March 17, 2021

Lori Shibanette
Commissioner, Department of Health and Human Services
State of New Hampshire
129 Pleasant Street
Concord, NH 03301

Dear Ms. Shibanette:

On February 12, 2021, the Centers for Medicare & Medicaid Services (CMS) sent you a letter regarding the November 30, 2018 extension of the section 1115 demonstration project entitled “New Hampshire Granite Advantage Health Care Program Demonstration” (Project Number 11-W-00298/1). The letter advised that CMS would commence a process of determining whether or not to withdraw the authorities previously approved in the Granite Advantage Health Care Program 1115 demonstration that permit the state to require work and other community engagement activities as a condition of Medicaid eligibility. It explained that in light of the ongoing disruptions caused by the COVID-19 pandemic, New Hampshire’s community engagement requirement risks significant coverage losses and harm to beneficiaries. For the reasons discussed below, CMS is now withdrawing approval of the community engagement requirement in the November 30, 2018 extension of the Granite Advantage Health Care Program, which is not currently in effect and which would have expired by its terms on December 31, 2023.

Section 1115 of the Social Security Act (the Act) provides that the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain programs under the Act, including Medicaid. In so doing, the Secretary may waive compliance with the Medicaid program requirements of section 1902 of the Act, and approve federal matching funds per section 1115(a)(2) for state spending on costs not otherwise matchable under section 1903 of the Act, which permits federal matching payments only for “medical assistance” and specified administrative expenses. Under section 1115 authority, the Secretary can allow states to undertake projects to test changes in Medicaid eligibility, benefits, delivery systems, provider payments and other rules across their Medicaid programs that the Secretary determines are likely to promote the statutory objectives of Medicaid.

As stated in the above referenced letter sent on February 12, 2021, under section 1115 and its implementing regulations, CMS has the authority and responsibility to maintain continued oversight of demonstration projects in order to ensure that they are currently likely to assist in promoting the objectives of Medicaid. CMS may withdraw waivers or expenditure authorities if

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1 42 U.S.C. § 1315.
it “find[s] that [a] demonstration project is not likely to achieve the statutory purposes.” 42 C.F.R. § 431.420(d); see 42 U.S.C. § 1315(d)(2)(D).

As the February 12, 2021 letter explained, the Granite Advantage Health Care Program community engagement requirement is currently not in effect. Although implementation began in June 2019, it was halted by court order in July 2019. The early evidence for New Hampshire, especially considered in light of the COVID-19 pandemic and its expected aftermath, makes clear that community engagement is infeasible. In addition, implementation of the community engagement requirement is currently prohibited by the Families First Coronavirus Response Act (FFCRA), Pub. L. No. 116-127, Div. F, § 6008(a) and (b), 134 Stat. 208 (2020), which conditions a state’s receipt of an increase in federal Medicaid funding during the pandemic on the state’s maintenance of certain existing Medicaid parameters. New Hampshire has chosen to claim the 6.2 percentage point FFCRA Federal Medical Assistance Percentage (FMAP) increase, and therefore, while it does so, must maintain the enrollment of beneficiaries who were enrolled as of, or after, March 18, 2020.

The February 12, 2021 letter noted that, although the FFCRA’s bar on disenrolling such beneficiaries will expire after the COVID-19 public health emergency ends, CMS still has serious concerns about testing policies that create a risk of substantial loss of health care coverage and harm to beneficiaries even after the expiration of the bar on disenrolling beneficiaries. The COVID-19 pandemic has had a significant impact on the health of Medicaid beneficiaries. Uncertainty regarding the current crisis and the pandemic’s aftermath, and the potential impact on economic opportunities (including job skills training and other activities used to satisfy community engagement requirements, i.e., work and other similar activities), and access to transportation and affordable child care have greatly increased the risk that implementation of the community engagement requirement approved in this demonstration will result in substantial unintended coverage loss. In addition, the uncertainty regarding the lingering health consequences of COVID-19 infections further exacerbates the harms of coverage loss for Medicaid beneficiaries.

Accordingly, the February 12, 2021 letter indicated that, taking into account the totality of circumstances, CMS had preliminarily determined that allowing the community engagement requirement to take effect in New Hampshire would not promote the objectives of the Medicaid program. Therefore, CMS provided the state notice that we were commencing a process of determining whether to withdraw the authorities approved in the Granite Advantage Health Care Program demonstration that permit the state to require work and other community engagement activities as a condition of Medicaid eligibility. See Special Terms and Conditions ¶ 11. The letter explained that if CMS ultimately determined to withdraw those authorities, it would “promptly notify the state in writing of the determination and the reasons for the amendment and withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS’s determination prior to the effective date.” Id. The February 12, 2021 letter indicated that, if the state wished to submit to CMS any additional information that in the state’s view may warrant not withdrawing those authorities, such information should be submitted to CMS within 30 days. We have not received any additional information from New Hampshire in response to the February 12, 2021 letter.
In light of these concerns, for the reasons set forth below, CMS has determined that, on balance, the authorities that permit New Hampshire to require work and community engagement as a condition of eligibility are not likely to promote the objectives of the Medicaid statute. Therefore, we are withdrawing the authorities that were extended in the Secretary’s November 30, 2018 extension approval of the Granite Advantage Health Care Program demonstration.

