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Dear Mr. Brunssen:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) 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 programs under the Act, 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)(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 Nebraska’s December 12, 2019 request to implement a voluntary incentive opportunity for the adult group expansion population. Certain members of this population will be able to receive demonstration-only benefits, in addition to those benefits authorized in the approved Alternative Benefit Plan (ABP), through a section 1115 demonstration project entitled, “Heritage Health Adult” (HHA) (Project Number 11-W-00337/7), in accordance with section 1115(a) of the Act.

This approval is effective October 20, 2020 through March 31, 2026, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. Implementation of the demonstration may begin no sooner than April 1, 2021. CMS’s approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been specifically listed as not applicable under the demonstration.

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. Under section 1901 of the Act, the Medicaid program provides federal funding to participating states “[f]or the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.” Act § 1901. As this statutory text makes clear, two Medicaid objectives are to enable states to “furnish ... medical assistance” – i.e., healthcare services – to certain vulnerable populations and to furnish those populations with rehabilitation and other services to help them “attain or retain capability for independence or self-care.” Act § 1901. 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 State, as far as practicable under the conditions in such State” to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need.

We are committed to supporting states that seek to test measures that are likely to increase coverage and improve the health of beneficiaries and make them more financially independent, which in turn supports the fiscal sustainability of states’ Medicaid programs. We expect that such demonstration policies will improve beneficiaries’ physical and mental health, resulting in these beneficiaries consuming fewer health care services and resources while they are enrolled in Medicaid, which will preserve Medicaid program resources, make the Medicaid program more efficient, and potentially reduce the program’s national average annual cost per beneficiary of \$7,871.¹ Moreover, we expect that such demonstration policies will increase beneficiaries’ financial independence and assist them in gaining financial security, which will obviate their need for public assistance as they secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility. Such measures can promote the objectives of the Medicaid statute by enabling states to make improvements and investments “as far as practicable under the conditions in such state[s],” Act § 1901, in the broader Medicaid program. These measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.² By the same token, such measures may also preserve states’ ability to continue to provide the optional services and coverage they already have in place.

¹ U.S. Department of Health and Human Services 2018 Actuarial Report on the Financial Outlook for Medicaid published by the CMS Office of the Actuary.

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

The measures being tested with this demonstration approval may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may “result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing,” as referenced in § 1115(d)(1) of the Act. But in the long term, these measures may help many beneficiaries enjoy the numerous personal benefits that come with improved health and financial independence and allow the state to more sustainably cover its vulnerable populations. In addition, section 1115 gives CMS the authority to offer states more flexibility in experimenting with different ways of expanding coverage, improving health outcomes and strengthening the financial independence of beneficiaries.

For example, through this demonstration, Nebraska will provide optional vision, dental, and over-the-counter (OTC) drug coverage to certain Medicaid expansion beneficiaries who otherwise would not have access to such benefits under the state plan. Besides affording additional coverage the state is under no obligation to provide, the demonstration will incentivize enrolled beneficiaries to complete beneficiary engagement activities, discussed below. CMS expects that participation in these activities will improve beneficiaries’ health outcomes as well as their financial independence, reducing costs to the Medicaid program and improving its fiscal sustainability, thereby enabling the state to furnish additional coverage for optional populations and benefits.

Thus, for three independently sufficient reasons, CMS has determined the Nebraska Heritage Health Adult demonstration is likely to promote Medicaid objectives, and the expenditure authority sought is necessary and appropriate to carry out the demonstration. First, the demonstration will provide a subgroup of the adult group expansion population with the option to choose to access vision services, adult dental services, and OTC drugs covered under section 1115(a)(2) of the Act that are not otherwise available to them under Nebraska’s state plan. Second, by providing incentives for beneficiaries to choose to opt into receiving this expanded, demonstration-only coverage, the demonstration will also test whether the opportunity to opt into additional services lowers program costs, including by improving beneficiary health, and thereby improves the fiscal sustainability of the Medicaid program. If the demonstration has the intended effects, Nebraska may be better able to provide medical assistance to a greater extent than it would otherwise. Third, the demonstration will test whether the incentive structure and availability of demonstration-only coverage will result in improved health outcomes and well-being.

Background on Medicaid Coverage in Nebraska

The Division of Medicaid & Long-Term Care (MLTC), a division of the Nebraska Department of Health and Human Services (DHHS), administers the State of Nebraska’s Medicaid program. The current Medicaid program serves pregnant women, low-income children and their parents, the aged, and individuals with disabilities. Beginning October 1, 2020, the state will cover the Medicaid adult expansion population described in section 1902(a)(10)(A)(i)(VIII) of the Act. The financing and eligibility State Plan Amendments (SPAs) for this expansion were approved in March 2020, and two ABP SPAs for the expansion population were approved in July 2020.

Medicaid is a significant payer of health services in Nebraska, and in state fiscal year 2019, the Division's appropriated budget of more than \$2 billion paid for services for the approximately 12 percent of Nebraskans who were Medicaid beneficiaries.

In November 2018, Nebraska voters passed Initiative 427, which called for the expansion of Medicaid eligibility to the adult group expansion population described at section 1902(a)(10)(A)(i)(VIII) of the Act. On April 1, 2019, MLTC announced its expansion of Medicaid eligibility to this group under the state plan. Nebraska's adult group expansion was implemented on October 1, 2020. The state expects the adult group expansion will total 80,500 individuals by the end of the demonstration, including all adult group beneficiaries regardless of enrollment in the demonstration. Under the ABP SPAs approved in July 2020, the state will offer two benefit packages to the adult group expansion population under the state plan. The first ABP, known as "Prime," includes all Medicaid benefits that are available under the Nebraska state plan to other full-benefit populations, including optional coverage of dental services, vision services, and OTC medications. These benefits are for members of the adult group expansion population who are pregnant, medically frail, or 19 or 20 years old. The second ABP, known as "Basic," includes most Medicaid benefits that are available under the Nebraska state plan to other full-benefit populations, including all of the mandatory Medicaid benefits, plus 35 optional Medicaid benefits, but it does not include vision services, dental services, or OTC medication. The Basic ABP is for all members of the Medicaid expansion population who are 21 years old and older, not pregnant, and not medically frail. Only those members of the adult group expansion population who receive the Basic ABP under the state plan will be included in this demonstration. The state estimates that approximately 43,100 beneficiaries will be served by the demonstration by the start of demonstration year 5 on April 1, 2025.

Extent and Scope of the Demonstration

The Nebraska Heritage Health Adult (HHA) demonstration provides certain members of the adult group expansion population with a voluntary opportunity to receive demonstration-only benefits by participating in beneficiary engagement activities. These activities include wellness initiatives and personal responsibility activities, including (beginning on April 1, 2022) community engagement activities. The demonstration-only benefits will be offered under a section 1115(a)(2) expenditure authority and thus will expand upon the state plan benefits offered through the Basic ABP for the component of the adult group expansion population enrolled in the demonstration.

This beneficiary engagement program will affect only a subset of individuals in the adult group expansion population described at section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119 who are aged 21 through 64 and who are not pregnant or medically frail (referred to below as the HHA expansion group or HHA beneficiaries). Through this demonstration, if these HHA beneficiaries choose to participate in beneficiary engagement activities, they can access the following benefits that are not available to them through the Basic ABP in the state plan: 1) vision services, including optometrist services and eyeglasses; 2) adult dental services, including dentures; and 3) OTC medications. These additional benefits are optional Medicaid benefits that federal statute and regulations at 42 CFR part 440, subpart C do not require the state to include in an ABP for the adult group expansion population.

HHH beneficiaries who choose not to participate in the beneficiary engagement activities will not lose eligibility for Medicaid, but they will not be able to access the additional benefits available through the demonstration. Most beneficiaries affected by the demonstration will begin their eligibility period with state plan coverage under the Basic ABP and will be able to establish eligibility to receive the demonstration-only benefits at their first benefit review, for a six-month period.³ These 6-month periods are called “benefit periods,” and they will generally be calculated starting on the date that a person becomes eligible for the new adult group as a non-medically-frail, non-pregnant individual aged 21 through 64, and thus becomes enrolled in the demonstration. However, in no case will any beneficiary’s benefit period begin sooner than the approved implementation date of the demonstration, April 1, 2021.

The state estimates that approximately 41,000 to 51,000 beneficiaries will be enrolled in the demonstration on April 1, 2021 and will gain the opportunity to qualify for the demonstration-only benefits. The state expects 45 percent of beneficiaries will choose to successfully meet the beneficiary engagement requirements and opt into receiving the additional benefits. For purposes of illustration, if 46,000 beneficiaries are enrolled in the demonstration on April 1, 2021, 45 percent of this group, or 20,700 beneficiaries, are expected to opt into receiving the demonstration-only benefits by successfully participating in the beneficiary engagement activities during their initial benefit period, and will start receiving coverage for demonstration-only benefits starting with the 6-month benefit period beginning October 1, 2021.

The state also estimates that approximately 1,200 Medicaid beneficiaries will transition from a current Medicaid eligibility category that already receives vision, dental, and OTC medication benefits to the adult group expansion population on October 1, 2020. The state estimates that 10 percent of individuals who transition from a current Medicaid eligibility group to the adult group expansion population will meet the criteria for automatic assignment to the Prime Benefit ABP ((medically frail, pregnant, and/or 19-20 years old)) and will receive coverage for vision, dental, and OTC benefits without having to meet the beneficiary engagement requirements under the demonstration. For purposes of illustration, of the 1,200 beneficiaries expected to move to the Medicaid adult group expansion population, 10 percent (or 120 beneficiaries) are expected to automatically meet the criteria for assignment in the Prime ABP and will not be included in the demonstration. Therefore, 1,080 individuals who transition from another Medicaid population to the adult expansion population are expected to be eligible to participate in the demonstration and opt into the additional demonstration-only benefits. The state expects 45 percent of this subgroup will choose to successfully meet the beneficiary engagement requirements and opt into receiving the additional benefits.⁴ Thus, 55 percent of this subgroup, or 594 beneficiaries, are expected to not opt into receiving the demonstration-only benefits, because they do not successfully participate in the beneficiary engagement activities.⁵

³ Beneficiaries who were receiving demonstration-only benefits but whose eligibility for such benefits has been suspended for failure to meet certain beneficiary engagement requirements will be required to wait for two six-month periods (that is, for 12 months) before they may again be eligible for coverage of demonstration-only benefits.

⁴ The 45 percent figure appears on page 28 of the state’s demonstration application entitled, “Nebraska Medicaid Section 1115 Heritage Health Adult Expansion Demonstration.”

⁵ Coverage for demonstration-only benefits will continue to be provided, temporarily, for all beneficiaries transitioning from another full-benefit Medicaid eligibility group to the adult expansion group and demonstration

Beneficiary Engagement Activities.

The activities that beneficiaries must engage in to opt into receiving the additional benefits offered through the demonstration include completing wellness initiatives, which include attending an annual health visit and completing a health risk assessment. Beneficiaries will also be required to engage in personal responsibility activities, which include maintaining affordable employer-sponsored coverage (if available to the beneficiary) and not missing three or more scheduled medical appointments in a 6-month period.

Additionally, beginning on April 1, 2022, beneficiaries who have the opportunity to participate in the demonstration must, in order to opt into receiving the additional benefits offered through the demonstration, engage in sufficient qualifying community engagement activities (typically, at least 80 hours per month).⁶ The community engagement qualifying activities include, but are not limited to, employment, participating in a Supplemental Nutrition Assistance Program (SNAP)-recognized or Temporary Assistance for Needy Families (TANF)-recognized job-seeking activity, at least half-time enrollment in any accredited college or post-secondary training program, or engaging in a volunteer activity for a public charity. Also, beginning April 1, 2022, in conjunction with the community engagement requirements, beneficiaries must also notify the state Medicaid agency in a timely manner of any changes that would affect eligibility for demonstration-only benefits.

