DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 2 1 2018

Stefanie Nadeau
Director
Office of MaineCare Services
Maine Department of Health and Human Services
221 State Street
Augusta, ME 04333

Dear Ms. Nadeau:

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 Maine's request for CMS approval of its Medicaid demonstration project, entitled "MaineCare" (Project Number 11-W-00322/1), in accordance with section 1115(a) of the Act. This approval is effective December 21, 2018 through December 31, 2023, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. Implementation of the demonstration may not begin sooner than July 1, 2019. CMS's approval is subject to the limitations specified in the attached waivers, and special terms and conditions (STCs). 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 project is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to "enabl[e] 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. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. But there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence. Therefore, we believe an objective of the Medicaid program, in addition to furnishing services, is to advance the health and wellness needs of its beneficiaries, and that it is appropriate for the state to structure its demonstration project in a manner that prioritizes meeting those needs.

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on evidence-based interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries' financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They 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 they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

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. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility may decrease the number of individuals who need financial assistance from the state. Such 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.[1] By the same token, such measures may also

[1] 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. The optional groups include a new, non-elderly adult population (ACA expansion population) that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of the ACA expansion population became optional as a result of the Supreme Court's decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they "have flexibility to start or stop the expansion." CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). 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

preserve states' ability to continue to provide the optional services and coverage they already have in place.

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. 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 Maine

Maine's Medicaid program provides health coverage to 258,000 individuals. Coverage under the program extends to some non-mandatory populations, such as individuals in need of family planning services, individuals receiving home and community-based services (HCBS) under a waiver, and individuals under 65 who need treatment for breast or cervical cancer but who are not otherwise eligible for Medicaid, in addition to the mandatory eligibility groups. The state also covers some non-mandatory benefits, including prescription drugs.

Extent and Scope of the Demonstration

The MaineCare demonstration provides the authority for the state to implement a community engagement initiative as a condition of eligibility for adult beneficiaries ages 19 to 64 who will be enrolled in the MaineCare program, with exemptions for certain individuals, including: pregnant women and individuals who are physically or mentally unable to work 20 or more hours per week, as determined by a medical provider.

Maine is applying the community engagement requirement to non-elderly, non-pregnant adult beneficiaries who are eligible for Medicaid on a basis other than disability. While this includes adults who are eligible as medically needy and adults who are covered under the state's HIV demonstration, not all of those beneficiaries will be able to fulfill the requirement, because they may be medically determined unable to work or receiving disability benefits, which we are using as a proxy for being unable to work. Therefore these individuals will be exempt from the community engagement requirement. Those who are not otherwise exempt and are capable of completing 80 hours per month of qualifying activities will be subject to the community engagement requirement. The state will take the necessary steps to determine beneficiaries who are eligible for an exemption, at application and renewal, without requiring additional information from the beneficiary. These steps include relying on information contained in the beneficiary's Medicaid account and databases, including claims and encounter data, as well as other data systems available to the state. Beneficiaries may also use standard Medicaid reporting processes to request an exemption. Notices will also inform beneficiaries as to what gives rise to disenrollment under this demonstration and how to avoid disenrollment if the beneficiary meets an exemption or qualifies for has good cause for failure to meet the requirement. The notices must also describe what kinds of circumstances might give rise to an exemption or good cause.

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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.

Beneficiaries must report their compliance with the community engagement requirement or that they meet the criteria for exemption, if the state has not already determined them exempt, at initial application or, for existing beneficiaries, no later than 90 days after the receipt of notice from the state that community engagement requirement apply to the beneficiary's eligibility. Beneficiaries must and will be able to report changes to their community engagement activities through the state's existing change in circumstances process. Qualifying activities include, but are not limited to: paid employment (including self-employment); workfare programs; volunteer community service; job search and readiness activities; and education. The state shall use information within its existing data systems to verify community engagement activities for individuals who are complying with or exempt from community engagement requirement for Supplemental Nutrition Assistance Program (SNAP) or Temporary Assistance for Needy Families (TANF).

Compliance with the community engagement initiative will be measured in 36-month periods. A beneficiary who does not comply with the community engagement requirement for a total of three months (consecutive or not) in a 36-month compliance measurement period will be disenrolled from MaineCare until the beneficiary can demonstrate one month of compliance with the community engagement requirement, experiences a life event that qualifies them for an exemption from the community engagement requirement, or becomes eligible for Medicaid in an eligibility group that is not subject to the community engagement requirement. Beneficiaries will also be able to reactivate eligibility if they can demonstrate good cause existed at the time of disenrollment and the state determines the beneficiary's failure to comply or report compliance at the time of disenrollment was the result of a catastrophic event or circumstance beyond the beneficiary's control. Beneficiaries who experience life events that would qualify them for an exemption from the community engagement requirement, or catastrophic events or circumstances beyond their control will receive retroactive coverage to the date coverage ended without need for a new application. If an individual with a disability is unable to meet requirement, seek good cause, or meet reporting requirements, for disability-related reasons, or did not get needed reasonable accommodations, this would be considered a circumstance beyond the beneficiary's control. Beneficiaries who do not reactivate eligibility during a compliance measurement period will be able to reapply at the start of the next compliance measurement period without the previous non-compliance affecting their eligibility.

To align coverage with commercial insurance principles and prepare beneficiaries for transitioning to commercial health insurance coverage, the MaineCare demonstration also includes waivers to allow the state to charge premiums based on income, not to exceed five percent of monthly household income, for certain beneficiaries aged 19-64 in the following groups: section 1931 parents and other caretaker relatives (who are eligible if they have incomes at or below 100 percent of the federal poverty level (FPL)), former foster care children, individuals eligible for family planning services, and medically needy parents and other caretaker relatives. Beneficiaries may be disenrolled for nonpayment of premiums for a period of up to 90 days or until all outstanding premium payments are made, whichever period is shorter. Beneficiaries will have a 60 day payment period to make a premium payment before being subject to a non-eligibility period. The demonstration also provides for a non-eligibility period of 90 days for failure to make a required premium contribution or failure to report a

change in circumstance related to a beneficiary's compliance with the community engagement requirement that affects their Medicaid eligibility.

This demonstration will also include a waiver of retroactive eligibility, which permits Maine to grant eligibility to state plan populations beginning the month they submit an application, and to waive the three-month retroactive eligibility period. The waiver of retroactive eligibility does not apply to applicants who would have been eligible at any point within the three month period immediately preceding the month in which an application was received, as pregnant women (and women during the 60-day period beginning on the last day of a pregnancy), infants under age 1 and children under age 19 (described in section 1902(l)(4) of the Act), and individuals who are applying for a long-term care determination. Maine proposes that this policy will encourage individuals to seek coverage when they are healthy instead of waiting for medical expenses to occur, a mindset necessary for commercial insurance coverage, which has a more limited enrollment period.

The state intends to evaluate whether the new policy improves health outcomes, as individuals who apply timely may begin receiving preventive care and establish a relationship with a primary care provider before a health crisis occurs. In circumstances where Medicaid eligibility depends upon a finding of disability or a certain diagnosis (e.g., of breast or cervical cancer), the state will evaluate whether the policy encourages beneficiaries to apply for Medicaid (including through an application for Supplemental Security Income [SSI] in the case that an SSI determination also provides a Medicaid eligibility determination) as soon as possible after the relevant finding or diagnosis. For example, for those who are aged, blind, or disabled, the state will evaluate whether the policy encourages beneficiaries to apply for Medicaid expeditiously when they believe they meet the criteria for eligibility, to ensure primary or secondary coverage through Medicaid to receive those services if the need arises. We note that Medicaid coverage in Maine begins on the first date of the month in which an eligible individual files a Medicaid application. This important safeguard balances the need for individuals to apply for Medicaid expeditiously with protections for individuals who may file an application mid-month.