**Background of New Hampshire’s Demonstration**

The New Hampshire Granite Advantage Health Care Program demonstration was originally approved by CMS on March 4, 2015 as the “New Hampshire Health Protection Program (NHHPP) Premium Assistance Demonstration” and provided premium assistance to non-medically frail individuals, ages 19 through 64, in the new adult coverage group to enable enrollment in qualified health plans offered in the Health Insurance Marketplace (Marketplace).

On May 7, 2018, CMS approved an amendment to the demonstration requiring all beneficiaries in the new adult group, ages 19 to 64, with certain exemptions, to participate in and timely report a minimum of 100 hours per month of work or community engagement activities, such as employment, education, job skills training, or community service, as a condition of continued Medicaid eligibility. Failure to comply with the requirement for a month would result in suspension of Medicaid eligibility after an additional one-month grace period to make up the deficient hours and come into compliance. The beneficiary would remain suspended unless he or she had good cause for the compliance failure, qualified for an exemption, or satisfied the requirements by making up the deficient hours for the month that resulted in non-compliance. If a beneficiary were still suspended at the time of his or her redetermination, the beneficiary would be disenrolled from Medicaid, but could re-apply for coverage at any time. The demonstration’s Special Terms and Conditions specified that the community engagement requirement was not authorized to be implemented sooner than January 1, 2019.

On November 30, 2018, CMS approved an extension of the demonstration for an additional five year period and the demonstration was renamed the “Granite Advantage Health Care Program” section 1115 demonstration project. This approval extended the authority to require work or other community engagement as a condition of eligibility and removed the authority for the Marketplace premium assistance program, as the state was moving to a different delivery system that did not require section 1115 authority.

**Early Experience from the Community Engagement Requirement in New Hampshire**

Early experience with the community engagement requirement in New Hampshire and other states that implemented similar demonstrations indicated that such a requirement risks rapid coverage loss.

Under the Granite Advantage demonstration, beneficiaries were required to comply with the community engagement requirement beginning June 1, 2019. On July 7, 2019, New Hampshire suspended the community engagement requirement for a three-month period. Shortly thereafter, on July 29, 2019, the U.S. District Court for the District of Columbia vacated the Secretary’s approval of the demonstration extension that authorized this requirement.
Under the demonstration, beneficiaries had a 75-day window from the date of the beneficiary’s eligibility determination to begin complying with the community engagement requirement. Beneficiaries not meeting the requirement for two consecutive months would have the opportunity to remediate, or “cure,” their community engagement hours, claim an exemption, or notify the state of good cause to avoid suspension of coverage. Within the short span of the policy’s implementation, almost 17,000 beneficiaries, or about 40 percent of those subject to the community engagement requirement, representing one-third of the demonstration’s total enrollment, were set to be suspended for non-compliance with the requirement and lose Medicaid coverage.  

Further underscoring these figures, one estimate, based on the 17,000 beneficiaries who would have been initially suspended after the community engagement requirement was in effect for just over a month, projected that between 30 and 45 percent of beneficiaries subject to the community engagement requirement would have been disenrolled within the first year of implementation. The magnitude and proportion of such coverage losses based on this count of 17,000 are even higher than the 6 to 17 percent coverage loss that Kaiser Family Foundation researchers forecasted could result from implementing community engagement requirements nationwide.

Despite the high rate of noncompliance during the first month of the demonstration, one study estimates that all but a small minority of Medicaid expansion beneficiaries in New Hampshire were either working or were ill or disabled (and therefore should have qualified for exemptions from the community engagement requirement). Before the community engagement requirement was implemented, based on data from the state, 47 percent of the Premium Assistance Program beneficiaries were employed or self-employed. According to research from the Kaiser Family Foundation using the Current Population Survey (CPS) data, in New Hampshire 65 percent (60

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percent nationally) of Medicaid beneficiaries aged 19 to 64 without Supplemental Security Income (SSI) in 2016 were working, and of those who were not working in New Hampshire, 49 percent (36 percent nationally) indicated that their reason for not working was due to illness or disability. While data for New Hampshire were too limited to be conclusive, nearly half of Medicaid beneficiaries not working nationally indicated they were caretaking or attending school. Under New Hampshire’s community engagement requirement, illness and disability were qualifying exemptions, while educational activities were qualifying community engagement activities and caregiving could have been either a qualifying exemption or a qualifying community engagement activity. Accordingly, these data suggest that the vast majority of beneficiaries subject to New Hampshire’s community engagement requirement who were not working were otherwise meeting or exempt from the community engagement requirement.