As noted above, persons who are pregnant, medically frail, or aged 19-20 will not be included in the demonstration, but instead will receive the Prime ABP, which includes dental, vision, and OTC medication coverage. Nebraska will allow beneficiaries to cite a good cause reason for not being able to meet any of the beneficiary engagement requirements. The community engagement requirement is more time-consuming than other beneficiary engagement requirements under the demonstration, and therefore, the state will exempt certain populations from the community engagement requirement where competing demands on time or other considerations would make the community engagement requirement an inappropriate imposition on the beneficiary. The following individuals in the HHA expansion population will be exempt from the community engagement requirement:

- Individuals participating in a substance use disorder or mental health treatment program;
- Individuals receiving unemployment compensation or who have applied for unemployment compensation and are fulfilling weekly work search requirements while in the waiting period. This includes individuals receiving Integrated Unemployment Compensation (IUC) or who are in compliance with IUC work search activities;

coverage on October 1, 2020, notwithstanding compliance with applicable beneficiary engagement requirements, depending on the continuation of the public health emergency for COVID-19. See STC 18.

⁶ While it cannot be known what the status of the current public health emergency for COVID-19 will be when the community engagement requirement takes effect in 2022, it is worth noting that recent research during the COVID-19 pandemic indicates that factors such as a lack of economic participation, social isolation, and other economic stressors have negative impacts on mental and physical health. See, e.g., Nirmita Panchal et al., *The Implications of COVID-19 for Mental Health and Substance Use*, Kaiser Family Found. (Apr. 21, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>. Structured properly, community-engagement incentives and requirements that increase such participation may have a positive effect on beneficiary health and economic mobility.

- Members of a federally recognized tribe;
- High school students of any age who are attending at least half time;
- Individuals aged 60 through 64;
- Individuals residing in an area that has been granted a federal SNAP Able-Bodied Adults without Dependents (ABAWD) waiver due to insufficient jobs to provide employment;
- Victims of domestic violence, when participation would make it harder to escape, penalize the individual, or put them at further risk of domestic violence;
- A parent, caretaker relative, guardian, or conservator of a dependent child;
- A parent, caretaker relative, guardian, or conservator responsible for the care of an elderly or disabled relative and who are providing care to these individuals in the home; and
- Participation in the SNAP Employment and Training (E&T) program or otherwise meeting SNAP (ABAWD) requirements.

Non-exempt beneficiaries whom the state determines have not satisfied the requirements to opt into receiving the additional benefits available through the demonstration will have the opportunity to file an administrative appeal under 42 C.F.R. part 431, subpart E to opt into or maintain access to the demonstration-only benefits, and will also have an opportunity to demonstrate that there was a “good cause” for failing to engage in the beneficiary engagement activities. If successful, the beneficiary will be able to opt into, or continue opting into, receiving the demonstration-only benefits. Good cause will be determined on a case-by-case basis. An example of a good cause explanation for missing an appointment might be the failure of a non-emergency medical transportation provider to transport the beneficiary to an appointment within the scheduled window. Examples of a good cause explanation for not being able to meet community engagement hours is a physical or mental health emergency, an unforeseen work schedule change, or a family emergency.

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

For reasons discussed below, the Secretary has determined that Nebraska’s HHA demonstration as a whole is likely to assist in promoting the objectives of the Medicaid program.

(1) The demonstration expands coverage beyond what the state plan provides.

Nebraska’s HHA demonstration is likely to assist in promoting the objective of furnishing medical assistance because it provides certain beneficiaries in the adult group expansion population with an opportunity to access benefits that are not included in the state plan ABP for this population. Accordingly, the demonstration as a whole is expected to provide greater access to coverage for low-income individuals than would be available absent the demonstration. The state estimates that approximately 43,100 Medicaid beneficiaries will opt into receiving the additional demonstration-only benefits by the fifth and final year of the demonstration, as a result of the demonstration. The demonstration provides benefits to certain members of the adult expansion population that the state is not obligated by federal statute to provide.

The demonstration includes provisions that could result in some individuals opting into the benefits available under the demonstration, but failing to maintain it, because they chose not to engage in the activities required to maintain it. However, the beneficiary engagement program is designed to make compliance with the requirements achievable. Nebraska has taken steps to ensure that the requirements apply only to persons who can reasonably be expected to meet them, and that beneficiaries are clearly informed of their responsibilities under the demonstration. Any individual whom the state determines is not eligible to access the demonstration-only benefits will have the right to appeal the state's decision, consistent with all existing appeal and fair hearing protections in 42 CFR part 431, subpart E. As part of its ongoing monitoring of the demonstration, the state will submit data to CMS on who is eligible for and accessing services covered by the demonstration-only benefits and will track changes in eligibility and access over time. The state will also be required to evaluate health outcomes for beneficiaries affected by the demonstration, including for those who fail to engage in the required activities and thus do not have coverage for the demonstration-only benefits. The state will undertake rigorous evaluation to understand the effect of the demonstration on beneficiary coverage and health outcomes. The state will also conduct regular monitoring of metrics on enrollment in the demonstration, completion of beneficiary engagement activities, access to care, and health outcomes. CMS reserves the right to require the state to take corrective action, which could include suspending implementation of the demonstration's beneficiary engagement requirements, if monitoring or evaluation data indicate substantial and sustained directional change inconsistent with state targets (e.g., substantial and sustained trends indicating increased difficulty accessing demonstration-only benefits by those making a good faith effort to choose to access them). CMS would further have the ability to suspend expenditure authority or require CMS-specified programmatic changes to avoid suspension of expenditure authority, should corrective actions not effectively resolve these concerns in a timely manner.

(2) The demonstration tests an approach to providing medical assistance that, if successful, might improve the fiscal sustainability of Nebraska's Medicaid program.

Nebraska's HHA demonstration is also likely to assist in promoting the objective of furnishing medical assistance as far as is practicable in Nebraska. The demonstration is designed to incentivize individuals to participate in beneficiary engagement activities, such as completing a health risk assessment, attending an annual health visit, and keeping scheduled medical appointments, which are expected to assist in the prevention and early detection of any potential health issues and may thus lead to improved health and wellness. Improved health and wellness, in turn, may reduce health care costs. Additionally, the demonstration incentivizes certain beneficiary behaviors that may help to ensure the efficient use of Nebraska's medical assistance budget, such as timely reporting changes in circumstances that may affect eligibility for demonstration-only benefits and maintaining access to affordable employer-sponsored coverage when eligible for both such coverage and for Medicaid. Finally, by including community engagement as one of the beneficiary engagement activities needed to opt into the demonstration-only benefits, Nebraska is testing whether some beneficiaries might not just improve their health outcomes, but also increase their earnings to the point where they no longer

need to rely on Medicaid for health coverage.⁷ 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 provide services beyond the statutory minimum.

In order to ensure that the experiment yields informative evidence, the state will be required to develop appropriate evaluation hypotheses and research questions that are designed to capture useful data to support the demonstration’s evaluation design, which will be subject to CMS approval (including the hypotheses and research questions). The state’s hypotheses, research questions, and overall evaluation approach must be substantially formalized in consultation with CMS before the demonstration’s beneficiary engagement requirements take effect on April 1, 2021. These will be documented in the state’s evaluation design, and subsequent interim and summative evaluations will be conducted consistent with the CMS-approved evaluation design.

The state must examine in the demonstration’s evaluation beneficiary understanding of the connection between engagement in wellness and personal responsibility initiatives, including community engagement activities, and eligibility for demonstration-only benefits. Evaluation hypotheses should also be related to beneficiary experience with these incentivized beneficiary engagement activities and the demonstration overall, and the demonstration’s effects on coverage (including employer-sponsored health coverage and other commercial insurance) and health outcomes. In evaluating and testing the hypotheses to assess the demonstration’s success in achieving the key policy outcomes and objectives, the state must carefully identify through robust statistical methods a comparison population, such that the impact of the demonstration can be estimated. It is plausible that the state might find it difficult to identify an in-state comparison group not subject to the beneficiary engagement activities that would otherwise be similar in demographic and other relevant characteristics that distinguish the HHA expansion group population. Therefore, the state might need to identify other-state comparison strategies, or apply alternative rigorous methodological approaches. In addition to examining some variant of the primary research questions, as outlined in CMS’s community engagement evaluation design guidance, the state would also need to be thoughtful about adopting, while adapting as relevant, some of the critical secondary research questions to adequately understand the pathway to the demonstration outcomes for the HHA expansion group population.

The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation and Medicaid health services expenditures. In addition, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability. Nebraska is testing whether the incentives created by the demonstration will improve beneficiaries’ health and financial independence and thereby enhance the fiscal sustainability of Nebraska’s Medicaid program. A broad range of social and economic factors can have a major impact on an individual’s health and wellness, and a growing body of evidence suggests that targeting certain health determinants, can improve health outcomes for the individual. Improved health outcomes should lead to increased financial sustainability of the Medicaid program as healthier beneficiaries will be less costly over time.

⁷ CMS State Medicaid Director Letter 18-002: “Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries,” available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf>

(3) The demonstration tests an approach to providing medical assistance that, if successful, might improve beneficiary health and overall beneficiary well-being.

With this approval, Nebraska will test whether incentivizing beneficiaries to choose to access demonstration-only benefits might improve the health of Medicaid beneficiaries and encourage them to make responsible decisions about their health and accessing health care. 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.”⁸

The beneficiary engagement requirements are expected to promote beneficiary use of preventive care and chronic condition management services, thereby positively affecting overall health outcomes. These activities may also support reductions in use of inappropriate care (e.g., non-emergent emergency department visits). Rewarding beneficiary engagement provides beneficiaries a greater stake in improving their health status, and thus may help enhance uptake of preventive services and improve health outcomes, and support sustainability goals.⁹ Additionally, other beneficiary engagement requirements like the community engagement requirements are expected to support increased or sustained employment and income, which in turn would promote beneficiary independence and ultimately help improve health outcomes.

Consideration of Public Comments

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

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 imposed no additional requirement on the states or the Secretary to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments (42 CFR 431.416(d)(2)).

⁸ CMS, Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid at 15 (Dec. 10, 2012) available at: <https://www.cms.gov/CCIIO/Resources/Files/Downloads/exchanges-faqs-12-10-2012.pdf>

⁹ For example, Michigan’s report focused on its Healthy Michigan Plan (HMP) demonstration beneficiaries who maintained continuous enrollment over a two-year period revealed that initiatives to promote regular primary care visits and health risk assessments were associated with lower rates of emergency department and inpatient utilization for HMP enrollees, particularly those with chronic conditions. See Sarah J. Clark, Lisa M. Cohn, John Z. Ayanian. (December 5, 2018.) Report on Health Behaviors, Utilization, and Health Outcomes in the Healthy Michigan Plan: Healthy Michigan Plan Evaluation Domain III. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/mi/Healthy-Michigan/mi-healthy-michigan-Q4-annl-rpt-2018.pdf>.

The federal public comment period opened on December 18, 2019 and closed on January 17, 2020. CMS received 425 public comments. All but one comment opposed Nebraska's proposed demonstration. Although CMS is not legally required to provide written responses to comments, CMS is addressing some of the central issues raised by the comments and summarizing CMS's analysis of those issues for the benefit of stakeholders. After carefully considering the public comments submitted during the federal comment period, CMS has concluded that the demonstration is likely to assist in promoting the objectives of Medicaid. CMS worked with the state to make changes to the state's original proposal in response to concerns from stakeholders. For example, CMS is not approving the state's request for a waiver of retroactive eligibility. In addition, CMS adjusted the structure of the demonstration so that beneficiaries are positively impacted by the demonstration. The state originally requested waiver authority to allow the state to offer an enhanced benefit package only to beneficiaries who met the beneficiary engagement requirements. However, CMS worked with the state to restructure the demonstration to rely on an expenditure authority to allow beneficiaries included in the demonstration to choose to access coverage for demonstration-only benefits. A number of commenters voiced concern about beneficiary protections. Due to those concerns, CMS and the state discussed including additional exemptions from the community engagement requirement. As a result, the state agreed to move some of what were qualifying activities for community engagement to the list of exemptions from the community engagement requirement, which reduces the burden on beneficiaries. For example, the state moved being a parent or caretaker relative from the list of community engagement qualifying activities to the list of exemptions. This reduces the burden on the beneficiary because the beneficiary has an overall exemption from the community engagement requirements rather than needing to report the hours spent taking care of a child. Another safeguard that CMS added to the demonstration was requiring the state to allow a beneficiary to seek a good cause exception for all of the beneficiary engagement requirements. Finally, CMS added a term and condition regarding beneficiary appeal rights where the state determines that a beneficiary has not met beneficiary engagement requirements.

