



*Administrator*  
Washington, DC 20201

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MAR 15 2019

Dear Ms. Corcoran:

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

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Ohio’s April 30, 2018, request for a section 1115 demonstration project entitled, “Group VIII Work Requirement and Community Engagement Section 1115 Demonstration” (Project No. 11-W-00323/5), in accordance with section 1115(a) of the Act.

This approval is effective March 15, 2019 through February 28, 2024, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. The state expects to implement the terms of the community engagement demonstration on January 1, 2021. CMS’s approval is subject to the limitations specified in the attached waiver authorities and special terms and conditions (STCs). The state may deviate from Medicaid state plan requirements only to the extent those requirements have been listed as waived.

### **Objectives of the Medicaid Program**

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to “enabl[e] each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or

retain capability for independence or self-care.” Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. But, there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence. Therefore, we believe an objective of the Medicaid program, in addition to furnishing services, is to advance the health and wellness needs of its beneficiaries, and that it is appropriate for the state to structure its demonstration project in a manner that prioritizes meeting those needs.

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries’ financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may “result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing.” Act § 1115(d)(1). But in the long term, they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

Section 1115 demonstration projects also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better “enabling each [s]tate, as far as practicable under the conditions in such [s]tate” to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or transition from Medicaid eligibility may decrease the number of individuals who need financial assistance, including medical assistance, from the state. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.<sup>1</sup> By the same

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<sup>1</sup> States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state’s program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of this new adult group became optional as a result of the Supreme Court’s decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they “have flexibility to start or stop the expansion.” CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by 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.

token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their Medicaid programs and to provide more medical services to more Medicaid beneficiaries. Accordingly, such demonstration projects advance the objectives of the Medicaid program.

### **Background on Medicaid Coverage in Ohio**

As of November 2018, Ohio's Medicaid program provides health coverage to over 2.4 million individuals. The Medicaid program includes non-mandatory populations, such as optional targeted low income children and independent foster care adults, in addition to the mandatory eligibility groups. The state also covers several categories of non-mandatory services, including prescription drugs, dental services, and clinic services, in addition to mandatory services. In addition, on January 1, 2014, Ohio expanded its Medicaid program to include coverage of the new adult group (also known as Group VIII) described at section 1902(a)(10)(A)(i)(VIII) of the Act.

Effective September 29, 2017, House Bill 49<sup>2</sup> generally requires Ohio's adult Medicaid expansion population to work and/or participate in community engagement activities as a condition of eligibility for Medicaid. In order to implement this state policy change, to help improve the overall health outcomes in Ohio, and to promote economic stability and financial independence of individuals, the Ohio Department of Medicaid submitted the section 1115 demonstration project application that CMS is approving today.

### **Extent and Scope of the Demonstration**

With approval of this demonstration, Ohio will require, as a condition of continued eligibility, that non-exempt beneficiaries in the new adult group at section 1902(a)(10)(A)(i)(VIII) of the Act, ages 19 through 49, engage in qualifying community engagement activities for at least 80 hours per month. CMS is providing the state with flexibility to exempt various groups that the state has determined are unlikely to be able to reasonably comply with the requirements, including: beneficiaries who are pregnant or 60 days or less post-partum; beneficiaries 50 years of age or older; beneficiaries who at the time of eligibility determination reside in an Ohio county approved by the U.S. Department of Agriculture, Food and Nutrition Service for a waiver of the Able-Bodied Adults Without Dependents (ABAWD) time limit; beneficiaries who are exempt for other reasons from Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) work registration or employment training requirements; beneficiaries who are applicants for or recipients of Supplemental Security Income

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<sup>2</sup> <http://codes.ohio.gov/orc/5166.37v1>: "The Medicaid director shall establish a Medicaid waiver under which an individual eligible for Medicaid on the basis of being included in the expansion eligibility group must satisfy at least one of the following requirements to be able to enroll in Medicaid as part of the expansion eligibility group: (A) Be at least fifty-five years of age; (B) Be employed; (C) Be enrolled in school or an occupational training program; (D) Be participating in an alcohol and drug addiction treatment program; (E) Have intensive physical health care needs or serious mental illness."

(SSI); beneficiaries who have applications pending for or are receiving unemployment compensation; beneficiaries who are Medicaid eligible but incarcerated; beneficiaries who are physically or mentally unfit for employment or other community engagement activities; beneficiaries who participate in the Specialized Recovery Services Program; beneficiaries caring for a disabled/incapacitated household member; parents, caretakers, or beneficiaries residing in the same household with a minor (defined as a child under 19); beneficiaries in school at least half-time, including GED programs; beneficiaries participating in a substance use disorder treatment; and beneficiaries identified as medically frail. Other non-exempt beneficiaries will have the opportunity to avoid the consequences of noncompliance by demonstrating a good cause for failure to meet the requirement.

To remain eligible for coverage, non-exempt beneficiaries must complete at minimum 20 hours per week (80 hours averaged monthly) of community engagement activities and report compliance on an annual basis. Non-exempt beneficiaries may satisfy this requirement through a variety of qualifying activities, including but not limited to, work or employment in exchange for money; self-employment; work in exchange for goods and services (“in kind” work); unpaid work, including formal and informal volunteer, community service, and public service activities; education and training activities, formal and informal job search or job readiness programs (for no more than 30 days per calendar year unless combined with another qualifying activity and less than half the required hours is spent in job search or job readiness programs or job search is the only activity completed); participation in and compliance with Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) work registration or employment and training (E&T) requirements.

Under Ohio’s demonstration, the state will notify beneficiaries of their need to participate in community engagement activities as a condition of continued coverage and eligibility. Beneficiaries will have 60 days post notification to report their compliance with the work and community engagement requirement. Beneficiaries will be allowed to report compliance with the work and community engagement requirement through methods consistent with the requirements in 42 CFR 435.907(a), such as in-person, over the phone, online or by mail. Once the beneficiary reports one time, no further reporting is required unless the beneficiary experiences a change in circumstance. If a beneficiary does not report within the 60 days that they are completing a qualifying activity, meet the criteria for an exemption, or experience a good cause circumstance, the beneficiary will be considered non-compliant and be disenrolled from Medicaid. Other than disenrollment, there are no additional penalties for noncompliance and the beneficiary will have the option of applying to re-enroll in Medicaid immediately. Prior non-compliance will not be a factor in any future determination of Medicaid eligibility.

Ohio requested to receive federal match for certain support services (e.g., transportation) to assist beneficiaries in meeting the community engagement requirement. CMS will not provide demonstration expenditure authority for these support services or any other costs associated with community engagement implementation. However, CMS can provide technical assistance if the state would be interested in learning whether costs to update state systems to reflect this approval, or other state administrative activities needed to implement the demonstration, may be federally matchable, either at the rates applicable to state expenditures on mechanized claims processing and information retrieval systems, or at the rate applicable to state administrative expenditures.

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

For reasons discussed below, the Secretary has determined that Ohio’s Group VIII Work Requirement and Community Engagement Section 1115 Demonstration is likely to assist in promoting the objectives of the Medicaid program.

