minimum of 80 hours of qualifying community engagement activities in the past month and report such compliance to the state to gain coverage, if the state is unable to verify that the applicant is in compliance with the requirements using its own administrative data. If an applicant is not in compliance with the community engagement requirements at application, the application will be denied if the applicant is not eligible for any other category of assistance. The individual may reapply at any time. If a non-exempt applicant does opt into coverage by reporting compliance with the community engagement requirements at application and is subsequently enrolled, the beneficiary must continue to complete 80 hours of qualifying community engagement activities each month and report such compliance on an annual basis for those employed at enrollment, and no more than quarterly for those meeting the requirements through other qualifying activities. The state will allow beneficiaries flexibility with completing the community engagement requirements by allowing extra hours to be spread across a 90-day period.

CMS is providing the state with flexibility to exempt various groups that the state has determined are unlikely to be able to reasonably comply with the requirements, including but not limited to: individuals receiving Supplemental Security Income (SSI); individuals in institutional placements; primary caregivers of a child up to age 18, and/or of a disabled adult; individuals identified as medically frail; members of federally recognized tribes; individuals diagnosed with

an acute medical condition that would prevent them from complying with the requirements; individuals who are exempt from Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) employment requirements; and individuals who are up 365 days or less post-partum. If the state is able to verify these exemptions, these individuals will be able to apply for "opt-in" coverage without reporting compliance with the community engagement requirement, and will be determined eligible if they meet all other eligibility criteria for their coverage group.

Non-exempt beneficiaries and applicants may satisfy the community engagement requirements through a variety of qualifying activities, including but not limited to, participation in and compliance with SNAP and/or TANF employment requirements; participation in an adult secondary education program through a public school district or technical college, including GED programs; at least half-time participation in a degree- or certificate- seeking program in an accredited institution of higher education, as defined by the South Carolina Commission on Higher Education; compliance with Unemployment Insurance (UI) work-search requirements (first 16 weeks of UI benefits); employment including self-employment for no less than 80 hours per month; participation in a tribal work program; community or public service, including verifiable volunteerism with public entities or qualified charitable corporations; or participation in and compliance with SUD treatment.

Under South Carolina's demonstration, the state will notify applicants who have met the community engagement requirements and have been determined eligible for this new coverage of their need to continue to participate in, or remain exempt from, community engagement activities in order to continue to opt into receiving Medicaid coverage. Applicants and beneficiaries will be allowed to report compliance with the community engagement requirements through methods consistent with the requirements in 42 CFR 435.907(a), such as in-person, over the phone, online or by mail. If at some point during the benefit year, a beneficiary no longer participates in community engagement or satisfies an exemption from the requirements, the beneficiary must report this change in circumstance and will have 90 days to report that they are either meeting the requirements again, qualify for an exemption, or experience a circumstance that would give rise to good cause. If a beneficiary does not report within the 90 days that they are meeting the requirements, either by participating in community engagement or reporting that they qualify for an exemption, or have experienced a circumstance that would give rise to good cause, the beneficiary will be considered non-compliant and have their coverage suspended until they come into compliance. If during the beneficiary's annual redetermination process the beneficiary is still suspended and non-compliant with the community engagement requirements, the beneficiary will be considered to have no longer opted into Medicaid and will be disenrolled unless eligible for another category of Medicaid assistance not subject to the requirements. Disenrollment does not affect an individual's ability to again apply to opt into Medicaid coverage through this demonstration at any time.

The state will require compliance with the community engagement requirements and will implement subsequent consequences for failure to meet the requirements no sooner than one year after this approval for both the Targeted Adult Group and the expanded P/CR group (Population I).

Elements of the Demonstration Request that CMS is Not Approving at This Time

In its application, South Carolina requested to apply the community engagement requirements to the state plan coverage groups of P/CR and Transitional Medical Assistance (TMA). CMS is approving this request through a separate section 1115 demonstration approval, titled "Healthy Connections Works."

The state also requested to make changes to its TMA program. The state requested expenditure authority to provide financial assistance to those individuals that lost Medicaid coverage due to employment and who are also not eligible for employer-sponsored insurance to purchase a qualifying health plan on the Exchange. CMS is not taking action on these aspects of the state's proposal in this demonstration at this time.

South Carolina also requested a number of eligibility and coverage changes for pregnant women and children. The state proposed to cover those eligible under the CHIP criteria for pregnant women with incomes from 194 percent FPL up to and including 241 percent FPL, covering the unborn population with up to and including 241 percent FPL, and covering those under age 19 who are eligible under CHIP criteria with incomes from 208 percent FPL up to and including 241 percent FPL. CMS is currently working with South Carolina to authorize coverage for these populations under Medicaid and CHIP state plan authority.

The state requested to extend coverage beyond the postpartum period to women eligible for Medicaid based on pregnancy and to the mothers of children previously covered under CHIP. South Carolina ultimately revised its request, and CMS is approving 1,000 additional slots within the Targeted Adult Group to prioritize coverage for pregnant women and parents of foster children, not otherwise eligible for Medicaid, needing SUD treatment and who meet specific eligibility criteria as described in the STCs.

Determination that the demonstration is likely to assist in promoting Medicaid's objectives

For reasons discussed below, the Secretary has determined that South Carolina's Palmetto Pathways to Independence demonstration is likely to assist in promoting the objectives of the Medicaid program.

The demonstration will expand coverage.

The approval of the community engagement program allows for individuals who would not otherwise have been eligible for the Medicaid program, namely the Targeted Adult Group and those in the extended P/CR group with incomes from 62 percent of the FPL up to and including 95 percent of the FPL, to opt into Medicaid and receive coverage. This is the first demonstration approved by the Secretary that tests an approach of offering currently non-eligible individuals an "opt-in" pathway to coverage by meeting the community engagement requirements at application and thereafter. This demonstration clearly advances the objectives of the Medicaid program because it is expected to result in significant coverage expansion in South Carolina. The state estimates that after one year following implementation, an estimated 32,300 individuals will be eligible for coverage in the expanded P/CR group (Population I). Within this group, the state estimates that 860 individuals who would otherwise qualify for the expanded P/CR group (Population I) will not meet or be exempt from the community engagement requirements at

application and therefore not opt into coverage and 340 individuals will enroll but subsequently become non-compliant with the community engagement requirements and be disenrolled. Additionally, 14,250 individuals will be eligible for coverage through the Targeted Adult Group, though the state estimates that within this group, 250 individuals would qualify for the Targeted Adult Group but not meet or report exemption from the community engagement requirements. Therefore, the state expects that in total, 45,100 beneficiaries may gain coverage through this demonstration.[3]

The South Carolina Palmetto Pathways to Independence demonstration contains provisions that could result in some individuals opting into coverage and then failing to maintain coverage after it had been obtained, as a result of not complying with the community engagement requirements. However, the demonstration is expected to result in significant coverage gains. A portion of the Targeted Adult Group and expanded P/CR group (Population I), namely those that are exempt from the community engagement requirements, will immediately be eligible to opt into Medicaid. The balance of these two groups are free to opt into Medicaid, so long as they also choose to comply with the community engagement requirements.

The community engagement program is designed to make compliance with the requirements achievable. South Carolina has taken steps to include adequate protections to ensure that the requirements apply only to those individuals who can reasonably be expected to meet them and that applicants and beneficiaries are clearly informed of their responsibilities under the demonstration. Any individual whose coverage is suspended or terminated for failure to meet the requirements, or who experiences any other adverse action, will have the right to appeal the state's decision, consistent with all existing appeal and fair hearing protections. As part of ongoing monitoring of the demonstration, the state will submit enrollment data and will track the change in enrollment over time. The state will also be required to evaluate access to health care and health outcomes of individuals impacted by the demonstration, including those who do not continue to opt into Medicaid coverage as a result of non-compliance with the requirements. CMS will be undertaking rigorous evaluation and monitoring of a variety of metrics, including these enrollment metrics. CMS also reserves the right to require the state to take corrective action, which could include suspending implementation of the community engagement requirements, if monitoring or evaluation data indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt in). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

The demonstration will furnish medical assistance in a manner that improves the sustainability of the safety net.

