



DEC 12 2019

Administrator

Washington, DC 20201

Joshua Baker
Director
State of South Carolina, Department of Health & Human Services
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Columbia, SC 29201

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 require participation in community engagement as a condition of eligibility for the Medicaid state plan Parent, Caretaker and Relative (P/CR) group and individuals eligible through Transitional Medicaid Assistance (TMA), through a section 1115 demonstration project entitled, “Healthy Connections Works” (Project No. 11-W-00334/4), in accordance with section 1115(a) of the Act.

This approval of Healthy Connections Works 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 waiver 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 waived.

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 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.

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.

Indeed, South Carolina has indicated that the approval of these community engagement requirements is giving the state the resources and ability to expand coverage to other vulnerable populations that would not otherwise be eligible for Medicaid. In its proposal, South Carolina requested authority to extend coverage to individuals who would otherwise qualify for the P/CR group and who have 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 Medicaid. Additionally, the state requested authority to extend coverage to a Targeted Adult Group, which extends Medicaid eligibility to individuals ages 19 through 64 who are otherwise not eligible for Medicaid and meet specific criteria, such as being chronically homeless, being justice involved and in need of substance use disorder (SUD) treatment, or being in need of SUD treatment. The state has also requested to expand coverage for pregnant women and children and will seek state plan authority to cover those individuals. While these requests are being approved under separate authorities from this demonstration, including as part of a separate demonstration testing certain hypotheses distinct from those tested in this demonstration, CMS acknowledges that the state's request to cover these additional populations was made as part of the state's request for the waivers CMS is approving in this demonstration and may not have been pursued in isolation.

The measures being tested 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 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 individuals 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 individuals 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 ensure compliance. In addition, section 1115 gives us the authority to offer states more flexibility in experimenting with different ways of improving health outcomes, strengthening the financial independence of beneficiaries, and ensuring the sustainability of the Medicaid program.

This demonstration is designed to support beneficiaries receiving coverage through the Medicaid state plan P/CR group and TMA as they move towards greater independence through community engagement. The state is committed to facilitating this transition to independence and commercial coverage, and has requested expenditure authority, which is being approved under a separate demonstration, to extend coverage to the P/CR group from the current standard of 62 percent of the FPL up to and including 95 percent FPL (effectively 100 percent of the FPL with a 5 percent income disregard) to ensure that beneficiaries affected by this demonstration will still be eligible for Medicaid coverage if their community engagement activities cause their income to

rise and exceed current state plan eligibility limits. Beneficiaries who become income eligible for the separately approved demonstration (called “Palmetto Pathways to Independence”) will also be subject to community engagement requirements under that demonstration.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries, which may lead to lower costs for the program due to improved health status of beneficiaries and through the impact of beneficiaries finding employment that provides access to health insurance. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their Medicaid programs and to provide more medical services to more Medicaid beneficiaries. Accordingly, such demonstration projects advance the objectives of the Medicaid program.

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, South Carolina’s 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 FPL, also known as the New Adult group.

Extent and Scope of the Demonstration

Community Engagement

With this demonstration approval, South Carolina will require community engagement as a condition of Medicaid eligibility for beneficiaries currently covered in the Medicaid state plan P/CR group and for those receiving TMA. 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. Unless exempt, applicants and beneficiaries will need to engage in qualifying community engagement activities for at least 80 hours per month. 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); 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 pregnant through 365 days postpartum.

To be eligible for coverage, non-exempt applicants and beneficiaries must complete a minimum of 80 hours monthly of community engagement activities. Those who are employed at enrollment are required to report compliance on an annual basis. Those who meet the requirement through other qualifying activities are required to report compliance on a quarterly basis. The state will allow beneficiaries flexibility with completing the community engagement requirements by allowing extra hours to be spread across a 90-day period. Non-exempt individuals may satisfy these 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 substance use disorder (SUD) treatment.

Under this demonstration, the state will notify newly enrolled beneficiaries who have met the community engagement requirements at application or, for beneficiaries currently enrolled at the implementation of community engagement at their next redetermination, and have been determined eligible for coverage of their need to continue to participate in community engagement activities as a condition of coverage and eligibility. 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 meets the community engagement requirements, the beneficiary must report this change in circumstance. The beneficiary will have 90 days to report that they are meeting the requirements again, that they qualify for an exemption, or that they have experienced a circumstance that would give rise to good cause, otherwise the beneficiary will be considered non-compliant and their coverage will be 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 disenrolled unless they are eligible for another category of Medicaid assistance not subject to the requirements. Disenrollment does not affect an individual's ability to apply and regain Medicaid coverage, if eligible.