Finally, the demonstration allows Maine to impose a transfer penalty for the purchase of certain Medicaid-compliant annuities for long-term care coverage determinations and to institute minimum pay out periods for the annuitant. Current law discourages the use of annuities to shelter assets in order to gain Medicaid eligibility and receive long-term care services, but prohibits penalizing transfers to certain Medicaid-compliant annuities. Under this demonstration, Maine will apply a transfer penalty to these Medicaid-compliant annuities to test whether and to what extent the penalties will better deter individuals from sheltering assets and preserve resources for the neediest of MaineCare beneficiaries. Maine believes that this aspect of the demonstration will safeguard state and federal resources for future sustainability of the program. CMS and Maine have developed safeguards described in the STCs that ensure that the most vulnerable individuals, including community spouses, are not negatively impacted by this element of the demonstration.

Determination that the Demonstration Project is Likely to Assist in Promoting Medicaid's Objectives

For reasons discussed below, the Secretary has determined that the MaineCare demonstration program 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, Maine and CMS will be able to evaluate the effectiveness of various policies that are designed to improve the health of Medicaid beneficiaries, encourage them to make responsible decisions about their health and accessing health care, and promote beneficiary financial independence. Promoting beneficiary health and independence advances the objectives of the Medicaid program. 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."[2]

Maine's community engagement requirement is designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that may lead to improved health and wellness. This feature of the demonstration is also intended to promote the objective of helping beneficiaries attain or retain financial independence. The community engagement provisions generally require MaineCare beneficiaries to work, look for work, or engage in activities that enhance their employability, such as job-skills training, education, and community service. Residential SUD treatment also qualifies as an exemption from the community engagement requirement while the beneficiary is in active treatment, which not only supports beneficiaries' health needs, but may also lead to healthier beneficiaries who therefore may better be able to attain and sustain employment after residential treatment is completed, which is incentivized through this demonstration. The demonstration will help the state and CMS evaluate whether the community engagement requirement helps adults in MaineCare transition from Medicaid to financial independence, thus reducing dependency on public assistance. Because the demonstration is intended to encourage beneficiaries to attain greater levels of financial independence, it contains policies designed to prepare people for the commercial health insurance market, including to prepare them for the federally subsidized insurance that is available through the Exchanges. The MaineCare demonstration seeks to provide beneficiaries the tools to utilize commercial market health insurance successfully, thereby removing potential obstacles to a successful transition from Medicaid to commercial coverage. For instance, MaineCare includes premium payment requirements (with a non-eligibility period for certain beneficiaries for non-payment, similar to provisions CMS has approved in other states[3]), which beneficiaries are likely to encounter should they transition off of Medicaid and into commercial coverage.

The waiver of retroactive eligibility, subject to specified exceptions, is also designed to promote continuity of care: (1) discouraging reducing gaps in coverage that can occur when beneficiaries

[2] 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 percent of the federal poverty level").
[3] https://www.medicaid.gov/medicaid/section-1L15-demo/demonstrat¡on-and-waiver-list/?entry=25478

churn on and off Medicaid or sign up for Medicaid only when sick; and (2) encouraging the receipt of preventive health services when beneficiaries are healthy. If eligible individuals wait until they are sick to enroll in Medicaid, they are less likely to obtain preventive services during periods when they are not enrolled, potentially resulting in worse health outcomes. CMS is requiring the state's evaluation design to include hypotheses on the effects of the waiver on enrollment and eligibility continuity (including for different subgroups of individuals, such as individuals who are healthy, individuals with complex medical needs, prospective applicants, and existing beneficiaries in different care settings), as well as the effects of the demonstration on health outcomes and the financial impact of the demonstration (for example, an assessment of medical debt and uncompensated care costs).

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

CMS has determined that the MaineCare demonstration is likely to promote the objective of furnishing medical assistance because certain other aspects of the demonstration, if successful, would promote the sustainability of Medicaid as a safety net for the neediest of Maine residents. If making the community engagement requirement a condition of eligibility achieves the state's goal of encouraging beneficiaries to secure employment, Maine will likely see some beneficiaries gaining financial security and moving off of public assistance. Beyond financial independence, if participating in community engagement activities improves beneficiaries' physical and mental health, these beneficiaries may consume fewer health care resources. Further, application of the asset transfer penalty to individuals that shelter assets in certain annuities will ensure that scarce Medicaid resources are staying focused on the neediest Maine residents. The waiver of retroactive eligibility is also expected to enable the state to better contain Medicaid costs and more efficiently focus resources on providing accessible and high-quality health care, thereby promoting the sustainability of its Medicaid program.
By incentivizing community engagement and preventive care, as described above, the demonstration is also designed to lead to higher quality care at a sustainable cost.

While the demonstration is designed to encourage continued coverage, we acknowledge that in some cases, individuals may chose not to comply with the community engagement requirement (or the requirements to pay premiums and report a change in circumstance), and may lose coverage as a result. Specifically, MaineCare contains provisions that could result in some beneficiaries losing coverage, including having their eligibility held in abeyance until they move into compliance with the community engagement requirement, or a non-eligibility period of 90 days for failure to make a required premium contribution or failure to report a change in circumstance related to a beneficiary's compliance with the community engagement requirement. However, 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 enhance fiscal sustainability and program integrity.

Further, while CMS and the state are testing the effectiveness of incentive structures that attach penalties to failure to take certain measures, the program is designed to make compliance with its requirements achievable. Maine has taken steps to include beneficiary protections to ensure that the demonstration's requirements generally apply only to those beneficiaries who can reasonably

be expected to meet them, to notify beneficiaries of their responsibilities under the demonstration, and to provide an opportunity to regain Medicaid coverage by coming back into compliance with the program. Any individual whose coverage is terminated for failure to meet the requirements, or who experiences any other adverse action, will have the right to appeal the state's decision as with other types of coverage terminations, consistent with all existing appeal and fair hearing protections. Individuals may re-apply for coverage at any time and may be determined eligible if they demonstrate compliance with the community engagement requirement and meet all other factors of eligibility, or if the individual is no longer subject to the MaineCare requirements. Furthermore, the incentives to meet the requirements, if effective, may result in individuals becoming ineligible because they have attained financial independence – a positive result for the individual.

As described in the STCs, if monitoring or evaluation data 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. Further, CMS reserves the right to withdraw waivers 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 Medicaid.

Consideration of Public Comments

To increase the transparency of demonstration projects, section 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 project 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 occurs at the federal level after the application is received by the Secretary.

Section 1115(d)(2)(A) and (C) of the Act further specify that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments.[4]

CMS received 92 comments during the federal comment period on MaineCare. Although CMS is not required to provide a written response to every comment, 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 most recent public comment period, CMS has concluded that the MaineCare advances the objectives of Medicaid.

[4] 42 CFR § 431.416(d)(2); see also Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation; Final Rules, 77 Fed. Reg. 11678, 11685 (Feb. 27, 2012) (final rule).

General Comments

The majority of the comments CMS received expressed general disagreement with the premise of the MaineCare demonstration. Many of those comments expressed concerns that these requirements would be burdensome for families or create barriers to coverage. CMS shares the commenters' concerns that everyone who needs Medicaid and meets programmatic eligibility criteria has access to it. 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 Maine. That is why CMS has carefully reviewed the demonstration as a whole to ensure it is likely to further Medicaid's objectives.

Specifically, this is designed to improve health outcomes, reduce dependency on public assistance by incentivizing beneficiaries to participate in community engagement activities as a means of moving towards financial independence, and enable the state to better contain Medicaid costs and more efficiently focus resources on providing accessible and high quality health coverage, thereby promoting the sustainability of its Medicaid program.