**The demonstration promotes beneficiary health and financial independence.**

With approval of the demonstration, Ohio and CMS will be able to evaluate the effectiveness of a policy that is designed to improve the health of Medicaid beneficiaries and promote their financial independence. Promoting beneficiary health and independence advances the objectives of the Medicaid program. 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.”<sup>3</sup>

The Group VIII Work Requirement and Community Engagement Section 1115 Demonstration is designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that may lead to improved health and wellness. It is also likely to promote the objective of helping beneficiaries attain or retain financial independence. The community engagement provisions generally require demonstration beneficiaries to work, look for work, or engage in activities that enhance their employability, such as job-skills training, education, and community service. The demonstration will thus help the state and CMS evaluate whether the community engagement requirement helps adults in the demonstration transition from Medicaid to financial independence, thus reducing dependency on public assistance. In order to determine whether community engagement requirements adequately incentivize individuals to work as a condition of receiving Medicaid, the state will be required to track effects on employment, including new employment among Medicaid beneficiaries.

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

CMS has determined that the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration is likely to promote the objective of furnishing medical assistance because the demonstration, if successful, would promote the sustainability of Ohio’s Medicaid program. By making the community engagement requirement a condition of continued eligibility, Ohio expects that some beneficiaries will gain financial security and move off of public assistance. Additionally, if participating in community engagement activities improves beneficiaries’ physical and mental health, these beneficiaries may consume fewer health care resources, thus reducing state Medicaid costs.

Some beneficiaries could lose coverage if they elect not to comply with the demonstration’s community engagement requirements. However, it furthers the Medicaid program’s objectives to allow states to experiment with innovative means of deploying their limited state resources in ways that could facilitate the state’s ability to continue to provide services beyond the statutory minimum, as Ohio does by covering the adult expansion population, as well as optional benefits, including dental services, vision services, and targeted case management. Enhancing fiscal

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

sustainability allows the state to provide services to Medicaid beneficiaries that it could not otherwise provide.

By incentivizing community engagement, as described above, the demonstration is also designed to lead to higher quality care at a sustainable cost. Promoting improved health and wellness ultimately helps to keep health care costs at sustainable levels. To the extent that the demonstration helps individuals achieve improved health and financial independence, the demonstration may make these individuals less costly for Ohio to care for, thus further advancing the objectives of the Medicaid program by helping Ohio stretch its limited Medicaid resources, helping to ensure the long-term fiscal sustainability of the program, and helping to ensure that the health care safety net is available to those Ohio residents who need it most. And, to the extent the community engagement requirement helps individuals achieve financial independence and transition to commercial coverage, the demonstration would enhance the state's ability to provide medical services to those who most need the safety net.

While CMS and the state are testing the effectiveness of incentive structures that attach penalties for failure to meet community engagement requirements, the program is designed to make compliance with requirements achievable. Ohio has taken steps to include adequate beneficiary protections to ensure that the community engagement requirements apply only to those beneficiaries who can reasonably be expected to meet them, and to ensure that beneficiaries are notified of their responsibilities under the demonstration.

Beneficiaries also will have the opportunity to apply and re-enroll in Ohio Medicaid immediately after disenrollment, and their prior noncompliance with the community engagement requirements will not be factored into any subsequent application for eligibility. Any beneficiary who is disenrolled for failure to meet the requirements, or who experiences any other adverse action, will have the right to appeal the state's decision consistent with all existing appeal and fair hearing protections. Furthermore, the incentives to meet the requirements, if effective, may result in individuals becoming ineligible because they have attained financial independence – a positive result for the individual.

As described in the STCs, if monitoring or evaluation data indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. Further, CMS reserves the right to withdraw waiver authority at any time it determines that continuing the waiver authority would no longer be in the beneficiaries' interest or promote the objectives of Medicaid.

### **Consideration of Public Comments**

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

Section 1115(d)(2)(A) & (C) of the Act further specify that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary to address those comments, as might otherwise be



required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments.<sup>4</sup>

CMS received approximately 630 comments during the federal comment period on the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration proposal. Although CMS is not legally required to provide written responses to comments, CMS is addressing some of the central issues raised by the comments and summarizing CMS's analysis of those issues for the benefit of stakeholders. After carefully reviewing the public comments submitted during the federal comment period, CMS has concluded that the demonstration project advances the objectives of Medicaid.

### ***General comments***

The majority of the comments CMS received opposed either the demonstration as a whole or certain features of it. Some of those comments expressed general concerns that the demonstration will result in many poor citizens losing Medicaid, or, will create a barrier to accessing Medicaid.

CMS shares the commenters' concern that everyone who needs Medicaid and meets programmatic eligibility criteria should have access to Medicaid. However, CMS believes this demonstration is designed to make the eligibility criteria achievable, and the demonstration as a whole is worth testing to determine whether there is a more effective way to furnish medical assistance to the extent practicable under the conditions in Ohio. We recognize that some individuals may choose not to comply with the community engagement requirements imposed by the demonstration, and therefore, may lose coverage. We note that individuals might also lose coverage if they choose not to comply with other program requirements that exist outside of this demonstration, such as participating in the renewal process. But, the goal of this policy is to incentivize compliance, not to reduce coverage due to lack of compliance with the community engagement requirement.

CMS has incorporated safeguards into the STCs that are intended to minimize coverage loss due to noncompliance, and CMS is committed to partnering with Ohio to ensure that the new requirement is appropriately incentivizing community engagement, and not acting as an unreasonable barrier to eligibility. These safeguards include providing for a range of qualifying activities, such as self-employment; work in exchange for goods and services ("in kind" work); and unpaid work, which includes unpaid formal and informal volunteer, community service and public service activities. Also, CMS added the following circumstances to the list of circumstances that would give a beneficiary good cause to fail to comply: if the beneficiary experiences severe inclement weather (including a natural disaster); and if 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 (P.L. 111-148) and was unable to meet the requirement for reasons related to that disability, but was not exempted from community engagement requirements.

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

CMS has also worked with Ohio to include guardrails that will protect beneficiaries. The STCs contain a series of assurances, including that the state will: screen beneficiaries and determine eligibility for other bases of Medicaid eligibility and review for eligibility for insurance affordability programs prior to disenrollment; provide full appeal rights prior to disenrollment; ensure that there are timely and adequate beneficiary notices provided in writing which address community engagement requirement features; assess areas within the state that experience high rates of unemployment, areas with limited economic 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; monitor the application of exemptions to ensure that there is not a disparate impact based on race and ethnicity; and maintain a system that provides reasonable modifications related to meeting the community engagement requirements to beneficiaries with disabilities, among other assurances. The STCs include a provision granting CMS the authority to discontinue the demonstration if the agency determines that it is not promoting Medicaid's objectives. Moreover, CMS will regularly monitor the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration and will work with the state to resolve any issues that arise as Ohio works to implement the demonstration.

Furthermore, we anticipate that some beneficiaries' income will increase above the Medicaid eligibility threshold as a result of the community engagement incentives, and that they will obtain employer-sponsored coverage or other commercial coverage once they no longer qualify for the Medicaid program.

Finally, we note that in some cases, reductions in Medicaid costs can further the Medicaid program's objectives, such as when the reductions stem from reduced need for the safety net or reduced costs associated with healthier, more independent beneficiaries. These outcomes promote the best interests of the beneficiaries whose health and independence are improved, while also helping states stretch limited Medicaid resources and ensure the long-term fiscal sustainability of the states' Medicaid programs.

More generally, some comments also reflect a misunderstanding of the nature of a demonstration project. It is not necessary for a state to show in advance that a proposed demonstration will in fact achieve particular outcomes; the purpose of a demonstration is to test hypotheses and develop data that may inform future decision-making. As HHS previously explained, demonstration projects can "influence policy making at the [s]tate and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other [s]tates." 77 Fed. Reg. at 11680. For example, the Temporary Assistance for Needy Families (TANF) work requirements that Congress enacted in 1996 were informed by prior demonstration projects. *See, e.g., Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973) (upholding a section 1115 demonstration project that imposed employment requirements as conditions of AFDC eligibility). Regardless of the degree to which Ohio's demonstration project succeeds in achieving the desired results, the information it yields will provide policymakers real-world data on the efficacy of such policies. That, in itself, promotes the objectives of the Medicaid statute.