Comments Regarding Tribal Consultation and Effects on Tribal Members

CMS received comments from several tribal organizations and tribal health provider organizations. One of the commenters alleged that the state did not follow the requirements of its state plan tribal consultation process in the development and submission of the HHA demonstration application. The commenter alleged that Nebraska neither provided a 60-day notification period to solicit advice from tribes on this demonstration, nor did it engage in regular and ongoing meetings during which comments could have been obtained. However, the state confirmed and CMS concurs that the state followed the current tribal notice and consultation rules as outlined in the Medicaid state plan. Specifically, as the state explains on page 38 of its application, the state sent a tribal pre-notification 1115 application to representatives and constituents of the state's federally recognized tribal organizations. The state also met with tribal representatives on October 10, 2019, at 1 p.m. at the Ponca Tribe of Nebraska Headquarters. Nebraska's approved tribal consultation SPA requires that the state send notification to its tribes prior to SPA or demonstration application submission. Therefore, the state's submission is in compliance with its tribal consultation SPA. The state did not receive any comments directly from tribes as a result of this consultation.

Other comments to CMS from the tribal organizations and tribal health provider organizations also indicated the beneficiary engagement requirements place undue administrative burdens on Indian health care systems, and are unrealistic in the light of the living conditions for many American Indian (AI) and Alaska Native (AN) beneficiaries, which include chronic transportation and communication challenges. The commenters also contend that the state is reimbursed for Medicaid services delivered to eligible AI/AN beneficiaries provided through an IHS facility whether operated by the IHS or by a Tribe at a 100 percent Federal Medical Assistance Percentage (FMAP), with no cost at all to Nebraska. As such, the commenters indicate there is no need to condition or otherwise restrict AI/AN access to expanded benefits. CMS has considered these comments and supports the state's decision generally to apply the beneficiary engagement requirements as a pathway to enhanced benefits to AI/AN HHA beneficiaries, since the state is providing a benefits package that meets the requirements of the Medicaid statute.

In addition, these commenters explained that the Social Security Act explicitly prohibits Nebraska from requiring AI/AN beneficiaries to enroll in a managed care organization and the commenters said that enrolling AI/AN beneficiaries in managed care is impermissible under 42 U.S.C. § 1396u-2(a)(2)(C). CMS points out that the law does not prohibit a state from requiring AI/AN beneficiaries to enroll in a Medicaid managed care plan when the state's Medicaid program delivers services through managed care under authority other than state plan authority, such as a section 1915(b) waiver or a section 1115 demonstration. The statutory prohibition on mandatory enrollment into managed care for AI/AN beneficiaries applies only to managed care authorized under the Medicaid state plan. See *CMCS Informational Bulletin*, "Indian Provisions in the Final Medicaid and Children's Health Insurance Program Managed Care Regulations" 4-5 (Dec. 14, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib121416.pdf>. CMS notes that this section 1115 demonstration does not provide the state with authority regarding managed care. Rather, Nebraska operates its managed care program under the authority of a section 1915(b) waiver, which (as noted above) is not subject to the statutory prohibition on enrollment in managed care that the commenters discussed. In addition, while CMS is approving the state's exemption of members of federally recognized tribes from the community engagement requirement, AI/AN beneficiaries will not be exempt from all beneficiary engagement requirements because these requirements are beneficial to the health and well-being of all individuals. As discussed above, CMS and the state believe that the community engagement requirement is similarly beneficial to health and well-being, but due to the unique status of tribal governments that have requested an exemption for AI/AN HHA beneficiaries and the additional time and effort needed for qualifying community engagement activities, members of federally recognized tribes will be exempt from the community engagement requirement. The state also provides ample opportunity for AI/AN beneficiaries and other beneficiaries to submit a good cause exception request if they are not able to comply with the beneficiary engagement requirements. Therefore, CMS determined that the beneficiary engagement requirements (with the exception of community engagement) should apply to AI/AN beneficiaries.

General Comments about Medicaid Objectives

All comments from advocacy, research, legal, and medical professional organizations expressed opposition towards the proposed demonstration or some aspect of the demonstration.

Organizations largely opposed the community engagement aspect of the demonstration because of the requirement's potential impact on Medicaid coverage. Commenters addressing the beneficiary engagement requirements most often suggested that all beneficiaries should receive the enhanced benefits package regardless of their participation in work or other community and beneficiary engagement activities.

Many of these commenters expressed the view that the beneficiary engagement requirements may result in beneficiaries losing access to health care and that the demonstration proposals are contrary to the objectives of Medicaid. CMS disagrees with these assertions. The demonstration promotes the Medicaid objective of providing medical assistance by giving beneficiaries the opportunity to opt into additional benefits not included in their state plan coverage, and which they otherwise would not receive if CMS did not approve this demonstration. Additionally, no HHA beneficiary will lose Medicaid eligibility or coverage because of this demonstration. All HHA beneficiaries will be assigned to the Basic ABP in the state plan, which includes all mandatory Medicaid state plan benefits. The Basic ABP benefit package includes most Medicaid benefits that are available under the Nebraska state plan to other full-benefit populations, including all of the mandatory Medicaid benefits, plus 35 optional Medicaid benefits, but it does not include vision services, dental services, and or OTC medication. CMS will regularly evaluate the effects of the demonstration on HHA beneficiaries and reserves the right to discontinue specific authorities if CMS determines that it would no longer be in the public interest or promote Medicaid's objectives to continue them. The STCs also give CMS the authority to require the state to take corrective action, which could include suspending implementation of the demonstration's beneficiary engagement requirements, if monitoring or evaluation data indicate substantial and sustained directional change inconsistent with state targets (e.g., substantial and sustained trends indicating increased difficulty accessing demonstration-only benefits by those making a good faith effort to choose to access them). CMS would further have the ability to suspend expenditure authority or require CMS-specified programmatic changes to avoid suspension of expenditure authority, should corrective actions not effectively resolve these concerns in a timely manner. In sum, CMS will carefully monitor the effects of the demonstration to ensure that it continues to promote the Medicaid objective of furnishing medical assistance.

Comments Addressing Beneficiary Engagement Activities

As indicated above, there were 425 public comments submitted to Medicaid.gov.

Approximately half of the opposing comments (45.1 percent) were concerned that the beneficiary engagement requirements of the proposed demonstration would cause beneficiaries to not be able to access health care. About a third of comments that addressed community engagement (32.8 percent) said the community engagement aspects of the demonstration would be unnecessarily burdensome for beneficiaries, primarily because of the complex reporting requirements. For example, a commenter indicated that it would place significant burden on providers and on patients with low health literacy and language barriers, for whom it would be

difficult to fill out additional paperwork. In addition, commenters suggested that the two-tiered benefit system as proposed is too complex for a beneficiary to maneuver. 24.1 percent of opposing comments expressed concern that the community engagement aspect of the proposed demonstration would cause negative health outcomes among beneficiaries, making beneficiaries less able to participate in employment. Slightly less than a quarter of opposing comments (22.1 percent) noted that most beneficiaries are already working. Commenters noted that limiting access to enhanced benefits would be confusing to patients and providers and make care and benefit administration unnecessarily complicated, particularly for beneficiaries who do not consistently comply with the beneficiary engagement requirements and therefore do not consistently receive the enhanced benefits package (the demonstration-only benefits, under the approved demonstration).

Some commenters argued that limiting access to the enhanced benefits package violates the spirit of Medicaid expansion as passed by Nebraska voters via ballot initiative and further suggested that the proposed demonstration is a stalling tactic used by the legislature to prevent Medicaid expansion and implementation. To be clear, Nebraska has already expanded its Medicaid program to include the adult group expansion population through a series of state plan amendments. This demonstration does not change the fact that the state has already expanded its Medicaid program to include this group, and it does not reduce the Medicaid coverage otherwise available to this group through the state plan. Rather, this demonstration is likely to assist in promoting the Medicaid objective of furnishing medical assistance by offering certain members of the adult group expansion population a voluntary opportunity to access benefits in addition to what they can otherwise receive under Nebraska's state plan. Moreover, conditioning eligibility for these demonstration-only benefits on compliance with certain requirements is an important element of the state's efforts, through experimentation, to furnish medical assistance as far as is practicable in Nebraska. Nebraska is testing whether the incentives created by the demonstration will improve beneficiaries' health and financial independence and thereby enhance the fiscal sustainability of Nebraska's Medicaid program, as well as improve the health outcomes and financial stability experienced by demonstration beneficiaries.

Nebraska HHA beneficiaries who choose not to participate in beneficiary engagement activities, including community engagement activities, will not lose Medicaid eligibility and will not lose access to any of the Medicaid benefits they receive under the state plan, much less lose access to health care entirely. At most, HHA beneficiaries who choose not to complete the requirements will not opt into accessing a limited range of Medicaid benefits that the state is not required to provide under the Medicaid statute to any beneficiary in the demonstration population. As such, any impact on beneficiaries' health outcomes and ability to participate in employment should be limited (and an important hypothesis being tested by the demonstration is that both health outcomes and participation in employment and other community engagement activities will improve as a result of the demonstration). We acknowledge commenters' concerns regarding the perceived burdensome reporting process to meet the community engagement requirement, and the state is committed to reducing reporting burdens. CMS acknowledges that many beneficiaries are already working and we note that employment is included as a qualifying activity that beneficiaries can engage in to comply with the community engagement requirement. The state is required to verify compliance with the community engagement requirement through internal resources and electronic data sources to reduce the reporting burden on beneficiaries.

Beneficiaries who do not participate in the beneficiary engagement activities may fail to opt into continued access to the demonstration-only benefits, at least temporarily. However, the demonstration is designed to create achievable opportunities for beneficiaries to opt into these benefits. The state is required to implement a number of strategies and supports to assist individuals in participating in the beneficiary engagement activities if they choose to do so. For example, the STCs require the state to conduct active outreach and education, beyond standard noticing, to help ensure that beneficiaries understand the program requirements and how to comply with them. Nebraska will maintain information on these topics on its public-facing website and employ other broad outreach activities that specifically target beneficiaries in the demonstration population. In addition, as noted above, the STCs give CMS the authority to take corrective action if monitoring or evaluation findings indicate substantial and sustained directional change inconsistent with state targets. CMS can also halt implementation of the demonstration's beneficiary engagement requirements should corrective action not effectively resolve these concerns in a timely manner.

Because a demonstration project, by its nature, tests innovations, it is not possible to know in advance whether the demonstration will have the intended effects, especially when the effects are dependent on beneficiary behavior. Through monitoring of various performance metrics, CMS will be able to observe trends and patterns that suggest possible effects of the demonstration's beneficiary engagement policies. It will take robust evaluation to determine the causal influences of the demonstration on expanded coverage, health outcomes, and the fiscal sustainability of the state's Medicaid program. Beneficiary survey data and other qualitative information applied to evaluation findings may be useful in contextualizing these findings, giving insight into why any measured impacts occurred.