CMS has worked together with Maine to include guardrails that will protect beneficiaries. 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 other bases of Medicaid eligibility and review for eligibility for insurance affordability programs prior to disenrollment; provide full appeal rights prior to disenrollment; and maintain a process that provides reasonable modifications necessary for meeting or reporting compliance with the community engagement requirement to beneficiaries with disabilities, among other assurances. To further support beneficiaries, CMS will require Maine to provide written notices to beneficiaries that include information such as how to ensure that they are in compliance with the community engagement requirement and how to appeal an eligibility termination or denial. The STCs include a provision granting CMS the authority to discontinue the demonstration if the agency determines that it is not furthering Medicaid's objectives. Moreover, CMS will regularly monitor MaineCare and will work with the state to resolve any issues that arise as Maine works to implement the demonstration. The state is required to create and submit several items to assist in monitoring and evaluation of the demonstration, including an evaluation design created by an independent party, and three quarterly reports and one annual report each year which provide updates on operation of the demonstration, performance metrics, financial performance, and information on evaluation activities and interim findings.

Some commenters expressed concern that various provisions of the demonstration would cause coverage losses amongst Medicaid beneficiaries in Maine. CMS acknowledges that individuals who fail to comply with the conditions of eligibility imposed by the demonstration may lose coverage. However, we note that conditioning eligibility for Medicaid coverage on compliance with certain measures is an important element of the state's efforts to get beneficiaries engaged in the desired activities.. To create an effective incentive for beneficiaries to take measures that promote health and independence, it may be necessary for the state to attach penalties for failure to take those measures, including with conditions designed to promote health and financial independence. This may mean that beneficiaries who choose not to comply will lose Medicaid

coverage, at least temporarily. This consequence is true for any individual who does not meet any other condition of eligibility imposed by the program, such as making premium payments or completing the appropriate verifications of income at renewal. Section 1115 explicitly contemplates that demonstrations may "result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing," section 1115(d)(1), and prior demonstrations have "constrained eligibility or benefits in ways not otherwise permitted by law," 75 Fed. Reg. at 56947. For example, prior demonstrations in other states have provided for a more limited set of benefits than the statute requires, covered only a subset of a specified optional population, implemented cost-sharing at levels that exceed statutory requirements, or included enrollment limits. *Id*. However, the incentives included in this demonstration are not designed to encourage coverage loss; rather, they are intended to incorporate achievable conditions of continued coverage. Any loss of coverage as the result of noncompliance must be weighed against the benefits Maine hopes to achieve through the demonstration project, including both the improved health and independence of the beneficiaries who comply and the state's enhanced ability to stretch its Medicaid resources and maintain the fiscal sustainability of the program.

Finally, we note that not all coverage losses will result in uninsurance. Some beneficiaries in the demonstration may find employment that provides access to health insurance.

Comments Addressing the Community Engagement Requirement

Commenters raised concerns about the application of community engagement requirement to certain populations, such as Medicaid beneficiaries with disabilities and the family members who are caring for individuals with disabilities. CMS has worked closely with Maine to ensure there are substantial beneficiary protections in place. The state included exemptions for: beneficiaries who are caretakers for an incapacitated individual of any age; parents or caretakers of a dependent child under 6 years of age; and beneficiaries who are physically or mentally unable to work at least 20 hours a week. Maine has also provided exemptions to the community engagement requirement and good cause exemptions from the 90 day non-eligibility period for failure to pay premiums and failure to report a change in circumstances for beneficiaries with disabilities as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the of the Patient Protection and Affordable Care Act (PPACA), and who are unable to participate because of their disability and for individuals with immediate family members in the home with a disability who are unable to participate for reasons related to the disability of that family member. MaineCare also provides good cause exemptions from the community engagement requirement for individuals experiencing family emergencies and life-changing events, including but not limited to hospitalization of a family member, divorce, or domestic violence.

The STCs require Maine to educate and reach out to beneficiaries and contain assurances that Maine will seek data from other sources, including SNAP, TANF and other existing data systems. This is expected to reduce the reporting burden on beneficiaries and allow the state to efficiently verify community engagement hours and process beneficiary redeterminations. The STCs require the state to provide CMS with a community engagement implementation plan and assurances regarding timely and adequate notices to beneficiaries.

Maine must provide reasonable accommodations related to meeting the community engagement requirement for beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the PPACA, when necessary, to enable them to have an equal opportunity to participate in and benefit from the program. This is a condition of approval, as provided in the STC. CMS also intends to monitor state-reported data on how the new requirement are impacting enrollment.

Other comments note concerns about areas of high unemployment or rural areas lacking in public transportation acting as barriers to meeting the community engagement requirement. The state assures that it 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 viable transportation to determine whether there should be further exemptions from the community engagement requirement and/or additional mitigation strategies, so that the community engagement requirement will not be impossible or unreasonably burdensome for beneficiaries to meet.

Comments Addressing Premiums

Some commenters expressed concerns that not all impacted beneficiaries will be able to afford premiums and that the application of premiums could decrease access to care. CMS notes that Maine has taken steps to protect beneficiaries by exempting certain vulnerable populations from the requirement to pay premiums, such as pregnant women, as well as by allowing beneficiaries to demonstrate good cause in certain circumstances for beneficiaries who cannot make premium payments. In addition to the potential benefits to beneficiaries of aligning program requirements with commercial health insurance approaches, establishing premiums may encourage members to place increased value on their health care and utilize it more effectively. Interim evaluation findings regarding premiums in one state found that beneficiaries who paid premiums were more likely to obtain primary care and preventive care, have better drug adherence, and rely less on the emergency room for treatment compared to those who do not.[5]

Comments Addressing Transfer of Asset Penalties

Two commenters raised concerns about the state's proposal to implement a transfer penalty for the purchase of certain Medicaid-compliant annuities for long-term care coverage determinations, and to institute minimum pay out periods for the annuitant. One commenter was specifically concerned about the impact of the transfer penalty on couples with one spouse residing in an institutional setting and one spouse in the community. Another commenter was concerned that the minimum pay-out period proposed by Maine would restrict the income of community spouses with short life expectancies, and that younger couples may be especially affected by this proposal.

CMS acknowledges those concerns and, as a result, the state developed safeguards that ensure that the most vulnerable individuals, including community spouses, are not negatively impacted by this element of the demonstration. Specifically, the STCs provide that penalties will not be

[5] The Lewin Group, Indiana Healthy Indiana Plan 2.0 Interim Evaluation Report (2016), available at: https://www.in.gov/fssa/files/Lewin_IN%20HIP%202%200%20Interim%20Evaluation%20Report_FINAL.pdf.

applied against the purchase of compliant annuities in circumstances where institutionalized individuals or their spouses will experience undue hardship as a result of the penalty. Safeguards have also been established to ensure that the transfer penalty will not be applied in certain circumstances where the most vulnerable individuals with income below the minimum monthly needs allowance would be negatively affected. The state will evaluate whether the penalty will be a more effective deterrent to asset-sheltering.

Other Information

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

Your project officer for this demonstration is Ms. Annie Hollis. She is available to answer any questions concerning your section 1115(a) demonstration. Ms. Hollis' contact information is follows:

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

Official communications regarding program matters should be simultaneously sent to Ms. Hollis and Mr. Richard McGreal, Associate Regional Administrator for the Division of Medicaid and Children's Health Operations in our Boston Regional Office. Mr. McGreal's contact information is as follows:

Mr. Richard McGreal
Associate Regional Administrator
Centers for Medicare & Medicaid Services
JFK Federal Building
15 New Sudbury Street, Room 2325
Boston, Massachusetts 02203
E-mail: Richard.Mcgreal@cms.hhs.gov

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

Sincerely,

[redacted]

Seema Verma

Enclosures

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: **11-W-00322/1**

TITLE: **MaineCare Section 1115 Demonstration**

AWARDEE: **Maine Department of Health and Human Services**

All requirements of the Medicaid program expressed in law, regulation and policy statement that are not expressly waived shall apply to the demonstration project beginning December 21, 2018, through December 31, 2023. In addition, these waivers may only be implemented consistent with the approved special terms and conditions (STCs).

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the MaineCare section 1115 demonstration, including the waivers described below, is likely to assist in promoting the objectives of title XIX of the Social Security Act (the Act).

Under the authority of section 1115(a)(1) of the Act, the following waivers of state plan requirements contained in section 1902 of the Act are granted, subject to the STCs.