The state will require compliance with the community engagement requirements and will implement the consequences for failure to meet the requirements no sooner than one year after this approval for both the Medicaid state plan P/CR group and for those receiving TMA.

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

In its application, South Carolina requested to newly expand coverage to individuals ages 19 through 64 who meet the criteria for the P/CR group but who have incomes above the Medicaid standard of 62 percent of the FPL up to 95 percent of the FPL (effectively 100 percent with the five percent income disregard) and who are not otherwise eligible for Medicaid. Additionally, the state requested to newly expand coverage 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, the state requested that beneficiaries in the expanded P/CR group and the Targeted Adult Group also engage in qualifying community engagement activities for at least 80 hours per month, should they wish to opt into receiving Medicaid benefits. CMS is approving this request through a separate section 1115 demonstration approval, titled “Palmetto Pathways to Independence.”

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 that 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., but acknowledges that the state’s request to cover these populations was included as part of the reforms CMS is approving today and may not have been pursued in isolation of the reforms being approved with this demonstration.

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 under the Palmetto Pathways to Independence demonstration 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 Healthy Connections Works demonstration is likely to assist in promoting the objectives of the Medicaid program.

The demonstration promotes beneficiary health and financial independence.

With approval of the demonstration, South Carolina and CMS will be able to evaluate the effectiveness of a policy that is designed to improve the health of Medicaid beneficiaries and promote their financial independence. Promoting beneficiary health and independence advances the objectives of the Medicaid program by itself, and as discussed below, because it is expected to make South Carolina’s Medicaid program more sustainable. Indeed, in 2012, HHS specifically encouraged states to develop demonstration projects “aimed at promoting healthy

behaviors” and “individual ownership in health care decisions” as well as “accountability tied to improvement in health outcomes.”³ The demonstration is designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that correspond with improved health and wellness. Improved health and wellness, in turn, may reduce health care costs. The community engagement provision generally requires applicants and beneficiaries to work, look for work, or engage in activities that enhance their employability, such as education and community service. SUD treatment also qualifies as a community engagement activity, which not only supports beneficiaries’ health needs, but may also lead to healthier beneficiaries who may better be able to attain and sustain employment. Such outcomes are incentivized through this demonstration.

The demonstration will help South Carolina and CMS evaluate whether the community engagement requirements help certain healthy, able-bodied adults in South Carolina transition from Medicaid to financial independence, thus reducing dependency on public assistance. 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. Examples of hypotheses the state will test include, but are not limited to, whether or not the demonstration: increases the average income of Medicaid beneficiaries subject to the requirements, increases the likelihood that Medicaid beneficiaries transition to commercial health insurance after separating from Medicaid, and improves the health outcomes of current and former Medicaid beneficiaries subject to the requirements. 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). 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 a comparison population, such that the impact of the demonstration can be estimated. It is plausible that the state might find it difficult to identify an in-state comparison group not subject to the community engagement requirements that would otherwise be similar in demographic and other relevant characteristics that distinguish the demonstration population. Therefore, the state might need to identify other-state comparison strategies, or apply alternative rigorous methodological approaches. Furthermore, in addition to examining some variant of the primary research questions—as outlined in CMS’s CE evaluation design guidance—the state would also need to be thoughtful about adopting, while adapting as relevant, some of the critical secondary research questions to adequately understand the pathway to the demonstration outcomes for this population.

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.

³ CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 15 (Dec. 10, 2012) (noting also that “states have considerable flexibility under ... [existing] law to design benefits for the new adult group and to impose cost-sharing, particularly for those individuals above 100% of the federal poverty level”).

Demonstration monitoring will also capture metrics on individuals who lost eligibility due to mid-year change in circumstance or at renewal, and transitioned to a qualified health plan offered on the Exchange. Additionally, the state will track the loss of Medicaid eligibility resulting from increased income among individuals who were subject to community engagement requirements and will also track transitions to or tenure in TMA, transitions to employer-sponsored insurance (ESI), or use of limited benefit packages for individuals formerly subject to community engagement requirements.