Comments Addressing Vulnerable Populations

A few comments expressed concern about how the demonstration would affect vulnerable populations. Beneficiaries in many vulnerable groups will not be affected at all by the demonstration, as it applies only to members of the adult group expansion population who are aged 21-64 and are not pregnant or medically frail. Therefore, beneficiaries who are eligible for Medicaid on the basis of a disability or who are medically frail will not be included in the demonstration or subject to its beneficiary engagement requirements, including the community engagement requirement. Additionally, the demonstration provides exemptions from the community engagement requirements for several vulnerable populations, including but not limited to individuals participating in a substance use disorder or mental health treatment program, victims of domestic violence, individuals age 60 through 64, parents or caretakers providing for a dependent child, and parents or caretakers responsible for the care of an elderly or disabled relative. The state notes that additional exemptions are needed for the community engagement requirements because community engagement requires more time and effort than the other beneficiary engagement requirements. For example, in many circumstances, a parent or caretaker could easily attend an annual wellness visit, complete a health risk screening, and attend scheduled appointments (and can request a good cause exception if, under the circumstances, he or she is unable to complete these activities). However, the state and CMS recognize that it could be challenging for parents and caretakers to meet community engagement

requirement while they are caring for children or elderly or disabled relatives. As a result, the state includes a variety of exemptions for the community engagement requirement. In addition, all of the beneficiary engagement requirements, including community engagement, are expected to lead to better health outcomes and overall well-being.

Nebraska will provide beneficiaries who do not meet the beneficiary engagement requirements (not limited to the community engagement requirement) with the opportunity to nonetheless be able to access demonstration-only benefits by demonstrating that they had a good cause not to meet the requirements. Nebraska will also provide reasonable modifications for beneficiaries with disabilities protected by the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act, and Section 1557 of the Patient Protection and Affordable Care Act.

Comments on Administrative and Financial Burden

Some comments suggested that implementing and maintaining the beneficiary engagement requirements would burden providers' and the state's administrative functions and could lead to increased costs for the state. Commenters also shared that they believed the community engagement aspect of the proposed demonstration would be difficult and costly for the state to administer. CMS acknowledges that implementing section 1115 demonstration projects that test innovative ways to furnish medical assistance in a manner that is practicable for a state may involve increased administrative costs for both the state and federal governments, particularly during the early stages of a demonstration. However, over time, these demonstrations may reduce the volume of services consumed, if healthier, more engaged beneficiaries consume fewer medical services and are generally less costly to cover. Further, measures that intended to help individuals' secure employer-sponsored or other commercial coverage or transition from Medicaid eligibility may decrease the number of individuals who need financial assistance, including medical assistance, from the state. Thus, over time, such demonstrations 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. Additionally, to assist in mitigating these concerns, Nebraska will leverage, to the extent possible, existing state processes and systems to minimize confusion and administrative burden and cost for the state, providers, and beneficiaries. For example, Nebraska will verify compliance with community engagement requirements through internal resources and electronic data sources such as the Nebraska Department of Labor, Nebraska Office of Vital Records, U.S. Social Security Administration, and other state programs. In addition, the state will use data that Managed Care Organizations (MCOs) have to ease the reporting burden on beneficiaries and providers. For example, the MCOs will be responsible for reporting to the state whether the beneficiary has completed the health risk assessment. Providers will not be required to document this assessment. The state will also use claims data to confirm that the beneficiary has met the annual wellness visit.

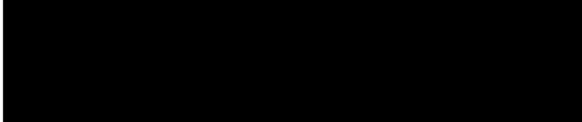
Other Information

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

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

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

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


Seema Verma

Enclosures

cc: Ashtan Mitchell, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 11-W-00337/7

TITLE: Nebraska Heritage Health Adult Demonstration

AWARDEE: Nebraska Department of Health and Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (“the Act”), expenditures made by Nebraska for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period from October 20, 2020 through March 31, 2026, unless otherwise specified, be regarded as expenditures under the state’s title XIX plan.

As discussed in the Centers for Medicare & Medicaid Services’ (CMS) approval letter, the Secretary of Health and Human Services has determined that the Heritage Health Adult Demonstration, including the granting of the expenditure authority described below, is likely to assist in promoting the objectives of title XIX of the Act.

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

1. Demonstration-only Benefits. Expenditures for benefits listed in section VI of the STCs for non-exempt beneficiaries who meet the requirements specified in section VII of the STCs.

Title XIX Requirements Not Applicable to the Expenditure Authority

All requirements of the Medicaid program expressed in law, regulation and policy statement, not expressly identified as not applicable below, shall apply to the demonstration project for the period of the demonstration. The state may not implement the demonstration any sooner than April 1, 2021.

1. Amount, Duration and Scope of Services **Section 1902(a)(17)**

To the extent necessary to enable the state to provide benefit packages to demonstration populations that differ from the Standard Medicaid state plan benefit package.

2. Comparability **Section 1902(a)(10)(B)**

To the extent necessary to permit the state to provide additional benefits to beneficiaries who meet the requirements specified in section VII of the STCs.

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

NUMBER: 11-W-00337/7

TITLE: Nebraska Heritage Health Adult Demonstration

AWARDEE: Nebraska Department of Health and Human Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Nebraska Heritage Health Adult (HHA) section 1115(a) Medicaid demonstration (hereinafter “demonstration”) to enable Nebraska to operate this demonstration. Pursuant to section 1115 of the Social Security Act, the Centers for Medicare & Medicaid Services (CMS) has approved expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, which are separately listed. 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 demonstration will be statewide and is approved from October 20, 2020 through March 31, 2026. The state will implement the demonstration no sooner than April 1, 2021.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Populations Affected
- V. Delivery System
- VI. Benefits
- VII. Beneficiary Engagement Activities: Wellness, Personal Responsibility, and Community Engagement Requirements
- VIII. General Reporting Requirements
- IX. General Financial Requirements Under Title XIX
- X. Monitoring Budget Neutrality for the Demonstration
- XI. Evaluation of the Demonstration
- XII. Schedule of Deliverables for the Demonstration

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

- Attachment A. Implementation Plan (Reserved)
- Attachment B. Monitoring Protocol (Reserved)
- Attachment C. Developing the Evaluation Design
- Attachment D. Preparing the Evaluation Report
- Attachment E. Evaluation Design (Reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The demonstration provides a voluntary incentive opportunity to individuals eligible through the Affordable Care Act's expansion eligibility group under Section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119 who are aged 21 through 64, are not pregnant, and are not medically frail. We refer throughout the STCs to this subset of the population eligible under Section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119 as "HHA beneficiaries" or the "HHA expansion group." If HHA beneficiaries meet the beneficiary engagement requirements described in the STCs, they will have access to a package of demonstration benefits that the state is not required to provide to them under federal law. HHA beneficiaries will receive all their other Medicaid benefits through the state plan, through an approved Alternative Benefit Plan (ABP) that includes all benefits required by statute (the Basic ABP). The beneficiary engagement activities will include wellness initiatives, personal responsibility activities, and (beginning on April 1, 2021) community engagement activities. HHA beneficiaries who do not engage in beneficiary engagement activities will not lose eligibility for Medicaid, but they will not be able to access the benefits available through this demonstration.

Nebraska will evaluate whether the incentives created by this beneficiary engagement program advance the following goals that the state has for the demonstration:

Goal #1: Improve the health of the HHA population through beneficiary engagement

Goal #2: Improve patient self-management in the HHA population through beneficiary engagement

Goal #3: Reduce inappropriate or unnecessary costs in the HHA population through beneficiary engagement to support the Medicaid program's overall fiscal sustainability.

Goal #4: Improve the provider and beneficiary experience of care through beneficiary engagement. Improving the provider and beneficiary "experience of care" refers to improving the quality of the interaction between providers and beneficiaries, and improving both the providers and beneficiaries' level of satisfaction with that interaction. Improving the experience of care is expected to help develop a strong beneficiary-provider relationship; and enhance beneficiary access to healthcare, including preventive care services; and facilitate overall improvement in health outcomes.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with all 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 Patient Protection and Affordable Care Act (ACA). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section

504, and Section 1557 with eligibility and documentation requirements, in understanding program rules and notices, in establishing eligibility for an exemption from the beneficiary engagement requirements on the basis of disability, in meeting and documenting compliance with the beneficiary engagement requirements (including community engagement), and meeting other program requirements necessary to obtain and maintain the benefits available through this demonstration's expenditure authority.

2. **Compliance with Medicaid and CHIP Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and written policy not expressly waived or identified as not applicable in the expenditure authority document (of which these terms and conditions are part), apply to the demonstration.
3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes made by CMS under this paragraph will take effect upon issuance of the approval letter by CMS. The state must accept the changes in writing.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.** 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 CHIP allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments.** The State will not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. In all such cases, the Medicaid state plan governs.
6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment,

benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 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 viable amendment request as found in this STC, and failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
 - a. *Demonstration Amendment Summary and Objectives.* The state must provide a detailed description of the amendment, including what the state intends to demonstrate via this amendment as well as the impact on beneficiaries, with sufficient supporting documentation, the objective of the change and desired outcomes including a conforming title XIX and/or title XXI state plan amendment, if necessary;
 - b. *Budget Neutrality Worksheet.* The state must provide a data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality expenditure limit;
 - c. *Waiver and Expenditure Authorities.* The state must provide a list of waivers and expenditure authorities that are being requested or terminated, along with the programmatic description of why these waivers and expenditure authorities are being requested for the amendment;
 - d. *Evaluation.* The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring, and measurement of the provisions; and;
 - e. *Public Notice.* The state must provide an explanation of the public process used by the state consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.
9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
- a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the comment into the revised transition and phase-out plan.
 - b. Transition and Phase-Out Plan Requirements: The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries whether currently enrolled or determined to be eligible individuals, as well as any community outreach activities 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 notice requirements found in 42 CFR 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR 431.220 and 431.221. If a demonstration beneficiary requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category.

- e. Exemption from Public Notice Procedures, 42 CFR 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
 - f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended.
 - g. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration, including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.
10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the beneficiaries' interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' 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 participants. CMS will withdraw or adjust an authority when demonstration monitoring data and evaluation findings indicate substantial and sustained directional change inconsistent with state targets, and the state has not implemented corrective action.
11. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid state plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. **Federal Financial Participation (FFP).** No federal matching funds for state expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, managed care organizations (MCOs), and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.
15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program—including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs or 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 46.104(d)(5).

IV. POPULATIONS AFFECTED

16. **Eligibility Methods and Standards.** Only beneficiaries eligible for Medicaid under the eligibility group listed in Table 1 are subject to the beneficiary engagement provisions within this demonstration.
17. **Affected Eligibility Group.** The eligibility group affected by the demonstration is listed in Table 1.

Table 1. Affected Eligibility Group

Eligibility Group	Social Security Act and CFR Citations	Income Level	Demonstration Component	Other Information
Heritage Health Adult (HHA) Expansion Group	1902(a)(10)(A)(i)(VIII) 42 CFR 435.119	0-138% FPL	Demonstration-only benefits	Only individuals in the population described in 1902(a)(10)(A)(i)(VIII) and 42 CFR 435.119 who are not medically frail, not pregnant, and who are aged 21 through 64 are included in this population

18. **Notification and Enrollment of HHA Demonstration Participants.** Eligibility for demonstration-only benefits will be determined every 6 months, beginning on the first calendar day of the month the individual becomes a member of the HHA expansion group. Each six-month period subsequent to that enrollment date is referred to as the beneficiary's "benefit period." However, no benefit period may begin sooner than the demonstration's April 1, 2021 implementation date. Individuals found to be out of compliance with the beneficiary engagement requirements will not receive the demonstration-only benefits for either one 6-month benefit period or two 6-month benefit periods, depending on which requirement(s) they did not meet, as listed in Table 2. Table 2 also includes a summary of the overarching monitoring and evaluation criteria for tracking and assessing compliance with the beneficiary engagement requirements. Additional monitoring and evaluation criteria to assess the beneficiary engagement policy outcomes are outlined in greater detail in STCs 33 and 34 (Section VIII) and STC 65 (Section XI). Beneficiaries will be notified of a change in access to demonstration benefits at the time of the benefit review which begins on the first day of the fifth month of the current benefit period. Because a benefit review may result in change in the benefits or services the beneficiary will receive, the state will follow the noticing requirements at 42 CFR 435.917.