1. Retroactive Eligibility **Section 1902(a)(10) and (a)(34)**

To the extent necessary to enable the state not to provide medical coverage for any month prior to the month in which an affected beneficiary's Medicaid application is filed as specified in these STCs. The waiver of retroactive eligibility does not apply to applicants who would have been eligible at any point within the three month period immediately preceding the month in which an application was received, as pregnant women (and women during the 60-day period beginning on the last day of a pregnancy), infants under age 1, children under age 19 (described in section 1902(l)(4) of the Act), and individuals who are applying for a long-term care determination. Coverage for affected beneficiaries will begin on the first day of the month in which the Medicaid application is filed.

2. Premiums **Section 1902(a)(14) insofar as it incorporates Sections 1916 and 1916A**

To the extent necessary to enable Maine to collect monthly premium payments, for beneficiaries with incomes above 50 percent of the federal poverty level (FPL) as described in these STCs.

3. Comparability **Sections 1902(a)(10)(B) and 1902(a)(17)**

To the extent necessary to enable Maine to vary premium requirements for different MaineCare program beneficiaries based on income.

4. Provision of Medical Assistance **Section 1902(a)(8) and 1902(a)(10)**

To the extent necessary to enable Maine to terminate eligibility for, and not make medical assistance available to, MaineCare beneficiaries who fail to comply with the community engagement requirement, as described in these STCs, unless the beneficiary is exempted as described in these STCs.

5. Eligibility **Section 1902(a)(10) and (a)(52)**

To the extent necessary to enable Maine to require community engagement as described in these STCs.

To the extent necessary to enable Maine to terminate eligibility and prohibit re-enrollment for MaineCare beneficiaries who have not met the community engagement requirement for three months, in accordance with these STCs.

To the extent necessary to enable Maine to prohibit re-enrollment, and deny eligibility for up to ninety days for MaineCare program beneficiaries who are disenrolled for failure to make their required premium contributions or who fail to report a change in circumstance that is related to the beneficiary's compliance with the community engagement requirement and would affect the beneficiary's eligibility for Medicaid as described in these STCs, subject to the exceptions described in these STCs.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00322/1

TITLE: MaineCare Section 1115 Demonstration

AWARDEE: Maine Department of Health and Human Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "MaineCare" demonstration under section 1115(a) of the Social Security Act (hereinafter "demonstration") to enable Maine 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 (the 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 MaineCare demonstration will be statewide and is approved for a 5-year period, from December 21, 2018 through December 31, 2023.

The STCs have been arranged into the following subject areas:

At the state's option, additional supplemental protocols describing various operational details of the MaineCare program may be submitted to CMS for approval and incorporation by reference into these STCs.

II. PROGRAM DESCRIPTION AND OBJECTIVES

On December 21, 2018, CMS approved the MaineCare demonstration, which will be implemented no sooner than July 1, 2019. Maine will enroll certain non-elderly adult beneficiaries who do not qualify for Medicaid on the basis of a disability into MaineCare. Groups in the MaineCare demonstration include two groups of low-income parents and caretaker relatives, including those described in section 1931(b) and (d) of the Act and those described in sections 1925 and 1931(c)(2) of the Act who are transitioning off of Medicaid due to increases in their income; former foster care children; individuals eligible for family planning services; and beneficiaries enrolled in the state's special benefits demonstration (HIV demonstration).

Maine will implement a community engagement initiative as a condition of eligibility for adult beneficiaries ages 19 to 64 who will be enrolled in the MaineCare program, with exceptions for certain groups, including but not limited to: pregnant women and individuals who are physically or mentally unable to work 20 or more hours per week, as determined by a medical provider.

Maine is applying the community engagement requirement (described in STCs 34-40) to adult beneficiaries ages 19 to 64 in the MaineCare program, with exemptions for various groups, including: beneficiaries who are pregnant or 60 days or less post-partum; individuals who do not qualify for Medicaid on the basis of a disability and are residing in certain residential facilities; beneficiaries receiving temporary or permanent disability benefits; beneficiaries who are determined physically or mentally unable to work; beneficiaries residing in a facility where the beneficiary is participating in a residential substance use disorder (SUD) treatment and rehabilitation program; designated caretakers of a child under age 6; caregivers who are responsible for the care of an incapacitated individual; and beneficiaries with a disability as defined by federal disabilities rights laws. To remain eligible for coverage, non-exempt beneficiaries must complete and report 80 hours per month of community engagement activities, such as employment, education, job skills training, job search activities, and community service. Maine will provide a three month grace period in a thirty-six month compliance measurement period. If a beneficiary does not fully comply with the community engagement requirements, including failure to report compliance for any month after the three month grace period, the state will disenroll the beneficiary from coverage. Beneficiaries who have been disenrolled can re-apply for coverage before the end of the thirty-six month compliance measurement period if they can demonstrate compliance with the community engagement requirements, or if it is determined that a beneficiary qualifies for another category of Medicaid eligibility that is not subject to the community engagement requirements, or meets the requirements for good cause.

CMS is also authorizing additional waiver authorities for the MaineCare program, including:

- Premiums (described in STCs 22-33) based on income for MaineCare beneficiaries in the demonstration (with exceptions for American Indians and Alaska Natives who are members of federally recognized tribes) with specified consequences for beneficiaries who do not pay premiums after a 60-day payment period (including a 90-day non-eligibility period) and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;

- A 90-day non-eligibility period (described in STC 20) for beneficiaries who fail to report a change in circumstance for changes related to the community engagement requirement affecting eligibility for Medicaid, and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;
  A waiver of retroactive eligibility (described in STC 16) for all Maine Medicaid beneficiaries, with exceptions for pregnant women; women who are 60 days or less postpartum; infants under age 1; children under age 19; and individuals seeking long-term care determinations; and
- A transfer penalty for the purchase of certain Medicaid-compliant annuities purchased after the effective date of this demonstration for long-term care coverage determinations and a new minimum pay out period for the annuitant.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. 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 in eligibility and documentation requirements, to ensure they understand program rules and notices, in establishing eligibility for an exemption from community engagement requirements on the basis of disability, and to enable them to meet and document community engagement requirements, as well as 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 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 written policy, come into compliance with 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. 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 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

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 to comply with such change. 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 federal 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 instances, the Medicaid state plan governs.

6. **Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, 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 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit reports required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

   a. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;

   b. 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;

c. An explanation of the public process used by the state consistent with the requirements of STC 13; and

d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and 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 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its 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 eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. 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 prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 C.F.R. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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. Expiring Demonstration Authority. For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a demonstration authority expiration plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

a. Expiration Requirements. The state must include, at a minimum, in its demonstration authority expiration 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 authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.

b. Expiration Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and

431.213. In addition, the state must assure all applicable appeal and hearing rights afforded are to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 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 prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

c. Federal Public Notice. CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the 30-day period during its review of the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.

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

11. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public 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.

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

13. 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 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.

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.

14. **Federal Financial Participation (FFP).** No federal matching for state expenditures under 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.

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 programs 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. **Waiver of Retroactive Eligibility Population.** Except as noted below, the waiver of retroactive eligibility applies to individuals who are eligible for Medicaid under the state plan (including all modified adjusted gross income (MAGI) and non-MAGI related groups).

    a. The state assures that it will provide outreach and education about how to apply for and receive Medicaid coverage to the public and to Medicaid providers, particularly those who serve vulnerable populations that may be impacted by the retroactive eligibility waiver.

    b. The waiver of retroactive eligibility for an initial application does not apply to applicants who would have been eligible at any point within the three month period immediately preceding the month in which an application was received, as pregnant women (and women during the 60-day period beginning on the last day of a pregnancy), infants under age 1 and children under age 19 (described in section 1902(l)(4) of the Act), and individuals applying for a long-term care determination.

c. The state assures that beneficiaries who are known to the state (such as beneficiaries who are eligible in a different Medicaid eligibility group) and who become dually eligible for Medicare and Medicaid in accordance with Section 1902(a)(10)(E) are enrolled in Medicaid as soon as they become eligible for Medicaid.