Despite state assurances in the demonstration’s Special Terms and Conditions that New Hampshire would provide the necessary outreach to Medicaid beneficiaries, experience from the state shows that lack of awareness of and administrative barriers associated with the community engagement requirement created serious challenges for eligible beneficiaries, which could have resulted in significant coverage losses. Many beneficiaries in New Hampshire reportedly did not know about the community engagement reporting requirement or received confusing and often contradictory notices about whether they were subject to the requirement. Additionally, these outreach efforts may not have reached transient populations and/or individuals without stable mailing addresses or telephone numbers. For example, on only 500 of the state’s 50,000 phone calls did a state official discuss the community engagement requirement with the person who would be affected by it, and the state’s 2,011 home visits reached only 270 people who would be affected. Community organizations in New Hampshire also raised concern about beneficiary awareness and understanding of the policy requirements. Additionally, beneficiaries reported barriers to obtaining exemptions from the community

engagement requirement, for example, beneficiaries with physical and behavioral health conditions reported that their providers were resistant to signing forms needed to establish that the beneficiary was unable to work so that the beneficiary could qualify for an exemption. This lack of understanding about the community engagement requirement and challenges in receiving exemptions may have contributed to the low compliance rate—only 32 percent of beneficiaries subject to the requirement met the 100-hour target in the first month of implementation.

As previously noted, based on the study from the Kaiser Family Foundation, nearly everyone who was targeted by the community engagement requirement in New Hampshire already met the requirement or was exempt from it, so there was little margin for the program to increase work or community engagement. This is consistent with research indicating more generally that most Medicaid beneficiaries are already working or are likely to be exempt from a potential community engagement requirement. For example, in a study published in 2018, researchers found that nearly 80 percent of adults with Medicaid coverage live in families with a working adult, and 6 in 10 are working themselves. Similarly, a study published in 2017 found that, out of the 22 million adults covered by Medicaid nationwide (representing 58 percent of all adults on Medicaid) who could be subject to a community requirement designed like that in the Granite Advantage demonstration, 50 percent were already working, 14 percent were looking for work, and 36 percent were neither working nor looking for work. For those beneficiaries not working or looking for work, 29 percent indicated that they were caring for a family member, 17 percent were in school, and 33 percent noted that they could not work because of a disability (despite excluding from analysis those qualifying for Medicaid on the basis of disability,

highlighting the difficulty with disability determination), with the remainder citing layoff, retirement, or a temporary health problem.

Thus, overall, prior to the pandemic, the available data indicated that the vast majority of the population that would be targeted by the community engagement requirement, as in New Hampshire’s demonstration, were already meeting the potential terms of such a requirement or would qualify for an exemption from it. This makes it challenging for community engagement requirements to produce any meaningful impact on employment outcomes by incentivizing behavioral changes in a small fraction of beneficiaries, all the while risking substantial coverage losses among those subject to the requirements.

In addition to New Hampshire, Arkansas and Michigan, the two other states where a community engagement requirement as a condition of Medicaid eligibility was in effect, provide some early data on potential enrollment impacts that accords with the New Hampshire experience. In Arkansas, for instance, before the court halted the community engagement requirement, the state reported that from August 2018 through December 2018, a total of 18,164 individuals were disenrolled from coverage for “noncompliance with the work requirement.” During these five months, the monthly rate of coverage loss as a percentage of those who were required to report work and community engagement activities fluctuated between 20 and 47 percent. Arkansas affected by disenrollment experienced significantly higher medical debt and financial barriers to care, compared to Arkansans ages 30 to 49 who maintained that coverage. Specifically, 50 percent reported serious problems paying off medical bills; 56 percent delayed seeking health care because of cost; and 64 percent delayed taking medications because of cost. Evidence also indicates that those with chronic conditions were more likely to lose coverage. In Michigan, before the policy was vacated by the courts, 80,000 beneficiaries—representing nearly 33 percent of individuals subject to the community engagement requirement—were at risk of suspension, if not loss of coverage, for failing to report compliance with the community engagement requirement. Similar to New Hampshire, there was widespread evidence of

confusion and lack of awareness among beneficiaries in these other states. Moreover, in all three states, evidence suggests that even individuals who were working or those who had serious health needs, and therefore should have been eligible for exemptions, lost coverage or were at risk of losing coverage because of complicated administrative and paperwork requirements.

Additionally, consistent and stable employment is often out of reach for beneficiaries subject to community engagement requirements. Many low-income beneficiaries face a challenging job market, which often offers only unstable or low-paying jobs with unpredictable or irregular hours, sometimes resulting in spells of unemployment, particularly in seasonal work. The rigid monthly requirement for reporting 100 or more hours in general is also of concern for low-income working adults who could be subject to a community engagement requirement, as research suggests that a large segment of this group could be at risk of losing coverage for one or more months because they would not meet the minimum in every month.