CMS has determined that South Carolina's Palmetto Pathways to Independence demonstration is likely to promote the objective of furnishing medical assistance because the demonstration, if successful, would promote the sustainability of South Carolina's Medicaid program. By making the community engagement requirements a condition of eligibility for the Targeted Adult Group

[3] South Carolina based these estimates on current program enrollment, Census, and other adjunct data such as demographic, employment and educational data as well as taking into account national trends.

and those in the expanded P/CR group (Population I), South Carolina expects that some beneficiaries will gain financial security, obviating their need for public assistance. Additionally, if participating in community engagement activities improves beneficiaries' physical and mental health, as discussed below, these beneficiaries may consume fewer health care resources while they are enrolled in Medicaid. And to the extent that either or both of these trends results in lower costs for the state over the long-term, it may allow the state to maintain the long-term fiscal sustainability of its Medicaid program and provide coverage for more medical services to more Medicaid beneficiaries. This will help South Carolina stretch its limited Medicaid resources and ensure that the health care safety net is available to those South Carolina residents who need it most. Accordingly, the demonstration project advances the objectives of Medicaid.

The demonstration as a whole will provide greater access to coverage for low-income beneficiaries in the Targeted Adult Group and the expanded P/CR group (Population I) than would be available absent the demonstration. By providing coverage to beneficiaries in these populations who can reasonably be expected to meet the community engagement requirements, South Carolina will be able to expand coverage in a way that is economically practicable and sustainable for the state. This coverage expansion for working members of the Targeted Adult Group and the expanded P/CR group (Population I) furthers the Medicaid program's objectives by allowing the state to experiment with innovative means of deploying its limited state resources so it may provide coverage beyond the statutory minimum and what it currently provides, including the expanded coverage for pregnant women and children that may be approved under the state plan. Conditioning eligibility for the coverage expansion under this demonstration on complying with requirements that have been designed to be achievable and to promote beneficiary health, beneficiary financial independence, and fiscal sustainability of the Medicaid program will further promote the objectives of the Medicaid program.

The demonstration tests reforms designed to promote financial independence, which we expect to improve continuity of coverage and lead to better health outcomes.

The community engagement requirements for the Targeted Adult Group and expanded P/CR group are designed to encourage individuals to opt into Medicaid by obtaining employment and/or undertaking other community engagement activities. The evaluation of the demonstration will assess the effectiveness of policies that are designed to strengthen employment and earnings among individuals subject to the demonstration requirements, which we expect will lead to other health insurance coverage from employers and other commercial sources for the populations eligible for this demonstration. We expect that the improved continuity of coverage that comes from participating in this demonstration will result in greater financial independence for the demonstration population as well as improved health status. These key ideas will be captured via hypotheses and research questions in the state's evaluation design and subsequent interim and summative evaluation report requirements, subject to CMS approval. In evaluating and testing the hypotheses to assess the demonstration's success in achieving the key policy outcomes and objectives, the state must carefully identify, through robust statistical methods within-state or out-of-state comparison populations—or use other rigorous methodological approaches—such that the impact of the demonstration can be estimated.

The evaluation will be designed to understand whether the demonstration's offer of an "opt in" to Medicaid promotes the goals of improving financial independence and beneficiary health. To that end, a key hypothesis that the evaluation will assess is whether the demonstration policies improve beneficiary financial independence, measured in terms of greater employment levels and earnings, and increase the likelihood that beneficiaries transition to commercial health insurance. The evaluation will identify appropriate research questions for testing the hypotheses around employment, income and coverage that provide information about the efficacy of offering an "opt in" to Medicaid and how such a policy impacts these outcomes. For example, the evaluation must examine whether employment, improved incomes, and employer-sponsored coverage among individuals offered coverage that is conditioned on meeting community engagement requirements are sustained over time, (i.e., for a year or more, including after separating from Medicaid), since financial independence would not be assured without sustained improvements in these outcomes. It would also be important to understand what the barriers to maintaining enrollment in new coverage might be, if newly eligible beneficiaries fail to act to maintain coverage. Also important will be to understand the trajectories of health status of individuals subject to the community engagement over time, including after separation from Medicaid.

Another unique feature of this demonstration is the removal of an existing benefit cliff that may be serving as a disincentive for individuals in the current P/CR group from earning more, as they would lose Medicaid coverage (and potentially lack access to affordable coverage) with increased incomes absent this demonstration. Therefore, the evaluation will test whether providing a bridge to higher earning through a coverage program that allows working individuals with rising incomes to stay enrolled results in individuals moving out of the regular P/CR group and into this income range overtime. The evaluation will also assess whether this transition out of poverty occurs faster or at higher magnitudes than it would have otherwise without this demonstration.

Furthermore, hypotheses focused on enrollment suspension for non-compliance will assess at least the following outcomes: beneficiary compliance with demonstration requirements, enrollment continuity, and health status (as a result of greater enrollment continuity). The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated care costs. In addition, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability. For example, it could be important to understand the demonstration's impact on program sustainability in the context of how long-term maintenance of employment, income and commercial coverage succeed in transitioning individuals off of other public support programs like TANF and SNAP, as well as in helping them avoid becoming eligible under a mandatory population in the future.

CMS has also included STCs in the monitoring and evaluation sections that align with CMS' current approach to monitoring and evaluation for section 1115 demonstrations. These STCs specify that CMS reserves the right to require the state to take corrective action, which could include suspending implementation of the community engagement requirements, if monitoring or evaluation data indicate substantial, sustained directional change, inconsistent with state

targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt in). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner. These STCs will better aid the state and CMS in measuring and tracking the demonstration's impact on South Carolinians affected by it, and give CMS additional tools to protect beneficiaries if necessary. Further, CMS reserves the right to withdraw expenditure authorities at any time it determines that continuing the expenditure authorities would no longer be in the beneficiaries' interest or promote the objectives of Medicaid.

Consideration of Public Comments

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

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

CMS received 39 comments during the federal comment period on the state's initial "Community Engagement" demonstration proposal (including on components that CMS is not approving as part of this demonstration). Although CMS is not legally required to provide written responses to comments, CMS is addressing some of the central issues raised by the comments and summarizing CMS's analysis of those issues for the benefit of stakeholders. After carefully reviewing the public comments submitted during the federal comment period, CMS has concluded that the demonstration project advances the objectives of Medicaid.

General comments

The majority of comments CMS received opposed the community engagement requirements. The most common opposing comments asserted that the demonstration may result in beneficiaries losing access to healthcare and expressed concern that the requirements would affect vulnerable populations. However, the Palmetto Pathways to Independence demonstration, which is narrower than the demonstration initially requested by the state, cannot adversely impact the coverage of any current Medicaid beneficiaries. Instead, this demonstration only expands coverage, by offering individuals who meet the eligibility criteria for the expanded P/CR group (Population I) and the new Targeted Adult Group authorized under this demonstration, but who are not currently eligible for Medicaid, an opportunity to opt into Medicaid coverage, should they also wish to comply with the community engagement requirements.

To ensure that vulnerable individuals are able to easily opt into and maintain this expanded coverage, or other Medicaid coverage for which they qualify, CMS has worked together with South Carolina to exempt certain vulnerable populations, as described below, from the community engagement requirements and to include certain guardrails. These guardrails, which take the form of a series of assurances in the STCs, include but are not limited to requirements that the state will screen applicants and determine eligibility for Medicaid on any other bases, and review for eligibility for other insurance affordability programs prior to suspension; provide full appeal and fair hearing rights to individuals whose eligibility is terminated or denied for failure to meet the community engagement requirements; develop and implement an outreach strategy to inform applicants and beneficiaries how to report compliance with the community engagement requirements; and maintain a system that provides reasonable modifications for meeting the community engagement requirements to beneficiaries with disabilities. The STCs include a provision granting CMS the authority to discontinue the demonstration if the agency determines that it is not furthering Medicaid's objectives.