17. Limitations on Annuities. Except as noted below, the state may apply transfer-of-asset penalties to beneficiaries eligible for Medicaid under the state plan who purchase, or whose spouses purchase, annuities that are otherwise compliant under Section 1917 of the Act with the annuity-related rules described in Section 1917 of the Act and that are purchased after the effective date of this demonstration.

a. Penalties will not be applied against the purchase of compliant annuities in circumstances in which the institutionalized individual, or the institutionalized individual's community spouse, may experience undue hardship as a result of the application of the penalty. The undue hardship standard is described in the state's approved state plan.

b. Penalties will not be applied against married institutionalized individuals for the purchase of compliant annuities when the resources used to purchase an annuity are deemed to be part of the community spouse resource allowance (CSRA).

c. Penalties will not be applied against married institutionalized individuals for the purchase of compliant annuities when the income of the community spouse is less than the minimum monthly maintenance needs allowance (MMMNA), and/or the income of family members is less than the family allowance, as described in section 1924(d)(1) of the Act, prior to the addition of the income produced by the annuity, and the annuity raises their income to an amount equal to or below the statutory minimums. If the annuity raises the income of the community spouse or family members of the institutionalized spouse above the statutory minimums, the entire amount used to purchase the annuity (subject to subsection (b)) may be penalized.

d. The amount that will be deemed to have been transferred for the purchase of compliant annuities will be limited to, for married individuals, amounts exceeding the CSRA that were used to purchase the annuities, and, for single individuals, amounts exceeding the resource standard for a single individual that were used to purchase the annuities.

e. The state assures that it will provide outreach and education about this waiver provision to the public and to Medicaid providers, particularly those who serve populations that may be impacted by the transfer-of-asset penalties, before this provision becomes effective.

18. MaineCare Populations. Adults aged 19-64 who are eligible for Medicaid under an eligibility group listed in Table 1 are subject to the provisions of the MaineCare program within this demonstration, as specified in these STCs.

Table 1. Medicaid Eligibility Groups Affected by MaineCare	
Eligibility Group	**Citations**

Parents and other caretaker relatives	1902(a)(10)(A)(i)(I) 1931 (b) and (d) 42 CFR 435.110
Transitional medical assistance	408(a)(11)(A) 1931(c)(2) 1925 1902(a)(52)
Former foster care children	1902(a)(10)(A)(i)(IX) 1902(a)(10)(A)(ii)(XX) 42 CFR 435.150 42 CFR 435.218
Individuals eligible for family planning services	1902(a)(10)(A)(ii)(XXI) 1902(ii) 1902(a)(10)(G)(XVI) 42 CFR 435.214
Medically needy parents and other caretaker relatives	1902(a)(10)(C) 42 CFR 435.310
Beneficiaries enrolled in the state's special benefits demonstration (HIV demonstration)	Maine HIV/AIDS Section 1115 Demonstration (Project Number 11-W-00128/1)

19. Failure to Report a Change in Circumstance. Beneficiaries who fail to report changes in circumstance in the required reporting period for changes related to the community engagement requirement that affect eligibility for Medicaid will be disenrolled for a period of 90 days. Disenrollment from Medicaid may only occur after the state conducts an administrative renewal for the beneficiary and determines the beneficiary ineligible for all other bases of Medicaid eligibility and reviews him/her for eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(f). Disenrollment will be limited to circumstances in which the failure to report a change affected eligibility; specifically if it led to additional month(s) of Medicaid eligibility during which the member was not eligible. After disenrollment, the individual will be prohibited from re-enrollment in the demonstration for up to ninety days.

a. Pregnant women and beneficiaries who are found physically or mentally unable to work 20 or more hours per week are exempt from this ninety day non-eligibility period. Any beneficiary who becomes pregnant, is determined to be physically or mentally unable to work 20 or more hours per week or otherwise becomes eligible for Medicaid under an eligibility group not subject to the provisions of this non-eligibility period can reactivate their eligibility with an effective date consistent with the beneficiary's eligibility category.

b. Disenrolled individuals will be eligible for early re-enrollment at any time prior to the end of the non-eligibility period consistent with STC 20.b.

c. The state must provide reasonable modifications to the obligation to report a change in circumstance for beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.

20. Failure to Report a Change in Circumstance: State Assurances. The state shall:

a. Assure that beneficiaries identified as failing to have reported a change in circumstance for changes related to the community engagement requirement affecting eligibility for Medicaid as outlined in STC 19 will have the opportunity to provide additional clarifying information indicating the beneficiary did report the change in circumstance or to demonstrate good cause for not reporting the change in circumstance, pursuant to 42 CFR 435.916(d)(1)(i), and further assures that it will observe all requirements for due process, including adequate notice and appeal rights, in connection with any non-eligibility period.

b. Allow those beneficiaries who demonstrate good cause for not reporting a change in circumstance to re-enroll under certain conditions without waiting ninety (90) days. Good cause circumstances must include, at a minimum, the following verified circumstances:

i. The beneficiary is out of town, hospitalized, otherwise incapacitated, or has a disability protected by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act, and as a result is unable to report the change during the entire change in circumstance reporting period as defined in the state plan, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to report the required changes in circumstance;

ii. A member of the beneficiary's immediate family (parent, step-parent, guardian, child, step-child, sibling, or step-sibling) who was living in the home with the beneficiary was institutionalized or died during the change in circumstance reporting period or the immediate family member 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 caretaking or other disability-related responsibilities resulted in an inability to report the change in circumstance;

iii. The beneficiary was the victim of a declared natural disaster, such as a flood, storm, earthquake, or serious fire that occurred during the change in circumstance reporting period as defined in the state plan;

iv. The beneficiary was evicted from home or experienced homelessness during the change in circumstance reporting period as defined in the state plan;

v. The beneficiary was a victim of domestic violence during the change in circumstance reporting period as defined in the state plan.

c. Assure that the non-eligibility period would only apply to beneficiaries where the unreported change in circumstance would affect eligibility as outlined in STC 19.

d. Provide written notice to beneficiaries of any non-eligibility period exemptions and of the opportunity to demonstrate good cause, as described in STC 19.a and subparagraph b, that would allow them to re-enroll during a non-eligibility period. Such notice must include an explanation of the availability of opportunities to demonstrate good cause, as indicated in this STC.

e. Provide notice to beneficiaries, prior to adverse action and in accordance with 42 CFR 431.211, about the non-eligibility period, and explaining what this status means, including but not limited to: their right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.

f. Provide beneficiary education and outreach that supports compliance with change in circumstance reporting requirements, such as through communications or coordination with state-sanctioned assistors, providers, or other stakeholders. Education and outreach may include mailings, relevant materials posted on a State of Maine website, or other methods the state uses to inform beneficiaries of program requirements.

g. Assure that disenrollment from Medicaid will only occur after an individual 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).

h. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to reporting a change in circumstance.

i. Maintain a process that identifies, validates, and provides reasonable modifications related to the obligation to report a change in circumstance to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.

V. BENEFITS

21. MaineCare Program Benefits.

a. All mandatory and optional Medicaid state plan eligible adults enrolled in the MaineCare demonstration will receive all services covered under Maine's state plan according to the limitations specified in the state plan.

b. Beneficiaries enrolled in the Maine HIV/AIDS Section 1115 Demonstration will receive targeted benefits described in the Maine HIV/AIDS Section 1115 Demonstration STCs.

VI. PREMIUMS AND COST SHARING

22. Premiums and Cost Sharing. Cost sharing for MaineCare beneficiaries 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), except as otherwise described in these STCs.

23. Premiums. All beneficiaries in the MaineCare program, except for beneficiaries also enrolled in the state's special benefits HIV demonstration (Maine HIV/AIDS Section 1115 demonstration) and beneficiaries eligible for transitional medical assistance, are required to make premium payments as described in STC 26.

a. MaineCare beneficiaries who are also enrolled in the state's special benefits HIV demonstration must pay premiums established in the STCs of the Maine HIV/AIDS Section 1115 demonstration.

b. Beneficiaries who are eligible for transitional medical assistance are exempt from premium payment requirements established by this demonstration. Beneficiaries who are eligible for transitional medical assistance are subject to premiums as established in the state's approved state plan, as authorized.