The standard benefit package for New Adult Group members who are not pregnant, not under age 21, or not medically frail will be the "Basic" ABP available to this population through the state plan (State Plan Amendment NE 19-0014). New Adult Group members who are pregnant, under age 21, or medically frail are not enrolled in or affected by the demonstration. New Adult Group members who are pregnant and/or under age 21 will receive benefits, including dental services, vision services, and over-the-counter medications, through another ABP in the state plan, the "Prime" ABP (State Plan Amendment NE 19-0001). New Adult Group members who are medically frail receive full Medicaid state plan benefits that include vision, dental, and over the counter medication. If New Adult Group members who are age 21 through 64, not pregnant, and not medically frail meet the beneficiary engagement requirements stipulated in the STCs, they will also become eligible for demonstration-only benefits, as described in STC 20. Except as described in the following paragraph, beneficiaries newly enrolling in the demonstration will not receive the demonstration-only benefits during their initial benefit period, but will have the opportunity to opt into receiving those benefits starting with their second benefit period by meeting all applicable beneficiary engagement activities, as determined at the beneficiary's first benefit review.

During the period of the COVID-19 public health emergency as defined in 42 CFR 400.200, if an individual who was in another eligibility group before becoming part of the New Adult Group is determined to be eligible for the New Adult Group, the beneficiary must receive the demonstration-only benefits through the last day of the month in which the public health emergency declared by the Secretary of Health and Human Services for COVID-19, including any extensions, terminates, as long as Nebraska elects to claim the temporary FMAP increase described in Families First Coronavirus Response Act (FFCRA) section 6008, subject to the terms and conditions set forth in FFCRA section 6008.

Once the public health emergency is over, or Nebraska elects to no longer claim the temporary FMAP increase described in FFCRA section 6008, these beneficiaries must

comply with the beneficiary engagement requirements to receive the demonstration-only services.

Table 2. Beneficiary Engagement Categories and Activities, Result of Not Meeting Required Activities, and Summary Monitoring/Evaluation Criteria

Beneficiary Engagement Category	Beneficiary Engagement Activity	Result of Not Meeting Required Activity	Summary Monitoring and Evaluation Criteria
Wellness Initiatives	Attend Annual Health Visit	No access to demonstration-only benefits for one 6-month Benefit Period	- Track compliance with wellness initiatives, including preventive care utilization and completion of health risk screening - Evaluate linkage of compliance with wellness initiatives to physical and mental health status and coverage outcomes among demonstration population, in relation to suitable comparison groups
	Health Risk Screening (HRS) Completion		
Personal Responsibility	Attending Appointments	No access to demonstration-only benefits for two 6-month Benefit Periods	- Track compliance with personal responsibility activities, including maintaining employer-sponsored coverage - Assess linkage of personal responsibility activities to maintaining health coverage
	Maintaining Employer-Sponsored Coverage		
	Timely Change Notification		
Community Engagement	Engage in qualified community engagement activities in Table 4	No access to demonstration-only benefits for one 6-month Benefit Period	- Track number of beneficiaries subject to the community engagement requirement and proportion of these beneficiaries who met the requirement for qualifying activities and receiving demonstration-only benefits - Evaluate the effect on likelihood of having health coverage, in relation to suitable comparison population

V. DELIVERY SYSTEM

19. **Overview.** Beneficiaries who meet the criteria for the demonstration-only benefits will receive vision and over-the-counter medication benefits through the Heritage Health managed care program and dental benefits through the state's dental prepaid ambulatory health program (PAHP). The Heritage Health managed care program and dental PAHP are full-risk arrangements for which Nebraska Medicaid makes monthly capitation payments for each beneficiary. The Heritage Health managed care program and dental PAHP are authorized under Nebraska Medicaid's 1915(b) waiver authority.

VI. BENEFITS

20. **Demonstration-only Benefits.** The benefits available only through this demonstration to the HHA expansion group are described below.

Table 3. Demonstration-only Benefits

Benefit	Amount, Duration, and Scope of the Benefit
Optometrist Services	The amount, duration, and scope parameters for this demonstration benefit are the same as those described in the Medicaid state plan for beneficiaries receiving the Prime ABP through the state plan.
Eyeglasses	The amount, duration, and scope parameters for this demonstration benefit are the same as those described in the Medicaid state plan for beneficiaries receiving the Prime ABP through the state plan.
Dental Services	The amount, duration, and scope parameters for this demonstration benefit are the same as those described in the Medicaid state plan for beneficiaries receiving the Prime ABP through the state plan.
Dentures	The amount, duration, and scope parameters for this demonstration benefit are the same as those described in the Medicaid state plan for beneficiaries receiving the Prime ABP through the state plan.
Over-the-Counter Medications	The amount, duration, and scope parameters for this demonstration benefit are the same as those described in the Medicaid state plan for beneficiaries receiving the Prime ABP through the state plan.

VII. BENEFICIARY ENGAGEMENT ACTIVITIES: WELLNESS, PERSONAL RESPONSIBILITY, AND COMMUNITY ENGAGEMENT REQUIREMENTS

21. **General Requirements.** The goal of the demonstration is to incentivize beneficiaries to engage in wellness, personal responsibility, and community engagement activities; the state is testing whether engagement in these activities improves beneficiary health outcomes and thereby the fiscal sustainability of the Medicaid program in the state. This section describes these requirements. This STC explains the overall requirements for these activities, including the topics listed below. Further details, including operational details, can be found in the implementation plan.
- a. Beneficiary reporting associated with these requirements (e.g., how the state will determine that the requirements are met or how beneficiaries will be expected to report or attest compliance);
 - b. Timing of consequences of failing to meet requirements (e.g., define what is meant by a “benefit period” and how it is measured; explain when beneficiaries must establish they have met requirements; explain when someone would not be able to access the demonstration-only benefits if the requirements are not met);
- A benefit review period is 6 months. An individual’s benefit period begins on the first calendar day of the month the individual is enrolled in the population included in the demonstration, but in no case can begin sooner than the approved implementation date for the demonstration, which is April 1, 2021.
- c. How to get demonstration-only benefits back after losing them;
 - d. State assurances to ensure beneficiaries are protected.
22. **Wellness Initiatives.** For all years of the demonstration, but beginning no sooner than April 1, 2021, a beneficiary must complete two wellness initiatives to be eligible for the demonstration-only benefits: (1) actively participate in case and care management, defined as completing a health risk screening (HRS); and (2) attend an annual health visit. Beneficiaries will also be encouraged to select a primary care provider, though this is not required to be eligible for demonstration-only benefits. The state must describe the processes and documentation required for all of these requirements in its implementation plan. The state must prioritize minimizing undue burden on beneficiaries in designing and implementing these procedures. For example, the state will use an automated claims review process to identify beneficiaries who have completed an annual wellness visit, and the state will require the MCOs to report to the state on each enrolled beneficiary’s HRS completion status.
- a. **Case and Care Management.** HHA beneficiaries must actively participate in Case and Care Management in order to access demonstration-only benefits. Specifically, HHA beneficiaries must complete a health risk screening (HRS) upon enrollment and then annually. The HRS includes a set of Department of Health and Human Services (DHHS)-developed questions that include questions about physical health, behavioral health, and Social Determinants of Health (SDoH). SDoH questions are designed to assess the beneficiary’s economic stability, housing stability, food security, education

and job opportunities, intimate partner violence, community and social support, and access to health care, while the physical health and behavioral health questions are designed to assess the beneficiary's health status. The state will contractually require MCOs with which HHA expansion group beneficiaries are enrolled to assist the beneficiary in completing the HRS within 90 days of the beneficiary's initial enrollment and annually thereafter.

- b. **Annual Health Visit.** In order to support the early identification of serious health conditions and better ensure the delivery of care in the most appropriate and cost effective setting, HHA beneficiaries must attend a qualifying annual health visit as defined below as a condition of receiving the demonstration-only benefits. The state must not impose cost sharing for these visits. A qualifying annual health visit is either of the following:

- (1) The beneficiary could attend an annual appointment with their Primary Care Provider (PCP) for a comprehensive assessment and screening of health status. PCPs are defined as doctors of medicine (MD), doctors of osteopathic medicine (DO), nurse practitioners (NP), or physician assistants (PA) working within general practice, family practice, internal medicine, or OB/GYN.

- (2) Alternatively, the beneficiary could attend a visit with a specialist for an updated assessment of current diagnoses for which the beneficiary is receiving ongoing care or treatment from a provider in that specialty.

- i. **Beneficiary reporting requirements.** Beginning no earlier than April 1, 2021, to satisfy the annual health visit (AHV) requirement, HHA beneficiaries will have to complete a qualifying AHV within the first 10 months of enrollment in the demonstration. If a beneficiary voluntarily completes the AHV in the two months prior to the beginning of their first benefit period, the state will count that voluntary AHV towards meeting the mandatory AHV requirement. Beneficiaries will be allowed to provide documentation that they had a qualifying AHV prior to enrollment in the demonstration. Documentation for the AHV may include an explanation of benefits (EOB), qualified provider's medical document, or other documentation. The state will define other possible AHV documentation in its implementation plan.

The state will not review for a completed AHV at the beneficiary's first benefit review that takes place before his or her second benefit period, to determine eligibility for demonstration-only benefits for the second benefit period. The first review for the AHV requirement will be conducted during the beneficiary's second benefit review, before his or her third benefit period. This approach will allow HHA beneficiaries 10 months to complete the AHV from the date their first benefit period begins. For example, an HHA beneficiary whose first benefit period begins on April 1, 2021 will not be evaluated for compliance with the AHV requirement during the first benefit review that occurs prior to the second benefit period starting October 1, 2021. He or she will first be evaluated for compliance with the AHV requirement at

the second benefit review, which begins starting on the first day of the fifth month of the second benefit period, or February 1, 2022. Thus, in this example, the beneficiary would have until January 31, 2022 to complete the AHV. For subsequent benefit reviews, the state will review for a completed AHV within the twelve-month period preceding the first day of the fifth month of the beneficiary's current benefit period as part of the benefit review.

- c. **State Encouragement of Primary Care Provider (PCP) Selection.** The state encourages beneficiaries to choose their PCP. If a beneficiary does not select a PCP at the time of enrollment in one of the state's Medicaid managed care plans for the HHA expansion group, the state will work with the beneficiary's plan and the state's contracted enrollment broker to assign a PCP to the beneficiary. Beneficiaries will still be able to access demonstration-only benefits, if they do not select a PCP. The state will encourage this by having the MCOs send information and reminders for the beneficiary to select a PCP.
23. **Personal Responsibility Activities.** To receive demonstration-only benefits, a beneficiary must: (1) not miss three or more scheduled medical appointments in a six month benefit period; (2) maintain employer-sponsored coverage that is available and affordable to the beneficiary, as specified below; (3) timely notify the state of any changes in status that may impact the beneficiary's eligibility for demonstration-only benefits; and (4) participate in community engagement activities.
- a. **Attending Appointments.** HHA beneficiaries who do not attend three or more scheduled appointments (without good cause for missing the appointment) in the six-month benefit period preceding the current benefit period (the lookback period) will not be able to access the demonstration-only benefits for the subsequent two 6-month benefit periods. The beneficiary will once again be assessed for the demonstration-only benefits during the benefit review that begins on the first day of the fifth month of the second 6-month benefit period of suspended demonstration-only benefits. The state will contractually require MCOs to accept reports of missed appointments from participating providers exclusively through submission of \$0 claims to the MCO. The state will require the MCO to report these claims to the state. This requirement only affects beneficiaries who schedule an appointment and fail to attend or reschedule (in accordance with the provider's policy) for three or more appointments within the lookback period. The requirement does not affect a beneficiary who has not scheduled an appointment; a beneficiary is not required to seek to schedule appointments under the terms of the demonstration. Thus, a beneficiary's access to demonstration-only benefits would not be affected if he or she failed to schedule three or more appointments during the lookback period. During the beneficiary's initial benefit review, the state will not review for instances of missed appointments.