### ***Comments addressing coverage losses***

Some commenters expressed concern that the requested demonstration will cause some individuals to lose Medicaid coverage, and for that reason, the demonstration cannot be



considered to be consistent with the objectives of the Medicaid program. In assessing the coverage impact of proposed demonstration features, the state noted in its application that of the 710,000 beneficiaries expected to be enrolled in the new adult group, approximately 36,000 would not be considered exempt or currently working and would need to complete qualifying activities to comply with the community engagement requirement. Of the beneficiaries considered not to be exempt, the state estimates that 10 percent of beneficiaries will elect not to comply and would thus lose their Medicaid coverage.<sup>5</sup> Actual coverage impact will greatly depend on the choices made by each individual beneficiary, and it is therefore challenging to estimate the impacts of this new program before it even begins. It is important to CMS that for all community engagement requirements, compliance is achievable for every beneficiary subject to the new requirements, such that every beneficiary enrolled in Medicaid can stay enrolled in Medicaid unless and until they move into other forms of coverage or become ineligible for reasons such as income. In light of the safeguards discussed above, CMS has determined that compliance with Ohio's community engagement requirement is achievable for every beneficiary. Furthermore, CMS is undertaking vigorous evaluation and monitoring of a variety of metrics, including enrollment metrics.

While CMS and the state acknowledge that some beneficiaries may choose not to meet the requirements, the state is required to implement a number of strategies and supports to minimize coverage loss due to non-compliance with the community engagement requirement. For example, the state will conduct active outreach and education, beyond standard noticing, to help ensure that beneficiaries understand the requirements and how to comply. Ohio will maintain such information on its public facing website and employ other broad outreach activities that are specifically targeted to beneficiaries. The state must discuss at least the following topics in its Community Engagement Implementation Plan: application assistance, reporting and processing, notices, coordinated agency responsibilities, coordination with other insurance affordability programs, appeals, renewals, coordination with other state agencies, beneficiary protections, and outreach. The STCs also require the state to provide outreach and education to stakeholders regarding the community engagement requirement, including but not limited to updating the state's website and training employees. While some beneficiaries may respond to the new work

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<sup>5</sup> Ohio's initial application provided an estimate that 50 percent of those subject to the community engagement requirement that were not currently working would lose coverage. This 50 percent coverage loss estimate was based on an article published by consultants in a journal sponsored by the Society of Actuaries, which examined policy and fiscal considerations relating to community engagement programs more generally, and did not focus on any particular state's proposal. See Society of Actuaries Social Insurance & Public Finance Section "In the Public Interest Issue 16" Jan. 2018 pgs. 6-11. Jason Clarkson, Amanda Schipp, and Robert Dalmer *available at* [https://www.soa.org/Search.aspx?q=In%20the%20public%20interest,%20Issue%](https://www.soa.org/Search.aspx?q=In%20the%20public%20interest,%20Issue%20). This analysis was conducted prior to implementation of any community engagement demonstration in any state, and estimates, without providing any underlying calculations, that 50 to 75 percent of individuals are likely to comply with the community engagement requirement. However, the authors note that "the compliance rates are certain to vary by state depending on programmatic structure and policy decisions," meaning the study did not account for the experience that would occur in Ohio. Specifically, while the study considered some general exemptions in community engagement demonstrations, it did not reflect all the specific exemptions included in Ohio's demonstration, such as beneficiaries living in a county with an ABAWD waiver who would be exempt. This study also did not account for all of the structural safeguards offered by Ohio, including the process to assist beneficiaries who may be in need of assistance in finding a qualifying activity, the opportunity quickly to regain coverage lost due to noncompliance, the ramp up to implementation of the new requirement, or the additional assurances included in the STCs.

and community engagement requirements by choosing not to comply and forgoing coverage, the goal is for everyone participating in the program to successfully complete its requirements.

We also note that Ohio provides coverage to individuals in the new adult group (described at section 1902(a)(10)(A)(i)(VIII) of the Act) that it is not required to cover. Any potential loss of coverage that may result from a demonstration is properly considered in the context of a state's substantial discretion to eliminate non-mandatory benefits or to eliminate coverage for existing (but non-mandatory) populations, such as (in light of the Supreme Court's ruling in *NFIB v. Sebelius*) the ACA adult expansion population. As of February 2019, more than 613,000 individuals are enrolled in Medicaid under Ohio's state plan as a result of Ohio's decision to participate in the ACA adult eligibility expansion. Moreover, conditioning eligibility for Medicaid coverage on compliance with certain measures is an important element of the state's efforts, through experimentation, to improve beneficiaries' health and independence and enhance programmatic sustainability. To create an effective incentive for beneficiaries to take measures that promote health and independence, it may be necessary for states to attach penalties to failure to take those measures, including with conditions designed to promote health and financial independence. This may mean that beneficiaries who fail to comply will lose Medicaid coverage, at least temporarily. However, the incentive included in Ohio's demonstration is not designed to encourage this result; rather, it is intended to incorporate achievable conditions of continued coverage. And, any loss of coverage as a result of noncompliance must be weighed against the benefits Ohio hopes to achieve through the demonstration project, including both the improved health and independence of the beneficiaries who comply and the state's enhanced ability to stretch its Medicaid resources and maintain the fiscal sustainability of the program.

It would be counterproductive to deny states the flexibility they need to implement demonstration projects designed to examine innovative ways to incentivize beneficiaries to engage in behaviors that improve health outcomes and lower healthcare costs, as well as innovative ways to stretch limited state resources, given that states have the prerogative to terminate coverage for non-mandatory services and populations. Because a demonstration project, by its nature, is designed to test innovations, it is not possible to know in advance the actual impact that its policies will have on enrollment, especially when the impact is dependent on beneficiary behavior. Through monitoring of enrollment and other performance metrics, CMS will be able to observe trends and patterns that suggest possible effects of these policies. It will take robust evaluation to determine the causal influences of the demonstration on enrollment. 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.

Furthermore, the Ohio Medicaid program covers other non-mandatory populations such as independent foster care adults, as well as non-mandatory services such as dental services. As a matter of federal law, it is the state's prerogative to reduce or eliminate non-mandatory coverage. Such judgements are left to the policy preferences of the state government and its electorate, and state are to be given great latitude in making tradeoffs in how the state furnishes medical assistance "as far as practicable under the conditions" in the state. Act § 1901. In evaluating Ohio's demonstration project, it is appropriate to consider the possibility of coverage loss against the benefits that may accrue to the state's other Medicaid eligibility groups as a result of the beneficiaries who are subject to the community engagement requirements growing more independent, healthier, and less expensive to cover. Ohio will measure actual effects on

enrollment as part of the demonstration, and that information should be useful in informing future Medicaid policy.

### ***Comments on Community Engagement***

General comments reflect a misunderstanding of the nature of the community engagement requirement, which the comments described as a work requirement. The community engagement requirement is designed to help individuals achieve financial independence and transition into employer-sponsored or other commercial coverage. CMS and Ohio have developed a broad range of qualifying activities that beneficiaries could engage in to comply with the community engagement requirement.