24. Notice. The state must notify MaineCare beneficiaries of premium payment requirements upon eligibility determination. The state must determine the amount of a beneficiary's monthly premium using methods consistent with statutory requirements and will notify the beneficiary of this amount. Monthly invoices must include information about how to report any change in income; the time period over which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; information on any outstanding premium payments and how a beneficiary can make payments for outstanding premiums; and the consequences of non-payment and failure to report changes in circumstance that could affect eligibility.

25. Payment Period. MaineCare beneficiaries will have at least sixty (60) calendar days from the date of the payment invoice to be considered in compliance with payment of premiums.

26. Premium Amounts. MaineCare beneficiaries who are subject to the requirement to pay premiums established in STC 23 are required to pay a monthly premium that shall not exceed two (2) percent of household income, except for individuals with income at or below 50 percent of the FPL, who are not subject to premiums. Premium amounts are listed in Table 2.

Table 2. MaineCare Premium Amounts.	
Income Range	**Monthly Premium by Household**
0-50% FPL	$0

Above 50-100% FPL	$10
Above 100-150% FPL	$20
Above 150-200% FPL	$30
Above 200% FPL	$40

27. Household Limits. Premium payments apply toward all MaineCare beneficiaries, as described in STC 23, in the household, such that premiums will not be collected on a person basis, but rather on a per household basis.

28. Recalculation of Premium Payments. At a minimum, at annual redetermination or any time the state is made aware that a beneficiary's household income has changed during the current eligibility period, the state must determine whether an adjustment to the member's monthly premium payment is necessary. Recalculated premium payments are effective the first day of the month following the recalculation. When a beneficiary has a change in circumstance, including household income, any overpayments made by a beneficiary shall reduce the premium contribution obligation for the next month(s). The state shall not be responsible for reimbursing a member for differences in premium payments that were received by the state and did not reflect changes in circumstances unreported to the state by the beneficiary.

29. Third Party Contributions. Third parties, except contracted MCOs, are permitted to pay premiums on behalf of MaineCare beneficiaries. There are no limits on the amounts third parties can contribute. Such third party contributions offset required beneficiary premium obligations only, and may not be used for any other purpose. Payments that exceed such obligations will be returned to the contributing third party. The payment must be used to offset the beneficiary's required premium payment obligation only, not the state's share. Healthcare providers or provider-related entities making premium payments on beneficiaries' behalf must have criteria for providing assistance that do not distinguish between beneficiaries based on whether or not they receive or will receive services from the contributing provider(s) or class of providers. Providers may not include the cost of such payments in the cost of care for purposes of Medicare and Medicaid cost reporting and such payments cannot be included as part of a Medicaid shortfall or uncompensated care.

30. Non-Payment of Premiums. At a minimum, at the beneficiary's annual renewal date, the state will conduct a review of the beneficiary's premium payments to determine whether the beneficiary or a third party has paid all premiums for the prior enrollment year. If the beneficiary has outstanding premium payments to be made that are outside the sixty (60) day payment period, the state will disenroll the beneficiary for a period of ninety (90) days or until all outstanding premium payments are made, whichever period is shorter. The state will provide a written notice to the beneficiary, prior to adverse action, which explains how the beneficiary can make an immediate payment (within 45 days of receipt of such notice) to avoid loss of coverage, the action being taken by the state and how the beneficiary can regain MaineCare coverage if the payment is not made in the timeframe established in this STC.

31. Eligibility Review. For each MaineCare beneficiary subject to disenrollment for non-payment under STC 23, the state must review that beneficiary's eligibility for all other

eligibility categories under the state's Title XIX program including notifying the beneficiary of the option to demonstrate good cause, consistent with STC 33.i.

32. Debt Collection. Maine and/or its vendor may attempt to collect unpaid premiums and the related debt from beneficiaries, but may not report the debt to credit reporting agencies, place a lien on an individual's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the individual's earnings for beneficiaries at any income level. The state and/or its vendor may not "sell" the debt for collection by a third party.

33. Premiums and Cost-Sharing: State Assurances. The state shall:

a. Monitor to ensure that beneficiaries do not incur household cost sharing and premiums that, combined, exceed 5 percent of the aggregate household income on a monthly or quarterly basis, in accordance with 42 CFR 447.56(f). Once a household reaches the cap, the state assures that no further copayments will be charged to beneficiaries.

b. Charge copayment amounts, if applicable, that do not exceed Medicaid cost sharing permitted by federal law and regulation and the terms of this demonstration. Copayment amounts are specified in the approved state plan.

c. Ensure that the state, or its designee, does not pass along the cost of any surcharge associated with processing payments to the beneficiary. Any costs incurred by the state in connection with payment processing are considered an administrative expense by the state.

d. Ensure that all payments from the beneficiary, or on behalf of the beneficiary, are accurately credited toward unpaid premiums in a timely manner, and provide the beneficiary an opportunity to review and seek correction of the payment history.

e. Ensure that the state has a process to refund any premiums paid for a month in which the beneficiary is ineligible for Medicaid services for that month.

f. Ensure that a beneficiary will not be charged a higher premium the following month due to nonpayment or underpayment of a premium in a previous month, except that amounts outstanding and due from the previous month/s may be reflected separately on subsequent invoices.

g. Ensure the state suspends monthly premium invoices to beneficiaries whose eligibility has been terminated for failure to meet the community engagement requirement, and provide written notice to prevent overpayment of premiums.

h. Conduct outreach and education to beneficiaries to ensure that they understand the program policies regarding premiums and associated consequences for nonpayment. Beneficiaries must be informed of how premium payments should be made; the potential impact of a change in income on premium payments owed; the consequences of failure to report a change in income or circumstances that affect eligibility; the time period over

which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; and how to reenroll if disenrolled for non-payment of premiums.

i. Provide opportunities to demonstrate good cause for failure to pay premiums described in STC 23 that would allow beneficiaries to avoid the consequences for non-payment described in STC 30, and (if applicable) re-enroll under certain conditions without requiring payment of overdue premiums for the sixty (60) day payment period in which the below circumstances occurred or waiting the full ninety (90) days. Good cause circumstances must include, at a minimum, the following:

   i. The beneficiary is hospitalized, otherwise incapacitated, or has a disability as defined by the Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act (PPACA), and as a result is unable to pay premiums during the entire sixty (60) day payment period, or is a person with a disability who was not provided with reasonable modifications needed to pay the premium, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to pay premiums during the entire sixty (60) day payment period;

   ii. A member of the beneficiary's immediate family (parent, step-parent, guardian, child, step-child, sibling, or step-sibling) who was living in the home with the beneficiary was institutionalized or died during the sixty (60) day payment period, or the immediate family member has a disability recognized under the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to pay the premiums;

   iii. The beneficiary was evicted from their home or experienced homelessness during the sixty (60) day payment period;

   iv. The beneficiary was the victim of a declared natural disaster, such as a flood, storm, earthquake, or serious fire that occurred during the sixty (60) day payment period; or

   v. The beneficiary was a victim of domestic violence during the sixty (60) day payment period.

j. Provide all applicants and beneficiaries with timely and adequate written notices of any decision affecting their eligibility, including an approval, denial, or termination of eligibility or a denial or change in benefits and services pursuant to 42 CFR 435.917. The state will also make program information available and accessible in accordance with 42 CFR 435.901 and 435.905. The state will provide beneficiaries with at least 10 days advance notice for any adverse action prior to the date of action pursuant to 42 CFR 431.211.

k. Provide notice to beneficiaries, prior to adverse action, about the non-eligibility period, and explaining what this period means, including but not limited to: their right to appeal,

their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange and access to premium tax credits through the Exchange), good cause, what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid eligibility group, as well as any implications with respect to whether they have minimum essential coverage.

l. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to premium payment.

m. Maintain a process that identifies, validates, and provides reasonable modifications related to the obligation to pay premiums to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the PPACA.