Furthermore, research examining the outcomes of statutorily authorized work requirements in other public assistance programs, such as Temporary Assistance for Needy Families (TANF) and Supplemental Nutrition Assistance Program (SNAP) indicates that such requirements generally have only modest and temporary effects on employment, failing to increase long-term

employment or reduce poverty.\textsuperscript{38,39,40} Additionally, studies have found that imposing work requirements in the SNAP program led to substantial reductions in enrollment, even after controlling for changes in unemployment and poverty levels.\textsuperscript{41} In fact, evidence suggests that there were large and rapid caseload losses in selected areas after SNAP work requirements went into effect, similar to the coverage losses that occurred when New Hampshire began implementing the community engagement requirement for its beneficiaries.

Therefore, existing evidence from states that have implemented community engagement requirements, evidence from other public programs with work requirements, and the overall work patterns and job market opportunities for the low-income adults who would be subject to such requirements highlight the potential ineffectiveness of community engagement requirements at impacting employment outcomes for the target population. And while there are variations in the design and implementation of community engagement requirements in each state that has implemented such a requirement, as well as differences in employment and economic opportunities, findings from the states that implemented community engagement requirements point in the general direction of coverage losses among individuals subject to such requirements.

Thus, CMS is not aware of any reason to expect that the community engagement requirement as a condition of eligibility in New Hampshire’s Medicaid demonstration project would have a different outcome in the future than what was observed during the initial implementation of such a requirement in other states, or than that suggested by New Hampshire’s own early experience with implementing the community engagement requirement, when almost 17,000 beneficiaries, or about 40 percent of those subject to the requirement, were set to be suspended for non-compliance and lose Medicaid coverage within just the first few weeks. Accordingly, there is risk that New Hampshire’s demonstration project, as extended in November 2018, will lead to substantial coverage losses, a risk that is exacerbated by the ongoing COVID-19 public health emergency and its likely aftermath.

**Impact of COVID-19 and its Aftermath**

The COVID-19 pandemic and the uncertainty surrounding the long-term effects on economic activities and opportunities across the nation exacerbate the risks associated with tying a


community engagement requirement to Medicaid eligibility, making such requirements infeasible under the current circumstances. There is a substantial risk that the COVID-19 pandemic and its aftermath will have a negative impact on economic opportunities for Medicaid beneficiaries. If employment opportunities are limited, Medicaid beneficiaries may find it difficult to obtain paid work in the aftermath of the COVID-19 pandemic.\textsuperscript{42,43}

As discussed above, prior to the pandemic, most adult Medicaid beneficiaries who did not face a barrier to work were working.\textsuperscript{44} However, one in three adult Medicaid beneficiaries was only working part-time during the COVID-19 public health emergency due to fewer opportunities for full-time employment and reduced availability of child care due to the public health emergency and its related economic effects.\textsuperscript{45}

Job and income loss have also been more acute among the low-income population, those with the least wherewithal to withstand economic shocks, and who are disproportionately enrolled in Medicaid.\textsuperscript{46} Fifty-two percent of lower income adults (annual income below $37,500) live in households where someone has lost a job or taken a pay cut due to the pandemic.\textsuperscript{47} And, understandably, households with a job or income loss were two–to-three times more likely to experience economic hardship than those who did not experience such a loss.\textsuperscript{48,49} Fifty-nine percent of lower-income adults said they worry every day or almost every day about paying their


bills. There is also racial and ethnic disparity in the likelihood of reporting hardships; for example, compared to White households, Black households reported significantly higher chances of putting off filling prescriptions and difficulties making housing and other bill payments. Also, Hispanic households were more likely to experience food insecurity compared to White households.

The pandemic may also exacerbate existing disparities, such as low-income individuals’ lack of access to computers and reliable internet. For example, 29 percent of adults in households with annual incomes below $30,000 did not own a smartphone, and 44 percent did not have home broadband services in 2019. Moreover, fewer than 8 percent of Americans with earnings below the 25th percentile have the capabilities to work remotely. These disparities will result in fewer opportunities for beneficiaries to satisfy a community engagement requirement, particularly as more jobs have shifted to telework or “work from home” during the public health emergency, thereby increasing the risk that implementation of the community engagement requirement approved in this demonstration will result in unintended coverage loss.

The impact of the COVID-19 public health emergency on the economy has been significant, and, importantly, experience with previous recessions suggest the impact is likely to persist for an extended period of time. While the unemployment rate has declined from 14.8 percent in April 2020 to 6.2 percent in February 2021, the labor force participation rate has shown no improvement since June 2020 and remains 1.9 percentage points below pre-pandemic levels.