For example, for a beneficiary whose initial benefit period under the demonstration begins on April 1, 2021, the beneficiary will not be evaluated for compliance with the missed appointment requirement at the first benefit review, which begins August 1, 2021, for the benefit period starting October 1, 2021. The beneficiary would first be evaluated for compliance at his or her second benefit review, which begins February

1, 2022, for the benefit period starting April 1, 2022. The lookback period at this benefit review would be the beneficiary's initial benefit period, from April 1, 2021 through September 30, 2021. If the beneficiary missed three or more scheduled appointments during this lookback period, in violation of the provider's appointment policy and without good cause, then coverage for his or her demonstration-only benefits would be suspended for the two benefit periods from April 1, 2022 through September 30, 2022, and from October 1, 2022 through March 31, 2023. If the beneficiary has met the appointment attendance requirement and all other applicable requirements as determined during the benefit review that begins February 1, 2023 for the benefit period starting April 1, 2023, then the beneficiary's coverage for demonstration-only benefits would resume for that benefit period.

Nebraska will incorporate language into beneficiary materials including initial enrollment materials to communicate missed appointment requirements to HHA beneficiaries. HHA beneficiaries will be subject to the provider's appointment attendance policy so long as the provider adheres to the following criteria:

- The provider has a policy for missed appointments and the policy for Medicaid beneficiaries is the same as the policy for all other patients regardless of payer,
- The provider clearly describes the missed appointment policy to individuals seeking to schedule an appointment and makes a written copy of the policy available upon request, and
- If the provider's policy includes a fee charged to the patient/client for missing an appointment, that fee may not be assessed with respect to a Medicaid beneficiary.

If these conditions are met, then so long as the beneficiary contacts the provider to cancel or reschedule a scheduled appointment within the timeframes specified in the provider's missed appointment policy, the state cannot count this instance as a missed appointment.

- b. **Maintenance of Employer-Sponsored Coverage.** HHA beneficiaries who voluntarily discontinue employer-sponsored health coverage that meets the definition of "affordable" coverage as defined in Section 1401(a) of the Affordable Care Act (Internal Revenue Code Section 36B(c)(2)(C)(i)) and its implementing regulations, after obtaining demonstration enrollment, will not be able to access demonstration-only benefits for the first two full 6-month benefit periods following the report (or other discovery) of the beneficiary's voluntary disenrollment from affordable employer-sponsored coverage while enrolled in the demonstration. The state will review for instances of voluntary discontinuation of employer-sponsored coverage within the six months preceding the benefit review date. During the benefit review that occurs during the second 6-month benefit period of suspended demonstration-only benefits, the beneficiary will be assessed again for access to the demonstration-only benefits starting with the third benefit period following the report (or other discovery) of the voluntary disenrollment from affordable employer-sponsored coverage. During this benefit review, the beneficiary will not be further penalized for

the disenrollment from employer-sponsored coverage that originally caused him or her to lose access to demonstration-only benefits for two benefit periods.

- c. **Timely Change Notification.** This provision will not be implemented until April 1, 2022. If a beneficiary does not report a change in circumstances that may affect their access to demonstration-only benefits, such as a change with respect to the beneficiary's compliance with (or exemption from) the community engagement requirement, within the required reporting period as defined in Nebraska Medicaid Regulations, the beneficiary will not be able to access demonstration-only benefits for the following two full 6-month benefit periods. Compliance will be assessed at each benefit review; however, a beneficiary will not be penalized for reporting a change through the benefit review process if the benefit review period begins within the required reporting period for the change in circumstances. The state will review for instances of failure to timely report a change in circumstance within the six months preceding the benefit review date. During the benefit review that occurs during second 6-month benefit period of suspended demonstration-only benefits, the beneficiary will be assessed again for access to the demonstration-only benefits starting with the third benefit period following his or her failure to meet the timely change notification requirement.

For example, if a beneficiary who is not exempt from the community engagement requirement and who is required to report hours of participation in qualifying activities fails to timely report a reduction in his or her participation in qualifying activities below the required level, then he or she fails to meet the timely change notification requirement. For a beneficiary who enrolls in the demonstration on April 1, 2023, if the failure to meet the timely change notification requirement is discovered through the benefit review that begins on August 1, 2023, then the beneficiary's coverage for demonstration-only benefits would be suspended for the two benefit periods from October 1, 2023 through March 31, 2024, and from April 1, 2024 through September 30, 2024. If the beneficiary has met all applicable requirements as determined during the benefit review that begins August 1, 2024 for the benefit period starting October 1, 2024, then the beneficiary's coverage for demonstration-only benefits would resume for that benefit period.

In this example, as specified in this STC 23.d, the beneficiary could lose access to demonstration-only benefits for one six-month benefit period for failure to meet the community engagement requirement. Where a beneficiary loses access to demonstration-only benefits for failure to meet more than one applicable beneficiary engagement requirement, all benefit suspension periods will run concurrently, and not sequentially. In this example, the beneficiary's demonstration-only benefits would be suspended for a total of two six-month benefit periods, not three.

The state will conduct periodic data reviews of available electronic data sources to identify potential changes in beneficiaries' eligibility for the demonstration-only benefits. Processes and data sources used to determine a beneficiary's compliance with applicable requirements, including timely change of circumstances notification, will be included in the implementation plan.

- d. **Community Engagement.** Beginning on April 1, 2022, to be eligible for the demonstration-only benefits, non-exempt beneficiaries in the HHA expansion group must engage in a qualifying community engagement activity or a combination of activities outlined in Table 4. Individuals must meet one of the exemptions listed in Table 5 to be exempt from the community engagement requirement. Non-exempt individuals who successfully demonstrate that they had a good cause not to engage in a qualifying community engagement activity will remain eligible for the demonstration-only benefits. Non-exempt beneficiaries who, without good cause, do not participate in qualifying community engagement activities will not be able to access the demonstration-only benefits for one six (6) month benefit period, but will not lose Medicaid eligibility.
- i. Beginning April 1, 2022, for the first benefit period during which a beneficiary is subject to the community engagement requirement, the beneficiary must satisfy the requirement in at least four of the six months of the benefit period. For subsequent 6-month benefit periods (beginning no earlier than October 1, 2022), beneficiaries must meet the requirement in each of the 6 months preceding the beneficiary's benefit review, which begins on the first day of the fifth month of the current benefit period. The state may not require compliance with the community engagement requirements and may not implement subsequent consequences for failure to meet the requirement sooner than April 1, 2022. The state must allow individuals to report their compliance with community engagement requirements and qualification for exemptions and good cause waivers by all means described in 42 CFR 435.907(a).
 - ii. The state will request that beneficiaries attest to their compliance with, or exemption from, the community engagement requirements. The state will verify the attested information by leveraging existing sources defined in the state's Medicaid eligibility verification plan which are applicable for community engagement. For example, the state will verify compliance with the community engagement requirements through internal resources and electronic data sources. Sources include, but are not limited to, Nebraska Department of Labor, Nebraska Office of Vital Records, other state programs, and the U.S. Social Security Administration. If DHHS is able to verify compliance with (or exemption from) the community engagement requirement electronically, the beneficiary will not be required to provide additional documentation for the relevant period. If DHHS is unable to verify or electronic data sources are not available, additional documentation will be required. The beneficiary will be sent written notification when additional documentation is required. Beneficiary requirements regarding the submission of supporting documentation that establishes compliance with community engagement activities as well as the process by which a community engagement exemption or good cause exception can be requested will be detailed in the state's Implementation Plan. The state will seek to minimize undue burden on beneficiaries in designing and implementing these procedures. For example, if a beneficiary provides documentation that

demonstrates they are enrolled at least half-time in a college program for a specific semester, the beneficiary will not have to again attest to or document compliance with CE for the other months within that semester, provided the beneficiary does not experience a related change in circumstances. In no event will a beneficiary be required to attest to compliance with, or exemption from, the community engagement requirement, or to provide supporting documentation for such an attestation, more frequently than monthly.

Table 4. Qualifying Community Engagement Activities Applicable to STC 23 d

Qualifying Activities <i>Weekly/Monthly Hour Requirements are noted when applicable.</i>
Currently employed or self-employed and working at least 80 hours per month. <i>Can be combined with other qualifying activities to meet an applicable participation hours requirement.</i>
Participating in volunteer activities with a public charity for at least 80 hours per month.* <i>Can be combined with other qualifying activities to meet an applicable participation hours requirement.</i>
Enrolled at least half time in any accredited college, university, trade school, or post-secondary training program including refugee employment programs. Half time enrollment is specific to the definition used by the institution. <i>Students enrolled in a qualifying program less than half time can combine education and training hours with other qualifying activities to meet an applicable participation hours requirement.</i>
Participation in a course of study leading to a Certificate of General Equivalence (GED) for at least 80 hours per month. <i>Can be combined with other qualifying activities to meet an applicable participation hours requirement.</i>
Participation in a Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) recognized job search activity for at least 20 hours per week. (The beneficiary is not required to be receiving SNAP/TANF for the job search activity to qualify.) <i>Can be combined with other qualifying activities to meet the 80 hours per month an applicable participation hours requirement.</i>
* Public charities for purposes of the Community Engagement requirements are entities that, at the time the beneficiary is participating as a volunteer: (1) possess 501(c)(3) status; (2) are deemed to hold charity status under IRC 508(c) and corresponding regulations (and also operate within the applicable rules); and/or (3) are governmental entities.

Table 5. Community Engagement Exemptions Applicable to STC 23 d

Exemptions
Individuals participating in a substance use disorder or mental health treatment program.
Individuals receiving unemployment compensation, or who have applied for unemployment compensation and are fulfilling weekly work search requirements while in the waiting period. This includes individuals receiving Integrated Unemployment Compensation (IUC) or who are in compliance with IUC work search activities. *
Members of a federally recognized tribe.
High school students over age 21 who are attending at least half time.
Individuals aged 60 through 64.
Individuals residing in an area that has been granted a federal SNAP Able Bodied Adult Without Dependents (ABAWD) waiver due to insufficient jobs to provide employment.
Victims of domestic violence, when participation would make it harder to escape, penalize the individual, or put them at further risk of domestic violence.**
Individuals who are: - A parent, caretaker relative, guardian, or conservator of a dependent child;¹ or - A parent, caretaker relative, guardian, or conservator responsible for the care of an elderly or disabled relative; and who are providing care to these individuals in the home. To qualify for the exception, the parent, caretaker, guardian, or conservator of a dependent child must share a home with the child receiving care. Caretakers responsible for the care of relatives who are elderly or disabled, could qualify for the exception even if they live elsewhere and provide care in the home of the person receiving care.
Participation in the SNAP Employment and Training (E&T) program or otherwise meeting SNAP (ABAWD) requirements.
Participation in the Temporary Assistance for Needy Families (TANF) Employment First (EF) program.

¹ Nebraska Medicaid currently defines Parent/Caretaker Relative of a Dependent Child in 477 NAC 1. Available at: https://sos.nebraska.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-477/Chapter-01.pdf

Exemptions

* Participation in SNAP and/or TANF recognized job search for at least 20 hours per week is a qualifying community engagement activity. The beneficiary can also use these job search hours in combination with another qualifying community engagement activity to fulfill the community engagement requirement. Individuals who are terminated by their employer for cause or are otherwise not eligible for unemployment are able to fulfill their community engagement requirement with job search alone if completing at least 20 hours of job searching per week.

