DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

OCT 19 2018

Dave Richard
Deputy Secretary for Medical Assistance
North Carolina Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-2001

Dear Mr. Richard:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) is approving North Carolina's (the state) request for a section 1115 Medicaid demonstration project, entitled "North Carolina Medicaid Reform Demonstration" (Project Number 11-W-00313/4), in accordance with section 1115(a) of the Social Security Act (the Act).

This approval is effective January 1, 2019 through October 31, 2024. CMS's approval is subject to the limitations specified in the attached waiver authorities, expenditure authorities, special terms and conditions (STCs), and subsequent attachments. The state will implement the substance use disorder (SUD) component of the demonstration no sooner than January 1, 2019, and the SUD component of the demonstration will expire on October 31, 2023. The state will implement the remaining components under the demonstration no sooner than November 1, 2019, and they will all expire on October 31, 2024. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been listed as waived or as not applicable to expenditures or individuals covered by expenditure authority.

Extent and Scope of Demonstration

Through this section 1115 demonstration, North Carolina seeks to improve beneficiary health outcomes with the implementation of a new delivery system, to maximize high-value care and to ensure sustainability of the state's Medicaid program, and reduce SUD throughout the state. Consistent with the Secretary's authority and with standard practice, this demonstration is being approved for the time periods listed above, subject to the attached STCs.

The demonstration allows the state to transition the state's Medicaid program from fee-for-service (FFS) to a managed care program. As part of the transition to managed care, the state will contract with plans that target high-need Medicaid populations, including plans for beneficiaries with behavioral health (BH) and intellectual/developmental disabilities (I/DD) diagnoses and specialized plans for foster care youth and North Carolina former foster care youth. The state also will implement an enhanced case management and other services pilot program.

This approval authorizes the state to receive federal financial participation (FFP) for the continuum of services to treat addictions to opioids and other substances, including services

provided to Medicaid enrollees with a SUD who are short-term residents in residential and inpatient treatment facilities that meet the definition of an Institution for Mental Diseases (IMD).

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Under section 1901 of the Act, the Medicaid program provides federal funding to participating states "[f]or the purpose of enabling each state, as far as practicable under the conditions in such state, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care."

As this statutory text makes clear, a basic objective of Medicaid is to enable states to "furnish ... medical assistance" to certain vulnerable populations (i.e., payment for certain healthcare services defined at section 1905 of the Act, the services themselves, or both). By paying these costs, the Medicaid program helps vulnerable populations afford the medical care and services they need to attain and maintain health and well-being. In addition, the Medicaid program is supposed to enable states to furnish rehabilitation and other services to vulnerable populations to help them "attain or retain capability for independence or self-care," per section 1901 of the Act.

We are committed to supporting states that seek to test policies that are likely to improve beneficiary health because we believe that promoting independence and improving health outcomes is in the best interests of the beneficiary and advances the fundamental objectives of the Medicaid program. Healthier, more engaged beneficiaries also may consume fewer medical services and have a lower risk profile, making the program more efficient and potentially reducing the program's national average annual cost per beneficiary of $7590.[1] Policies designed to improve beneficiary health that lower program costs make it more practicable for states to make improvements and investments in their Medicaid program and ensure the program's sustainability so it is available to those who need it most. In so doing, these policies can promote the objectives of the Medicaid statute.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration projects are likely to better enable states to serve their low-income populations, through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, information technology (IT) systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

[1] U.S. Department of Health and Human Services 2017 Actuarial Report on the Financial Outlook for Medicaid.

In its consideration of the North Carolina Medicaid Reform Demonstration proposal, CMS examined whether the demonstration was likely to assist in improving health outcomes, whether it would address health determinants that influence health outcomes, and whether it would incentivize beneficiaries to engage in their own health care and achieve better health outcomes. CMS has determined the North Carolina Medicaid Reform Demonstration is likely to promote Medicaid objectives, and the waiver and expenditure authorities sought are necessary and appropriate to carry out the demonstration.

Allowing managed care in the state is likely to increase program sustainability by lowering costs to the state and making costs more predictable each year.

Allowing managed care in the state is likely to promote efficiencies that would help ensure Medicaid's sustainability for beneficiaries over the long term. Managed care allows the state to have a more predictable budget each year and may slow the costs of the Medicaid program from growing year over year, which CMS expects will allow beneficiaries to continue receiving Medicaid coverage over the long term in the state. The state will have six Medicaid regions covering the state as part of the Medicaid reform plan. Beneficiaries must have the choice of at least two managed care organizations (MCOs).

The state requested to transition its 1915(c) Home and Community Based Services (HCBS) waivers for Innovation Waiver Services (NC-0423.R02.00) and Traumatic Brain Injury Services (NC-1326.R00.00) into the demonstration. CMS determined the state could effectively operate its HCBS waivers under the 1915(c) authorities concurrently with 1115 authority requiring Medicaid beneficiaries, except those excluded or exempted, to enroll into a managed care plan to receive state plan and HCBS waiver services.

The demonstration is likely to assist in improving health outcomes through a pilot program designed to address certain health determinants.

North Carolina's section 1115 demonstration supports coordinated strategies to address the needs of certain populations and health determinants, as well as promotes health and wellness through greater independence and improved quality of life. The North Carolina Enhanced Case Management and Other Services Pilot Program (the "pilot program") is designed to address eligible enrollees' specific health determinants to improve health outcomes and lower healthcare costs.

The state will implement the pilot program in two to four regions throughout the state to pilot evidence-based interventions addressing housing, transportation, food, and interpersonal safety and toxic stress. Pilot regions will be determined through a competitive procurement process in which Lead Pilot Entities (LPEs) will submit proposals based on target populations, objectives and evidence-based interventions for health and cost outcome. Pilot providers delivering health and social services will coordinate non-medical care to address health determinants potentially adversely affecting health and promotion of community. Under the pilot program, North Carolina will develop a pathway to value-based payments for the pilot providers, Medicaid Prepaid Health Plans (PHPs), and LPEs by incentivizing the delivery of high-quality Enhanced Case Management and Other Services by increasingly linking payments for services to

demonstration outcomes and the gathering of data and experience necessary for complex risk-based models.

CMS has long supported policies that recognize the importance of coordinating care and services to improve the well-being and health of Medicaid beneficiaries. CMS recognizes health determinants can influence health outcomes, and research supports the hypothesis that state's proposed enhanced case management services will improve health outcomes. Similarly, the Rural Health Information Hub supported by the Health Resources and Services Administration acknowledges the importance of transportation in a person's ability to access appropriate and well-coordinated healthcare, purchase nutritious food, and otherwise care for themselves.[2] In addition, Mental Health America affirms interpersonal violence and toxic stress lead to poor outcomes across the lifespan with an individual's health and productivity. The effects of toxic stress in children are known to lead to the development of mood and anxiety disorders, aggression, social skills deficits, peer relations and substance use in children and youth.[3] CMS has not previously approved a demonstration that includes enhanced case management. However, given the potential health benefits of making these services available to certain high-risk and high-need Medicaid beneficiaries, CMS believes that state Medicaid programs should be able to support these activities and test incentives that are appropriate for these populations and are likely to lead to improved health outcomes.

BH I/DD tailored plans will allow the state to address the complex needs of individuals with behavioral health and I/DD diagnoses, and the specialized plan will allow the state to address the complex needs of foster care/former North Carolina foster care youth.

Incorporating tailored plans into the North Carolina Medicaid Reform Demonstration will allow the state to address specific complex needs for the Medicaid BH I/DD populations. The tailored plans will include coverage for whole-person services specifically designed to meet complex needs, including the physical health, BH, and social needs, of these populations. The state anticipates that providing services tailored to these populations will address the healthcare needs and provide high quality care for these complex populations.

The tailored plans will be implemented by the end of third year of the demonstration. Prior to the implementation of BH I/DD tailored plans, BH I/DD qualified beneficiaries will remain in the fee for service Medicaid system for physical health services and in the state's 1915(b) program for BH I/DD services rather than being mandatorily enrolled in the standard plan. Once the BH I/DD tailored plans are implemented, eligible beneficiaries will be transitioned to (or if they had opted into Standard Plans, given the option to transition to) the tailored plan in their region with the option to opt out within 90 days to a standard plan, consistent with the process described in these STCs.

The state will develop a specialized plan to be offered by PHP for children in foster care meeting a set of care management and medication management requirements specific for this population. This specialized plan will provide coverage to children in county-operated foster

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[2] (Hub 2017)

[3] Shern, D.L. (2014). Impact of Toxic Stress on Individuals and Communities: A review of the Literature. Mental Health America.

care, children in adoptive placements, and former North Carolina foster care youth up to age 26 who aged out of care. Children will be automatically enrolled in the specialized foster care plan with the option to change to the Standard Plan for any reason at any time during the coverage year.

Approving the SUD program will allow the state to address opioid use disorders and other SUDs, which are a serious public health concern in North Carolina.