As described in the STCs, CMS has also included STCs in the monitoring and evaluation sections to align those sections with CMS' current approach to monitoring and evaluation for section 1115 demonstrations, and to specify 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 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 increases in disenrollment, difficulty accessing services, provider uncompensated care costs or unpaid medical bills). 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 updates 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 demonstration will furnish medical assistance in a manner that improves the sustainability of the safety net.

CMS has determined that this 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 community engagement a condition of eligibility for certain state plan populations, South Carolina expects that some beneficiaries will gain financial security and move off of public assistance. Additionally, if participating in community engagement activities improves beneficiaries' physical and mental health, these beneficiaries may consume fewer health care resources, thus reducing state costs for Medicaid. And, to the extent the community engagement requirements help individuals achieve financial independence and transition to commercial coverage, the demonstration would enhance the state's ability to provide medical services to those who most need the safety net.

By incentivizing community engagement, as described above, the demonstration is also designed to lead to higher quality care at a sustainable cost. Promoting improved health and wellness ultimately helps to keep health care costs at sustainable levels. To the extent that the demonstration helps individuals achieve improved health and financial independence, the demonstration may make these individuals less costly for South Carolina to care for, thus further advancing the objectives of the Medicaid program by making additional resources available for the state to provide the additional coverage expansions that are authorized under this demonstration and through the state plan. The requirements ultimately help South Carolina stretch its limited Medicaid resources, ensure the long-term fiscal sustainability of the program,

and ensure that the health care safety net is available to those South Carolina residents who need it most.

Enhancing fiscal sustainability allows the state to provide services and cover additional Medicaid beneficiaries that it could not otherwise provide. Evidence of this demonstration approval making additional resources available to South Carolina to cover additional populations is found in the state's initial request for broader demonstration authority, which also included requests to cover: individuals who otherwise meet the eligibility criteria for the P/CR group but who have with incomes above the Medicaid standard of 62 percent of the FPL but at or below 95 percent FPL (effectively 100 percent with the five percent disregard); a Targeted Adult Group of individuals ages 19 through 64 who are otherwise not eligible for Medicaid and meet specific criteria, such as being chronically homeless, justice involved and in need of substance use disorder (SUD) treatment, or in need of SUD treatment; and additional pregnant women and children. These coverage expansions, which are being approved using both state plan authority and through a separate demonstration, are expected to result in significant net coverage gains in South Carolina. The state's request to cover these additional populations may not have been pursued in isolation of the reforms being approved with this demonstration. Accordingly, it furthers the Medicaid program's objectives to allow states to experiment with innovative means of deploying their limited state resources in ways that may allow them to extend coverage beyond the statutory minimum.

The demonstration includes policies like suspension for certain beneficiaries for failure to comply with community engagement requirements that may impact overall coverage levels if the beneficiaries subject to this demonstration choose not to comply with them. As noted above, the community engagement program is designed to make compliance achievable and includes adequate beneficiary protections to ensure that the program applies only to those beneficiaries who can reasonably be expected to meet the requirements.

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 imposed 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, such as children and individuals living with chronic health conditions. South Carolina does not seek to require that children under the age of 19 participate in the community engagement requirements. Additionally, 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, and individuals who have an acute medical condition. The state will also use administrative data to proactively identify applicants and beneficiaries who meet an exemption from the requirements, and will allow other beneficiaries to attest to needing an exemption. South Carolina will also provide applicants and beneficiaries with the opportunity to avoid the consequences for failure to comply with the requirements by demonstrating that they had a good cause not to meet it, and provide reasonable modifications for beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA.

To ensure that vulnerable applicants and beneficiaries are protected, CMS has worked together with South Carolina to exempt certain vulnerable individuals, as described below, from community engagement requirements and to include certain guardrails. These guardrails, which take the form of a series of assurances in the STCs, include requirements that the state: screen beneficiaries and determine eligibility for Medicaid on any other basis, 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 program requirements; develop and implement an outreach strategy to inform beneficiaries how to report compliance with community engagement requirements; and maintain a system that provides reasonable modifications for meeting community engagement requirements to beneficiaries with disabilities, among other assurances.