Many commenters expressed concern that the community engagement requirement is not necessary because many beneficiaries are already working, going to school, or engaging in some other employment and training activity. CMS and Ohio acknowledge that many beneficiaries are already working or attending school and we note that these activities are included as qualifying activities that beneficiaries can engage in to comply with the community engagement requirement. In order to determine whether community engagement requirements adequately incentivize individuals to work as a condition of receiving Medicaid, the state will be required to track effects on employment, including new employment among Medicaid beneficiaries.

Other commenters expressed concern regarding how the community engagement requirement will impact individuals with disabilities, noting that people with disabilities either may not be able to work or may not be able to find work which can accommodate their needs. Participation in this demonstration is limited to adults aged 19 through 49 eligible under the state plan consistent with section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR § 435.119, meaning that it will not impact individuals eligible for Medicaid on the basis of a disability. We also note that beneficiaries who are applicants for or recipients of Supplemental Security Income (SSI); beneficiaries who are physically or mentally unfit for employment or other community engagement activities; and beneficiaries identified as medically frail are exempt. Further, as a condition of approval for this demonstration, the state must provide reasonable modification related to meeting the community engagement requirements for beneficiaries with disabilities, when necessary, to enable them to have an equal opportunity to participate in, and benefit from, the demonstration. This includes exempting individuals with disabilities from community engagement requirements when they are unable to comply for reasons related to their disabilities. Other commenters expressed concern about the potential impact on individuals with substance use disorder (SUD). CMS and Ohio share the commenters' concern that the community engagement requirement should not unduly burden individuals with disabilities, including those with substance use disorder (SUD). Regarding individuals with SUD, the individuals who participate in the Specialized Recovery Services Program or who are participating in a SUD treatment are exempt from the community engagement requirement.

Several commenters expressed concern that individuals who wish to be employed may not always be able to maintain full or part-time employment due to job loss or the temporary or seasonal nature of some positions and would not be able to meet the community engagement requirement. CMS and Ohio recognize that it may not always be possible for an individual to be employed. Therefore, community engagement is structured to be more than a work requirement and includes non-employment qualifying activities, including but not limited to: community service; education; job search activities; and job readiness programs. Furthermore, the state will

exempt beneficiaries who have applications pending or are receiving unemployment compensation.

CMS notes that while some of the qualifying activities that meet the community engagement requirement may not immediately cause all beneficiaries to be financially independent, those activities are nonetheless positive steps for beneficiaries to take on their path to financial independence. In addition, participation in these activities may reduce social isolation, which multiple studies have linked to higher rates of mortality.<sup>6</sup> At the very least, whether or not the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration community engagement requirement will lead to beneficiaries' financial independence is an open question, which is why this demonstration project is necessary to test whether the incentive structure will have the desired effect. That is also why CMS will regularly evaluate the effects of this demonstration on affected beneficiaries and reserves the right to discontinue specific waiver authorities if CMS determines that it would no longer be in the public interest or promote Medicaid's objectives to continue them. Moreover, even if those activities do not cause beneficiaries to become financially independent, they are nevertheless correlated with improved health outcomes, which itself furthers Medicaid's objectives.

### ***Comments on Racial Disparities***

Many commenters suggested that the demonstration, as structured in the state's initial application, would create racial disparities by allowing an exemption from the community engagement requirement for beneficiaries who reside in the 26 Ohio counties which, at that time, had been granted a waiver of SNAP work requirements for the Able-Bodied Adults without Dependents (ABAWD) time limit. Some of the public comments on the demonstration expressed concern about the data showing that the counties with SNAP exemptions have a higher percentage of white residents than other counties, and therefore that this exemption could have a disparate impact on the basis of race.

We understand that, beginning in and for the duration of, federal fiscal year (FFY) 2019, 12 additional counties in Ohio have been added to the SNAP waiver, including 2 counties with large urban areas. CMS and the state have analyzed the demographic makeup of the exempted counties, based on 2017 United States Census Bureau data. When comparing the 38 counties with a waiver of SNAP work requirements against the remaining 50 counties in Ohio, the Census data show that the racial makeup is similar. This reduces the concern raised by commenters.

CMS appreciates the concerns raised by commenters and has determined that it would also be prudent for CMS and Ohio to monitor this issue. The state will assess areas within the state that experience high rates of unemployment, areas with limited economic 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. The state also will monitor the application of exemptions to ensure that there is not a disparate impact based on race and ethnicity.

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<sup>6</sup> Holt-Lunstad J, Smith TB, Baker M, Harris T, Stephenson D. Loneliness and social isolation as risk factors for mortality: a meta-analytic review. *Perspect Psychol Sci* 2015;10:227–37. [PubMed]

We are cognizant of the state's interest in aligning the demonstration's community engagement requirement, to the extent practicable, with the state's SNAP work requirement. Aligning the community engagement requirements with the state's SNAP work requirement will help reduce both beneficiaries' burden and their potential confusion.

***Comments on Administrative and Financial Burden***

Some comments suggested that a community engagement requirement would burden the state's administrative functions at the county level of social services and could lead to increased costs for the state.

CMS acknowledges that implementing section 1115 demonstration projects may involve increased administrative costs, particularly during the early stages of a demonstration. However, over time, demonstrations designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or 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, Ohio will leverage existing state processes and systems to minimize confusion and administrative burden and cost for the state and beneficiaries.

**Other Information**

CMS's approval of this demonstration project is conditioned upon compliance with the enclosed list of waiver authorities and the STCs defining the nature, character, and extent of anticipated federal involvement in the 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. Rachel Nichols. She is available to answer any questions concerning your section 1115 demonstration. Ms. Nichols' contact information is as follows:

Centers for Medicare & Medicaid Services  
Center for Medicaid and CHIP Services  
Mail Stop: S2-02-28  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
Email: [Rachel.Nichols@cms.hhs.gov](mailto:Rachel.Nichols@cms.hhs.gov)

Official communications regarding program matters should be sent simultaneously to your project officer and Mr. James Scott, Director of Field Operations North. Mr. Scott's contact information is as follows:

Mr. James Scott  
Director  
Centers for Medicare & Medicaid Services  
Richard Bolling Federal Building  
601 East 12<sup>th</sup> Street, Room 355  
Kansas City, MO 64106-2808  
Email: [James.Scott1@cms.hhs.gov](mailto:James.Scott1@cms.hhs.gov)

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

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

Sincerely,



Seema Verma ✓

Enclosures



cc: James Scott, Director, Division of Field Operations North

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

**NUMBER:** 11-W-00323/5

**TITLE:** Group VIII Work Requirement and Community Engagement Section 1115 Demonstration

**AWARDEE:** Ohio Department of Medicaid

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived shall apply to the demonstration project effective from March 15, 2019 through February 28, 2024. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

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

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

To the extent necessary to enable Ohio to require community engagement as a condition of continued eligibility as set forth in these STCs.

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

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

**NUMBER:** 11-W-00323/5

**TITLE:** Group VIII Work Requirement and Community Engagement Section 1115 Demonstration

**AWARDEE:** Ohio Department of Medicaid

**I. PREFACE**

The following are the Special Terms and Conditions (STCs) for the Ohio Group VIII Work Requirement and Community Engagement Section 1115 Demonstration (hereinafter “demonstration”) to enable the State of Ohio (hereinafter “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of requirements under section 1902(a) of the Social Security Act (Act). These STCs further set forth in detail the nature, character, and extent of federal involvement in the demonstration, the state’s implementation of the waiver, and the state’s obligations to CMS related to this demonstration. The demonstration will be statewide and is approved from March 15, 2019 through February 28, 2024. The state intends to implement January 1, 2021.