The SUD program will improve access to high-quality addiction services and is critical to addressing SUD in the state. Under this program, all Medicaid beneficiaries will continue to have access to all current mental health and SUD benefits. In addition, all beneficiaries ages 21 through 64 will have access to additional covered services, authorized under section 1115(a)(2) of the Act, including SUD treatment services provided to individuals with SUD who are short-term residents in residential treatment facilities that meet the definition of an IMD. These services would otherwise be excluded from federal reimbursement.

Elements of the demonstration request CMS is not approving at this time

In the amended demonstration application, the state requested certain additional flexibilities, and CMS is not approving the following at this time. CMS intends to continue discussing flexibilities with the state.

The state requested to provide short-term behavioral health crisis services in the IMD setting for beneficiaries with behavioral health as a primary diagnosis. Consistent with CMS policy, CMS does not currently provide expenditure authority for behavioral health IMD services.

North Carolina requested to incorporate a workforce development program into its demonstration as a two-part approach: complete a workforce development assessment to identify healthcare provider gaps throughout the state and establish a workforce incentive fund to address shortages identified in the workforce assessment through loan repayment and recruitment bonuses for critical provider types. CMS recommends the state develop and implement a one-time workforce development assessment to identify gaps in the healthcare provider workforce throughout the state. Following the analysis and completion of the workforce development assessment, the state may submit a demonstration amendment highlighting identified gaps in the provider workforce, conclusions and recommendations for the workforce development proposal for further consideration.

In its amended demonstration application, the state also requested authority for certain features of a new program entitled Carolina Cares. As described in the amended demonstration application, as proposed, the Carolina Cares program would require beneficiaries in the new adult group to pay monthly premiums and participate in community engagement activities as a condition of eligibility. Enrollees in this program would have been required to be employed or engaged in activities promoting employment to fulfill the community engagement requirement. Failure to pay the monthly premium or complete required community engagement requirements would have led to disenrollment from the program following appropriate notice and a grace period. Enrollees that would have been

exempt from the premium requirement are those with medical or financial hardship, member of a federally recognized tribe or a veteran in transition seeking employment. Enrollees caring for a dependent minor child, an adult disabled child, or a disabled parent; receiving active SUD treatment; or medically frail are exempt from the community engagement requirement. The state does not currently have state legislative authority for the Carolina Cares program, and CMS will not consider this program without state legislative authority.

The state also requested to implement a telemedicine program through two initiatives: the Telemedicine Innovation Fund to support PHPs addressing Medicaid quality strategy goals and unmet needs of the Medicaid population, and the Telemedicine Alliance to administer the Telemedicine Innovation Fund and provide a forum for sharing and disseminating best practices throughout the state. CMS has given the state information about other available resources to facilitate implementing a telemedicine program outside of the 1115 demonstration, and CMS is not approving this request.

The state requested expenditure authority to make wrap-around payments to safety-net providers to cover the difference between PHP reimbursement and provider costs. In the current FFS system, the state is currently covering these costs to ensure beneficiaries have access to providers having a limited ability to offset losses with revenue from other payers. Consistent with current CMS policies, CMS is not approving this request for expenditure authority.

In addition, the state requested expenditure authority to make advanced payments to support capacity building to health home providers delivering health home services to enrollees in a BH I/DD tailored plan. Capacity building funding would support IT supports for the care management agencies and provider and support for training the care management workforce to meet the needs of these complex populations. CMS is not approving this request for expenditure authority and will continue to work with the state on this program.

North Carolina also requested CMS approval of a tribal uncompensated care program as part of the 1115 demonstration. The state requested expenditure authority to receive the 100 percent federal medical assistance percentage under section 1905(b) of the Act for its expenditures on a tribal uncompensated care pool that would support the Cherokee Indian Hospital Authority (CIHA), an Indian Health Service (IHS) hospital. Payments under this program would offset CIHA's cost for delivery of services for uninsured individuals, and unreimbursed costs of Medicaid-covered services would not be included in the uncompensated care costs. CMS is unable to provide section 1115 authority for this proposal. The 100 percent federal match available under section 1905(b) of the Act applies only to Medicaid services received through IHS and tribal facilities, and the proposed uncompensated care payments are not payment for Medicaid services. Section 1115(a)(1) waiver authority extends only to provisions of section 1902 of the Act, and does not extend to provisions of section 1905 of the Act, such as section 1905(b). Nor is CMS able to grant the state's request by providing expenditure authority under section 1115(a)(2)(A) of the Act. Section 1115(a)(2)(A) only permits state expenditures to be regarded as federally matchable. It does not allow applicable federal match rates to be altered.

Consideration of Public Comments

CMS and the state received numerous comments throughout the federal and state comment periods. Consistent with federal transparency requirements, CMS reviewed all of the received public comments along with the summarized public comments submitted by the state, when evaluating whether the demonstration and the proposed projects were likely to promote the objectives of the Medicaid program, and whether the waiver and expenditure authorities sought were necessary and appropriate to implement the demonstration. In addition, public comments were considered in the development of the STCs that accompany this approval, and that will bolster beneficiary protections, including specific state assurances around these protections to further support Medicaid beneficiaries.

Commenters expressed concerns regarding the state's request to implement the Carolina Cares program through the establishment of a new adult group that would charge enrollees a monthly premium and require enrollees to complete work requirements to maintain Medicaid coverage. North Carolina acknowledged the concerns of many of the commenters and expressed the state's commitment to ensuring enrollees have access to affordable health care. The state also acknowledged that it would need state legislative authority to implement the Carolina Cares program. The state does not have legislative authority for the Carolina Cares program and the Carolina Cares program is not being approved under this demonstration.

Additional commenters expressed concerns regarding the state's proposal to transition 1915(c) waivers into the demonstration and the possibility of unintended consequences such as disruptions of continuity of care and reductions in the budget. CMS has decided to approve operation of these waivers concurrently with the 1115 demonstration, which we believe should alleviate the commenter's concerns as the 1915(c) waivers will continue to operate as previously approved. The only difference created by this approval is that the 1915(c) waiver services will now be delivered through managed care plans for these populations under the authority of section 1115 of the Act. The state has been thoughtful in its approach to transition from FFS to managed care and has been working closely with CMS in preparation for the transition. Specifically, North Carolina first came to CMS with an interest in implementing managed care, including Managed Long-Term Services and Supports in June 2016. Since that time, CMS has been providing technical assistance to the state, including preparing the state to meet readiness review expectations under 42 CFR 438.66, which address network adequacy and access. CMS is confident that North Carolina is prepared for the transition to managed care and is able to avoid the unintended consequences identified by commenters.

We received comments regarding the sufficiency of the state's SUD proposal in the amended demonstration. Commenters expressed concerns that the proposal did not align closely with the State Medicaid Director Letter (SMDL) released November 1, 2017. One commenter indicated the state's proposal only seeks permission to reimburse for inpatient and residential care, not addressing care coordination and would not adequately address the opioid crisis or improve SUD services. Another commenter recommended the state incorporate the goals and milestones outlined in the SUD SMDL to ensure the state's residential treatment providers will deliver SUD services consistent with the nationally recognized SUD criteria and provide evidence-based SUD treatment, including medications for treatment in the opioid disorder. The STCs require that the

state not only submit a SUD Implementation Plan Protocol, but that the SUD Implementation Plan Protocol reflect key goals and milestones, including but not limited to the use of nationally recognized SUD-specific program standards to set provide qualifications for residential treatment facilities.

CMS's approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and the STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. Your project officer for this demonstration is Ms. Sandra Phelps. She is available to answer any questions concerning your demonstration project. Ms. Phelps' contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-1968
E-mail: Sandra.Phelps@cms.hhs.gov

Official communications regarding this demonstration should be sent simultaneously to Ms. Phelps and Ms. Shantrina Roberts, Associate Regional Administrator (ARA) in our Atlanta Regional Office. Ms. Roberts' contact information is as follows:

Centers for Medicare & Medicaid Services
Atlanta Regional Office
61 Forsyth Street SW
Atlanta, GA 30303
Telephone: (404) 562-7418
E-mail: Shantrina.Roberts@cms.hhs.gov

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

Sincerely,

Seema Verma

cc: Shantrina Roberts, ARA, CMS Atlanta Region

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: **11W00313/4**

TITLE: **North Carolina Medicaid Reform Demonstration**

AWARDEE: **North Carolina Department of Health and Human Services**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration, from November 1, 2019 through October 31, 2024, unless otherwise specified. 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 in order to enable North Carolina (the state) to carry out the North Carolina Medicaid Reform Demonstration.

1. Statewide Operation **Section 1902(a)(1)**

To the extent necessary to enable the state to operate managed care on less than a statewide basis based on a phase-in schedule set forth in the STCs.

To the extent necessary to enable the state to implement the enhanced case management and other services pilot program in geographically limited areas of the state as described in these STCs.

2. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable the state to restrict freedom of choice of provider through the use of mandatory enrollment in managed care plans for the receipt of covered services including individuals in the Innovations and TBI 1915(c) waivers NC 0423.RO2.00, NC1326.R00.00, respectfully. No waiver of freedom of choice is authorized for family planning providers.

3. Amount, Duration, & Scope **Section 1902(a)(10)(B)**

To the extent necessary to enable the state to vary the amount, duration, and scope of services offered to individuals in managed care under this demonstration, regardless of eligibility category.

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11W00313/4**

TITLE: **North Carolina Medicaid Reform Demonstration**

AWARDEE: **North Carolina Department of Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by North Carolina for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, incurred from November 1, 2019 to October 31, 2024 unless otherwise specified, shall be regarded as expenditures the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable North Carolina to operate the North Carolina Medicaid Reform 1115 demonstration.

1. **Residential and Inpatient Treatment for Individuals with a Substance Use Disorder (SUD).** Effective January 1, 2019 through October 31, 2023, expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

2. **Enhanced Case Management and Other Services Pilot Program**. Effective November 1, 2019, expenditures not to exceed $650 million to conduct the enhanced case management and other services pilot program in two to four regions of the state to improve health-related needs for Medicaid eligible individuals enrolled in a PHP who meet the eligibility criteria specified in the special terms and conditions. The expenditure authority will expire on October 31, 2024.

Title XIX Requirements not applicable to the Enhanced Case Management and Other Services Pilot Program.

All title XIX requirements that are waived for Medicaid eligible groups are also not applicable to the enhanced case management and other services pilot program. In addition, the following Medicaid requirement is not applicable:

1. **Comparability** **Section 1902(a)(17)**
   To enable the state to provide additional benefits to Medicaid beneficiaries who are enrolled in the enhanced case management and other services pilot program.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STCs)

NUMBER: **11W00313/4**

TITLE: **North Carolina Medicaid Reform Demonstration**

AWARDEE: **North Carolina Department of Health and Human Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "North Carolina Medicaid Reform Demonstration" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the North Carolina Department of Health and Human Services (the 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), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to this demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The STCs are effective as of the date of the approval letter, unless otherwise specified, for the period beginning November 1, 2019 through October 31, 2024. The SUD component of the demonstration will be effective as of the date of the approval letter, unless otherwise specified, for the period beginning January 1, 2019 through October 31, 2023.

The STCs have been arranged into the following subject areas:

Attachment D: Reserved for SUD Implementation Plan Protocol
Attachment E: Reserved for SUD Monitoring Protocol
Attachment F: SUD Health Information Technology (Health IT) Protocol
Attachment G: Enhanced Case Management and Other Services Pilot Program Eligibility and Services

II. PROGRAM DESCRIPTION AND OBJECTIVES

In September 2015, the state passed legislation to transition its Medicaid (Title XIX) program care delivery system to a Medicaid managed care program and delegate direct management of medical services and financial risks to Managed Care Organizations called Prepaid Health Plans (PHPs) for Medicaid enrollees, except for those excluded.

To improve beneficiary outcomes, the new managed care program will be paired with initiatives to further improve the capabilities of Medicaid providers and increase access to care across the state. North Carolina seeks to transform its Medicaid delivery system by meeting the following goals:

- Measurably improve health outcomes via a new delivery system;
- Maximize high-value care to ensure sustainability of the Medicaid program; and
- Reduce Substance Use Disorder (SUD).

The state will test and evaluate the following hypotheses in pursuit of its aforementioned goals:

Measurably Improve Health

- The implementation of tailored plans and the specialized foster care plan will increase the quality of care for individuals with serious mental illness, serious emotional disturbance, substance use disorder, and intellectual and developmental disability (I/DD), and for children in foster care and North Carolina former foster care youth.
- The implementation of Medicaid managed care will increase the rate of use of behavioral health services in the appropriate level of care and improve the quality of behavioral health care received.
- The implementation of Medicaid managed care will decrease the long-term use of opioids and increase the use of medication-assisted treatment (MAT) and other opioid treatment services.

Maximize High-Value Care to Ensure the Sustainability of the Program

- The implementation of Medicaid managed care will decrease the use of emergency departments for non-urgent use and hospital admissions for ambulatory sensitive conditions.
- The implementation of Medicaid managed care will increase the number of enrollees receiving care management, overall and during transitions in care.

Reduce Substance Use Disorder (SUD)

- Expanding coverage of SUD services to include residential services furnished in institutions for mental disease (IMDs) as part of a comprehensive strategy will decrease the long-term use of opioids and increase the use of MAT and other opioid treatment services.
- Expanding coverage of SUD services to include residential services furnished to short-term residents in IMDs with a SUD diagnosis as part of a comprehensive strategy will result in improved care quality and outcomes for patients with SUD.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
2. **Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program, or the Children's Health Insurance Program (CHIP) for the separate CHIP population, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change. The modified budget neutrality agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.
    b. If mandated changes in the federal law require state legislation, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.

5. **State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid state plan governs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, delivery systems, cost sharing, 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. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.

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 the failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

    a. An explanation of the public process used by the state, consistent with the requirements of STC 15. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

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

    c. An up-to-date CHIP allotment worksheet, if necessary.

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

    e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request demonstration extensions under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, if the state intends to request a demonstration extension under section 1115(a) of the Act, the state must submit the

extension application no later than 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 CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 10.

a. As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements 42 CFR §431.412 and the public notice and tribal consultation requirements outlined in STC 15.

b. Upon application from the state, CMS reserves the right to temporarily extend the demonstration including making any amendments deemed necessary to effectuate the demonstration extension including but not limited to bringing the demonstration into compliance with changes to federal law, regulation and policy.

9. **Compliance with Transparency Requirements 42 CFR Section 431.412.** As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements set forth in 42 CFR Section 431.412 and the public notice and tribal consultation requirements outlined in STC 15, as well as include the following supporting documentation:

a. Demonstration Summary and Objectives: The state must provide a narrative summary of the demonstration project, reiterate the objectives set forth at the time the demonstration was proposed and provide evidence of how these objectives have been met as well as future goals of the program. If changes are requested, a narrative of the changes being requested along with the objective of the change and desired outcomes must be included.

b. Waiver and Expenditure Authorities: The state must provide a list along with a programmatic description of the waivers and expenditure authorities that are being requested in the extension.

c. Quality: The state must provide summaries of: External Quality Review Organization (EQRO) reports; managed care organization (MCO) reports; state quality assurance monitoring; and any other documentation that validates the quality of care provided or corrective action taken under the demonstration.

d. Compliance with Budget Neutrality Cap: The state must provide financial data (as set forth in the current STCs) demonstrating the state's detailed and aggregate, historical and projected budget neutrality status for the requested period of the extension as well as cumulatively over the lifetime of the demonstration. CMS will work with the state to ensure that federal expenditures under the extension of this project do not exceed the federal expenditures that would otherwise have been made. In doing so, CMS will take into account the best estimate of current trend rates at the time of the extension. In addition, the state must provide up to date responses to the CMS Financial Management standard questions. If title XXI funding is used in the demonstration, a CHIP Allotment Neutrality worksheet must be included.

e. Evaluation Report: The state must provide an evaluation report reflecting the hypotheses being tested and any results available. For the proposed extension period, the state must provide a narrative summary of the evaluation design, status (including

evaluation activities and findings to date), and plans for evaluation activities during the extension period.

f. Documentation of Public Notice 42 CFR section 431.408: The state must provide documentation of the state's compliance with public notice process as specified in 42 CFR section 431.408 including the post-award public input process described in 431.420(c) with a report of the issues raised by the public during the comment period and how the state considered the comments when developing the demonstration extension application.

10. 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 phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft phase-out plan to CMS, the state must publish on its website the draft phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received the state's response to the comment and how the state incorporated the received comment into a revised phase-out plan.

The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of phase-out activities must be no sooner than 14 calendar days after CMS approval of the phase-out plan.

b. Phase-out Plan Requirements: The state must include, at a minimum, in its 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 for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

c. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR §431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and 431.221. If a demonstration participant 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 as discussed in October 1, 2010, State Health Official Letter #10-008.

d. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

11. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

12. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge CMS' finding that the state materially failed to comply.

13. **Withdrawal of 1115(a) Authority.** CMS reserves the right to withdraw waiver or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services and administrative costs of disenrolling participants.

14. **Adequacy of Infrastructure.** The state will 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.

15. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR section 447.205 for changes in statewide methods and standards for setting payment rates.

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR section 431.408(b), State Medicaid Director Letter #01-024, and contained in the state's approved Medicaid State plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

16. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter, or later date if so identified elsewhere in these STCs or in the list of waiver or expenditure authorities.

17. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

18. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities which may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and which are designed to study, evaluate, or otherwise examine the Medicaid program – including public benefit or service programs; procedures for obtaining Medicaid benefits or services; possible changes in or alternatives to those programs or procedures; or possible changes in methods or level of payment for benefits or services under those programs. CMS 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. ELIGIBLITY AND ENROLLMENT

All eligibility is defined under the State Plan or, where applicable, the 1915(c) waiver. This demonstration affects all eligibility groups other than those listed in Table 1, except that STC 19 applies to all eligibility groups, including those listed in Table 1.

TABLE 1: GROUPS EXCLUDED FROM ENROLLMENT IN PHPs

GROUP NAME	CITATIONS
Duals Eligible for Cost-Sharing Assistance • Qualified Medicare Beneficiaries • Qualified Disabled and Working Individuals • Specified Low Income Medicare Beneficiaries • Qualifying Individuals	• 1902(a)(10)(E) • 1905(p)
Duals Eligible for Full Medicaid, except those eligible to enroll in BH I/DD tailored plans	• 1902(e)(8) • 1905(p)(1) • 1935(c)(6)
Medically Needy • Medically Needy Pregnant Women except those covered by Innovations or TBI waivers • Medically Needy Children under 18 except those covered by Innovations or TBI waivers • Medically Needy Children Age 18 through 20 except those covered by Innovations or TBI waivers • Medically Needy Parents and Other Caretaker Relatives except those covered by Innovations or TBI waivers • Medically Needy Aged, Blind, or Disabled except those covered by Innovations or TBI waivers • Medically Needy Blind or Disabled Individuals Eligible in 1973 except those covered by Innovations or TBI waivers	• 1902(a)(10)(C)

GROUP NAME	CITATIONS
Presumptively Eligible • Presumptively Eligible Pregnant Women • Presumptively Eligible MAGI Individuals	• 1902(a)(47) • 1920 • 1920A • 1920B • 1920C
Individuals Participating in the Program of All-Inclusive Care for the Elderly (PACE)	• 1905(a)(26) • 1934
Individuals Receiving Refugee Medical Assistance	• 8 USC § 1522 • 45 CFR Part 400
Individuals Participating in the NC Health Insurance Premium Payment (HIPP) program except those covered by Innovations or TBI waivers	State Plan Eligibility
Individuals with Limited or no Medicaid Coverage (e.g., eligible for emergency services only)	See Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996
Individuals Eligible for Family Planning Services	• 1902(a)(10)(A)(ii)(XXI) • 42 CFR 435.214
Prison Inmates *(Inpatient stays only)*	• Clause (A) following 1905(a)(29)(A) • 42 CFR 435.1009, 1010
Medicaid-only Beneficiaries Receiving Long-Stay Nursing Home Services	State Plan Eligibility
Community Alternatives Program for Children (CAP/C)	1915(c) waiver
Community Alternatives Program for Disabled Adults (CAP/DA)	1915(c) waiver
Individuals in any eligibility category not otherwise excluded during their period of retroactive eligibility or prior to the effective date of PHP coverage	1902(a)(34)

V. DEMONSTRATION PROGRAMS AND BENEFITS

19. <u>Opioid Use Disorder/Substance Use Disorder Program.</u> Effective upon CMS' approval of the OUD/SUD Implementation Plan Protocol, the demonstration benefit package for North Carolina Medicaid recipients must include OUD/SUD treatment services, including short-term residential services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for North Carolina Medicaid recipients who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. The state

must aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 19(b) below, to ensure short-term residential treatment stays. Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD and other SUD treatment services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The coverage of OUD/SUD residential treatment and withdrawal management during short-term residential and inpatient stays in IMDs will expand the state's current SUD benefit package available to all North Carolina Medicaid recipients as outlined in Table 2. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Table 2: North Carolina OUD/SUD Benefits Coverage with Expenditure Authority

SUD BENEFIT	***MEDICAID AUTHORITY***	***EXPENDITURE AUTHORITY***
Screening, Brief Intervention and Referral to Treatment	State Plan (Individual services covered)	
Outpatient Behavioral Health Services Provided by Direct Enrolled Provider	State Plan (Individual services covered)	
Substance Abuse Intensive Outpatient Program	State Plan (Individual services covered)	Services provided to individuals in an IMD
Substance Abuse Comprehensive Outpatient Treatment Program	State Plan (Individual services covered)	Services provided to individuals in an IMD
Substance Abuse Halfway House Services	State Plan (Individual services covered: contingent on SPA approval)	Services provided to individuals in an IMD
Clinically Managed Population-Specific High Intensity Residential Services	State Plan (Individual services covered: contingent on SPA approval)	Services provided to individuals in an IMD
Substance Abuse Non-Medical Community Residential Treatment	State Plan (Individual services covered)	Services provided to individuals in an IMD
Substance Abuse Medically Monitored Community Residential Treatment	State Plan (Individual services covered)	Services provided to individuals in an IMD

SUD BENEFIT	*MEDICAID AUTHORITY*	*EXPENDITURE AUTHORITY*
Medically Managed Intensive Inpatient	State Plan (Individual services covered)	Services provided to individuals in an IMD
Outpatient Opioid Treatment Program	State Plan	Services provided to individuals in an IMD
Office Based Opioid Treatment Program	State Plan	Services provided to individuals in an IMD
Ambulatory Withdrawal Management without Extended On-Site Monitoring	State Plan	
Ambulatory Withdrawal Management with Extended On-Site Monitoring	State Plan (Individual services covered: contingent on SPA approval)	
Social Setting Detoxification Withdrawal Management	State Plan (Individual services covered: contingent on SPA approval)	Services provided to individuals in an IMD
Non-Hospital Medical Detoxification Withdrawal Management	State Plan	Services provided to individuals in an IMD
Medically Supervised or Alcohol and Drug Abuse Treatment Center (ADATC) Detoxification Crisis Stabilization	State Plan	Services provided to individuals in an IMD
Medically Managed Intensive Inpatient Withdrawal Management	State Plan	Services provided to individuals in an IMD

The state attests that the services indicated in Table 2, as being covered under the Medicaid state plan authority are currently covered in the North Carolina Medicaid state plan, except those that are listed as being contingent on SPA approval.

a. **SUD Implementation Plan Protocol.** The state must submit an OUD/SUD Implementation Plan Protocol within 90 calendar days after approval of the SUD program under this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the SUD Implementation Plan Protocol. Once approved, the SUD Implementation Plan Protocol will be incorporated into the STCs, as Attachment D, and once incorporated, may be altered only with CMS approval. After approval of the SUD Implementation Plan Protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Plan Protocol will be considered a material failure to comply with the terms of the demonstration project as

described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the OUD/SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral.

At a minimum, the SUD Implementation Plan Protocol must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the SUD component of this demonstration :

i. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;

ii. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;

iii. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;

iv. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in North Carolina Administrative Code (10A NCAC 27G.0401). The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD program demonstration approval;

v. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

vi. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;

vii. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of SUD program demonstration approval;

viii. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 19(g) and Attachment F; and

x. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

b. **SUD Monitoring Protocol.** The state must submit a SUD Monitoring Protocol using the CMS SUD Monitoring Protocol template within 150 calendar days after approval of the SUD program under this demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the SUD Monitoring Plan Protocol will include reporting relevant to each of the program implementation areas listed in STC 19(a). The SUD Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in STC 24 of the demonstration. In addition, the SUD Monitoring Protocol must identify a baseline and a target to be achieved by the end of the demonstration. Where possible, baselines must be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the SUD Monitoring Protocol must be reported via the quarterly and annual monitoring reports.

c. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment by DY 3 (November 1, 2021) of the demonstration. The state must require that the assessor collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The state must require that the assessment include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan Protocol, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol. The state must require that the assessment include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not

yet met and about the risk of possibly missing those milestones and performance targets. The state must require that the mid-point assessment must also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the state must require the assessor provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The state must require the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation Plan Protocol and SUD Monitoring Plan Protocol for ameliorating these risks subject to CMS approval.

d. **SUD Evaluation.** The OUD/SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as listed in sections VIII General Reporting Requirements and X Evaluation of the Demonstration of the STCs.

e. **SUD Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, the Evaluation Design, including the SUD program with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. 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 state must use an independent evaluator to develop the draft Evaluation Design.

   i. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) 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 Quarterly and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

   ii. **Evaluation Questions and Hypotheses Specific to the OUD/SUD Program.** 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 must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid

and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

f. **SUD Health Information Technology (Health IT).** The state must provide CMS with an assurance that it has a sufficient health IT infrastructure "ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it must submit to CMS a plan to develop the infrastructure/capabilities. This "SUD Health IT Plan," or assurance, must be included as a section of the state's "Implementation Plan Protocol" (see STC 19(a)) to be approved by CMS. The SUD Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The SUD Health IT Plan must also be used to identify areas of SUD health IT ecosystem improvement.

   i. The SUD Health IT section of the SUD Implementation Plan Protocol must include implementation milestones and dates for achieving them (see Attachment F).

   ii. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

   iii. The SUD Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP)[1]

   iv. The SUD Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

   v. The SUD Health IT Plan must, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state must also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.
[2] *Ibid*.

vi. The SUD Health IT Plan must describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

vii. In developing the Health IT Plan, states should use the following resources.

1. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."
2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

h. The state must include in its Monitoring Plan (see STC 19(b)) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

i. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (see STC 27).

j. As applicable, the state must advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable state procurements (e.g., including managed care contracts) that are associated with this demonstration.

i. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state must use the federally-recognized standards, barring another compelling state interest.

ii. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state must use the federally-recognized ISA standards, barring no other compelling state interest.

VI. COST SHARING

20. <u>Cost Sharing</u>. Cost sharing under this demonstration is consistent with the provisions of the approved state plan.

[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

VII. DELIVERY SYSTEM

21. <u>Managed Care Organizations (MCO)</u>. Beneficiaries, except those excluded or exempted, shall be enrolled to receive services through an MCO called a Prepaid Health Plan (PHP) in the state that will be under contract to the state. The MCOs (PHPs) are subject to and must comply with the federal laws and regulations as specified in 42 CFR Part 438, unless specified otherwise herein. The state must comply with 42 CFR 438 in connection with managed care plans offered under this demonstration unless specified otherwise herein.

A. **Populations Enrolled in Managed Care.** All Medicaid populations will be mandatorily enrolled in PHPs except for those who will be excluded or exempt according to the managed care phase-in schedule detailed below in Table 3.

Table 3: Managed Care Phase-in Schedule

POPULATIONS	DY 2-3[4]	DY 4-6
Medicaid beneficiaries except those excluded, exempted individuals who choose not to enroll in managed care, or enrolled in a BH I/DD tailored plan or specialized plan	Standard plan	Standard plan
Medicaid beneficiaries eligible to enroll in BH I/DD tailored plans except populations listed below	Medicaid fee-for-service/local management entity-managed care organization (LME-MCO)[5]	BH I/DD tailored plan
Legal aliens eligible to enroll in BH I/DD tailored plans	Medicaid fee-for-service	BH I/DD tailored plan
Children under age three eligible to enroll in BH I/DD tailored plans	Medicaid fee-for-service (Children 0-3 of age are exempt from LME-MCOs)	BH I/DD tailored plan
Beneficiaries dually eligible for Medicare and Medicaid and eligible to enroll in BH I/DD tailored plans	Medicaid fee-for-service/LME-MCO	Medicaid fee-for-service/BH I/DD tailored plan[6]
Innovations waiver enrollees[7]	Medicaid fee-for-service/LME-MCO	BH I/DD tailored plan

[4] Populations enrolling in BH I/DD tailored plans may not be included in the demonstration until demonstration year 3, when BH I/DD tailored plans are scheduled to begin.
[5] LME-MCOs are limited benefit prepaid inpatient health plans.
[6] Beneficiaries dually eligible for Medicare and Medicaid and who are eligible to enroll in a BH I/DD tailored plan are included in the demonstration may enroll in BH I/DD tailored plans in year 3 for Medicaid-covered behavioral health, I/DD, and TBI services, only. They will receive all other Medicaid-covered services through Medicaid fee-for-service. All other individuals dually eligible for Medicare and Medicaid will be excluded from enrolling in managed care.
[7] All Innovations waiver enrollees including certain children in foster care, NC Health Insurance Premium Payment (HIPP) program participants and medically needy beneficiaries will obtain coverage through Medicaid fee-for-service/LME-MCOs during DY 2 – 3 of PHP implementation before enrolling in BH I/DD tailored plans in by the end of DY 3. Innovations waiver beneficiaries who are dually eligible for Medicare and Medicaid will enroll in BH I/DD tailored plans by the end of DY 3 for Medicaid-covered behavioral health, I/DD (including Innovations

Traumatic Brain Injury waiver enrollees[8]	Medicaid fee-for-service/LME-MCO	BH I/DD tailored plan
Children in county-operated foster care; children in adoptive placements; and North Carolina former foster youth up until age 26 who aged out of foster youth in North Carolina	Medicaid fee-for-service/LME-MCO	Specialized PHP for children in foster care

B. **Excluded Populations.** Excluded populations that will continue to receive benefits through Medicaid fee-for-service or their existing delivery system are outlined in Table 1 under Section IV: Eligibility and Enrollment.

C. **Exempt Populations.** "Indians," as the term is defined in 42 CFR § 438.14(a), will be able, but not required, to enroll in PHPs. Such individuals may voluntarily enroll in PHPs on an opt-in basis and may disenroll without cause at any time. In addition, the state must require PHPs to comply with the regulation at 42 CFR § 438.14 when covering such individuals.

D. **Contracts**. Consistent with section 1903(m) and State Medicaid Manual § 2087, no FFP is available for activities covered under contracts and/or modifications to existing contracts that are subject to 42 CFR 438 requirements prior to CMS approval of such contracts and/or contract amendments. The state must provide CMS with a minimum of 60 days to review and approve changes.

E. The state is authorized to contract with Managed Care Organizations (MCOs), Prepaid ambulatory health plans (PAHPs), and Prepaid inpatient health plans (PIHPs) all of which are defined under 42 CFR 438.2. The state must contract with MCOs that provide any of the following three types of plans:
    a. Standard Plans that serve Medicaid enrollees, except those in excluded populations, individuals in exempt populations who choose not to enroll, or enrollees in BH I/DD Tailored Plans or Specialized Plans. The state must require that the Standard Plans include coverage of comprehensive services, including integrated physical health, behavioral health, and pharmacy.
    b. BH I/DD Tailored Plans that provide integrated physical health, behavioral health, I/DD, TBI, and pharmacy services to its enrollees. The following Medicaid enrollees, unless they are in excluded populations or exempt populations who do not opt-in to managed care, must be enrolled in BH I/DD Tailored Plans consistent with STC 23(h):
        i. Diagnosed with Serious Mental Illness;
        ii. Serious Emotional Disturbance;

waiver), and TBI services, only; these dually eligible beneficiaries will receive all other Medicaid-covered services through Medicaid fee-for-service.

[8] All TBI waiver enrollees including children in foster care, NC HIPP program participants and medically needy beneficiaries will receive coverage through Medicaid fee-for-service/LME-MCOs during DY 2 – 3 of PHP implementation before enrolling in BH I/DD tailored plans by the end of DY 3. TBI waiver beneficiaries who are dually eligible for Medical and Medicaid will enroll in BH I/DD tailored plans by the end of DY 3 for Medicaid covered behavioral health, BH I/DD (including Innovations waiver), and TBI services, only these dually eligible beneficiaries will receive all other Medicaid-covered services through Medicaid fee-for-service.

iii. Substance Use Disorder; and
iv. I/DD and/or TBI needs.

c. Specialized Plans for Children in Foster Care and North Carolina former Foster Care Youth that provide coverage to children in:
i. County-operated foster care;
ii. Children in adoptive placements; and
iii. Former North Carolina Foster Care Youth up until age 26.

F. The state must require that all Managed Care health plans providing comprehensive coverage have a comprehensive risk contract between the state and an MCO covering comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:
a. Outpatient hospital services
b. Rural health clinic services
c. Federally Qualitied Health Center (FQHC) services
d. Other laboratory and X-ray services
e. Nursing facility services
f. Early and periodic screening, diagnostic and treatment (EPSDT) services
g. Family planning services
h. Physician services
i. Home health services

G. **Standard Plan Enrollment**. Beneficiaries will be mandatorily enrolled into managed care, and must be given an opportunity to select an MCO at the time of application. Beneficiaries must have the choice of at least 2 MCOs. A beneficiary who does not make an MCO selection at the time of application may be auto-assigned to a MCO by the state consistent with 42 C.F.R. § 438.54(d)(5). Upon enrollment, whether by auto-assignment or enrollee selection, the state or its designee must send a notice to enrollees confirming their enrollment in the plan. Pursuant to 42 C.F.R. § 438.56, beneficiaries must have 90 days to change plans after initial enrollment and at least once every 12 months thereafter.

H. **BH I/DD Tailored Plan Enrollment and Specialized Plan for Children in Foster Care and Formerly in Foster Care Enrollment.** Beneficiaries must be determined eligible for BH I/DD Tailored Plans and Specialized Plan for Children in Foster Care through the use of available data (e.g., historical claims and encounters). Enrollees eligible for a BH I/DD Tailored Plan or Specialized Plan will be mandatorily enrolled into that plan, and will be auto-assigned to a plan consistent with § 438.54(d)(2)(ii). Enrollees eligible for both the BH I/DD tailored plan and the specialized plan must have the opportunity to select the plan they would like to be enrolled in, and such enrollees will have the choice of one BH I/DD tailored plan or one specialized plan. Enrollees will have 90 days to change plans after initial enrollment and at least once every 12 months thereafter.