** A domestic violence exception for community engagement is allowable currently for Nebraska TANF participants. The current process to establish this exemption for TANF is based on an assessment by the State's employment contractor completed verbally with the individual to obtain the attestation of the situation and is completed every six months. If a Medicaid participant is also participating in TANF and has the exemption granted by the contractor, it will then be used to exempt the individual from Medicaid community engagement requirements. If the individual is not a TANF participant, the state's current domestic violence protocol for case restriction for Medicaid cases will be used to determine if the individual meets the exception. Domestic abuse notification is initiated by the beneficiary. The beneficiary provides a verbal account to a Medicaid eligibility worker; it does not require the individual to submit paper verification. The beneficiary's case is assigned to a dedicated staff member and assessed at the time of the individual's renewal of Medicaid eligibility.

24. **Good Cause.** At any point during the benefit period, a beneficiary may request a good cause exception in the event he or she experiences circumstances that constitute good cause for why he or she is not able to meet one or more applicable beneficiary engagement requirements. Additional detail regarding good cause can be found in STC 28c. The state must provide education and outreach to individuals about the opportunity to demonstrate good cause, and must give individuals the opportunity to seek to demonstrate good cause by all means described in 435.907(a). If it has already been suspended, a beneficiary's coverage for demonstration-only benefits will be reinstated to the date coverage was suspended, upon a successful demonstration of good cause for failure to meet an applicable beneficiary engagement requirement. Good cause will be assessed on a case-by-case basis.
25. **State Assurances Related to Beneficiary Engagement.** Prior to the implementation of the beneficiary engagement requirements as a condition of eligibility for demonstration-only benefits, the state must:
 - a. Ensure that specific activities that may be used to satisfy all beneficiary engagement requirements are available during a range of times and through a variety of means (e.g., online, in person).
 - b. Maintain system capabilities to operationalize the loss of demonstration-only benefits and the reinstatement of demonstration-only benefits once the beneficiary engagement requirements are met.

- c. Provide outreach and education, beyond standard noticing, at the time of enrollment in the demonstration to inform beneficiaries about the beneficiary engagement requirements and how they can be satisfied. Nebraska will maintain information on these topics on its public-facing website and employ other broad outreach activities that specifically target beneficiaries in the affected population.
- d. Ensure that timely and adequate beneficiary notice regarding all beneficiary engagement requirements is provided in writing. Beneficiary notices must include, but are not limited to including, the following information:
 - i. Whether a beneficiary is exempt from certain requirements, how the beneficiary must indicate to the state that she or he is exempt, and under what conditions the exemption would end;
 - ii. A list of the specific activities that may be used to satisfy beneficiary engagement requirements;
 - iii. Information about resources that help connect beneficiaries to opportunities for activities that would meet the beneficiary engagement requirements, and information about the community supports that are available to assist beneficiaries in meeting beneficiary engagement requirements;
 - iv. What gives rise to a denial or loss of demonstration-only benefits, what denial or loss would mean for the beneficiary, and how to avoid denial or loss of demonstration-only benefits, including how to apply for a good cause exception and what kinds of circumstances might give rise to good cause for failure to meet an applicable beneficiary engagement requirement;
 - v. If a beneficiary has sought to demonstrate good cause, that the application for a good cause exception has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial;
 - vi. If a beneficiary is not in compliance, that the beneficiary is out of compliance, and, if applicable, how the beneficiary can obtain eligibility for the demonstration-only benefits;
 - vii. If a beneficiary loses access to and/or is denied access to the demonstration-only benefits, information on how to appeal that decision and/or how to reinstate the demonstration-only benefits;
 - viii. The right of individuals with disabilities to reasonable modifications in beneficiary engagement requirements, with examples of the reasonable modifications in those requirements to which individuals may be entitled, including, assistance with documenting participation, exemptions from requirements if an individual is unable to participate for a disability-related reason, and reductions in hours of required participation if an individual is unable to participate in the otherwise required number of hours.

- ix. Notice requirements specific to community engagement include:
 - 1. The specific number of community engagement hours per month that a beneficiary is required to complete, and when and how the beneficiary must report participation or request an exemption;
 - 2. Any differences in the program requirements that beneficiaries will need to meet in the event they transition off SNAP or TANF but remain subject to the community engagement requirements of this demonstration;
 - 3. Information about how community engagement hours will be counted and documented;
- e. Provide outreach and education, beyond standard noticing, at the time of enrollment in the demonstration to inform beneficiaries about the beneficiary engagement requirements and how they can be satisfied. Nebraska will maintain information on these topics on its public-facing website and employ other broad outreach activities that specifically target beneficiaries in the affected population.
- f. Provide notice and fair hearing rights as required under 42 CFR 435.917 and 42 CFR part 431, subpart E prior to the denial of or loss of access to demonstration-only benefits and for denial of requests for good cause exceptions. As a part of the fair hearing process, beneficiaries must be allowed the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the denial of or loss of access to demonstration-only benefits, and provide additional documentation.
- g. Develop and implement an outreach strategy to inform demonstration enrollees how to report compliance with or exemption from the beneficiary engagement requirements, changes in circumstances that would affect eligibility for demonstration-only benefits, and how to request good cause exceptions. This outreach strategy must specify how notices provided at demonstration enrollment will provide information on resources available to beneficiaries who may require assistance reporting compliance with or exemption from the beneficiary engagement requirements, changes in circumstances that would affect eligibility for demonstration-only benefits, and/or requesting good cause exceptions.
- h. Establish appropriate beneficiary protections. For example, regarding community engagement requirements, appropriate beneficiary protections would include (but not be limited to) assuring that beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require employment or another form of community engagement.
- i. Make good faith efforts to connect beneficiaries to existing community supports that are available to assist beneficiaries in meeting the beneficiary engagement requirements, including available non-Medicaid assistance with transportation, childcare, language access services and other supports.

- j. For community engagement requirements, ensure the state will assess areas within the state that experience high rates of unemployment, areas with limited economies and/or educational opportunities, and areas with lack of public transportation to determine whether there should be further exemptions from the community engagement requirements and/or additional mitigation strategies, so that the community engagement requirements will not be unreasonably burdensome for beneficiaries to meet.
 - k. For community engagement requirements, develop and maintain an ongoing partnership with the Nebraska Department of Labor to assist recipients with identifying and accessing opportunities for workforce training, complying with community engagement requirements, and moving toward independence and self-sufficiency.
 - l. Provide each individual who has lost access to coverage for demonstration-only benefits with information on how to access the demonstration-only services (vision, dental and OTC) at low or no cost to the individual. This material will include information about free health clinics and community health centers including clinics. Nebraska 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 access to coverage for demonstration-only benefits.
26. **Protections for Beneficiaries with Disabilities.** The state must assure that the state is in compliance with protections for beneficiaries with disabilities under the ADA, Section 504, or Section 1557 of the Patient Protection and Affordable Care Act. In particular, the state must:
- a. Make good faith efforts to connect beneficiaries with disabilities as defined above with services and supports necessary to enable them to meet the beneficiary engagement requirements;
 - b. Maintain a system that provides reasonable modifications related to meeting the beneficiary engagement requirements to individuals with disabilities as defined above;
 - c. Ensure the state will assess whether people with disabilities have limited job or other opportunities for reasons related to their disabilities. If these barriers exist for people with disabilities, the state must address those barriers; and
 - d. Provide individuals with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting the beneficiary engagement requirements.
 - e. Ensure that the state will monitor the application of exemptions to ensure that there is not a disparate impact based on race or ethnicity.
27. **Reasonable Modifications.** The state must provide reasonable accommodations related to meeting all of the beneficiary engagement requirements 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, when necessary, to enable them to have an equal opportunity to participate in, and benefit from, the program. The state must also provide reasonable modifications for program protections and procedures, including but not limited to, understanding notices and program rules related to beneficiary engagement requirements, documenting beneficiary engagement activities, assistance with demonstrating eligibility for exemptions or circumstances that give rise to good cause; appealing denials and loss of access to the demonstration-only benefits; navigating ADA compliant web sites as required by 42 CFR 435.1200(f); and other types of reasonable modifications. Reasonable modifications must include exemptions from participation where the beneficiary is unable to participate or report for disability-related reasons, modification in the number of hours of participation required where a beneficiary is unable to participate for the otherwise-required number of hours for compliance with the community engagement requirement, and provision of support services necessary to participate, where participation is possible with supports. In addition, the state should evaluate a beneficiary's ability to participate and the types of reasonable modifications and supports needed.

28. **Non-Compliance.** Beneficiaries who are subject to the beneficiary engagement requirements and who do not meet the applicable requirements will not receive the demonstration-only benefits.
- a. Effective Date. Beneficiaries who fail to comply with the beneficiary engagement requirements, including those who do not have an exemption from meeting the community engagement requirements as described in STC 23 and do not have good cause exception as described in STC 24, will not receive the demonstration-only benefits for one to two six (6) month benefit periods (as described in Table 2 in STC 18). Loss of access to demonstration-only benefits will take effect on the first day of the first month of the next 6 month benefit period, unless an appeal is timely filed.
 - b. Re-establishment of Demonstration-only Benefits Following Non-Compliance. After the one- or two- 6-month demonstration-only benefit suspension period (as specified in Table 2), the beneficiary may regain coverage for demonstration-only benefits by meeting all beneficiary engagement requirements or qualifying for an exemption or good cause exception. Coverage will begin on the first day of the first month of the next 6-month benefit period.
 - c. Good Cause Exception for Beneficiary Engagement Requirements. The state will consider a beneficiary to be compliant with the beneficiary engagement requirements if the beneficiary demonstrates good cause for failing to meet one or more beneficiary engagement requirements during the benefit period or the benefit review period. Beneficiaries may report a good cause circumstance for the state's approval at any time, beginning as soon as the beneficiary becomes aware of the circumstance, until the date that 30 days after the date of the notice of action indicating the the beneficiary's coverage for demonstration-only benefits has been suspended for failure to satisfy the beneficiary engagement requirements. For example, a beneficiary has a benefit review date of August 1, 2022. The state completes the benefit review on August 1, 2022. This review results in a determination that the beneficiary will not

have access to the demonstration-only benefits due to the beneficiary having missed three scheduled appointments in violation of the provider's appointment policy. The notice of action is issued with a date of August 1, 2022. The beneficiary must report a good cause circumstance by August 31, 2022 to request a good cause exception for this violation. However, if the beneficiary sooner requests an appeal of the demonstration-only benefit suspension, the beneficiary must request a good cause exception through the appeal process, before the issuance of the appeal decision. As applicable, the circumstances constituting good cause must have occurred during the month(s) for which the beneficiary is seeking a good cause exception. The state must provide details regarding the good cause exception operational process in the implementation plan. The recognized circumstances that may support a good cause exception include, but are not limited to, the following verified circumstances:

- i. The beneficiary has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and is or was unable to meet the requirement for reasons related to that disability; or has an immediate family member who has a disability as defined by the ADA, section 504, or section 1557, and is or was unable to meet the requirement for reasons related to the disability of that family member;
- ii. The beneficiary or an immediate family member who is or was living in the home with the beneficiary experiences a hospitalization or a serious illness;
- iii. The beneficiary experiences the birth, or death, of a family member living with the beneficiary;
- iv. The beneficiary experiences severe inclement weather (including a natural disaster) and therefore is or was unable to meet the requirements;
- v. The beneficiary has a family emergency or other life-changing event (e.g., divorce or domestic violence); or
- vi. The beneficiary experiences a temporary or short-term illness documented by a clinician.