The STCs are effective on the date of the signed approval. The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility
- V. Benefits
- VI. Premiums & Cost-Sharing
- VII. Delivery System
- VIII. Community Engagement Requirement
- IX. General Reporting Requirements
- X. General Financial Requirements
- XI. Monitoring Budget Neutrality
- XII. Evaluation of the Demonstration

Attachment A: Developing the Evaluation Design  
Attachment B: Preparing the Evaluation Report  
Attachment C: Evaluation Design (reserved)  
Attachment D: Implementation Plan (reserved)  
Attachment E: Monitoring Protocol (reserved)

## II. PROGRAM DESCRIPTION AND OBJECTIVES

To help improve the overall health outcomes in Ohio, and to promote the economic stability and financial independence of beneficiaries who would be subject to the community engagement requirement in this demonstration, the Ohio Department of Medicaid (ODM) submitted the “Group VIII Work Requirement and Community Engagement Section 1115 Demonstration” on April 30, 2018 to implement a statewide community engagement requirement for CMS review and approval.

On March 15, 2019, CMS approved the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration, which the state intends to implement January 1, 2021. The group affected by this demonstration are the beneficiaries referred to in section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119, also referred to as the “New Adult Group.”

Ohio is applying the community engagement requirement (described in STCs 21-29) to adult beneficiaries ages 19 through 49 in the Group VIII Work Requirement and Community Engagement Section 1115 Demonstration, with exemptions for various groups, including: beneficiaries who are pregnant or 60 days or less post-partum; beneficiaries 50 years of age or older; beneficiaries at the time of eligibility determination, live in an Ohio county approved by the U.S. Department of Agriculture. Food and Nutrition Service for a waiver of the Able-Bodied Adults Without Dependents time limit; beneficiaries who are exempt for other reasons from Supplemental Nutrition Assistance Program and/or Temporary Assistance for Needy Families work registration or employment training requirements; beneficiaries who are applicants for or recipients of Supplemental Security Income; beneficiaries who have applications pending for or are receiving unemployment compensation; beneficiaries who are Medicaid eligible but incarcerated; beneficiaries who are physically or mentally unfit for employment or other community engagement activities; beneficiaries who participate in Specialized Recovery Services Program; beneficiaries caring for a disabled/incapacitated household member; parents, caretakers, or beneficiaries residing in the same household with a minor (defined as a child under 19); beneficiaries in school at least half-time; beneficiaries participating in a substance use disorder treatment; or beneficiaries identified as medically frail. Other non-exempt beneficiaries will have the opportunity to avoid the consequences of noncompliance by demonstrating a good cause for failure to meet the requirement.

To remain eligible for coverage, non-exempt beneficiaries must complete at minimum 20 hours per week (80 hours averaged monthly) of work and/or community engagement activities. Non-exempt beneficiaries may satisfy this requirement through a variety of qualifying activities, including work or employment in exchange for money; self-employment; work in exchange for goods and services (“in kind” work); unpaid work, including formal and informal volunteer, community service, and public service activities; education and training activities, formal and informal job search or job readiness programs (for no more than 30 days per calendar year unless combined with another qualifying activity and less than half the required hours is spent in job search or job readiness programs or job search is the only activity completed); participation in and compliance with Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) work registration or employment and training (E&T) requirements; or other qualifying community engagement activities.

Group VIII Work Requirement and Community Engagement Section 1115 Demonstration  
Approval Period: March 15, 2019 – February 28, 2024

Under Ohio’s demonstration, after a beneficiary is determined eligible for Medicaid, the state will notify beneficiaries of whether they are required to participate in community engagement activities as a condition of eligibility or whether they are exempt. Non-exempt beneficiaries will have 60 days after this notification to report their compliance with the work and community engagement requirement. Beneficiaries will be allowed to report compliance with the work and community engagement requirement consistent with the requirements in 42 CFR 435.907(a) (such as in-person, over the phone, online, or by mail). Once the beneficiary reports one time, no further reporting is required unless the beneficiary experiences a change in circumstance consistent with 42 CFR 435.916(c). If a beneficiary does not report within the 60 days that they are completing a qualifying activity, meet the criteria for an exemption, or experience a good cause circumstance, the beneficiary will be considered non-compliant and be disenrolled from Medicaid. Other than disenrollment, there are no additional penalties for non-compliance and the beneficiary will have the option of applying to re-enroll in Medicaid immediately. Prior non-compliance will not be a factor in any future determination of Medicaid eligibility.

### **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 Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, to ensure they understand program rules and notices, in establishing eligibility for an exemption from community engagement requirements on the basis of disability, and to enable them to meet and document the community engagement requirement, as well as meeting other program requirements necessary to obtain and maintain benefits.
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and written policy, not expressly waived in the waiver document (of which these terms and conditions are part), apply to the demonstration.
- 3. Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
  - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under 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 instances, the Medicaid state plan governs.
- 6. Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, whether for administrative or service-based expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as found in this STC, and failure by the state to submit reports required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
- a. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;
  - b. A data analysis worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable “with waiver” and “without waiver” status on both a summary



and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

- c. An explanation of the public process used by the state consistent with the requirements of STC 13; and
- d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

**8. Extension of the Demonstration.** States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 Code of Federal Regulations (CFR) 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.

**9. Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

- a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
- b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information regarding the beneficiary’s appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase-Out Plan Approval: The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out

activities. Implementation of transition and phase-out activities must begin no sooner than 14 days after CMS approval of the transition and phase-out plan.

- d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to demonstration beneficiaries as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- 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. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP): FFP will be limited to normal closeout costs associated with termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

- a. Expiration Requirements. The state must include, at a minimum, in its demonstration authority expiration plan, the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to termination of the demonstration authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.
- b. Expiration Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and

431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

- c. Federal Public Notice. CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the 30-day period during its review of the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.
- d. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the expiration of the demonstration authority including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

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

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

**13. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the

demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such a request.

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

The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

**14. Federal Financial Participation (FFP).** No federal matching for state expenditures under this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

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

**IV. ELIGIBILITY**

**16. Populations Affected by the Demonstration.** This demonstration affects adults aged 19 through 64 eligible under the state plan consistent with section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119. Eligibility and coverage for these individuals are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan except to the extent expressly waived in this demonstration and consistent with these STCs.

<b>Table 1. Medicaid Eligibility Groups Affected by Demonstration</b>	
<b>Eligibility Group</b>	<b>Citations</b>
New adult group	1902(a)(10)(A)(i)(VIII) 42 CFR 435.119

## V. BENEFITS

- 17. Benefits for Participants in the Demonstration.** Beneficiaries who are eligible for the demonstration will receive the same benefits as set forth in section 1905(y)(2)(B) of the Act and in 42 CFR 433.204(a)(2) and described in the Medicaid State Plan.
- 18. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT).** The state must comply with all requirements regarding EPSDT services established by federal law and regulation.

## VI. PREMIUMS & COST SHARING

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

## VII. DELIVERY SYSTEM

- 20. Delivery System.** Demonstration beneficiaries will receive services through the same managed care and fee-for-service arrangements as currently authorized in the state.