Evidence shows that losing a job can have significant long term effects on an individual’s future earnings. Studies have found that workers who lose their jobs in mass layoffs still earn 20

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percent less than similar workers who kept their jobs, 15 to 20 years after the layoff, and the impacts are greater for individuals who lose their jobs during a recession. On average, men lost 2.8 years of pre-layoff earnings when the mass layoff occurred in a time when the unemployment rate was above eight percent. Further, workers who enter the labor market during a recession face long-term consequences for their earnings. Also, nonwhites and individuals with lower educational attainment have experienced larger and more persistent earning losses than other groups who enter the labor market during recessions. These layoffs can also impact an individual’s mortality risk. For example, workers experienced mortality rates that were 50-100 percent higher than expected in the year after a layoff occurred, and 20 years later, mortality rates remained 10-15 percent higher for these individuals. Furthermore, displaced workers have lower levels of healthcare utilization, and healthcare coverage losses and lack of care continuity could play a role in long-term effects on mortality rates.

The pandemic could also bring long-term changes in the labor market, as levels of remote work are likely to remain higher than pre-pandemic levels, reducing the need for support staff and service industry workers in many cities. The disproportionate level of disruption in certain sectors also presents a significant concern about potential inequities in the economic recovery, as declines in employment have been much higher for Black and Hispanic women and in certain low-wage service sectors, such as hospitality and leisure, while certain sectors, such as financial services, have seen virtually no change. In April 2020, the estimated unemployment rates (including individuals who were employed but absent from work and those not in the workforce but who wanted employment) for Black and Hispanic populations were as high as 32 and 31 percent, respectively, compared to 24 percent for White populations. Hispanic populations specifically are more likely to be affected due to their disproportionate representation in

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industries such as hospitality and construction, which have been most affected by the pandemic-related layoffs.\textsuperscript{65,66,67}

Given the short- and long-term negative consequences from the loss of timely access to necessary healthcare, the potential for coverage loss would be particularly harmful in the aftermath of the pandemic. During the pandemic, individuals have delayed or postponed seeking care, either due to concerns with out-of-pocket expenses, or to avoid risk of contact with infected individuals in healthcare settings. For example, one study showed that screenings for breast, colon, prostate, and lung cancers were between 56 and 85 percent lower in April 2020 than in the previous year.\textsuperscript{68} Results of another survey-based study show that 40 percent of respondents canceled upcoming appointments due to the pandemic, and another 12 percent reported they needed care but did not schedule or receive services. These pandemic-related delays in seeking care are estimated to increase annual healthcare costs by a range of $30 to $65 billion.\textsuperscript{69}

Moreover, unmet need in healthcare may lead to substantial increases in subsequent mortality and morbidity.\textsuperscript{70} In addition, the uncertainty regarding the lingering health consequences of COVID-19 infections further exacerbates the harms of any potential coverage loss for Medicaid beneficiaries.

Furthermore, as reported, the pandemic has had a disparate effect on the physical and mental health of Medicaid beneficiaries. Racial minorities and people living in low-income households are more likely to work in industries that are considered “essential services,” which have remained open during the pandemic.\textsuperscript{71} Additionally, occupations with more frequent exposure to COVID-19 infections, and that require close proximity to others (such as personal care aides and bus drivers) employ Black individuals at higher rates than Whites.\textsuperscript{72} As a result, Black people may be at higher risk of contracting COVID-19 through their employment. The pandemic’s


\textsuperscript{66} Industries like health care and transportation have been less affected by the pandemic, and that has provided some cushion for black workers. See Despard et al. (2020).


mental health impact also has been pronounced among populations experiencing disproportionately high rates of COVID-19 cases and deaths. Specifically, Black and Hispanic adults have been more likely than White adults to report symptoms of anxiety and/or depressive disorder during the pandemic.73

Withdrawal of Community Engagement Requirement in the November 30, 2018 Extension of the Granite Advantage Health Care Program Demonstration

Based on the foregoing, and pursuant to our obligation under section 1115 of the Act to review demonstration projects and ensure they remain likely to promote the objectives of Medicaid, CMS has determined that, on balance, the extension approval authorizing New Hampshire to implement a community engagement requirement as a condition of eligibility is not likely to promote the objectives of the Medicaid program. At a minimum, in light of the significant risks and uncertainties described above about the adverse effects of the pandemic and its aftermath, the information available to CMS does not provide an adequate basis to support an affirmative judgment that the community engagement requirement is likely to assist in promoting the objectives of Medicaid. Accordingly, pursuant to its authority and responsibility under applicable statutes and regulations to maintain ongoing oversight of whether demonstration projects are currently likely to promote those objectives, CMS is hereby withdrawing its approval of that portion of the November 30, 2018 extension that permits the state to require work and community engagement as a condition of eligibility under the New Hampshire Granite Advantage Health Care Program demonstration. The provisions of CMS’s letter approving the November 30, 2018 extension and the corresponding provisions of the waivers and Special Terms and Conditions that authorize the community engagement requirement are withdrawn.