Additionally, this demonstration is designed to make it more likely that individuals will be able to obtain and retain private or employer-sponsored coverage as they gain additional work experience and their income rises, while simultaneously providing a bridge to such commercial coverage. For example, without this demonstration, beneficiaries in the P/CR group whose income rises above the eligibility threshold lose Medicaid eligibility altogether, yet often are not earning enough to receive federal assistance in the form of an Advanced Premium Tax Credit (APTC) to purchase coverage on the Exchange. This demonstration will allow these individuals to increase their income so they can purchase private insurance while providing them with health coverage until they cross the income threshold to be eligible for APTCs.

CMS will regularly monitor the demonstration and will work with the state to resolve any issues that arise as South Carolina works to implement the demonstration. Monitoring metrics will cover enrollment, suspension by specific demographics and reason, participation in community engagement qualifying activities, access to care, and health outcomes through monitoring reports to see how the demonstration impacts beneficiaries. Additionally, CMS has the authority to require the state to submit a corrective action plan if monitoring or evaluation data indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid. The STCs further specify that any such state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where data indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt-in). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner. This will better aid the state in measuring and tracking the demonstration's impact on South Carolinians affected by it, and give CMS additional tools to protect beneficiaries if necessary.

The goal of these policies is to incentivize compliance and enhance coverage within the two demonstration populations. CMS has incorporated safeguards into the STCs intended to maximize coverage gains among the demonstration populations, and CMS is committed to partnering with South Carolina to ensure that the demonstration advances the objectives of Medicaid. We recognize that some beneficiaries may choose not to continue to comply with the

conditions of eligibility imposed by the demonstration, and therefore may be unable to continue to opt into Medicaid. But we also anticipate that many other individuals will successfully be able to continue to opt into new Medicaid coverage, and furthermore, some beneficiaries' income will increase above the Medicaid eligibility thresholds as a result of the community engagement incentives and that they will obtain employer sponsored coverage or other commercial coverage once they no longer qualify for the Medicaid program. Indeed, as mentioned above, to support this transition to commercial coverage, South Carolina has increased the eligibility threshold for the P/CR group through the demonstration up to 95 percent of the FPL (effectively 100 percent with a 5 percent disregard), which is the threshold for eligibility for APTC support.

CMS believes the features of this demonstration are worth testing to determine whether there is a more effective way to furnish medical assistance to the extent practicable under the conditions in South Carolina.

Comments on Community Engagement and Reporting Requirements

CMS acknowledges that commenters made remarks based on South Carolina's demonstration proposal as initially structured, which included demonstration eligibility expansions for an expanded P/CR group (Population I) and a Targeted Adult Group, along with a request to require community engagement for both these expansion groups and for the state plan P/CR group and for those receiving state plan TMA. However, CMS is more narrowly structuring this as an "opt into" coverage demonstration, approving coverage expansion to the expanded P/CR group and the Targeted Adult Group, along with community engagement requirements for these individuals. Therefore, this demonstration offers potential coverage gains for individuals who otherwise would not have been eligible for Medicaid, and as such, any concerns about "coverage loss" as a result of the community engagement requirements are inapposite.

A majority of opposing commenters expressed concern about how the community engagement requirements would affect vulnerable populations such as children and individuals living with chronic health conditions. The commenters' concerns appear to be in response to the state's original proposal, which included children and individuals living with chronic health conditions who are currently eligible under the state plan for Medicaid services. This demonstration only offers coverage opportunities to individuals not currently eligible, and thus the concerns that community engagements will make people "lose" coverage are inapposite. Additionally, individuals must be between the ages of 19 and 65 to be eligible for the demonstration's opt-in coverage expansion. Children will not be affected by this demonstration, including the community engagement requirements. However, the demonstration provides exemptions from the community engagement requirements for a number of vulnerable populations, including individuals who are the primary caregiver of a child (up to age 18) or disabled adult, individuals who are medically frail, individuals who have an acute medical condition, and beneficiaries with disabilities. The state will also use administrative data to proactively identify applicants who meet an exemption from the requirements, and will allow other individuals to attest to needing an exemption. South Carolina will also provide applicants and beneficiaries with the opportunity to continue to opt into Medicaid by demonstrating that they had a good cause not to meet the community engagement requirements, and the state will provide reasonable modifications for

applicants and beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA.

Opposing commenters also believe that South Carolina's community engagement requirements are complex and place a reporting burden on beneficiaries. Many commenters indicated that beneficiaries would be unable to meet the community engagement requirements, even if they would like to do so, because burdensome reporting requirements may make compliance too difficult. To address this concern, South Carolina will use its own administrative data to verify that applicants and beneficiaries are in compliance with the requirements without the individual having to report compliance, and will provide a variety of mechanisms for individuals to attest to meeting the requirements if necessary. Reporting will only be required if the state cannot confirm beneficiary compliance based on the data available to the state. The state will also minimize potential reporting burden based on the activity the beneficiary is completing. If an applicant is employed at the time of application, she or he will only be required to report compliance on an annual basis; individuals meeting the requirements through other community engagement activities will only be required to report compliance every 90 days.

Some commenters noted that the community engagement requirements will lead to negative health outcomes. However, individuals eligible for this demonstration can choose to opt in to Medicaid coverage that would otherwise be unavailable to them if this demonstration were not approved. Commenters did not specifically explain how beneficiaries who gain coverage through these eligibility expansions, even if they also comply with community engagement as a result of gaining coverage, would have worse health outcomes than if they never had access to Medicaid coverage at all absent this demonstration. In fact, the opposite may be true, and the purpose of this demonstration is to test whether that is the case. Those who do comply with this demonstration's community engagement requirements will be able to obtain health coverage that is otherwise unavailable without this demonstration, and we expect that those who comply will experience the improved outcomes that are correlated with being employed or otherwise more engaged in their communities. Individuals who choose not to comply with the community engagement requirements will be no worse off than they are without this demonstration. This demonstration advances the objectives of Medicaid by testing whether non-Medicaid eligible individuals who are given an opportunity to opt into Medicaid if they comply with community engagement requirements experience better health and financial independence, and if the state's provision of services to this population improves the fiscal sustainability of its Medicaid program. CMS recognizes that an individual's health and well-being are important and that there are a broad array of factors that impact one's health such as social, economic, and behavioral factors. In fact, as noted a 2013 Gallup poll found that unemployed Americans are more than twice as likely as those with full-time jobs to say they currently have or are being treated with depression.[4] Additionally, other community engagement activities such as volunteering are also associated with improved health outcomes.[5,6] For beneficiaries who may have difficulty in

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[4] Crabtree,S. In U.S., Depression Rates Higher for Long-Term Unemployed. (2014). Gallup. http://news.gallup.com/poll/171044/depression-rates-higher-among-long-term-unemployed.aspx

[5] United Health Group. Doing good is good for you. 2013 Health and Volunteering Study.

[6] Jenkins, C. Dickens, A. Jones, K. Thompson-Coon, J. Taylor, R. and Rogers, M., Is volunteering a public health intervention? A systematic review and meta-analysis of the health and survival of volunteers. BMC Public Health 2013. 13 (773)

meeting the community engagement requirements due to a health related issue, the state is exempting vulnerable populations, as discussed above, so that they may still be able to opt into this coverage expansion without participating in community engagement. In addition, the state allows applicants and beneficiaries who experience a circumstance that would give rise to good cause to not be required to meet the community engagement requirements during that time. Examples of good cause include, but are not limited to: a recent hospitalization, a beneficiary that is disabled, and if a beneficiary experiences the birth or death of a family member living with the beneficiary.