## VIII. COMMUNITY ENGAGEMENT REQUIREMENT

- 21. Overview.** The state will implement a community engagement requirement as set forth in STCs 22-29, as a condition of continued eligibility for beneficiaries in the demonstration who are not exempt and who do not demonstrate good cause. The state will provide outreach and education to stakeholders regarding the community engagement requirement, including but not limited to updating the state's website and training employees.
- 22. Exempt Populations.** The following beneficiaries are exempt from the community engagement requirement:
- a. Pregnant women and women during the 60-day postpartum period beginning on the last day of the pregnancy;
  - b. Beneficiaries 50 years of age or older;
  - c. Beneficiaries who, at the time of eligibility determination, reside in an Ohio county approved by the U.S. Department of Agriculture, Food and Nutrition Service (FNS) for a waiver of the Able-Bodied Adults without Dependents (ABAWD) time limit;
  - d. Beneficiaries who are exempt for other reasons from Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) work registration or employment and training (E&T) requirements;
  - e. Beneficiaries who are applicants for or recipients of Supplemental Security Income (SSI);
  - f. Beneficiaries who have applications pending for, or are receiving, unemployment compensation;
  - g. Beneficiaries who are Medicaid eligible but incarcerated;

- h. Beneficiaries who are physically or mentally unfit for employment or other community engagement activities;
- i. Beneficiaries who participate in the Specialized Recovery Services Program;
- j. Beneficiaries caring for a disabled/incapacitated household member;
- k. Parents, caretakers, or beneficiaries residing in the same household with a minor child (defined as a child under age 19);
- l. Beneficiaries in school at least half-time including GED programs (as defined by the state in its Community Engagement Implementation Plan, see STC 33);
- m. Beneficiaries participating in a substance use disorder treatment; or
- n. Beneficiaries identified as medically frail (as defined by the state in its Community Engagement Implementation Plan, see STC 33).

**23. Qualifying Activities.** Non-exempt beneficiaries may satisfy their community engagement requirement through participation in one or more of the following activities, including but not limited to:

- a. Work or employment in exchange for money;
- b. Self-employment;
- c. Work in exchange for goods and services (“in kind” work);
- d. Unpaid work, which includes unpaid formal and informal volunteer, community service and public service activities;
- e. Education and training activities;
- f. Formal (facilitated) and informal (independent) job search or job readiness programs (for no more than 30 days in a year unless combined with another qualifying activity and less than half the required hours are spent in job search or job readiness programs or job search is the only activity completed); or
- g. Participation in and compliance with Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) work registration or employment and training (E&T) requirements.

**24. Hour Requirement.** Beneficiaries who do not meet exemption criteria described in STC 22 or who do not need a reasonable modification related to this hour requirement described in STC 25 must participate in one of the qualifying activities, or a combination of the qualifying activities listed in STC 23 for a minimum of 20 hours per week (80 hours averaged monthly) to meet the community engagement requirement. Beneficiaries who engage in extra hours of qualifying activities above what is required in a week can apply the extra hours to other weeks within that same month, but cannot apply those extra hours to any other month.

**25. Reasonable Modifications.** The state must provide reasonable modifications related to meeting community engagement requirements for beneficiaries with disabilities as defined under the ADA, Section 504, or Section 1557, when necessary, to enable them to have an equal opportunity to participate in, and benefit from, the program. The state must also provide reasonable modifications for program protections and procedures, including but not limited to: assistance with demonstrating good cause; appealing suspensions; documenting qualifying activities and other documentation requirements; understanding notices and program rules; 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 a beneficiary is unable to participate for disability-related reasons, modification in the number of hours of participation required where an individual is unable to participate for the required number of hours, and provision of support services necessary to participate, where participation is possible with supports. In addition, the state must evaluate beneficiaries' ability to participate and the types of reasonable modifications and supports needed.

- 26. Application of the Community Engagement Requirement.** After implementation of the community engagement requirement, after a beneficiary is determined eligible for Medicaid (for new applicants), or, following Medicaid eligibility renewal (for current beneficiaries) the state will notify beneficiaries of whether they are required to participate in community engagement activities as a condition of continued eligibility or whether they are exempt. Non-exempt beneficiaries will have 60 days after this notification to report their compliance with the work and community engagement requirement (and may self-attest to meeting the community engagement requirement during that time). Beneficiaries will be allowed to report compliance with the work and community engagement requirement consistent with requirements in 42 CFR 435.907(a), (such as in-person, over the phone, online, and by mail). Once the beneficiary reports one time, no further reporting is required unless the beneficiary experiences a change in circumstance consistent with 42 CFR 435.916(c).
- 27. Renewal.** The state will follow the standard renewal process set forth in 42 CFR 435.916 and the notice requirements set forth in 42 CFR 435.917, 435.918, and 435.1200(h), including the use of an ex parte review process and prepopulated renewal forms, for all beneficiaries (exempt and non-exempt) subject to the demonstration. Information regarding a beneficiary's community engagement status (meaning, either how the beneficiary is exempt or how the beneficiary is meeting the community engagement requirement) will be included alongside this standard process and included in the prepopulated renewal form. The state will use this information to notify beneficiaries of their status with meeting the requirement and next steps, if any, the beneficiary needs to complete.
- 28. Non-Compliance.** The state will determine a beneficiary to be non-compliant with the community engagement requirement if the state is unable to verify via data available through state systems and data sources that the beneficiary is compliant or if the beneficiary has not reported their compliance to the state within 60 days of being notified that they are required to participate in community engagement. If a compliant beneficiary later notifies the state that they have become non-compliant, they will have 60 days from that notification to report their compliance. Prior written notice of adverse action will be provided to beneficiaries to ensure their due process rights, with disenrollment of their Medicaid coverage effective when the adverse action period expires. A beneficiary will be disenrolled from Medicaid for non-compliance with the community engagement requirement consistent with the state's standard disenrollment process.

  - a. Good Cause.** The state will not disenroll beneficiaries if they failed to meet the community engagement requirement, but demonstrate good cause for their failure to meet the requirement, due to life circumstances that created barriers to employment or

community engagement. The demonstration allows beneficiaries to self-attest to good cause criteria. The recognized good cause circumstances include, but are not limited to:

- i. The beneficiary has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and was unable to meet the requirement for reasons related to that disability, but was not exempted from community engagement requirements, or has an immediate family member in the home with a disability under federal disability rights laws and was unable to meet the requirement for reasons related to the disability of that family member;
  - ii. The beneficiary experiences a hospitalization or serious illness;
  - iii. The beneficiary has an immediate family member who experiences an illness that requires the presence of the beneficiary or has an immediate family member who is living in the home with the beneficiary who experiences a hospitalization or serious illness;
  - iv. The beneficiary experiences an emergency as defined by the state;
  - v. The beneficiary experiences severe inclement weather (including a natural disaster);
  - vi. The beneficiary experiences the unavailability of transportation; or
  - vii. The beneficiary is a victim of domestic violence.
- b. **Disenrollment Effective Date.** The effective date of a disenrollment for failure to meet the community engagement requirement will be no sooner than the first day of the month following appropriate notice after the end of the 60-day period by which the beneficiary was notified to meet the community engagement requirement, as described in STC 26.
- c. **Re-enrollment Following Non-Compliance.** A beneficiary who is disenrolled for non-compliance with the community engagement requirement can reapply for Medicaid immediately or at any time following disenrollment due to community engagement non-compliance. When an individual who was disenrolled for non-compliance with the community engagement requirement reapplies:
- i. An individual's previous non-compliance with the requirement will not be factored into the state's determination of that individual's eligibility for re-enrollment;
  - ii. Beneficiaries will automatically be re-enrolled in Medicaid, if
    - (a) they are determined to be eligible for Medicaid in a category that is not subject to the community engagement requirement,
    - (b) they are determined to qualify for an exemption from the community engagement requirement, or
    - (c) they demonstrate good cause for failure to meet the requirement.