CMS will regularly monitor the demonstration and will work with the state to resolve any issues that arise as South Carolina implements 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 the 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 increases in disenrollment, difficulty accessing services, provider

uncompensated care costs or unpaid medical bills). These updates 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. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

We recognize that some beneficiaries may choose not to continue to comply with the conditions of eligibility imposed by the demonstration, and therefore may lose coverage, as may occur when individuals fail to comply with other requirements like participating in the redetermination process. But the goal of these policies is to incentivize compliance, not reduce coverage. CMS has worked with South Carolina to ensure that compliance with the community engagement requirements is reasonably achievable for everyone subject to those requirements and has incorporated safeguards into the STCs intended to minimize coverage loss due to noncompliance, and CMS is committed to partnering with South Carolina to ensure that the demonstration advances the objectives of Medicaid. Furthermore, we anticipate that 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.

The community engagement program is designed to make compliance achievable. South Carolina has taken steps to include adequate beneficiary protections to ensure that the program applies only to those beneficiaries who can reasonably be expected to meet community engagement requirements and that beneficiaries are clearly informed of their responsibilities under the demonstration. Any individual whose coverage is suspended or terminated for failure to meet program 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. And to the extent that this results in lower costs for the state, this outcome is not inconsistent with the objectives of the program.

CMS shares the commenters' concern that everyone who needs Medicaid and is eligible for it should have access to it. CMS also shares the public's interest in improved health outcomes for beneficiaries. As previously stated, however, 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. That is why CMS has carefully reviewed the demonstration as a whole to ensure it is likely to promote sometimes competing Medicaid objectives.

Comments on Community Engagement and Reporting Requirements

Opposing commenters believe that South Carolina's community engagement requirements are complex and place a reporting burden on beneficiaries. Many commenters indicated that beneficiaries would lose access to Medicaid for failing to comply with burdensome reporting requirements. 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 them having to report compliance, and will provide a variety of mechanisms for applicants and beneficiaries 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 activity the beneficiary is completing. If an individual is employed at the time of application, the individual will only be required to report compliance on an annual basis; beneficiaries 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. 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, 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 For applicants or beneficiaries who may have difficulty in meeting the community engagement requirements due to a health related issue, the state is exempting vulnerable populations such as beneficiaries who are medically frail, qualified as Working Disabled, enrolled in the breast and cervical cancer program, participating in and compliant with an SUD treatment program, and individuals diagnosed with an acute medical condition that would prevent them from complying with the requirements, among other exemptions. In addition, the state allows individuals 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 circumstances giving rise to good cause include, but are not limited to a recent hospitalization, an individual that is disabled, or if an individual experiences the birth or death of a family member living with the individual.

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. The state has done an analysis of potential projected coverage loss as a result of this demonstration and noted that of the 188,000 beneficiaries currently enrolled in the Medicaid state plan P/CR group or receiving TMA that will be subject to community engagement requirements, the state estimates that 168,000 will be exempt or are already meeting program requirements based on eligibility and claims data. These beneficiaries will be determined compliant without any additional effort on their part and thus we do not expect that any of them would lose coverage as a result of this demonstration. The state expects 20,000 beneficiaries would need to complete qualifying activities to comply with the community engagement requirements, unless they meet an exemption that South Carolina could not identify through eligibility or claims data. Of the 20,000 beneficiaries in the Medicaid state plan P/CR group or receiving TMA considered not to be exempt or already meeting the requirements, the state estimates that 7,100 beneficiaries (6,745 Medicaid state plan P/CR and 355 TMA) will elect not to comply and may have their Medicaid coverage suspended. Actual coverage impact will greatly depend on the choices made by each individual, and it is therefore challenging accurately to predict the impacts of this new program before it even begins. These potential coverage losses must be balanced against the potential gains in beneficiary health and financial independence from participating in community engagement, as well as the potential increase in the fiscal sustainability of the state's Medicaid program. In particular, this increased fiscal sustainability can allow the state to offer additional

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>

services and benefits to other individuals, as evidenced by the state's desire, expressed in its initial demonstration request, to cover additional populations.

It is important to CMS that compliance is achievable for every beneficiary subject to the new community engagement requirements, such that every beneficiary enrolled in Medicaid can stay enrolled in Medicaid unless and until they move into other forms of coverage or become ineligible for reasons such as income. In light of the safeguards discussed above, CMS has determined that compliance with South Carolina's community engagement requirements is achievable for every beneficiary subject to such requirements. Furthermore, CMS is undertaking rigorous evaluation and monitoring of a variety of metrics, including enrollment metrics. 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). 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 may choose not to continue to meet the requirements, the state is required to implement a number of strategies and supports to minimize coverage loss due to non-compliance with the community engagement requirements. For example, the state will conduct active outreach and education, beyond standard noticing, to help ensure that beneficiaries understand program requirements and how to continue to comply with such requirements. South Carolina will maintain such information on its public facing website and employ other broad outreach activities that are specifically targeted to 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, 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.