I. **Disenrollment from BH I/DD Tailored Plan and Specialized Plan for Children in Foster Care and Formerly in Foster Care**. Beneficiaries eligible for the BH I/DD Plan, Specialized Plan for Children in Foster Care and Formerly in Foster Care may disenroll from either a BH I/DD Tailored Plan or specialized plan pursuant to STC 19(g) into a Standard Plan, but will lose access to the specialized services offered under

those specialized plans. An eligible beneficiary must have the option to re-enroll in a BH I/ DD Tailored Plan or the Specialized Plan for Children in Foster Care and Formerly in Foster Care at any time following the beneficiary's voluntary disenrollment.

J. **BH I/DD Tailored Plans Benefits**. Specialized behavioral health services, including Innovations and TBI waiver services and services now covered under 1915(b)(3) must be available only through BH I/DD Tailored Plans.

K. **Managed Care Implementation.** The state will execute the managed care program by implementing the Standard Plan on a rolling regional basis during DY 2 and complete implementation in all regions by the end of DY 2. The state must implement Managed Care in two state regions by November 2019 and the remaining four regions must be implemented by February 2020. The state must implement each plan type according to the following schedule:

Plan Type	**Demonstration Year**
Standard Plan	Starting Demonstration Year 2
BH I/DD Tailored Plan	Before the beginning of Demonstration Year 4
Specialized Foster Care Plan	Before the beginning of Demonstration Year 4

L. **Managed Care Readiness.** The state must assess readiness pursuant to 438.66(d). Assignment into an MCO may only begin when each MCO has been determined by the state to meet certain readiness and network requirements.

M. **Incentive Payments to PHPs**. Any incentive payments that meet the definition of incentive arrangement under 42 CFR 438.6(a) must meet the requirements of 42 CFR 438.6(b).

N. **State-directed payments**. To the extent that the state directs managed care plans to pay providers, such arrangements will be consistent with 42 CFR 438.6(c). The state must work with CMS to identify all 438.6(c) payments prior to the submission of their rates and contracts as required under 42 CFR 438.4 and 438.5.

O. **Innovations/Traumatic Brain Injury 1915(c) Waivers.** The state will operate this demonstration concurrently with the state's approved section 1915(c) Innovations and Traumatic Brain Injury Home and Community-Based Services (HCBS) waivers and together provides the authority necessary for the state to require enrollment of Medicaid beneficiaries except those excluded and exempted across the state into a managed care delivery plan to receive state plan and HCBS waiver services.

   i. Eligibility. Under the demonstration, there is no change in Medicaid eligibility. Standards for eligibility remain set forth under the state's Innovations and Traumatic Brain Injury HCBS waiver programs in the concurrent approved 1915(c) waivers. Medicaid 1915(c) Innovations and Traumatic Brain Injury services are delivered through a statewide comprehensive managed care delivery system. Beneficiaries eligible for HCBS provided through the concurrent 1915(c) waivers are required to enroll in managed care to obtain covered benefits.

   ii. HCBS Authority. The 1915(c) waivers of NC-0423.R02.00 and NC-1326.R00.00 will continue to be the authority under which HCBS operates until such time the

State Medicaid Agency requests and receives approval of an 1115 amendment to incorporate the 1915(c) services into the section 1115 demonstration. The state must follow the section 1915(c) amendment process to make alterations to its HCBS waivers. The state must notify CMS demonstration staff in writing of any proposed amendments to the 1915(c) waivers concurrently with the submission of the 1915(c) amendment.

P. **Enhanced Case Management and Other Services Pilot Program.** The state will be authorized up to $650 million in expenditure authority, $100 million of which is available for capacity building (as described in STC 21(P)(vi)(d) below, to establish the public-private regional enhanced case management and other services pilot program (the "pilot program") in two to four regions of the state to serve approximately 25,000 to 50,000 beneficiaries throughout the state during the demonstration approval period of November 1, 2019 through October 31, 2024. The pilot regions must have specific target populations of high-need Medicaid beneficiaries within their geographic region, and the state must provide services, including case management services based on evidence-based interventions for certain diagnosis and risk factors, to improve health outcomes and lower healthcare costs.

The state must develop an assessment tool using standardized case management questions to screen eligible enrollees to determine if the target population criteria is met related to the following four risk factors of the pilot: housing instability, food insecurity, transportation insecurity, and interpersonal violence/toxic stress. The state must require that each participating PHP determines the services to be provided and will review the plan of care with the enrollee after the assessment is complete. Following implementation of the pilot program, the state must require that each participating PHP: review the pilot services the enrollee is receiving every three months to verify the services are meeting the needs of the enrollee; and reassess the enrollee's eligibility in the pilot program every six months.

The state must submit to CMS a plan to incorporate pilot interventions determined effective through the pilot evaluation process into the state's Medicaid managed care program throughout the state at the conclusion of the 5-year demonstration.

i. Eligible Enrollees. Medicaid beneficiaries in each pilot region enrolled in a PHP must be assessed for pilot services by the PHP to determine their eligibility for services through this pilot program based on meeting one needs-based criterion and having one risk factor, as outlined in Attachment G. This is a voluntary pilot program. Once an enrollee is determined eligible, the state must require that the PHP seek consent from the enrollee to participate in the pilot program and the enrollee will have the option to opt-out at any time from the pilot program. An eligible enrollee must have the option to re-enroll in the pilot program at any time following the enrollee's voluntary disenrollment. Enrollees who do not opt-out will remain enrolled in the pilot program until they no longer meet the eligibility criteria and do not require pilot services to address an unmet need as determined in the six-month pilot eligibility reassessment. Under the state's Medicaid managed care program, a PHP will be permitted to set enrollment caps in its pilot region(s),

following review and approval by the state, if the PHP has limited funding capacity to serve all eligible enrollees.

ii. Enrollees Determined Ineligible. The state must require that enrollees determined ineligible during the assessment period must have the opportunity to request to have their eligibility status be reassessed when there is an indication the enrollee's health status or social risk factors have changed. Upon a determination of ineligibility, the state must require that PHP will communicate to the enrollee the process to request a reassessment. Eligibility reassessments will consist of utilizing the same tools and staff previously used to evaluate the enrollee in the initial assessment.

iii. Determination of Pilot Regions. The state shall release a Request for Proposal (RFP) detailing roles, responsibilities and expectations for potential Lead Pilot Entities (LPEs) in two to four regions within the state by November 1, 2019. LPEs must be evaluated on their ability to meet the requirements outlined in the RFP.

iv. Enhanced Case Management and Other Services. The state must require the PHPs to develop an enrollee care plan for each enrollee in the pilot program and provide a set of evidence-based enhanced case management and other services addressing enrollee needs directly related to: food, transportation, housing support, and interpersonal safety to directly improve health, promote community engagement and lower healthcare costs. The services that can be provided in this pilot program are outlined in Attachment G. Changes to this list, based on emerging evidence and the state's rapid cycle assessment, must be subject to CMS review to determine if the proposed change(s) require following the amendment process described in STC 7, or if the change can be implemented with a technical correction update. The state must submit to CMS the proposed change(s) providing the following details: a description of the services(s) being added, modified, and/or deleted, the number of pilot participants impacted by the proposed service change(s), and the financial impact on the demonstration by the proposed change(s). CMS will review the proposed change(s) and notify the state of the process to implement the service change(s) within 30 calendar days of receipt of the request. No FFP is available until CMS approves the amendment, and FFP is not available retroactive to the date of submission of the amendment. An enrollee receiving services through this pilot program is not prohibited from receiving services outside of this pilot program.

v. Lead Pilot Entities (LPEs). The state must select a LPE for each pilot region through a competitive procurement process to serve as the regional pilot coordinator, and be accountable for the pilot operations. The LPE will support the PHP(s) in its region in identification of eligible pilot enrollees; the LPE will develop the network of participating pilot providers delivering pilot services and ensure the enrollee receives services based on identified care needs. The state must require that the LPE's key responsibilities include:

   a. Developing, contracting with, and managing a network of pilot providers to deliver enhanced case management and other services, including community-based organizations (CBOs), social service agencies and healthcare providers.
   b. Convening pilot providers and PHPs to establish a governance structure consistent with state guidelines, and determine operational roles, responsibilities and procedures.

c. Developing an infrastructure for reimbursing and tracking reimbursement to pilot providers and payment protocols and procedures.
d. Working in collaboration with PHPs, pilot providers, and other stakeholders to determine locally available and appropriate enhanced case management and other services based on the pilot provider network.
e. Providing technical assistance to PHPs, pilot providers, and other stakeholders on enhanced case management and other services and sharing best practices across regions.
f. Working in collaboration with PHPs to track provision of enhanced case management and other services and data collection to report on metrics needed for rapid cycle evaluation and summative evaluation.
g. Participation in "learning communities" to ensure that the pilot regions are sharing and adopting best practices throughout the duration of the five-year demonstration period of November 1, 2019 through October 31, 2024.