VII. COMMUNITY ENGAGEMENT INITIATIVE

34. Overview. This demonstration will implement a community engagement requirement as a condition of eligibility for non-exempt adult MaineCare beneficiaries ages 19-64, described in STC 18. To maintain MaineCare coverage, non-exempt members will be required to participate in and report the manner in which the community engagement requirement is being met.

35. Exempt Populations. Beneficiaries who report (either at application or through the state's standard change in circumstances process) that they meet the criteria for one or more of the exemptions listed below will not be required to complete community engagement related activities to maintain eligibility. A Medicaid beneficiary is exempt from the community engagement requirement if the beneficiary is:

- An individual who does not qualify for Medicaid on the basis of a disability and is residing in a residential facility (defined as a nursing facility, adult family care home, intermediate care facility for the intellectually disabled, private non-medical institution, psychiatric residential treatment facility, or home and community-based services waiver home);
- Residing in a facility where the beneficiary is participating in a residential substance use treatment and rehabilitation program;
- Caring for a dependent child under age six;
- Providing caregiver services for an incapacitated individual;
- Pregnant;
- Physically or mentally unable to work 20 or more hours per week, as determined by a medical provider; or
- Receiving temporary or permanent disability benefits issued by governmental or private resources.

36. Qualifying Activities. Non-exempt beneficiaries may satisfy their community engagement requirements through a variety of activities, including but not limited to:

- Working in paid employment at least a total of 80 hours per month;
- Self-employment for at least 80 hours per month, receiving weekly earnings at least equal to the state or federal minimum wage, whichever is higher, multiplied by 20 hours;
- Participating in and complying with the requirements of a Department-approved work program for at least 80 hours per month;
- Workfare programs, as defined by the state, or volunteer community service for at least 24 hours/month;
- Individual or group job search and job readiness assistance for 20 hours per week;
- Enrollment as a student at least half time as determined by the academic institution;
- Participating in a combination of qualifying activities, for a total of 80 hours per month, except that if an individual is satisfying the community engagement requirements with volunteer or community service alone, the hour requirement is limited to 24 hours/month;
- Receiving unemployment benefits;
- Complying with, or exempt from, work requirements for SNAP or TANF;
- Participating in tribal work or community engagement programs; or
- Other community engagement activities, subject to state approval.

37. Hour Requirements and Reporting. The community engagement initiative will require MaineCare beneficiaries to participate in 80 hours per calendar month of one, or any combination, of the qualifying activities listed in STC 36.

a. The state shall use information within its existing data systems to verify compliance with community engagement activities for individuals who are complying with or exempt from community engagement requirements for SNAP or TANF.

b. Individuals who are satisfying the community engagement requirement in whole or in part by engaging in volunteer community service must provide documentation to the state on a monthly basis certifying their participation in volunteer community service activities.

c. Beneficiaries must report their compliance with the community engagement requirements at initial application or, for existing beneficiaries, no later than 90 days after the receipt of notice from the state that community engagement requirements apply to the beneficiary's eligibility. Beneficiaries must report any changes to their community engagement activities through the state's existing change in circumstances process.

38. Reasonable Modifications. Maine must provide reasonable accommodations for beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act and Section 1557 of the PPACA, 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: assistance with demonstrating eligibility for good cause exemptions; appealing diserollments; documenting community engagement activities and other documentation

requirements; understanding notices and program rules related to community engagement requirements; navigating the state's accessible web site as required under 42 CFR 435.1200(f); and other types of reasonable modifications. The reasonable modifications must include exemptions from participation where an individual is unable to participate for disability-related reasons. In addition, the state should evaluate individuals' ability to participate in community engagement requirements and the types of reasonable modifications and supports needed for beneficiaries to comply with these requirements. This may be achieved by working with other departments within the state, or outside consumer advocacy groups, to educate individuals regarding their rights for reasonable modifications.

39. Non-Compliance. Beneficiaries who are subject to the community engagement requirement and do not comply will lose eligibility for MaineCare consistent with the terms of these STCs. Beneficiaries who submit an appeal request or report a good cause exemption prior to disenrollment will maintain services as provided under 42 CFR 431.230. Beneficiaries who experience circumstances leading to a good cause exemption that prevented them from requesting the exemption prior to disenrollment will be permitted to re-enroll pursuant to subparagraph c by providing verification of the exception.

a. **Good Cause Exemption**. The state will not count any month of non-compliance with the community engagement requirement toward the three months of non-compliance that are permitted before disenrollment under this STC 40 for beneficiaries who demonstrate good cause for failing to meet the community engagement hours otherwise required for that month. The circumstances constituting good cause must have occurred during the month for which the beneficiary is seeking good cause. Good cause includes, but is not limited to, at a minimum, the verified circumstances listed in STC 20.b.

b. **Disenrollment Effective Date**. Beneficiaries are allowed three months in a 36-month compliance measurement period during which the beneficiary does not comply with the community engagement requirement before the beneficiary is subject to disenrollment. Disenrollments for non-compliance with the community engagement requirement are effective the first day of the month following the first month after proper notice is provided during the third month of non-compliance, unless an appeal is filed timely or a good cause exemption is requested as specified in (a).

c. **Re-enrollment Following Non-Compliance**. Eligibility will be terminated for beneficiaries who are non-compliant with the community engagement requirement for any three months (consecutive or non-consecutive) during a 36-month compliance measurement period.

i. To participate in the program again after a beneficiary has been disenrolled during this period pursuant to this STC, the beneficiary must file a new application to receive an eligibility determination. At any time, such individuals can reapply for coverage and will be eligible to enroll with an effective date consistent with STC 16 or with the approved state plan, as applicable, if they demonstrate compliance with one month's required hours of community engagement participation.

A beneficiary who is disenrolled pursuant to this STC can also reapply at any time and will be eligible to enroll with an effective date consistent with STC 16 or with the approved state plan: (1) if he or she is determined eligible for another eligibility group that is not subject to the community engagement requirement; (2) if he or she would have qualified for a good cause exemption in accordance with STC 20.b at the time of disenrollment and the state determines the beneficiary's failure to comply or request a good cause exemption was the result of a catastrophic event or circumstance beyond the beneficiary's control; (3) if the beneficiary demonstrates current compliance with one month's required hours of community engagement participation; or (4) if the beneficiary experiences a life event that qualifies him or her for an exemption from the community engagement requirement pursuant to STC 35. Beneficiaries who experienced catastrophic events or circumstances beyond their control, or who experienced life events that would qualify them for an exemption from the community engagement requirement, will receive retroactive coverage to the date coverage ended without need for a new application.

ii. Beneficiaries who do not reactivate eligibility following their disenrollment prior to the end of the 36-month compliance measurement period can apply for eligibility to begin the start of the next compliance measurement period. Their previous noncompliance with the community engagement requirement will not be factored into the state's determination of their eligibility for the new 36-month compliance measurement period.