VIII. GENERAL REPORTING REQUIREMENTS

29. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or 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) calendar days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty (30) calendar days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
 - b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable 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.
 - e. 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.
30. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
31. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 waiver 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, Transformed Medicaid Statistical Information System (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.
32. **Implementation Plan.** The state must submit to CMS a draft Implementation Plan comprising two parts, as outlined and described below. The Implementation Plan must cover the key policies being tested under this demonstration, i.e., wellness initiatives, personal responsibility activities, and community engagement. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment A. At a minimum, the Implementation Plans 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 Plans include, reporting, and processing; notices; coordinated agency responsibilities; coordination with other insurance affordability programs; appeals; coordination with other state agencies; beneficiary protections; and outreach.
- a. Part 1 of the Implementation Plan will include two key beneficiary engagement categories being tested under this demonstration and effective beginning April 1, 2021. These include the Personal Responsibility (except community engagement) and the Wellness Initiatives. This component of the Implementation Plan is due to CMS no later than 90 calendar days after the approval date of the demonstration.
 - b. Part 2 will include the community engagement component of the demonstration, as will be effective beginning April 1, 2022. This part of the Implementation Plan is due to CMS no later than 90 calendar days after the HHA demonstration is effective (April 1, 2021).

The state must submit a revised Implementation Plan—for Part 1 and Part 2—within sixty (60) calendar days after receipt of CMS's comments on the initial submission, if any.

33. **Monitoring Protocol.** The state must submit to CMS for review and comment a draft Monitoring Protocol no later than one hundred fifty (150) calendar days after the approval date of the demonstration. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments, if any. Once approved, the Monitoring Protocol will be incorporated into the STCs as Attachment B.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS's template. Any proposed deviations from CMS's 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 34.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 the beneficiary engagement categories, such as wellness and personal responsibility initiatives and community engagement. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 34.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.

34. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework and template provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis. Upon CMS's review of each report, the state may be required to submit revisions to specific segments, if applicable, within a timeframe agreed upon by CMS and the state.
- a. Operational Updates - 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: beneficiary engagement, including community engagement. The performance metrics will also reflect all other components of the state's demonstration. For example, these metrics will cover enrollment in the demonstration, completion of wellness and personal responsibility initiatives and demonstration-only benefits granted for meeting them, participation in community engagement qualifying activities, demonstration-only benefit coverage, access to care, and health outcomes.
 - c. 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.

- d. 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.
 - e. Financial Reporting Requirements - Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
 - f. 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.
35. **Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of beneficiary engagement requirements, in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with state targets (e.g., substantial and sustained trends indicating increased difficulty accessing demonstration-only benefits by those making a good faith effort to choose to access them). A corrective action plan may be an interim step to withdrawing expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend expenditure authority or require CMS-specified programmatic changes to avoid suspension of expenditure authority, should corrective actions not effectively resolve these concerns in a timely manner.
36. **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 29.

37. **Monitoring Calls.** CMS will convene periodic conference calls with the state.
- a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
 - b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
 - c. The state and CMS will jointly develop the agenda for the calls.
38. **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) calendar days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

IX. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

39. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.²
40. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) calendar days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the

² For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

state, and include the reconciling adjustment in the finalization of the grant award to the state.

41. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XI:
- a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
42. **Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
- a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
 - b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.
43. **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
 - b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation

of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
 - d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
 - e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
44. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
45. **Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 6: Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW Per Capita	Brief Description
Demonstration-only Benefits	Hypo 1	X		X	Vision, dental, and over-the-counter medication benefits for demonstration-eligible New Adult Group beneficiaries who meet the demonstration's beneficiary engagement requirements

46. **Reporting Expenditures and Member Months.** For demonstration-only benefits, the state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00337/7). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.
- Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
 - Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
 - Pharmacy Rebates.** Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy

rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

- d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section VIII, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive demonstration-only benefits. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 7: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Demonstra tion-only Benefits	Demonstrati on-only benefits	n/a	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	04/1/2021	3/31/2026

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

Table 8: Demonstration Years		
Demonstration Year 1	April 1, 2021 through March 31, 2022	12 months
Demonstration Year 2	April 1, 2022 through March 31, 2023	12 months
Demonstration Year 3	April 1, 2023 through March 31, 2024	12 months
Demonstration Year 4	April 1, 2024 through March 31, 2025	12 months
Demonstration Year 5	April 1, 2025 through March 31, 2026	12 months

48. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in section X. CMS will provide technical assistance, upon request.³
49. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.
50. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

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

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 51. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.
- 52. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an

aggregate method is used, the state accepts risk for both enrollment and per capita costs.

53. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
54. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
55. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.
56. **Hypothetical Budget Neutrality Test 1:** The table below identifies the MEG that is used for Hypothetical Budget Neutrality Test 1. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.” MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against this budget neutrality expenditure limit. Any

expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 9: Hypothetical Budget Neutrality Test									
MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
Demonstration- only Benefits	PC	Both		5.5%	\$32.79	\$34.59	\$36.50	\$38.50	\$40.62

57. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
58. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from April 1, 2021 to March 31, 2026. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.
59. **Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the table below as a guide for determining when corrective action is required.
60. **Hypothetical Budget Neutrality Test(s)**

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent

DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XI. EVALUATION OF THE DEMONSTRATION

61. **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, 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 29.
62. **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.
63. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after the approval date of the demonstration.

Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

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

64. **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) calendar 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.
65. **Evaluation Questions and Hypotheses.** Consistent with Attachments C and D (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, 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). The state must consider hypotheses related to beneficiary understanding of and experience with wellness and personal responsibility initiatives and community engagement as an incentive for demonstration-only benefits, and the interface between these initiatives and incentives and coverage (including employer-sponsored health insurance and other commercial insurance) and health outcomes. In addition to evaluating health coverage outcomes, including demonstration-only benefits and commercial insurance, hypotheses for beneficiary engagement must also relate to (but are not limited to) outcomes such as employment levels, income, and health status. The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, and Medicaid health service expenditures. In addition, the state must use results of hypothesis tests and cost analyses to assess the demonstration's effects on Medicaid program sustainability.
66. **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.
67. **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 would make changes to the demonstration in its application for renewal, the report should include how the evaluation design would be adapted to accommodate the proposed policy changes. 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 a revised Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, and the state must post the final Interim Evaluation Report to the state's website.
 - e. The Interim Evaluation Report must comply with Attachment D (Preparing the Evaluation Report) of these STCs.
68. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment D (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 a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
 - b. Upon approval from CMS, the final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.
69. **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. A state corrective action plan could include a temporary suspension of implementation of beneficiary engagement requirements, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with state targets (substantial and sustained trends indicating increased difficulty accessing demonstration-only benefits by those making a good faith effort to choose to access them).

A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10, when evaluation evidence indicates substantial and sustained directional change inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend or require CMS-specified programmatic changes to avoid suspension of expenditure authority, should corrective actions not effectively resolve these concerns in a timely manner.

70. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.
71. **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.
72. **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.

XII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Due Date	Deliverable	STC
30 calendar days after approval date	State acceptance of demonstration Expenditure Authority and STCs	Approval letter
90 calendar days from the demonstration approval date	Draft Implementation Plan Part I for all beneficiary engagement requirements (with the exception of community engagement)	STC 32
60 calendar days after receipt of CMS comments on the Draft Implementation Plan Part I	Revised Implementation Plan Part I for all beneficiary engagement requirements (with the exception of community engagement)	STC 3232
90 calendar days after the demonstration is effective (Demonstration is effective April 1, 2021. Therefore, 90 days after April 1, 2021 is	Draft Implementation Plan Part II for the Community Engagement Requirements	STC 32

June 30, 2021.)		
60 calendar days after receipt of CMS comments on the Draft Implementation Plan Part II	Revised Implementation Plan Part II for the Community Engagement Requirements	STC 3232
150 calendar days from the demonstration approval date	Draft Monitoring Protocol	STC 33
60 calendar days after receipt of CMS comments on the Draft Monitoring Protocol	Revised Monitoring Protocol	STC 3333
180 calendar days from the demonstration approval date	Draft Evaluation Design	STC 63
60 calendar days after receipt of CMS comments on the Draft Evaluation Design	Revised Draft Evaluation Design	STC 64
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC 71
March 31, 2025 or With renewal application	Draft Interim Evaluation Report	STC 67.c
60 calendar days after receipt of CMS comments on the Draft Interim Evaluation Report	Revised Interim Evaluation Report	STC 67.d
Within 18 months after September 30, 2025	Draft Summative Evaluation Report	STC 68
60 calendar days after receipt of CMS comments on the Draft Summative Evaluation Report	Revised Summative Evaluation Report	STC 68.a
Monthly Deliverables	Monitoring Call	STC 37
Quarterly monitoring reports due 60 calendar days after end of each	Quarterly Monitoring Reports, including implementation updates; Quarterly Expenditure Reports	STC 34

quarter, except 4th quarter.		
Annual monitoring reports due (90) calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 34

**Attachment A:
Implementation Plan (Reserved)**

Attachment B:
Monitoring Protocol (Reserved)

Attachment C: Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions.

Technical assistance resources for constructing comparison groups, identifying causal inferences, and phasing implementation to support evaluation are available on Medicaid.gov:
<https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html>.

Expectations for Evaluation Designs

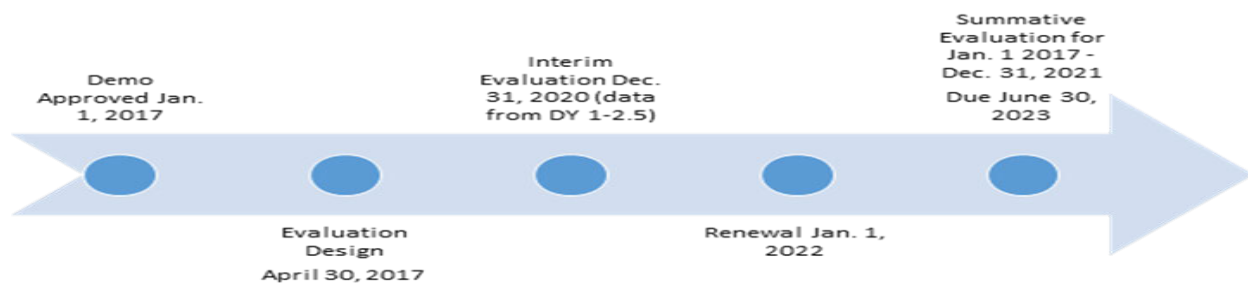
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

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

Attachment D: 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.

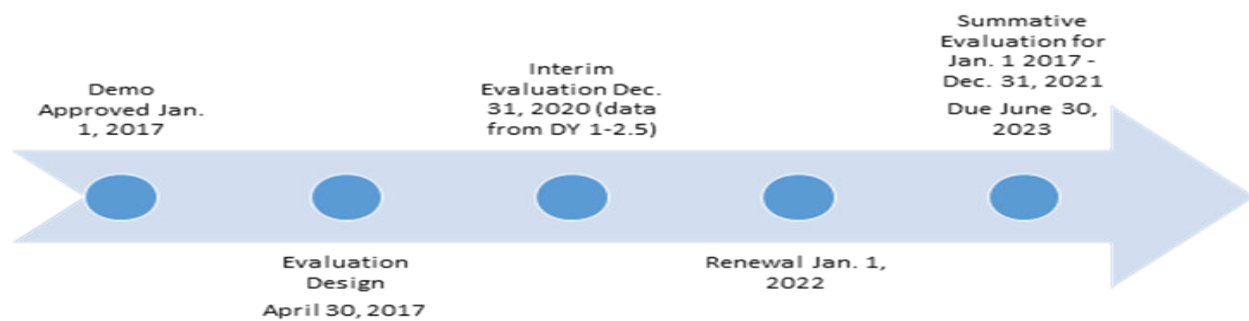
The format for the Interim and Summative Evaluation reports is as follows:

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 E:
Evaluation Design (Reserved)**