The withdrawal of these authorities is effective on the date that is thirty days after the date of this letter, unless the state timely appeals, as discussed below. The waivers, expenditure authorities, and Special Terms and Conditions reflecting this change are attached to this letter and will govern the New Hampshire Granite Advantage Health Care Program demonstration from the effective date of the withdrawal of the community engagement authorities until the demonstration expires on December 31, 2023.

As indicated in CMS’s February 12, 2021 letter, CMS is also reviewing the other authorities that CMS previously approved in the New Hampshire Granite Advantage Health Care Program demonstration. That review remains ongoing. The state and CMS will work together to update the evaluation design, as needed, to reflect all the key policies that are implemented during the approval period. The current established timeline for the interim and summative evaluation reports will remain in effect. CMS looks forward to continuing to work with the state on the evaluation design, interim and summative evaluation reports.

**Procedure to Appeal This Decision**

In accordance with Special Terms and Conditions 13 and 42 C.F.R. § 430.3, the state may request a hearing to challenge CMS’s determination prior to the above-referenced effective date by appealing this decision to the Departmental Appeals Board (DAB or Board), following the procedures set forth at 45 C.F.R. part 16. This decision shall be the final decision of the Department unless, within 30 calendar days after the state receives this decision, the state delivers or mails (the state should use registered or certified mail to establish the date) a written notice of appeal to the DAB.

A notice of appeal may be submitted to the DAB by mail, by facsimile (fax) if under 10 pages, or electronically using the DAB’s electronic filing system (DAB E-File). Submissions are considered made on the date they are postmarked, sent by certified or registered mail, deposited with a commercial mail delivery service, faxed (where permitted), or successfully submitted via DAB E-File. The Board will notify the state of further procedures. If the state faxes its notice of appeal (permitted only if the notice of appeal is under 10 pages), the state should use the Appellate Division’s fax number, (202) 565-0238.

To use DAB E-File to submit your notice of appeal, the state’s Medicaid Director or its representative must first become a registered user by clicking "Register" at the bottom of the DAB E-File homepage, https://dab/efile.hhs.gov; entering the information requested on the "Register New Account" form; and clicking the "Register Account" button. Once registered, the state’s Medicaid Director or its representative should login to DAB E-File using the e-mail address and password provided during registration; click "File New Appeal" on the menu; click the "Appellate" button; and provide and upload the requested information and documents on the "File New Appeal-Appellate Division" form. Detailed instructions can be found on the DAB E-File homepage.

Due to the COVID-19 public health emergency, the DAB is experiencing delays in processing documents received by mail. To avoid delay, the DAB strongly encourages the filing of materials through the DAB E-File system. However, should the state so choose, written requests for appeal should be delivered or mailed to U.S. Department of Health and Human Services, Departmental Appeals Board MS 6127, Appellate Division, 330 Independence Ave., S.W., Cohen Building Room G-644, Washington, DC 20201. Refer to 45 C.F.R. Part 16 for procedures of the Departmental Appeals Board.

The state must attach to the appeal request, a copy of this decision, note its intention to appeal the decision, a statement that there is no dollar amount in dispute but that the state disputes CMS’s withdrawal of certain section 1115 demonstration authorities, and a brief statement of why the decision is wrong. The Board will notify the state of further procedures. If the state chooses to appeal this decision, a copy of the notice of appeal should be mailed or delivered (the state should use registered or certified mail to establish the date) to Judith Cash, Acting Deputy Director, Center for Medicaid and CHIP Services at 7500 Security Blvd, Baltimore, MD 21244.
If you have any questions, please contact Judith Cash at (410) 786-9686.

Sincerely,

Elizabeth Richter
Acting Administrator
CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: 11-W-00298/1

TITLE: New Hampshire Granite Advantage Health Care Program 1115 Demonstration

AWARDEE: New Hampshire Department of Health and Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived, shall apply to the demonstration project effective from January 1, 2018 through December 31, 2023. 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. Retroactive Eligibility

Section 1902(a)(10) and Section 1902(a)(34)

To the extent necessary to enable the state not to provide medical coverage for any month prior to the month in which an affected beneficiary’s Medicaid application is filed as specified in these STCs. The waiver of retroactive eligibility applies to beneficiaries described in STC 16 and does not apply to the following beneficiaries who would have been eligible in or after the third month before the month in which an application was made: pregnant women (including women during the 60-day period beginning on the last day of a pregnancy), infants under age 1 and children under age 19 (described in section 1902(l)(4) of the Act), parents and caretaker relatives, and individuals eligible in aged, blind, or disabled eligibility groups (including those who are applying for a long-term care determination). Coverage for affected beneficiaries will be effective as of the date of application.
I. PREFACE

The following are the Special Terms and Conditions (STCs) for the “New Hampshire Granite Advantage Health Care Program” (Granite Advantage) section 1115(a) Medicaid demonstration (hereinafter demonstration) to enable the State of New Hampshire (hereinafter state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (Act) which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to this demonstration. The New Hampshire Granite Advantage Health Care Program demonstration will be statewide and is approved for a 5-year period, from January 1, 2019 through December 31, 2023.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description And Objectives
III. General Program Requirements
IV. Eligibility
V. General Reporting Requirements
VI. Monitoring Calls and Discussions
VII. General Financial Requirements
VIII. Monitoring Budget Neutrality
IX. 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

The demonstration affects individuals in the new adult group covered under Title XIX of the Social Security Act, section 1902(a)(10)(A)(i)(VIII), who are adults from age 19 up to and
including age 64 with incomes up to and including 133 percent of the federal poverty level (FPL), and who are not enrolled in (or eligible for) Medicare.