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

a. Maintain system capabilities to operationalize the denial of eligibility and the re-enrollment of beneficiaries once community engagement requirements are met.

b. Ensure that there are processes and procedures in place to seek data from other sources, including SNAP and TANF, and systems to permit beneficiaries to efficiently report community engagement hours or obtain an exemption, in accordance with 42 CFR 435.907(a) and 435.945, and to permit Maine to monitor compliance.

c. Ensure that there are timely and adequate beneficiary notices provided in writing, including but not limited to:

i. When the community engagement requirement will commence for that specific beneficiary;

ii. Whether a beneficiary is exempt, and under what conditions the exemption would end;

iii. A list of the specific activities that may be used to satisfy the community engagement requirement;

iv. The specific number of community engagement hours per month that a beneficiary is required to complete to meet the requirement, and when and how the beneficiary must report participation or request an exemption or seek to demonstrate good cause;

v. Information about resources that help connect beneficiaries to opportunities for activities that would meet the community engagement requirement, and information about the community supports that are available to assist beneficiaries in meeting the community engagement requirement;

vi. Information about how community engagement hours will be counted and recorded;

vii. What gives rise to disenrollment under this demonstration and how to avoid disenrollment if the beneficiary meets an exemption or good cause for failure to meet the requirement, and what kinds of circumstances might give rise to an exemption or good cause;

viii. If a beneficiary is not in compliance for a particular month, that the beneficiary is out of compliance, and how the beneficiary can cure the non-compliance in the immediately following month;

ix. If a beneficiary has eligibility denied or terminated, how to appeal a termination or denial of eligibility, including the number of community engagement hours that must be performed in the specified timeframe by the specific terminated beneficiary to re-enter; and

x. If a beneficiary has sought to demonstrate good cause, whether good cause has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial or termination.

d. Provide full appeal rights, consistent with all federal statute and regulation, prior to disenrollment and observe all requirements for due process for beneficiaries who will be suspended for failing to comply with the applicable community engagement requirements, including allowing beneficiaries the opportunity to raise additional issues in a hearing (in addition to whether the beneficiary should be subject to termination) or provide additional documentation through the appeals process.

e. Assure that termination or denial of eligibility will only occur after an individual 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).

f. Establish beneficiary protections, including assuring that MaineCare beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require community engagement and employment.

g. With the assistance of other state agencies including the Maine Department of Labor and other public and private partners, DHS will make good faith efforts to connect MaineCare beneficiaries 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.

h. 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 viable transportation to determine whether there should be further exemptions from the community engagement requirements and and/or additional mitigation strategies, so that the community engagement requirements will not be impossible or unreasonably burdensome for beneficiaries to meet in impacted areas.

i. Provide each beneficiary who has been disenrolled from MaineCare 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. Maine 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.

j. Ensure that 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 these barriers.

k. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting and reporting community engagement requirements.

l. Maintain a process that provides reasonable modifications related to meeting the community engagement requirement to beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act.

VIII. GENERAL REPORTING REQUIREMENTS

41. 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.

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

43. 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.

44. Implementation Plan. The state must submit an Implementation Plan to CMS no later than 90 calendar days after approval of the demonstration. The Implementation Plan must cover at least the key policies being tested under this demonstration, including community engagement, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and the waivers of retroactive eligibility and NEMT. 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.

45. Tribal Consultation Plan. The state must consult with, and provide outreach and education to, federally recognized tribal governments and with Indian health care providers, and through consultation, identify any tribal concerns. The state must deliver to CMS a plan and timeline for working with the tribes and Indian health care providers to address any issues identified related to implementation of the community engagement requirements. The plan and timeline are due to CMS within 60 calendar days after approval of this demonstration and will be incorporated into the STCs as Attachment F. CMS will work with the state if we determine changes are necessary to the state's submission, or if issues are identified as a part of the review.

46. Monitoring Protocol. The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. 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 47.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, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and waivers of retroactive eligibility and NEMT. 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 47.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.

47. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) Annual 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 Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual 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 policies under this demonstration -- community engagement, premiums, consequences for failure to complete redetermination or report changes in circumstances, incentives for health behaviors, and the waiver of retroactive eligibility. The performance metrics will also reflect all other components of the state's demonstration, including metrics associated with the waiver of NEMT. For example, these metrics will cover enrollment, disenrollment, or suspension by specific demographics and reason, participation in community engagement qualifying activities, access to care, and health outcomes.

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

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

c. Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstrations 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.

48. 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. This may be an interim step to withdrawing waivers, as outlined in STC 11.

49. 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 41.

50. 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 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.

51. 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.

IX. GENERAL FINANCIAL REQUIREMENTS

This demonstration is approved for Title XIX expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

52. General Financial Requirements. The state must comply with all general financial requirements under Title XIX, including reporting requirements related to monitoring budget neutrality, set forth in Section X of these STCs.

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

53. 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.

XI. EVALUATION OF THE DEMONSTRATION

54. 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 41.

55. 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.

56. 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. All applicable Evaluation Design guidance, including guidance about community engagement, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and the waiver of retroactive eligibility. Community engagement hypotheses will include (but not be limited to): effects on enrollment and continuity of enrollment; and effects on employment levels, income, transition to commercial health insurance, health outcomes, and Medicaid program sustainability. Hypotheses for premiums (including premiums for beneficiaries eligible for family planning services and beneficiaries eligible in the medically needy group) and incentives for healthy behaviors will include (but not be limited to): effects on access to care and health outcomes, and financial impact to Medicaid of imposing premiums on these populations. Hypotheses for the waiver of retroactive enrollment will include (but not be limited to): the effects of the waiver on enrollment and eligibility continuity (including for different subgroups of individuals, such as individuals who are healthy, individuals with complex medical needs, prospective applicants, and existing beneficiaries in different care settings). Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs); and the effect of the demonstration on Medicaid program sustainability.

b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD evaluation designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

57. 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 an attachment 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.

58. 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).

59. 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.

60. 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.

61. 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.

62. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's interim evaluation report. This may be an interim step to withdrawing waivers, as outlined in STC 11.

63. 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.

64. 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.

65. 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.

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.

Expectations for Evaluation Designs

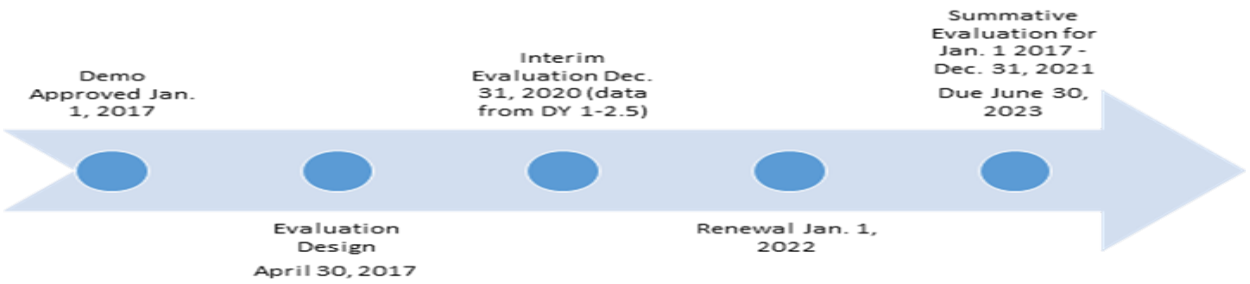
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

Submission Timelines

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



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

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

3) Identify the state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

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

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

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

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

   If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

7) *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 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.

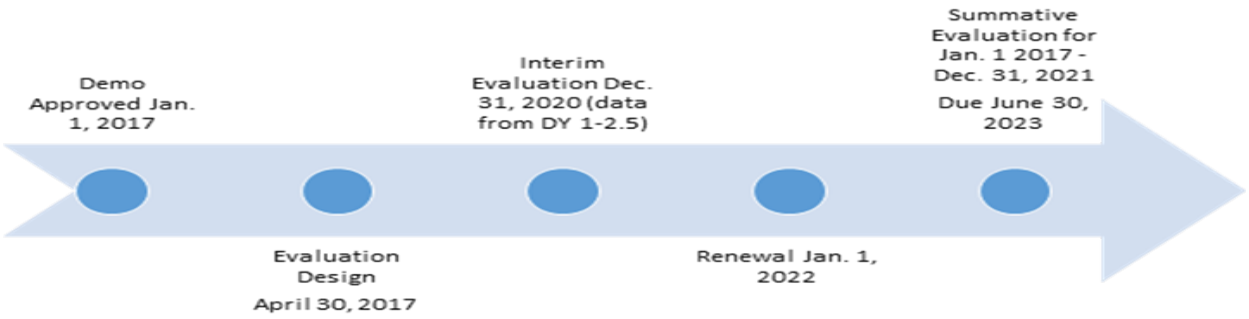
The format for the Interim and Summative Evaluation reports is as follows:

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 – Community Engagement Implementation Plan (Reserved)

Attachment E: Monitoring Protocol (reserved)