Comments addressing coverage losses

Some commenters cited specific coverage loss figures from South Carolina's application as their rationale for not supporting community engagement in South Carolina. As discussed above, the state's initial estimates of coverage gains and losses are not directly applicable to this demonstration, which cannot adversely impact the coverage of any current Medicaid beneficiaries. The state has done an analysis of potential projected coverage impact and this approval provides for estimated coverage gains of 45,100 beneficiaries in both the expanded P/CR group (Population I) and the Targeted Adult Group. As described earlier, the state estimates that 31,100 individuals will gain coverage through the expanded P/CR Group (Population I) while 1,200 will not opt in or will have their eligibility suspended in the expanded P/CR group (Population I) due to non-compliance with the community engagement requirements.[7] The Targeted Adult Group will allow an estimated 14,000 individuals to opt into coverage. Of the non-exempt individuals in the two demonstration populations, some will elect not to comply and would thus not be able to opt into Medicaid. Actual coverage impact will greatly depend on the choices made by each individual, and it is therefore challenging to estimate the impacts of this new program before it even begins. In light of the safeguards discussed above, CMS has determined that compliance with South Carolina's community engagement requirements are achievable for every non-exempt individual who otherwise meeting the eligibility criteria for the demonstration population that would like to opt into Medicaid. Furthermore, CMS is undertaking rigorous evaluation and monitoring of a variety of metrics, including enrollment metrics. CMS also reserves the right to require the state to take corrective action, which could include suspending implementation of the community engagement requirements, if monitoring or evaluation data indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt in). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

While CMS and the state acknowledge that some beneficiaries who gain coverage as a result of this expansion may choose not to continue to opt into the Medicaid program, the state is required to implement a number of strategies and supports for those who wish to opt into the Medicaid program and comply with the community engagement requirements. For example, the state will conduct active outreach and education, beyond standard noticing, to help ensure that applicants and beneficiaries understand the requirements and how to comply with them. South Carolina will maintain such information on its public facing website and employ other broad outreach

[7] South Carolina based these estimates on current program enrollment, census, and other adjunct data such as demographic, employment and educational data as well as taking into account national trends.

activities that are specifically targeted at beneficiaries. As required in the STCs, the state must submit its Implementation Plan no later than 90 days after approval of this demonstration, and discuss at least the following topics in its Implementation Plan: application assistance, reporting and processing, notices, coordinated agency responsibilities, coordination with other insurance affordability programs, appeals, renewals, coordination with other state agencies, applicant and beneficiary protections, and outreach. The STCs also require the state to provide outreach and education to stakeholders regarding the community engagement requirements, including but not limited to updating the state's website and training employees. While some individuals may respond to the new community engagement requirements by choosing not to take advantage of the opportunity to opt into Medicaid, the goal is for everyone potentially eligible for this new coverage to be able to obtain it.

As discussed above, the demonstration overall will increase coverage and access to Medicaid in South Carolina. With this demonstration, the state will be providing coverage to an estimated 45,100 new beneficiaries, which supports the determination that the demonstration as a whole is likely to assist in promoting Medicaid's objectives. The state's original estimates of coverage loss are not applicable to this demonstration, as no beneficiary loses coverage since the demonstration provides for otherwise ineligible individuals to opt into Medicaid coverage through meeting or being exempt from the community engagement requirements.

Other Demonstration Elements

Generally commenters spoke positively of South Carolina's proposal to increase eligibility income thresholds for the P/CR group, pregnant women, and CHIP eligibility groups and to provide 365 days of full Medicaid benefits to postpartum women. Commenters also spoke positively about the decision to provide benefits to the Targeted Adult Group and expanding SUD coverage and treatment services. While some of these comments are in response to the state's application, which contained requests beyond what we are approving in this particular demonstration, CMS appreciates the commenters' support.

Other Information

CMS's approval of this demonstration project is conditioned upon compliance with the enclosed list of expenditure authorities and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer for this demonstration is Ms. Valisha Andrus. She is available to answer any questions concerning your section 1115 demonstration. Ms. Andrus' contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-02-28
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Valisha.Andrus@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to your project officer and Ms. Shantrina Roberts, Deputy Director of Field Operations South. Ms. Roberts's contact information is as follows:

Ms. Shantrina Roberts
Deputy Director
Centers for Medicare & Medicaid Services
Atlanta Federal Center, 4th Floor
61 Forsyth Street, South West, Suite 4T20
Atlanta, GA 30303-8909
Email: Shantrina.Roberts@cms.hhs.gov

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

Thank you for all your work with us, as well as stakeholders in South Carolina, over the past months to reach approval.

Sincerely,

[redacted]

Seema Verma

Enclosures

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 11-W-00335/4

TITLE: Palmetto Pathways to Independence

AWARDEE: South Carolina Department of Health and Human Services

Title XIX Costs Not Otherwise Matchable Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by South Carolina for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from December 12, 2019 through November 30, 2024, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. **Population I.** Expenditures to provide Medicaid state plan coverage to individuals that meet the criteria for the Parents and Other Caretaker Relatives group with incomes above the Medicaid standard but at or below 95 percent of the federal poverty level (FPL) (effectively 100 percent with the five percent income disregard) who are not otherwise eligible for full Medicaid coverage and meet or are exempt from the community engagement requirements as a condition of eligibility, as described in these STCs.

2. **Targeted Adult Group.** Expenditures to provide Medicaid state plan coverage to certain individuals, ages 19 through 64, who meet specific criteria and meet or are exempt from the community engagement requirements as a condition of eligibility, as described in these STCs.

Title XIX Requirements Not Applicable to the Demonstration Eligible Populations

All requirements of the Medicaid program expressed in law, regulation, and policy statement not expressly identified as not applicable to these expenditure authorities shall apply to the demonstration for the period of this demonstration.

1. **Reasonable Promptness** **Section 1902(a)(8)**
   To the extent necessary to enable South Carolina to deny enrollment in the Targeted Adult Group when enrollment is closed, as described in the STCs.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00335/4**

TITLE: **Palmetto Pathways to Independence**

AWARDEE: **South Carolina Department of Health and Human Services**

I. PREFACE

The following are the STCs for the "Palmetto Pathways to Independence" section 1115(a) Medicaid demonstration (hereinafter demonstration) to enable the South Carolina Department of Health and Human Services (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to this demonstration. The Palmetto Pathways to Independence demonstration will be statewide and is approved for a 5-year period, from December 12, 2019 through November 30, 2024.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility
V. Benefits
VI. Cost Sharing
VII. Delivery System
VIII. Community Engagement Requirements
IX. General Reporting Requirements
X. General Financial Requirements Under Title XIX
XI. Monitoring Budget Neutrality
XII. Evaluation of the Demonstration
XIII. Schedule of Deliverables for 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 Evaluation Report
Attachment C: Evaluation Design (reserved)
Attachment D: Implementation Plan (reserved)
Attachment E: Monitoring Protocol (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

New Coverage for Parents

With this approval, South Carolina will newly provide full Medicaid coverage to individuals who meet the criteria for the Parents and Other Caretaker Relatives (P/CR) group with incomes above the Medicaid standard of 62 percent of the federal poverty level (FPL) but at or below 95 percent FPL (effectively 100 percent with the five percent disregard) who are not otherwise eligible for full Medicaid coverage. Under this demonstration this group is identified as Population I.

Targeted Adult Group

This demonstration also allows South Carolina to provide state plan benefits to a Targeted Adult Group for adults, ages 19 through 64, who otherwise would not be eligible for Medicaid, and who meet additional defined criteria, including being chronically homeless, being justice involved and in need of substance use disorder (SUD) treatment, or needing substance use disorder treatment. The Targeted Adult Group will receive full Medicaid state plan benefits for an initial 12 month period. Beneficiaries in the Targeted Adult Group who, at the end of the 12 month period are still engaged in treatment, will continue to receive Medicaid benefits unless the individual becomes eligible under another state plan group.

Community Engagement

South Carolina is authorized to require community engagement as a condition of Medicaid eligibility (described in STCs 24-30) for applicants and beneficiaries in Population I and the Targeted Adult Group with exemptions for some applicants and beneficiaries, described in STC 25. To be eligible for coverage, non-exempt individuals must complete a minimum of 80 hours monthly of community engagement activities and report compliance on an annual basis for those already employed at initial enrollment and quarterly for those completing other qualifying community engagement activities. Non-exempt applicants and beneficiaries may satisfy this requirement through a variety of qualifying activities, described in STC 26.

CMS has included monitoring and evaluation sections of the STCs, and specifies that CMS has the authority to require the state to submit a corrective action plan if monitoring or evaluation data indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid. The STCs further specify that any such corrective action plan, submitted by the state, could include a temporary suspension of implementation of demonstration programs, in circumstances where data indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt-in). These updates will aid the state in measuring and tracking the demonstration's impact on South Carolinians affected by it, and give CMS additional tools to protect applicants and beneficiaries if necessary. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with 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 Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, understanding program rules and notices, in establishing eligibility for an exemption from the community engagement requirements on the basis of disability, meeting and documenting the community engagement requirements, and meeting other program requirements necessary to obtain and maintain benefits.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program, expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal 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 under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
   a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet as necessary, as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
   b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (SPA) 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 appropriate state plan may be required, except as otherwise noted in these STCs. In all such cases, the Medicaid state plans governs.