vi. Pre-Paid Health Plans (PHPs). Under the oversight of the state's Medicaid managed care program, the state shall require that all PHPs that have any share of their business within any of the four pilot regions be contractually obligated to participate in the pilot program, and be responsible for authorizing the provision of all pilot services to eligible managed care enrollees within state guidelines and these STCs. The state shall require that the PHP serve as a point of contact with the state. The state shall require that PHP key responsibilities in the pilot program include:
a. Screening Medicaid managed care beneficiaries to identify those who are eligible for receiving services through this pilot program.
b. Obtaining consent for enrollment in the pilot program.
c. Determining and authorizing the specified enhanced case management and other services that are necessary and appropriate for beneficiaries.
d. Working in collaboration with the LPE to track the provision of enhanced case management and other services.
e. Managing budgets and submitting any enrollment restrictions to the state for approval.
f. Participation in "learning communities" to ensure that pilots are sharing and adopting best practices throughout the duration of the five-year demonstration period.

vi. Pilot Funding Flow. The state must distribute funding for pilot-related authorized services and capacity building.
a. Pilot Services Payment. The state must distribute funding to the PHPs from a PHP specific capped allocation based on the volume and cost of pilot services delivered to its pilot-enrolled beneficiaries inclusive of a PHP administrative fee. The administrative fee will be determined by the state and will be a component of pilot service payments, but the majority of the service payment must be used to pay for the delivery of pilot services. The state must require that the PHPs distribute the payments to the LPE. The state must require the PHPs to implement the requirement that the LPE distribute the funds to a network of providers authorized to deliver pilot services based on standards and requirements set forth by the state.

i. The state must require that the PHP, in collaboration with the LPE, track and report the services provided to beneficiaries, ensuring accountability for service delivery and payment, monitoring against fixed allotments, and bundled services updates.
ii. The state must develop a methodology for PHP funding allocation based on the regional participants and establish reporting requirements.
iii. The state must conduct periodic audits of payments to verify accurate reporting and spending.
iv. The state must conduct quarterly reviews of PHP spending against capped funds.
v. FFP will be based on the aggregated amounts actually paid by the state to providers, LPEs, and PHPs for authorized pilot purposes, as defined in these STCs.

b. Service Reimbursement. Pilot services will be reimbursed through two methods: fee-for-service/cost-based reimbursement and bundled payments.
   i. Fee for Service (FFS) Schedule/Cost-Based Reimbursement Sets. The state must develop a pilot service fee schedule and cost-based reimbursement service sets and submit to CMS for approval no later than July 1, 2019. Failure to submit this deliverable to CMS will result in a funding deferral. Furthermore, FFP is not available until the FFS fee schedule and cost-based reimbursement service sets are approved. The FFS schedule must outline select services assigned to a specific cost that reflect the intensity of the service (e.g., repairs for tenancy-related issues impacting the occupants health condition, targeted nutritious food or meal delivery services for individuals with medical or medically-related special dietary needs). The cost-based reimbursement sets must identify sets of services with capped amounts (i.e., cost of public transportation that enables a beneficiary to access pilot services, expenses related to utility set-up and security deposit).
   ii. Bundled Payments. The state must establish a fee schedule for authorized bundles of pilot services, through which bundles of complementary services addressing a need will be bundled together under an assigned payment rate. The cost of a bundle of services must reflect the intensity of the included services, but may allow for setting and frequency of specific services to vary based on the beneficiaries' circumstances and local resources. Bundled services must be organized into domain-tiers that reflect both the type of service and level of intensity, and must be based on evidence-based averages regarding the number of visits and months it takes to achieve the desired outcome. Bundled payments must not include additional fee for service and must be accepted as payment in full. The state must submit the bundled pilot service fee schedules to CMS for approval no later than July 1, 2019. Failure to submit this deliverable to CMS will result in a funding deferral.

c. Incentive Payments to PHPs for Pilot Services. Any incentive payments that meet the definition of incentive arrangement under 42 CFR 438.6(a) must meet the requirements of 42 CFR 438.6(b). To the extent that the state directs managed care plans under this pilot program to pay providers, such arrangements will be consistent with 42 CFR 438.6(c). The state must work with CMS to

identify all 438.6(c) payments prior to the start of the pilot program and prior to the submission of their rates and contracts as required under 42 CFR 438.4 and 438.5.

d. Capacity Building. The state must provide funding to the LPEs to build capacity. Capacity building for ECM will be considered an administrative cost and must be capped and time limited. The pilot funding is capped at $100 million for pilot regions that begin their first pilot year in the time period between November 1, 2019 through October 31, 2021. LPEs will be eligible for capacity building funding for up to two years after their contractual effective date. Unspent capacity building funding must be used for authorized ECM purposes only. The state must notify CMS prior to shifting capacity building funding to any other authorized purposes.
    i. The state must require that the LPE may use this capacity building funding only to:
        a. Through collaboration with stakeholders (PHPs, social services agencies, Community Based Organizations), develop necessary infrastructure/systems to prepare providers to deliver authorized services, receive payment, and reporting of information for managing patient care, monitoring outcomes, and ensuring program integrity.
        b. Providing technical assistance and collaboration with stakeholders.

e. Pathway to Value-Based Payments. The state must establish an incentive payment fund to incorporate value-based payments to incentivize the delivery of high-quality care by increasingly linking payments for pilot program services to health and socioeconomic outcomes based on the pilot services provided during the demonstration and gathering the required data and experience needed for more complex risk-based models. The funding for the incentive payment fund must be a subset of the $650 million authorized for the enhanced case management and other services pilot program.
    i. Pilot Year 1: Incentives for meeting pilot implementation measures. A pilot's first year will begin the state's collaboration with the LPEs and PHPs for launching the pilots, including establishing a pilot provider network, providing training to providers and care management staff, and establishing payment and reporting processes. The state must require that the PHPs and LPEs complete all of these activities before any PHPs begin delivering pilot services; however, LPEs may continue to expand their provider networks, provide ongoing training, and refine their payment and reporting process after they begin delivering services. To ensure the pilots launch in a timely manner, the state must establish an incentive payment fund to provide rewards for achieving or surpassing specific metrics. Incentive payments for PHPs must reflect their key role in standing up and implementing the pilots (e.g., Completing implementation of a robust pilot-specific training series for care managers in pilot region(s); and Completion of readiness testing on data collection and reposting systems to support oversight and evaluation). The state must require that incentive payments for LPEs are only made if the LPE meets key metrics and timelines established through the contracting process

related to establishing provider networks, payment and reporting systems, and training.

ii. Pilot Year 2: Incentives for meeting service delivery performance metrics. During a pilot's second year, participating PHPs must begin enrolling beneficiaries and delivering pilot services. Incentive payments must be provided to PHPs and LPEs based on role specific criteria.
    a. The state must require that PHPs eligibility for incentive payments be based on exceeding timeliness and accuracy standards related to data collection and reporting as essential components of the state's oversight of the pilots and the RCAs. PHPs may also receive an incentive payment for developing a system to seamlessly share valuable information and feedback with the LPEs to improve the LPEs' performance.
    b. The state must require that LPEs eligibility for incentive payments be based on the LPEs capacity to ensure enrolled beneficiaries actively access services and beneficiaries' experience with their in-network providers. Example areas of focus include:
        i. Percentage of pilot enrollees that have accessed pilot services
        ii. Timeliness standards for communications and payment
        iii. Pilot provider satisfaction with LPE communications and payment
        iv. Beneficiary satisfaction scores with in-network pilot providers
        v. Access to in-network pilot providers with hours of operation that include evenings and weekends.
    c. The state must require that LPEs must provide a percentage of their earned incentive payments to Pilot Providers based on quality of care and eligibility metrics outcomes achieved, such as average wait times for a beneficiary to receive pilot services, hours of operation for pilot services, and beneficiary satisfaction scores. The LPEs must develop an approach outlining how pilot providers will receive incentive payments for state review and approval.

iii. Pilot Year 3: Withholds for exceeding resource outcome benchmarks. In a pilot's third year, the state must evaluate whether the LPEs and pilot program services are effective in addressing beneficiaries' unmet social needs. The state must withhold a portion of the payments to LPEs and to PHPs, repaying it in the following circumstances:
    a. The state must require that LPEs' withhold payments in a pilot's third year be tied to measurable improvement above a defined benchmark in pilot enrollees' self-reported unmet resource needs, with varying specifications for each service domain.
    b. Pilot providers will receive a percentage of the LPE's earned withhold payments based on the LPE's state approved plan for sharing any earned withhold payments with pilot providers that have contributed to the improvements in outcomes by delivering high-quality services.

c. The state must require that PHPs' withhold payments in a pilot's third year be linked to their capacity to exceed expectations related to data collection and reporting requirements that support the state's rapid cycle assessments, including timeliness of reporting and accuracy standards.