Other Information

CMS's approval of this demonstration 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: S2-25-26

7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Valisha.Andrus@cms.hhs.gov

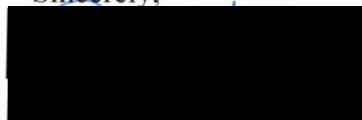
Official communications regarding program matters should be sent simultaneously to your project officer and Ms. Shantrina Roberts, Deputy Director of Field Operations South. Ms. Roberts's contact information is as follows:

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,

A large black rectangular redaction box covering the signature area.

Seema Verma

Enclosures

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

NUMBER: 11-W-00334/4

TITLE: Healthy Connections Works

AWARDEE: South Carolina Department of Health and Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities, shall apply to the demonstration project from December 12, 2019 through November 30, 2024. In addition, these waivers may only be implemented consistent with the approved special terms and conditions (STC).

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

1. Reasonable Promptness **Section 1902(a)(8)**

To the extent necessary to enable South Carolina to deny enrollment for individuals who would otherwise be eligible for this demonstration but do not meet the community engagement requirements at application and redetermination, as described in these STCs.

2. Eligibility and Provision of Medical Assistance **Section 1902(a)(8)**
Section 1902 (a)(10) and
Section 1902(a)(52)

To the extent necessary to enable South Carolina to require community engagement as a condition of initial and continued eligibility, as described in these STCs.

To the extent necessary to enable South Carolina to deny eligibility for, and not make medical assistance available to, beneficiaries subject to the community engagement requirements who fail to comply with the community engagement requirements unless the beneficiary is exempted, or demonstrates good cause, as described in these STCs.

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

NUMBER: 11-W-00334/4

TITLE: Healthy Connections Works

AWARDEE: South Carolina Department of Health and Human Services

I. PREFACE

The following are the STCs for the “Healthy Connections Works” 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 the state waivers of requirements under section 1902(a) of the Social Security Act (Act), 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 Healthy Connections Works 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

Community Engagement

South Carolina is authorized to require community engagement as a condition of Medicaid eligibility (described in STCs 21-27) for beneficiaries ages 19 through 64 in the Parents and Other Caretaker Relatives (P/CR) group, and those receiving Transitional Medical Assistance (TMA), with exemptions for some beneficiaries, described in STC 22. After implementation of the community engagement requirements, the state will notify newly enrolled, non-exempt beneficiaries who met the community engagement requirements at application of their need to continue to participate in community engagement activities as a condition of coverage and eligibility. For non-exempt beneficiaries currently enrolled in Medicaid at the implementation of the community engagement requirements, the state will notify those beneficiaries of their need to be in compliance with the community engagement requirements at their next redetermination following the implementation of the community engagement requirements. Non-exempt beneficiaries must complete a minimum of 80 hours monthly of community engagement activities and report compliance on an annual basis if they are employed at initial enrollment or quarterly if they are completing other qualifying community engagement activities. Non-exempt beneficiaries may satisfy this requirement through a variety of qualifying activities, described in STC 23.

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 increases in disenrollment, difficulty accessing services, provider uncompensated care costs, or unpaid medical bills). 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 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. Mandatory and optional Medicaid state plan populations derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan, except expressly waived and as described in these STCs.

17. Populations Affected by the Demonstration. The demonstration is comprised of the P/CR group, and those receiving Transitional Medical Assistance (TMA).

Table 1. Populations Affected by the Demonstration		
Demonstration Feature	Eligibility Group	Citations
Community Engagement Requirements	Parents and Other Caretaker Relatives (P/CR)	<ul style="list-style-type: none"> • 1931; • 1902(a)(10)(A)(i) • 42 CFR 435.110
Community Engagement Requirements	Transitional Medical Assistance (TMA)	<ul style="list-style-type: none"> • 408(a)(11)(A) • 1931(c)(2) • 1925 • 1902(a)(52)

V. BENEFITS

18. Benefits for Participants in the Demonstration. Beneficiaries who are affected by the demonstration will receive the same benefits as 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. The demonstration does not affect the benefits received by populations impacted by the demonstration.