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 service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
    a. An explanation of the public process used by the 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 worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include 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 detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
    d. An up-to-date CHIP allotment worksheet, if necessary;
    e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs, must submit a phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements:
    a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the received comment into the revised transition and phase-out plan.
    b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities, including community resources that are available.
    c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 days after CMS approval of the transition and phase-out plan.
    d. Transition and Phase-out Procedures. The state must comply with all notice requirements found in 42 CFR 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a demonstration beneficiary requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category.
    e. Exemption from Public Notice Procedures, 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
    f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the

demonstration, enrollment of new individuals into the demonstration must be suspended.

g. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

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

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

    The state must also comply with tribal and Indian Health Program/Urban Indian Health 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 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, MCOs, and any other contracted

entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program – including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid program and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY

16. **Eligibility.** Only beneficiaries eligible for Medicaid under an eligibility group listed in Table 1 are subject to the provisions within this demonstration. Demonstration eligible populations are not otherwise eligible for Medicaid through the state plan, and are only covered under Medicaid through the section 1115 demonstration.

17. **Populations Affected by the Demonstration.** The demonstration is comprised of the following Eligibility Groups:
    a. Population I: Defined as individuals not otherwise eligible for Medicaid with incomes from 62 percent of the FPL up to and including 95 percent of the FPL (effectively 100 percent of the FPL with a five percent of income disregard) who are U.S. citizens/qualified non-citizens, are residents of South Carolina, and who otherwise meet the eligibility criteria for the Parents and Other Caretaker Relatives group in the state plan.
    b. The Targeted Adult Group: Defined as individuals age 19 up to and including 64 not otherwise eligible for full coverage Medicaid with no dependent children, and who meet any one of the following additional criteria:
        i. Be chronically homeless, defined as:
            1) An individual who has been continuously homeless for at least 12 months; or
            2) An individual has experienced four episodes of homelessness (greater than 30 days) in the past three years; or
            3) An individual currently in supportive housing but have met the prior definitions of homelessness; and
            4) Have an income of 0 percent FPL (effectively 5 percent with the income disregard); and
            5) The individual must consent to referral to and application for other benefits as may be available, including but not limited to those offered

through the Veterans' Affairs Administration (VA) and Social Security Administration (SSA).

ii. Involved in the criminal justice system and in need of substance use or mental health treatment, defined as:
    1) The individual must demonstrate a need for treatment for a substance use disorder or mental illness; and
    2) Have an income less than 95 percent FPL (effectively 100 percent with the 5 percent income disregard); and
    3) Have been released within the preceding six months from a South Carolina Department of Corrections (SCDC) facility; and
    4) Have been sentenced to a term of imprisonment within a SCDC facility of not more than five years; and
    5) Consent to a health and social determinants screening and risk assessment and agree to a risk mitigation plan prior to release.

iii. In need of substance use treatment, defined as:
    1) Diagnosed with a SUD or serious mental illness; and
    2) Have an income less than 95 percent FPL (effectively 100 percent with the 5 percent income disregard).
        a. To promote positive fetal maternal health, the state elects to set aside 1,000 slots split evenly between the below criteria.
        b. Women who:
            A. Are otherwise not eligible for Medicaid coverage; and
            B. Have an income less than 194 percent FPL; and
            C. Have a diagnosed SUD, serious mental illness (SMI), or both; and
            D. Are pregnant or up to 12 months postpartum.
        c. Parents of foster children who:
            A. Are otherwise not eligible for Medicaid coverage; and
            B. Have an income less than 133 percent FPL (effectively 138 percent with 5 percent income disregard); and
            C. Have not had their parental rights terminated; and
            D. Are completing or complying with a SUD treatment program as part of a family reunification plan.

18. Targeted Adult Group Enrollment. Individuals applying for Medicaid must be screened for eligibility in other Medicaid programs before being enrolled in the Targeted Adults Group. Beneficiaries enrolled in the Targeted Adult Group, unless otherwise exempt, must meet the community engagement requirements as a condition of eligibility. Enrollment in the Targeted Adult Group may be prioritized based on Opioid use disorder (OUD)/SUD diagnoses. If a beneficiary enrolled in this group continues to be actively engaged in a treatment plan for SUD/OUD at the end of the 12 month period, the state must continue to extend coverage as long as the beneficiary otherwise remains eligible for the Targeted Adult Group.

a. Enrollment Caps. Each subset of the Targeted Adult Group will have enrollment caps. The Targeted Adult Group or any subset of this group may be closed to new

enrollment at the state's election. If this eligibility group is closed to new enrollment, the state will continue to take applications. The state will process these applications to check for eligibility in other Medicaid state plan groups. If the application is only eligible for the Targeted Adult Group, the application will be held for a new enrollment period and the individual will be placed on a waitlist. When the new enrollment period opens the state will conduct a redetermination on held applications. Below outlines the upper limit of enrollment for each subset:

i. Chronically Homeless: 3,000 beneficiaries;
ii. Justice-involved and in need of SUD treatment: 5,000 active beneficiaries and up to 20,000 incarcerated beneficiaries who will be in a suspended status prior to release; and
iii. Beneficiaries in need of SUD treatment: 6,000 beneficiaries

Table 1. Populations Affected by the Demonstration		
Demonstration Feature	**Eligibility Group**	**Citations**
Demonstration Eligible Group and Community Engagement Requirements	Population I – Individuals who meet the criteria of P/CR with incomes from 62% FPL up to and including 95% FPL	Expenditure Authority
Demonstration Eligible Group and Community Engagement Requirements	Targeted Adult Group – • Chronic Homeless – 0% FPL • Justice involved in need of SUD treatment- Up to and including 95% FPL • Individuals in need of SUD treatment – Up to and including 95 % FPL	Expenditure Authority

V. BENEFITS

19. Population I. Beneficiaries enrolled in this eligibility category with incomes from 62 percent of the FPL up to and including 95 percent of the FPL will receive the same benefits set forth in section 1905(y)(2)(B) of the Act and in 42 CFR 433.204(a)(2) and described in the Medicaid state plan.

20. Targeted Adult Group. Beneficiaries enrolled in this eligibility category will receive the same benefits set forth in section 1905(y)(2)(B) of the Act and in 42 CFR 433.204(a)(2) for a 12 month period. If a beneficiary enrolled in this group continues to be actively engaged in a

treatment plan for SUD/OUD at the end of the 12 month period, the state must continue to extend coverage consistent with the criteria described in STC 18.

VI. COST SHARING

21. **Cost Sharing for Participants in the Demonstration**. Cost sharing for beneficiaries in this demonstration must be in compliance with federal requirements that are set forth in statute, regulation and policies, including exemptions from cost sharing set forth in 42 CFR 447.56(a).

VII. DELIVERY SYSTEMS

22. **Delivery system**. All demonstration beneficiaries except for the Targeted Adults group will receive services through the same managed care and fee-for-service (FFS) arrangement as currently authorized in the state.

23. **Targeted Adults Delivery System.** Benefits will be delivered through FFS.

VIII. COMMUNITY ENGAGEMENT REQUIREMENTS

24. **Overview**. The state will implement community engagement requirements as a condition of eligibility for beneficiaries ages 19 through 64 enrolled in Population I and the Targeted Adult Group, and who are not otherwise subject to an exemption described in STC 25 or with circumstances that give rise to good cause described in STC 38(c). As a condition of Medicaid eligibility, non-exempt beneficiaries without good cause circumstances will be required to participate in the activities specified in STC 26 and report compliance as specified in STC 27. The state may not require compliance with the community engagement requirements and may not implement subsequent consequences for failure to meet the requirement sooner than one year after demonstration approval.