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

- a. Maintain mechanisms to stop payments to a Managed Care Organization (MCO) when a beneficiary is disenrolled from Medicaid for failure to comply with program requirements and to trigger payment when Medicaid eligibility is re-authorized and a beneficiary is enrolled into an MCO.

- b. Ensure that:
  - i. There are processes and procedures in place to seek data from other sources, including SNAP and TANF, regarding a beneficiary's potential satisfaction of or exemption from the community engagement requirement;
  - ii. In cases where the state cannot locate data through available systems and data sources, beneficiaries can attest to compliance with, or qualification for an exemptions from, the community engagement requirement in a manner consistent with 42 CFR 435.945;
  - iii. There are systems to permit beneficiaries to efficiently self-attest to meeting the community engagement requirement or self-attest to an exemption or demonstrate good cause, in accordance with 42 CFR 435.907(a), 435.916(c), and 435.945;
  - iv. The state uses available systems and data sources to verify that beneficiaries are meeting the community engagement requirement or are exempt from the requirements;
  - v. There are processes and procedures in place to permit the state to monitor compliance.
- c. Ensure that disenrollment will occur only after a beneficiary has been screened and determined ineligible for all other bases of Medicaid eligibility and reviewed for eligibility for insurance affordability programs in accordance with 42 CFR 435.916(f).
- d. Ensure that there are timely and adequate beneficiary notices provided in writing, including but not limited to:
  - i. When the community engagement requirement will commence for that specific beneficiary;
  - ii. Whether a beneficiary has already been determined to be exempt, how the beneficiary may attest that she or he meets the requirements for an exemption, and under what conditions the exemption would end;
  - iii. The specific number of community engagement hours per month that a beneficiary is required to complete to meet the requirements, and when and how the beneficiary must report participation, report any changes in circumstance, or request an exemption;
  - iv. A list of the specific activities that may be used to satisfy the community engagement requirement, as described in STC 23;
  - v. Information about resources that help connect beneficiaries to opportunities for activities that would meet the community engagement requirement, and information about the community supports that are available to assist beneficiaries with meeting the community engagement requirement;
  - vi. Information about how community engagement hours will be counted and documented;
  - vii. What gives rise to disenrollment, what disenrollment would mean for the beneficiary, including how disenrollment for failure to meet the community engagement requirement does not affect subsequent Medicaid application or renewal, and how to avoid disenrollment, including how to seek to demonstrate

- good cause for failing to meet the requirement, and what kinds of circumstances might give rise to good cause;
  - viii. If a beneficiary sought to demonstrate good cause, whether good cause has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial;
  - ix. Any differences in the program requirements that beneficiaries will need to meet in the event they transition off of SNAP or TANF but remain subject to the community engagement requirement of this demonstration;
  - x. If a beneficiary is out of compliance with the requirement, information regarding the reason why the beneficiary is out of compliance, and the consequences of non-compliance, and how the beneficiary can be in compliance in the month immediately following;
  - xi. If a beneficiary is disenrolled, information regarding how to appeal that decision and/or how to reapply for Medicaid benefits;
- e. Ensure that specific activities that may be used to satisfy the community engagement requirements are available during a range of times and through a variety of means (e.g., online, in-person) at no cost to the beneficiary.
  - f. Conduct active outreach and education beyond standard noticing for beneficiaries to help ensure successful compliance with the community engagement requirements as beneficiaries move toward self-sufficiency and economic security.
  - g. Maintain an annual renewal process, including systems to complete ex parte renewals and use of notices that contain prepopulated information known to the state, consistent with all applicable Medicaid requirements.
  - h. Provide full appeal rights as required under 42 CFR, Part 431, subpart E prior to disenrollment, and observe all requirements for due process for beneficiaries who will be disenrolled for failing to meet the community engagement requirement, including allowing beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to disenrollment, and provide additional documentation through the appeals process.
  - i. Establish beneficiary protections, ensuring that beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require community engagement and employment.
  - j. With the assistance of other state agencies and other public and private partners, make good faith efforts to connect beneficiaries to existing community supports that are available to assist beneficiaries with meeting the community engagement requirement, including available non-Medicaid assistance with transportation, child care, language access services, and other supports.
  - k. With the assistance of other state agencies and other public and private partners, make good faith efforts to connect beneficiaries with disabilities as defined in the ADA,

Section 504, or Section 1557 with services and supports necessary to enable them to meet the community engagement requirement. The existence of separate programs and services providing such supports does not relieve the state of its obligation to provide reasonable modifications (see STC 25) for people with disabilities with respect to the community engagement requirements.

- l. Ensure application assistance is available to beneficiaries (in person and by phone).
- m. Maintain ability to report on and process applications in-person, via phone, via mail and electronically.
- n. Maintain timely processing of applications to avoid delays in accessing benefits when beneficiaries reapply following a disenrollment.
- o. 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.
- p. Ensure that the state will monitor the application of exemptions to ensure that there is not a disparate impact based on race or ethnicity.
- q. Ensure that the state will assess whether people with disabilities have limited job or other opportunities for reasons related to their disabilities. If these barriers exist for people with disabilities, the state must address these barriers.
- r. Provide each beneficiary who has been disenrolled from Medicaid with information regarding how to access primary care and preventative care services at low or no cost to the beneficiary. This material will include information about free health clinics and community health centers including clinics that provide behavioral health and substance use disorder services. Ohio shall also maintain such information on its public-facing website and employ other broad outreach activities that are specifically targeted to beneficiaries who have lost coverage.
- s. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting the community engagement requirement.
- t. Maintain a system that provides reasonable modifications related to meeting the community engagement requirement to beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 that is consistent with STC 25.

## IX. GENERAL REPORTING REQUIREMENTS

**30. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or 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.

In the event that either (1) the state has not submitted a written request to CMS for approval of an extension, as described below, within thirty (30) days after a deliverable was due, or (2) the state has not submitted a revised submission or a plan for corrective action to CMS within thirty days after CMS has notified the state in writing that a deliverable was not accepted for being inconsistent with the requirements of this agreement including the information needed to bring the deliverable into alignment with CMS requirements; the following process is triggered:

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

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state’s failure to submit all required reports, evaluations, and other



deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

- 31. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 32. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
- a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
  - b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
  - c. Submit deliverables to the appropriate system as directed by CMS.
- 33. Community Engagement Implementation Plan.** The state must submit a Community Engagement Implementation Plan to CMS no later than 90 calendar days after approval of the demonstration. The Implementation Plan is an operational companion document and must cover the key policies being tested in this demonstration. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as an Attachment. At a minimum, the Community Engagement Implementation Plan must include definitions (including but not limited to the state's definition for medically frail (which must at a minimum be consistent with 42 CFR 440.315(f)), and its definition for half-time enrollment in school) and parameters of key policies (including but not limited to the requirements in STCs 21-29), and describe the state's strategic approach to implementing the policies, including reports on any recently met milestones and timelines for meeting milestones associated with these key policies. The state must discuss at least the following topics in its Community Engagement Implementation Plan: application assistance, reporting and processing, notices, coordinated agency responsibilities, coordination with other insurance affordability programs, appeals, renewals, coordination with other state agencies, beneficiary protections, and outreach.
- 34. Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. Once approved, the Monitoring Protocol will be incorporated into the STCs, as an Attachment.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS' template. Any proposed deviations from CMS' template must 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 35b below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and analysis covering key policies being tested under this demonstration, including 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 35a 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.