VI. COST SHARING

19. 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

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

VIII. COMMUNITY ENGAGEMENT REQUIREMENTS

21. Overview. The state will implement community engagement requirements as a condition of eligibility for individuals ages 19 through 64 enrolled in the P/CR group and for those receiving TMA, provided that such individuals are not otherwise subject to an exemption described in STC 22 or with circumstances that give rise to good cause described in STC 25(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 23 and report compliance as specified in STC 24. 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.

22. 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 participating in a Home and community-based services (HCBS) waiver or beneficiaries in institutional placements;
- Former Foster Care Youth;
- Individuals participating in the Breast and Cervical Cancer Program (BCCP);
- 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 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 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.

23. Qualifying Activities. Applicants and beneficiaries who are not exempt under STC 22 or who do not meet a good cause circumstance under STC 25(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.

24. Hour Requirements and Reporting. Prior to the implementation date of the community engagement requirements as a condition of eligibility, beneficiaries currently enrolled in the P/CR group and TMA will be encouraged to participate in and report community engagement activities but will not have eligibility suspended if they fail to meet the requirement as described in this STC. Following the implementation date of the community engagement requirements as a condition of eligibility, currently enrolled beneficiaries will be required to be in compliance with the community engagement requirements at their next redetermination following implementation in order to receive coverage for the following year. If a beneficiary does not report compliance with the community engagement requirements at their redetermination, the beneficiary will be disenrolled. However, the individual can reapply at any time. After implementation, 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. Beneficiaries not subject to an exemption described in STC 22 or who do not meet a good cause circumstance under STC 25(c) must continue to participate in one or a combination of the qualifying activities listed in STC 23 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 beneficiary will not have to report again until it is time for their annual eligibility redetermination/ renewal. 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.

25. 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. Beneficiaries 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 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 25(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 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 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 beneficiary or an immediate family member who was living in the home with the beneficiary experiences a hospitalization or a serious illness;
 - iii. The beneficiary experiences the birth, or death, of a family member living with the beneficiary;
 - iv. The beneficiary experiences severe inclement weather (including a natural

- disaster) and therefore was unable to meet the requirements;
- v. The beneficiary has a family emergency or other life-changing event (e.g., divorce or domestic violence); or
- vi. The beneficiary experiences a temporary or short-term illness documented by a clinician.

26. 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 a 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 a beneficiary's ability to participate and the types of reasonable modifications and supports needed.

27. 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 a beneficiary or applicant 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. When the community engagement requirements will commence for that specific beneficiary;
 - ii. Whether a beneficiary is exempt, how the applicant or beneficiary must indicate to the state that she or he is exempt, and under what conditions the exemption would end;
 - iii. The specific number of community engagement hours per month that a beneficiary is required to complete, and when and how the beneficiary must report participation or request an exemption;
 - iv. A list of the specific activities that may be used to satisfy community engagement requirements, and a list of the specific activities that beneficiaries can engage in to cure an impending suspension of eligibility as described in STC 25.
 - v. Information about resources that help connect beneficiaries to opportunities for activities that would meet the community engagement requirements, and information about the community supports that are available to assist beneficiaries in meeting community engagement requirements;
 - vi. Information about how community engagement hours will be counted and documented;
 - vii. What gives rise to a denial or suspension of eligibility, what denial or suspension would mean for the beneficiary, including how a suspension 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;
 - viii. If a 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;
 - ix. 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;
 - x. 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;
 - xi. If a beneficiary is suspended, information on how to appeal that decision and/or how to reinstate Medicaid benefits;
 - xii. 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 or 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 beneficiaries 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 beneficiaries 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

28. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter 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.

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

30. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 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.

31. 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.

32. 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 31 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 33(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 33(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.

33. 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.

Demonstration monitoring will also capture metrics on individuals who lost eligibility due to mid-year change in circumstance or at renewal, and transitioned to a qualified health plan offered on the Exchange. Additionally, the state will track the loss of Medicaid eligibility resulting from increased income among individuals who were subject to community engagement requirements and will also track transitions to or tenure in TMA, transitions to employer-sponsored insurance (ESI), or use of limited benefit packages for individuals formerly subject to community engagement requirements.

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.

34. 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 increases in disenrollment, difficulty accessing services, or unpaid medical bills). 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.

- 35. 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 28.

- 36. 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.

- 37. 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

- 38. General Financial Requirements.** The state must comply with all general financial requirement under Title XIX, as well as any applicable reporting requirement related to monitoring budget neutrality, set forth in Section XI of these STCs.