25. **Exempt Populations**. Applicants and beneficiaries who report, in accordance with 42 CFR 435.945(a), meeting one or more of the following exemptions will not be required to complete community engagement related activities to attain or maintain eligibility for so long as they continue to qualify for one or more of these exemptions. Applicants and beneficiaries may report that they qualify for one of the following exemptions at any time after implementation of the community engagement requirements, including at application and at eligibility redetermination. Exempt beneficiaries will not be required to regularly report that they continue to be exempt, although they may be required to report whether they qualify for an exemption at eligibility redetermination and will be required to report consistent with 42 CFR 435.916(c) if they experience a change in circumstance that makes them no longer eligible for an exemption. The following applicants and beneficiaries are exempt from the community engagement requirements:
    - Individuals receiving Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI);
    - Individuals qualified as Working Disabled;
    - Primary caregiver of a child, up to age 18, and/or disabled adult;

- Individuals identified as medically frail under 42 CFR 440.315(f);
- Members of federally recognized tribes;
- Individuals s diagnosed with an acute medical condition that would prevent them from complying with the requirement (as validated by a medical professional);
- Individuals who are participating in and exempt from Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) employment requirements;
- Individuals participating in a Medicaid covered treatment program for alcohol or substance abuse addiction, including opioid addiction;
- Individuals who are pregnant or 365 days or less post-partum; and
- Individuals residing in regional areas that experience an unemployment rate of 8 percent or greater or when the statewide unemployment rate is 8 percent or greater.

26. Qualifying Activities. Applicants and beneficiaries who are not exempt under STC 25 or who do not meet a good cause circumstance under STC 28(c) may satisfy their community engagement requirements through participation in one or more of the following activities, including but not limited to:

- Participation in and compliance with SNAP and/or TANF employment requirements;
- Participation in an adult secondary education program through a public school district or technical college, including GED programs;
- At least half-time enrollment in a degree- or certificate- seeking program in an accredited institution of higher education, as defined by the South Carolina Commission on Higher Education;
- Compliance with Unemployment Insurance (UI) work-search requirements (limited to the first 16 weeks that a beneficiary receives the UI benefit);
- Subsidized or unsubsidized employment including self-employment for no less than 80 hours per month;
- Participation in a tribal work program; or
- Community or public service, including verifiable volunteerism with public entities or qualified charitable corporations.

27. Hour Requirements and Reporting. After implementation of the community engagement requirements, all new applicants must be in compliance with the community engagement requirements at the time of application to be enrolled. If an individual is not in compliance with the community engagement requirements at application, the application will be denied if the individual is not eligible for any other category of assistance. The individual may reapply at any time. Applicants and beneficiaries not subject to an exemption described in STC 25 or who do not meet a good cause circumstance under STC 28(c) must continue to participate in one or a combination of the qualifying activities listed in STC 26 for 80 hours per month to meet the community engagement requirements. If the applicant meets the requirement through subsidized or unsubsidized employment at application, the individual will not have to report again until it is time for their annual eligibility redetermination. Other than reporting a change in circumstance, beneficiaries must report their community engagement hours no more frequently than at least once every 90 days for other qualifying activities,

including if the beneficiary newly meets the requirement through employment at some point after enrollment.

a. Extra Hours. Beneficiaries who engage in extra hours of qualifying activities above what is required in a month, can apply the extra hours to other months within a quarter, but cannot apply those extra hours to another quarter. That is, beneficiaries may distribute the required 80 hours per month in any manner throughout the quarter, but no hours may carry over from one quarter to the next.

28. Non-Compliance. Beneficiaries who are subject to the community engagement requirements and who do not meet the requirement within 90 days of receiving notice of non-compliance will be suspended.

a. Suspension Effective Date. Applicants who fail to comply with the community engagement requirements as described in STC 24–27, and who do not have an exemption from meeting the community engagement requirements as described in STC 25 or do not have good cause circumstances as described in STC 28(c), will have their application denied if they do not meet the community engagement requirements at application. Beneficiaries who are enrolled in the demonstration who fail to comply with the community engagement requirements as described in STC 21–25, and who do not have an exemption from meeting the community engagement requirements as described in STC 22 or do not have good cause circumstances as described in STC 25(c), will have their eligibility suspended on the first day of the month following notification to the beneficiary of his or her non-compliance, unless an appeal is timely filed or a beneficiary has a good cause circumstance as specified in STC 28(c).

b. Reinstatement Following Non-Compliance. Beneficiaries may have coverage reinstated during a suspension if the beneficiary provides notification of compliance with or exemption from the community engagement requirements. Coverage will be reinstated back to the first day of the month in which the beneficiary provided notification of compliance with the requirement or, for an exemption, back to the first day of the month in which the exemption occurred. If a beneficiary remains suspended at the end of the beneficiary's eligibility period and is not eligible for Medicaid on another basis after redetermination, the beneficiary will be determined ineligible due to non-compliance and the beneficiary will be disenrolled.

c. Good Cause. The state will consider an applicant or beneficiary to be compliant with the community engagement requirements for a month if the applicant or beneficiary demonstrates good cause for failing to meet the community engagement hours required for that month. Beneficiaries may report a good cause circumstance for the state's approval up to 1 day prior to suspension. The circumstances constituting good cause must have occurred during the month(s) for which the beneficiary is seeking good cause. The recognized circumstances that give rise to good cause include, at a minimum, but are not limited to, the following verified circumstances:

i. The applicant or beneficiary has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and was unable to meet the requirement for reasons related to that disability; or has an immediate family member who has a disability as defined by the ADA, section 504, or section 1557, and was

unable to meet the requirement for reasons related to the disability of that family member; The beneficiary experienced a hospitalization or serious illness;

ii. The applicant or beneficiary or an immediate family member who was living in the home with the beneficiary experiences a hospitalization or a serious illness;

iii. The applicant or beneficiary experiences the birth, or death, of a family member living with the beneficiary;

iv. The applicant or beneficiary experiences severe inclement weather (including a natural disaster) and therefore was unable to meet the requirements;

v. The applicant or beneficiary has a family emergency or other life-changing event (e.g., divorce or domestic violence); or

vi. The applicant or beneficiary experiences a temporary or short-term illness documented by a clinician.

29. Reasonable Modifications. The state must provide reasonable accommodations related to meeting the community engagement requirements for applicants and beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act and Section 1557 of the Patient Protection and Affordable Care Act, when necessary, to enable them to have an equal opportunity to participate in, and benefit from, the program. The state must also provide reasonable modifications for program protections and procedures, including but not limited to, understanding notices and program rules related to community engagement requirements, documenting community engagement activities, assistance with demonstrating eligibility for exemptions or circumstances that give rise to good cause; appealing suspensions and disenrollments; navigating ADA compliant web sites as required by 42 CFR 435.1200(f); and other types of reasonable modifications.

Reasonable modifications must include exemptions from participation where the applicant or beneficiary is unable to participate or report for disability-related reasons, modification in the number of hours of participation required where an applicant or beneficiary is unable to participate for the otherwise-required number of hours, and provision of support services necessary to participate, where participation is possible with supports. In addition, the state should evaluate an applicant or beneficiary's ability to participate and the types of reasonable modifications and supports needed.