- 35. Monitoring Reports.** The state must submit three (3) Quarterly Reports and one (1) Annual Report each DY. The fourth-quarter information that would ordinarily be provided in a separate quarterly report should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework to be provided by CMS, which will be organized by milestones. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.
- a. Operational Updates – The operational updates must focus on progress towards meeting the milestones identified in CMS' framework. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
  - b. Performance Metrics – The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS' framework which includes the following key policies under this demonstration- community engagement. The performance metrics will reflect all components of the state's demonstration, and may include, but are not limited to, measures associated with enrollment, disenrollment by specific demographics and reason, participation in community engagement qualifying activities, access to care, effects on employment, including new employment, and health outcomes.

Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also

include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals.

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

- c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on CMS-64.
- d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

**36. Corrective Action.** If federal monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing the waivers or expenditure authorities, as outlined in STC 11.

**37. Close-Out Report.** Within 120 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 30.

**38. Monitoring Calls.** CMS will convene periodic conference calls with the state.

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- 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.

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

## **X. GENERAL FINANCIAL REQUIREMENTS**

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

## **XI. MONITORING BUDGET NEUTRALITY**

**41. Budget Neutrality.** CMS has determined that this demonstration is budget neutral based on CMS's assessment that the waiver authorities granted for the demonstration are unlikely to result in any increase in federal Medicaid expenditures for medical assistance, and that no expenditure authorities are associated with the demonstration. The state will not be allowed to obtain budget neutrality "savings" from this demonstration. The demonstration will not include a budget neutrality expenditure limit, and no further test of budget neutrality will be required. CMS reserves the right to request budget neutrality worksheets and analyses from the state whenever the state seeks a change to the demonstration, per STC 7.

## **XII. EVALUATION OF THE DEMONSTRATION**

**42. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents; providing data and analytic

files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 30.

**43. 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.

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

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

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

- a. All applicable Evaluation Design guidance, including guidance about community engagement. Community engagement hypotheses will include (but not be limited to): effects on enrollment and continuity of enrollment; and effects on employment levels (including by tracking new employment), income, transition to commercial health insurance, health outcomes, the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs), and Medicaid program sustainability.
- b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD evaluation designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a draft evaluation design.

**45. Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved

Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. 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.

**46. Evaluation Questions and Hypotheses.** Consistent with attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS' Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS' measure sets for eligibility and coverage (including community engagement), Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF).

**47. 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.

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

- a. The Interim Evaluation report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.
- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration

phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

- d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
- e. The Interim Evaluation Report must comply with attachment B (Preparing the Evaluation Report) of these STCs.

**49. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
- b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

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

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

**52. 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.

**53. Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS

may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.



## **Attachment A Developing the Evaluation Design**

### **Introduction**

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

### **Expectations for Evaluation Designs**

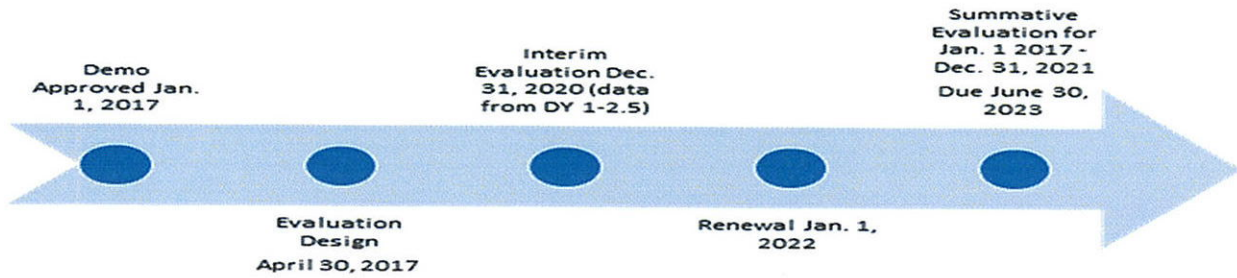
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

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

### **Submission Timelines**

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



**Required Core Components of All Evaluation Designs**

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

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

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

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

- 1) Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind

the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:

<https://innovation.cms.gov/files/x/healthwoaimsdrivers.pdf>.

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

**C. Methodology** – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references). This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.
- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
  - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

- b. Qualitative analysis methods may be used, and must be described in detail.
  - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
  - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
  - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
  - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

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

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

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

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

**E. Special Methodological Considerations** – CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include when the demonstration is considered successful without issues or concerns that would require more regular reporting, such as:

- a. Operating smoothly without administrative changes; and
- b. No or minimal appeals and grievances; and
- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans (CAP) for the demonstration.

**F. Attachments**

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

## **Attachment B**

### **Preparing the Evaluation Report**

#### **Introduction**

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

#### **Expectations for Evaluation Reports**

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

#### **Intent of this Attachment**

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

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

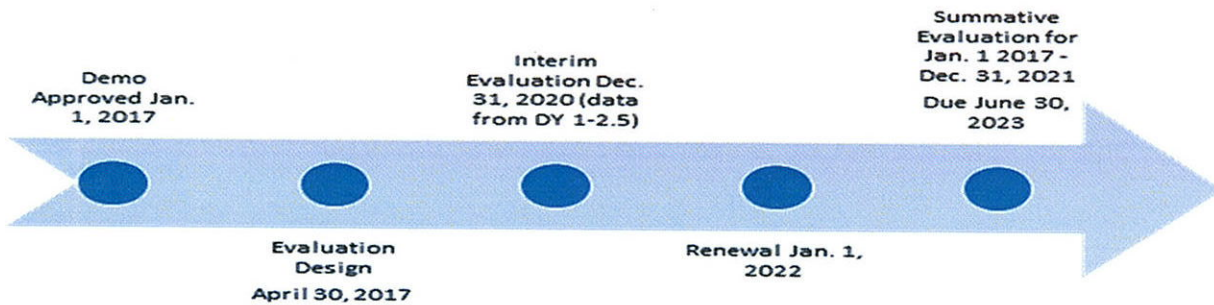
- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;



- D. Methodology;
- E. Methodological Limitations;
- F. Results;
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

**Submission Timelines**

There is a specified timeline for the state’s submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state’s website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



**Required Core Components of Interim and Summative Evaluation Reports**

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state’s Driver Diagram (described in the Evaluation Design Attachment) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state’s submission must include:

**A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

**B. General Background Information about the Demonstration** – In this section, the state



should include basic information about the demonstration, such as:

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

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

- 1) Describe how the state’s demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
- 2) Identify the state’s hypotheses about the outcomes of the demonstration;
  - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
  - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
  - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the

data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

- 1) *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc?
- 2) *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
- 3) *Evaluation Period* – Describe the time periods for which data will be collected
- 4) *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
- 6) *Analytic Methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
- 7) *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

#### **E. Methodological Limitations**

This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

**F. Results** – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

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

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
  - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

#### **H. Interpretations, Policy Implications and Interactions with Other State Initiatives** –

In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make

judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

- I. Lessons Learned and Recommendations** – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:
- 1) What lessons were learned as a result of the demonstration?
  - 2) What would you recommend to other states which may be interested in implementing a similar approach?

**J. Attachment**

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

**Attachment C:  
Evaluation Design (reserved)**

**Attachment D:  
Implementation Plan (reserved)**

**Attachment E:  
Monitoring Protocol (reserved)**