XI. MONITORING BUDGET NEUTRALITY

- 39. Budget Neutrality.** Consistent with the August 22, 2018, State Health Official Letter #18-009, CMS has determined that this demonstration is budget neutral based on CMS's

assessment that the waiver authorities granted for the demonstration are unlikely to result in any increase in federal Medicaid expenditures for medical assistance, and that no expenditure authorities are associated with the demonstration. The state will not be allowed to obtain budget neutrality “savings” from this demonstration. The demonstration will not include a budget neutrality expenditure limit, and no further test of budget neutrality will be required. CMS reserves the right to request budget neutrality worksheets and analyses from the state whenever the state seeks a change to the demonstration, per STC 7.

XII. EVALUATION OF THE DEMONSTRATION

40. 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 28.

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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 increases in disenrollment, difficulty accessing services or unpaid medical bills). 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.

49. 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.

50. 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.

51. 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 2: 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 31
150 calendar days after Implementation Plan Completeness	Monitoring Protocol	STC 32
180 calendar days after approval date	Draft Evaluation Design	STC 45
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 45
30 calendar days after CMS Approval	Approved Evaluation Design published to state’s website	STC 46

October 31, 2023, or with renewal application	Draft Interim Evaluation Report	STC 49
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 49
Within 18 months after October 31, 2024	Draft Summative Evaluation Report	STC 50
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 50
Monthly Deliverables	Monitoring Call	STC 36
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4 th quarter.	Quarterly Progress Reports, including implementation updates	STC 33
	Quarterly Expenditure Reports	STC 33(c)
Annual Deliverables - Due 90 calendar days after end of each 4 th quarter	Annual Reports	STC 33

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

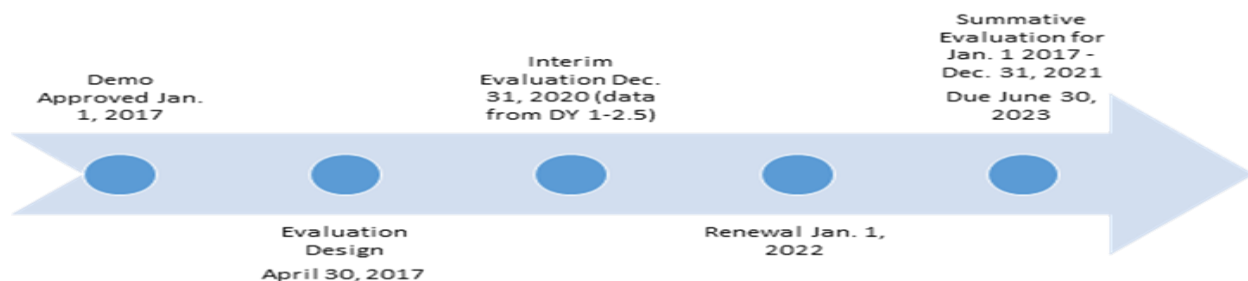
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

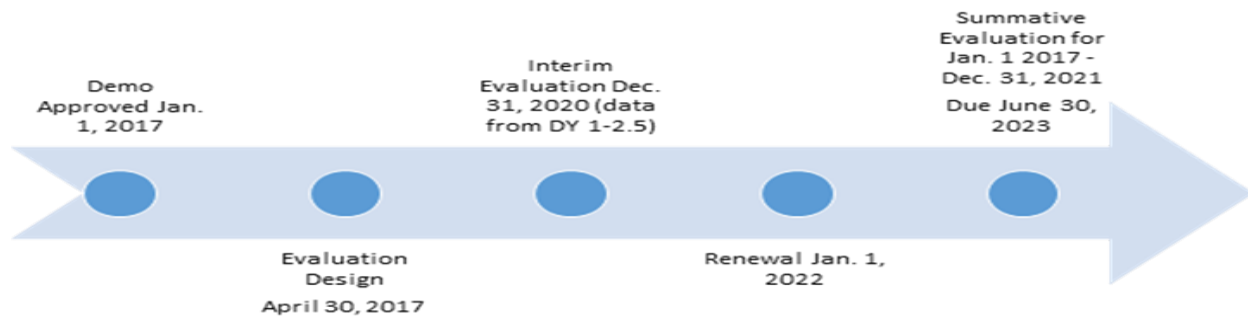
The format for the Interim and Summative Evaluation reports is as follows:

- 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)**