Through the demonstration, until December 31, 2018, the state used a premium assistance model to support the purchase of coverage by beneficiaries eligible under the new adult group provided by certain qualified health plans (QHPs) doing business in the individual market through the Health Insurance Exchange operating in the state. As of October 2018, the demonstration provided coverage to approximately 51,000 beneficiaries who, through this date, were enrolled in an Exchange QHP as authorized under the demonstration project. Beneficiaries received the state plan Alternative Benefit Plan (ABP) and had cost sharing obligations consistent with the state plan. The ABP was the same benchmark plan chosen by New Hampshire to establish Essential Health Benefits.

With this extension, beginning January 1, 2019, the state will eliminate its premium assistance program under the demonstration. Granite Advantage beneficiaries will transition to the state’s Medicaid Care Management (MCM) delivery system, and non-exempt beneficiaries will be mandatorily enrolled into managed care organizations (MCOs), effective January 1, 2019, pursuant to authority in the state plan, and for relevant populations, the State approved 1915(b) waiver. In addition, the state has aligned its state plan benefit package with the Alternative Benefit Plan (ABP) for the new adult group. Since benefits are aligned between the ABP and the state plan, the state will no longer give medically frail beneficiaries in the new adult group the option of selecting between ABP and state plan benefits.

Beginning January 1, 2019, the state is discontinuing the cost-sharing schedule for beneficiaries in the new adult group with incomes over 100 percent of the FPL. Instead, Granite Advantage will implement the state plan copayment schedule for all beneficiaries subject to cost sharing, which currently applies only to pharmaceuticals. American Indians/Alaska Natives receiving services through Indian Health Service, Tribal, or urban Indian organization (I/T/U) facilities will remain exempt from copayments.

III. GENERAL PROGRAM REQUIREMENTS

1. Compliance with Federal Non-Discrimination Laws. The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557).

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 written policy, 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 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

   a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

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

5. **State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (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, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit reports.
required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

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

b. A data analysis worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

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

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

8. Extension of the Demonstration. States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.

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

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries,
the content of said notices (including information on the beneficiary’s appeal rights), the
process by which the state will conduct administrative reviews of Medicaid eligibility
prior to the termination of the demonstration for the affected beneficiaries, and ensure
ongoing coverage for eligible beneficiaries, as well as any community outreach activities
the state will undertake to notify affected beneficiaries, including community resources
that are available.

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

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

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

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

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

**10. Expiring Demonstration Authority.** For demonstration authority that expires prior to the
demonstration’s expiration date, the state must submit a demonstration authority expiration
plan to CMS no later than six months prior to the applicable demonstration authority’s
expiration date, consistent with the following requirements:
a. **Expiration Requirements.** The state must include, at a minimum, in its demonstration authority expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary’s appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.

b. **Expiration Procedures.** The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights 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. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS’ determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.
12. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

13. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request.

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

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

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

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

IV. **Eligibility**

16. **Populations Affected by the Demonstration.** The Granite Advantage Demonstration affects the coverage for adults aged 19 through 64 in the new adult group, eligible under the state plan consistent with section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR section 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. Implementation of such waiver authority must be consistent with these
STCs. Any Medicaid state plan amendments to this eligibility group will apply to this demonstration.

<table>
<thead>
<tr>
<th>Medicaid State Plan Mandatory Groups</th>
<th>Federal Poverty Level</th>
<th>Funding Stream</th>
<th>Expenditure and Eligibility Group Reporting</th>
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</thead>
<tbody>
<tr>
<td>Adults in Section 1902(a)(10)(A)(i)(VIII) Group</td>
<td>Adults at or below 133 percent FPL.</td>
<td>Title XIX</td>
<td>MEG – 1</td>
</tr>
</tbody>
</table>

17. **Retroactive Coverage.** The state will not provide medical coverage to adults under the demonstration for any month prior to the month in which a beneficiary’s Medicaid application is filed, except for a pregnant woman (including during the 60-day period beginning on the last day of the pregnancy), an infant under age 1, a child under age 19, a parent or caretaker relative, or an individual eligible in aged, blind, or disabled eligibility groups (including those who are applying for a long-term care determination). The state assures that it will provide outreach and education about how to apply for and receive Medicaid coverage and the importance of maintaining coverage when well and receiving regular preventative services. Outreach and education will be provided to the public and to Medicaid providers, particularly those who serve vulnerable populations that may be impacted by the retroactive eligibility waiver.