30. Community Engagement: State Assurances. Prior to implementation of the community engagement requirements as a condition of continued eligibility, the state shall:

a. Ensure that there are processes and procedures in place to stop or recoup payments to a Managed Care Organization (MCO) when a beneficiary is suspended for failure to comply with program requirements and to trigger payment when eligibility is reinstated**.**

b. Ensure that there are processes and procedures in place to seek data from other sources, including SNAP and TANF, and systems to permit applicants and beneficiaries to efficiently report community engagement hours or demonstrate circumstances that give rise to good cause, in accordance with 42 CFR 435.907(a), 435.916(c), and 435.945, and to permit the state to monitor compliance.

c. Ensure that specific activities that may be used to satisfy community engagement requirements are available during a range of times and through a variety of means (e.g., online, in person).
d. Assure that suspension or denial of eligibility will only occur after an applicant or beneficiary has been screened and determined ineligible for all other bases of Medicaid eligibility and reviewed for eligibility for insurance affordability programs in accordance with 42 CFR 435.916(f).
e. Maintain system capabilities to operationalize both the suspension of eligibility and the reinstatement of eligibility once the community engagement requirements are met.
f. Provide outreach and education to inform new applicants about the community engagement requirements and how it must be satisfied at application.
g. Ensure that there are timely and adequate beneficiary notices provided in writing, including but not limited to:
    i. Whether a beneficiary is exempt, how the beneficiary must indicate to the state that she or he is exempt, and under what conditions the exemption would end;
    ii. The specific number of community engagement hours per month that an applicant or beneficiary is required to complete, and when and how the beneficiary must report participation or request an exemption;
    iii. A list of the specific activities that may be used to satisfy community engagement requirements, and a list of the specific activities that applicants and beneficiaries can engage in to cure an impending suspension of eligibility as described in STC 26.
    iv. Information about resources that help connect applicants and beneficiaries to opportunities for activities that would meet the community engagement requirements, and information about the community supports that are available to assist applicants and beneficiaries in meeting community engagement requirements;
    v. Information about how community engagement hours will be counted and documented;
    vi. What gives rise to a suspension of eligibility, what suspension would mean for the beneficiary, including how it could affect redetermination, and how to avoid suspension, including how to apply for good cause and what kinds of circumstances might give rise to good cause;
    vii. If an applicant or beneficiary has sought to demonstrate good cause, that the good cause has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial;
    viii. Any differences in the program requirements that beneficiaries will need to meet in the event they transition off of SNAP or TANF but remain subject to the community engagement requirements of this demonstration;
    ix. If a beneficiary is not in compliance, that the beneficiary is out of compliance, and, if applicable, how the beneficiary can resume compliance in the month immediately following in order to avoid suspension of eligibility;
    x. If a beneficiary is suspended, information on how to appeal that decision and/or how to reinstate Medicaid benefits;

xi. The right of individuals with disabilities to reasonable modifications in community engagement requirements, with examples of the reasonable modifications in those requirements to which individuals may be entitled, including, assistance with documenting participation, exemptions from requirements if an individual is unable to participate for a disability-related reason, and reductions in hours of required participation if an individual is unable to participate in the otherwise required numbers of hours.

h. Provide full appeal rights as required under 42 CFR, Part 431, subpart E prior to suspension, denial of eligibility, or dis-enrollment, and observe all requirements for due process for beneficiaries whose eligibility will be suspended for failing to meet the community engagement requirements, including allowing beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the suspension, and provide additional documentation through the appeals process.

i. Maintain an annual redetermination process, including systems to complete ex parte redeterminations and use of notices that contain prepopulated information known to the state, consistent with all applicable Medicaid requirement.

j. Develop and implement an outreach strategy to inform applicants and beneficiaries how to report compliance with or exemption from the community engagement requirements, changes in circumstances, and how to request good cause, including how notices provided at enrollment, suspension will provide information on resources available to beneficiaries who may require assistance reporting compliance with or exemption from the community engagement requirements, changes in circumstances, and/or requesting good cause.

k. Establish applicant and beneficiary protections, including assuring that beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require employment or another form of community engagement.

l. Make good faith efforts to connect beneficiaries and applicants to existing community supports that are available to assist beneficiaries in meeting community engagement requirements, including available non-Medicaid assistance with transportation, child care, language access services and other supports.

m. Ensure the state will assess areas within the state that experience high rates of unemployment, areas with limited economies and/or educational opportunities, and areas with lack of public transportation to determine whether there should be further exemptions from the community engagement requirements and/or additional mitigation strategies, so that the community engagement requirements will not be unreasonably burdensome for applicants and beneficiaries to meet.

n. Develop and maintain an ongoing partnership with the South Carolina Department of Social Services and the South Carolina Department of Employment and Workforce to assist recipients with identifying and accessing opportunities for workforce training, complying with community engagement requirements, and moving toward independence and self-sufficiency.

o. Provide each individual who has been denied eligibility or disenrolled from Medicaid with information on how to access primary care and preventative care services at low or no cost to the individual. This material will include information about free health clinics and community health centers including clinics that provide behavioral health

and substance use disorder services. South Carolina shall also maintain such information on its public-facing website and employ other broad outreach activities that are specifically targeted to beneficiaries who have lost coverage.

p. Make the general assurance that the state is in compliance with protections for beneficiaries with disabilities under the ADA, Section 504, or Section 1557 of the Patient Protection and Affordable Care Act and:
    i. Make good faith efforts to connect applicants and beneficiaries with disabilities as defined above with services and supports necessary to enable them to meet the community engagement requirements;
    ii. Maintain a system that provides reasonable modifications related to meeting the community engagement requirements to individuals with disabilities as defined above;
    iii. Ensure the state will assess whether people with disabilities have limited job or other opportunities for reasons related to their disabilities. If these barriers exist for people with disabilities, the state must address those barriers; and
    iv. Provide individuals with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting the community engagement requirements.
q. Ensure that the state will monitor the application of exemptions to ensure that there is not a disparate impact based on race or ethnicity.

IX. GENERAL REPORTING REQUIREMENTS

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

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

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

CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

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

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

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

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

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

34. Implementation Plan. The state must submit a draft Implementation Plan to CMS no later than ninety (90) calendar days after approval of the demonstration for CMS review and comment. The state must submit a revised Implementation Plan within sixty (60) calendar days after receipt of CMS' comments. The Implementation Plan must cover at least the key policies being tested under this demonstration, including community engagement. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment D. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, and processing; notices; coordinated agency responsibilities; coordination with other insurance affordability programs; appeals; renewals; coordination with other state agencies; beneficiary protections; and outreach.

35. Monitoring Protocol. The state must submit to CMS for review and comment a draft

Monitoring Protocol no later than one hundred and fifty (150) calendar days after the Implementation Plan noted in STC 34 has been determined complete. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment E.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS' template. Any proposed deviations from CMS' template should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as described in STC 36(b) below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and analysis covering the key policies being tested under this demonstration, including but not limited to community engagement. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 39(a) below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.

36. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth-quarter information that would ordinarily be provided in a separate quarterly report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework to be provided by CMS, which will be organized by milestones. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress towards meeting the milestones identified in CMS' framework. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the

progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS' framework which includes the following key policy under this demonstration: community engagement. The performance metrics will also reflect all other components of the state's demonstration. For example, these metrics will cover enrollment, disenrollment or suspension by specific demographics and reason, participation in community engagement qualifying activities, including employment for meeting the majority of their required hours, access to care, and health outcomes.

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

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

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

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

37. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt-in). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend

implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

38. **Close Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.
    a. The draft report must comply with the most current guidance from CMS.
    b. The state will present to and participate in a discussion with CMS on the Close-Out report.
    c. The state must take into consideration CMS' comments for incorporation into the final Close Out Report.
    d. The final Close Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
    e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 31.

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

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

X. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

41. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval periods 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.

42. **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 expenditure for services provided under this demonstration following routing 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 thirty (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.

43. 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 demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XI:

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

44. Sources of Non-Federal Share. The state certifies that its match for non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. The state acknowledges that CMS has the authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding al sources of the non-federal share of funding.

45. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers may certify that state of local monies have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR §433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR §433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health acer providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR §447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments related to taxes, including health care provider-related taxes, feed, business relationship 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.

46. 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.

47. Medicaid Expenditure Groups (MEG). MEGs 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 following table provides a master list of MEGs defined for this demonstration.

Table 2: Master MEG Chart					
MEG	**To Which BN Test Does This Apply?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
Population I	Hypo 1	X			See Expenditure Authority #1
Targeted Adult Group	Hypo 2	x			See Expenditure Authority #2

48. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00332/4). 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. 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 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 Master MEG Chart table, 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 IX, 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, 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 3: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Population I	Refer to STC 17(a)	N/A	Population I	Date of payment to a provider of service(s)	MAP	Y	December 12, 2019	November 30, 2024
Targeted Adult Group	Refer to STC 17(b)	N/A	Targeted Adult Group	Date of payment to a provider of service(s)	MAP	Y	December 12, 2019	November 3, 2024

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

Table 4: Demonstration Years		
Demonstration Year 1	December 12 , 2019 to November 30, 2020	12 months
Demonstration Year 2	December 12, 2020 to November 30, 2021	12 months
Demonstration Year 3	December 12, 2021 to November 30, 2022	12 months
Demonstration Year 4	December 12, 2022 to November 30, 2023	12 months
Demonstration Year 5	December 12, 2023 to November 30, 2024	12 months

50. 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 demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.[1]

51. 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 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.

52. 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 letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustment to the budget neutrality limit if any health care related tax that was in effect during the base

[1] 42 CFR §431.420(a)(2) provides that 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 in states agree to use the tool as a condition of demonstration approval.

year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

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

c. The state certifies that the data provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditure limit or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulation, 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.

XI. MONITORING BUDGET NEUTRALITY

53. 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 may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

54. Risk. The budget neutrality expenditure limits are determined on wither a per capita or aggregate basis. 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 has there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

55. 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.

56. Main Budget Neutrality Test. This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

57. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that state should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent determined limits to which the state and CMS agree, and that CMS approves, as part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

58. Hypothetical Budget Neutrality Test 1: 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 re 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 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 5: Hypothetical Budget Neutrality Test									
MEG	**PC or Agg***	**WOW Only, WW Only, or Both**	**BASE YEAR 2019**	**TREND**	**DY 1**	**DY 2**	**DY 3**	**DY 4**	**DY 5**
Population I	PC	Both	$476.39	4.5%	$497.83	$520.23	$543.64	$568.66	$593.66
Targeted Adult Group	PC	Both	$767.23	4.5%	$801.76	$837.84	$875.54	$914.94	$956.11

59. 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 it the ration calculated by dividing the sum of total of FFP received by the stat 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 Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

60. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from December 12 to November 30, 2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

61. Mid-Course Correction. 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 level in the tables below as a guide for determining when corrective action is required.

Table 6: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	**Percentage**
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent

DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit	0.0 percent

XII. EVALUATION OF THE DEMONSTRATION

62. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce, or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 31.

63. Independent Evaluator. Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

64. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after approval of the demonstration.

Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

a. Attachment A (Developing the Evaluation Design) of these STCs, all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.
b. All applicable evaluation design guidance, including guidance about community engagement.

65. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval.

66. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS's measure sets for eligibility and coverage (including community engagement), Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF). Community engagement hypotheses must relate to (but are not limited to) the following outcomes: employment levels, income, transitions to commercial health insurance, and health status. Hypotheses for suspension for non-compliance must relate to (but are not limited to) the following outcomes: beneficiary compliance with demonstration requirements, enrollment continuity, and health status (as a result of greater enrollment continuity). The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated costs. In addition, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability.

67. Evaluation Budget. A budget for the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses, and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

68. Interim Evaluation Report. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.

b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted, should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
e. The Interim Evaluation Report must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

69. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.
a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

70. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services by those attempting to opt-in). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

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

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

73. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles, or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Table 7: Schedule of Deliverables for the Demonstration Period

Date	Deliverable	STC
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after approval date	Implementation Plan	STC 34
150 calendar days after Implementation Plan Completeness	Monitoring Protocol	STC 35
180 calendar days after approval date	Draft Evaluation Design	STC 64
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 64
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC 65
October 31, 2023, or with renewal application	Draft Interim Evaluation Report	STC 68
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 68
Within 18 months after October 31, 2024	Draft Summative Evaluation Report	STC 69

60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 69
Monthly Deliverables	Monitoring Call	STC 39
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Progress Reports, including implementation updates	STC 36
	Quarterly Expenditure Reports	STC 36(c)
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Reports	STC 36

Attachment A
Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. 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 on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. Technical assistance resources for constructing comparison groups, identifying causal inferences, and phasing implementation to support evaluation are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

Expectations for Evaluation Designs

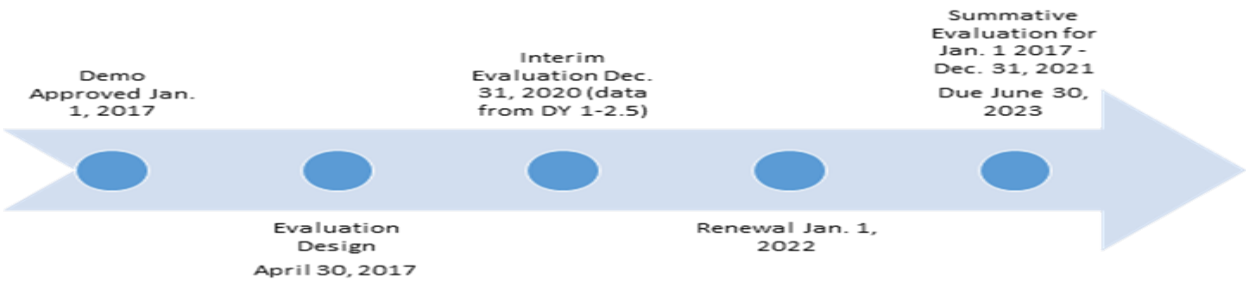
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). 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 days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs

The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

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

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes;

5) Describe the population groups impacted by the demonstration.

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

1) 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 could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

3) Identify the state's hypotheses about the outcomes of the demonstration:

   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

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, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes 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 will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include 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. 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.) Include numerator and denominator information. Additional items to ensure:

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. 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 (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources. If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to 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). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

1) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

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

E. Special Methodological Considerations – CMS 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. Examples of considerations include:

1) When the demonstration is:
   a. Long-standing, non-complex, unchanged, or
   b. Has previously been rigorously evaluated and found to be successful, or
   c. 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; and
   b. No or minimal appeals and grievances; and

c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

F. 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, prepare an objective Evaluation Report, and that there would be no conflict of interest. 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 cost, 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 or if CMS finds that the draft Evaluation Design is not sufficiently developed.
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 an Interim and Summative Evaluation. 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 Evaluation Report

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. 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 on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is 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). To this end, 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. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. 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. 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.

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 submission must provide a comprehensive written presentation 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.

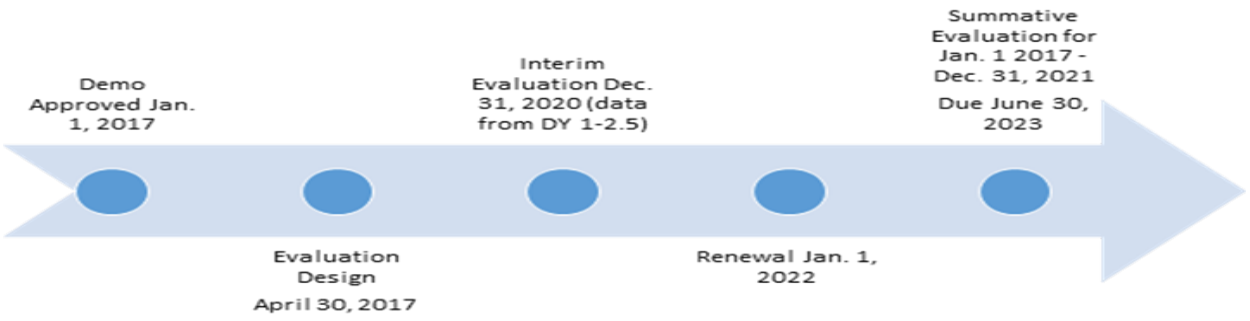
The format for the Interim and Summative Evaluation reports is as follows:

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).

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 this timeline). 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 evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report 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. A copy of the state's Driver Diagram (described in the Evaluation Design Attachment) must be included with an explanation of the depicted information. The Evaluation Report 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. Therefore, the state's submission must include:

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

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

1) 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. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
    a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
    b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
    c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

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

An interim 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.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used;

reported on, controlled for, and made 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.
Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1) *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc?
2) *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3) *Evaluation Period* – Describe the time periods for which data will be collected
4) *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6) *Analytic Methods* – Identify specific statistical testing which will be 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 show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

G. Conclusions – In this section, the state will present the conclusions about the evaluation results.

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) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? 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 interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

I. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

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?

J. Attachment

1) Evaluation Design: Provide the CMS-approved Evaluation Design

Attachment C:
Evaluation Design (reserved)

Attachment D:
Implementation Plan (reserved)

Attachment E:
Monitoring Protocol (reserved)