V. **GENERAL REPORTING REQUIREMENTS**

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

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

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverable(s).
b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state’s anticipated date of submission. Should CMS agree to the state’s request, a corresponding extension of the deferral process will be provided. CMS may agree to accept a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state’s written extension request.

c. If CMS agrees to an interim corrective action plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of 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 with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified 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.

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

20. 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.

21. Implementation Plan. The state must submit an Implementation Plan to CMS no later than 90 calendar days after approval of the demonstration. The Implementation Plan must cover at least the key policies being tested under this demonstration, including the waiver of retroactive eligibility. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment D. At a minimum, the Implementation Plan must
include definitions and parameters of key policies, and describe the state’s strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, and processing; notices; coordinated agency responsibilities; coordination with other insurance affordability programs; appeals; renewals; coordination with other state agencies; beneficiary protections; and outreach.

22. Monitoring Protocol. The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment E.

At a minimum, the Monitoring Protocol will affirm the state’s commitment to conduct quarterly and annual monitoring in accordance with CMS’ template. Any proposed deviations from CMS’ template should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as described in STC 23(b) below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and analysis covering the key policies being tested under this demonstration, including but not limited to the waiver of retroactive eligibility. 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 23(a) below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state’s quarterly and annual monitoring reports.

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

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

b. **Performance Metrics.** The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS’ framework which includes the following key policies under this demonstration –the waiver of retroactive eligibility. The performance metrics will also reflect all components of the state’s demonstration. For example, these metrics will cover enrollment, disenrollment, or suspension by specific demographics and reason, access to care, and health outcomes.

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

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

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

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

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

25. **Close Out Report.** Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.
a. The draft report must comply with the most current guidance from CMS.

b. The state will present to and participate in a discussion with CMS on the Close Out report.

c. The state must take into consideration CMS’ comments for incorporation into the final Close Out Report.

d. The final Close Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS’ comments.

e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 25.

VI. MONITORING CALLS AND DISCUSSIONS

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

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

27. 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.

VII. GENERAL FINANCIAL REQUIREMENTS

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

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

VIII. MONITORING BUDGET NEUTRALITY

29. **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, 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.

IX. EVALUATION OF THE DEMONSTRATION

30. **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 18.

31. **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.

32. **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 the waiver of retroactive eligibility. Hypotheses for the waiver of retroactive eligibility will include (but not be limited to): the effects of the waiver on enrollment and eligibility continuity (including for different subgroups of individuals, such as individuals who are healthy, individuals with complex medical needs, prospective applicants, and existing beneficiaries in different care settings). Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs); and the effect of the demonstration on Medicaid program sustainability.

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

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

34. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS’s measure sets for eligibility and coverage, 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).

35. 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.

36. 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.

37. 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.

38. **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.

39. **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.

40. **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.

41. **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.

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

2) 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. 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: 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.

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

New Hampshire Granite Advantage Health Care Program  
Approval Period: January 1, 2019 – December 31, 2023  
Amended: March 17, 2021  
Page 21 of 30
<table>
<thead>
<tr>
<th>Research Question</th>
<th>Outcome measures used to address the research question</th>
<th>Sample or population subgroups to be compared</th>
<th>Data Sources</th>
<th>Analytic Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hypothesis 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research question 1a</td>
<td>Measure 1 - Measure 2 - Measure 3</td>
<td>Sample e.g. All attributed Medicaid beneficiaries - Beneficiaries with diabetes diagnosis</td>
<td>Medicaid fee-for-service and encounter claims records</td>
<td>Interrupted time series</td>
</tr>
<tr>
<td>Research question 1b</td>
<td>Measure 1 - Measure 2 - Measure 3 - Measure 4</td>
<td>Sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)</td>
<td>Patient survey</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td><strong>Hypothesis 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research question 2a</td>
<td>Measure 1 - Measure 2</td>
<td>Sample, e.g., PPS administrators</td>
<td>Key informants</td>
<td>Qualitative analysis of interview material</td>
</tr>
</tbody>
</table>

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

E. **Special Methodological Considerations**– CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

1) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
   a. Operating smoothly without administrative changes; and
   b. No or minimal appeals and grievances; and
   c. No state issues with CMS-64 reporting or budget neutrality; and
   d. No Corrective Action Plans (CAP) for the demonstration.

F. **Attachments**

1) **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of
the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include a “No Conflict of Interest” statement signed by the independent evaluator.

2) Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) Timeline and Major Milestones. Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B
Preparing the Evaluation Report

Introduction
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need improved quantitative and qualitative evidence to inform policy decisions.
Expectations for Evaluation Reports
Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state’s website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

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

The format for the Interim and Summative Evaluation reports is as follows:
A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

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