iv. Pilot Year 4: Withholds for exceeding health and utilization outcome benchmarks. In a pilot's fourth year, the state must begin withholding a share of the LPE payments contingent on achieving specific targets for their enrollees' healthcare utilization and health outcomes.

a. The state must require that LPE benchmarks be designed to take into account the eligible populations, services provided and related outcome measures, for example reductions in hospital admissions related to uncontrolled diabetes in adults and pediatric pilot enrollees receiving medically tailored meal services. To the maximum extent possible, the outcome measures selected for the LPE withhold design must align with the state's Medicaid Managed Care Quality Measures, to which the PHPs are being held accountable through robust requirements, incentives and withholds in the Medicaid managed care program. By combining the PHPs' and LPEs' goals, the entities have aligned financial incentives to deliver high-quality medical, behavioral and social services that improve beneficiaries' health.

b. Pilot providers will receive a percentage of the LPE's earned withhold payments based on the LPE's state approved plan for sharing any earned withhold payments with pilot providers that have contributed to the improvements in outcomes by delivering high-quality services.

c. The state must require that the PHPs' withhold payments in a pilot's fourth year must be linked to their capacity to exceed expectations related to data collection and reporting requirements that support the state's rapid cycle assessments, including timeliness of reporting and accuracy standards.

v. Pilot Year 5: Shared savings for exceeding health and utilization outcome benchmarks and reduction in total cost of care. By a pilot's fifth year, the state expects PHPs, LPEs, and pilot providers to have together achieved measurable reductions in total cost of care due to the pilot program.

a. LPEs are eligible to receive shared savings from the PHP under the following circumstances:

i. The LPE continues to meet the health and utilization benchmarks outlined in Pilot Year 4.

ii. There is a reduction in average total cost of care per beneficiary. This measure must be:

- Based on the costs of a subset of pilot enrollees whose services are likely to result in decreased medical expenses in the short-term (e.g., homeless adults with multiple chronic conditions or high ED or hospital

admission utilizations who receive housing services). This assures that LPEs are not penalized for delivering effective, evidence-based interventions that result in a financial return on investment over the longer-term (i.e., children who have experienced three categories of adverse childhood experiences who receive home-based visiting services to strengthen stronger and healthier parental relationships).

- Assessed in comparison with a comparable control group.

iii. Pilot providers must receive a percentage of the shared savings based on the LPE's state approved plan for sharing savings with pilot providers that have contributed to the improvements in outcomes by delivering high-quality services.

vii. Pilot Evaluation. The state must develop an evaluation design for the pilot program and will submit to CMS for review and approval within 120 days of approval of this demonstration. The PHPs, LPEs and pilot providers are required to meet evaluation and reporting requirements to track and document the effectiveness of the interventions.

a. A comprehensive, summative pilot program evaluation must be conducted by an independent entity identified by the state. The purpose of the evaluation will be to understand the extent to which pilot services were effective in improving health and reducing costs over the duration of the demonstration.
b. The state must develop a pilot services evaluation strategy that will incorporate rapid cycle assessments (RCAs) into the process to obtain timely information on the effectiveness of pilot services. These evaluations will allow the state to discontinue services determined to have minimal effectiveness and redeploy resources to more valuable strategies, serving as another mechanism for promoting value within the program. RCAs must be conducted by an independent entity identified by the state. The state, in collaboration with stakeholders, must develop process-based and outcome-based metrics, which must be submitted for review and approval by CMS in the evaluation design, and the state will report annually to CMS on these metrics.

Transition Plan: As a result of the RCAs, the state must submit a plan to CMS by December 31, 2023 outlining how the state anticipates it will incorporate effective pilot program services into its managed care program.

viii. Enhanced Case Management and Other Services Pilot Program Integrity. The state must maintain program integrity standards in the pilot program, including:

a. Quarterly accounting on delivered pilot services
    i. Invoices must be transmitted in accordance with all privacy and security requirements and must include the following standardized information:
        1. Beneficiary name and Medicaid identification number
        2. Provider organization name
        3. Description of services(s) rendered
        4. Date(s) and/or duration of services(s) delivery

5. Number of unit(s) of services(s) delivered
6. Cost of services(s) delivered
7. Service indicator (reason for service delivery)

ii. LPE Role. For the LPE to develop and manage the pilot provider network, the state must require the LPE to develop an infrastructure allowing:
1. Pilot providers to submit invoices for the delivery and authorized bundles of pilot services.
2. The LPE to pay pilot providers based on invoices submitted.
3. The LPE to track payments to pilot providers.
4. The LPE to submit invoices for reimbursement to the PHPs.

iii. PHP Role. The state must require the PHPs review the invoices submitted by the LPE to ensure it contains all of the required elements and that it is for authorized services prior to paying the invoices. PHPs will be required to submit quarterly reports to the state summarizing the contents of the invoices including:
1. Number of pilot enrollees who receive pilot services.
2. Number of invoices submitted and bundles of pilot services provided.
3. A list of which bundles of pilot services have been authorized for which type of pilot enrollee (e.g., child, pregnant woman or adult).
4. Number of pilot provider organizations that provided the services.
5. Analysis of total costs expended to date in relation to PHP's capped pilot funding.

b. Audit Process. The PHP will be required to ensure Medicaid payments are for services covered under this pilot program that were actually provided and properly billed and documented by the pilot providers through the following processes:

i. Invoice Analysis
1. As part of their general Medicaid program integrity requirements, the state must require that PHPs analyze claims submitted by providers and invoices submitted by the LPEs to ensure that they: (1) accurately and appropriately represent the delivery of authorized services, and (2) identify irregularities, discrepancies, or outliers requiring further investigation.
2. To the extent that PHPs identify irregularities, the state must require PHPs to refer those irregularities to their Special Investigations Unit for follow-up and report them to the state's Program Integrity Division.

ii. Visit Verification Procedures
1. In accordance with the state's Medicaid program integrity requirements, the state must require the PHPs regularly validate services, including those delivered through the pilots, that were rendered as provided and properly billed and documented by

pilot providers through conducting visit verification procedures on a random sample of claims/invoices. Verification procedures may include:

a. Outreach to beneficiaries to confirm receipt of services
b. Outreach to providers to require documentation of provided services

2. As part of the state's overarching oversight strategy, the state's Program Integrity Division must review and monitor the PHPs' policies, including sample sizes and targeted provider types, and sample visit verification cases.

c. Ensuring action is taken to address identified non-compliance
    i. Recoupment of Overpayments. Under the state's Medicaid program integrity requirement, the state must require the PHPs to monitor payments and identify issues of overpayment. PHPs and LPEs must regularly monitor their payments to Pilot Providers to identify potential overpayments. If an overpayment is discovered, the PHP or LPE must calculate the payback amount and return the overpayment no later than sixty (60) days from the date the overpayment was identified.
    ii. Suspension, Withhold, Sanctions and Termination Activities due to Findings of Fraud or Abuse. In accordance with the state's Medicaid program integrity requirements:
        1. The state reserves the right to direct a PHP to impose a payment suspension or withhold on any provider, including pilot providers and LPEs, due to potential or actual instances of fraudulent behavior.
        2. The state, PHPs and LPEs will have the right to terminate a pilot provider for reasons related to substantiated fraudulent behavior.
        3. The state will have the right to impose other sanctions or intermediate sanctions on, or require a corrective action plan from a PHP, LPE, or pilot provider.
        4. LPEs must submit monthly reports to the state on all pilot provider terminations or non-renewals due to fraudulent behavior, including terminations and non-renewals initiated by the LPE, a PHP or the state.

d. Auditing compliance. The state must audit PHPs to ensure their compliance with the pilot program requirements and take action to address any identified non-compliance.

ix. Pilot Termination. The state may suspend or terminate the entire pilot program, any pilot region, or a LPE, PHP, or pilot provider in any pilot region, if corrective action has been imposed and poor performance continues. The state must notify CMS when a pilot is placed under a corrective action plan, suspended, or terminated. The state must review and approve each pilot's protocols for notifying affected beneficiaries in the event of a suspension or termination.

VIII. GENERAL REPORTING REQUIREMENTS

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

23. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in the amount of $5,000,000 (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. Specifically:

a. Thirty (30) calendar days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.

b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).

   i. CMS may decline the extension request.

   ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.

   iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.

c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.

d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, what quarter the deferral applies to and how the deferral is released.

24. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones. Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the SUD Implementation Plan Protocol and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5M for services rendered in IMDs will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

25. 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.

26. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must 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 and providing data and analytic files to CMS, including 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 must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such 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 23.

IX. MONITORING

27. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter 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 compiled Annual Report 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 provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

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

b. Performance Metrics. 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 writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

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.

e. SUD Health IT. The state must include a summary of progress made in regards to SUD Health IT requirements outlined in STC 19(g).

f. ECM Reporting Requirements. The state must include in their quarterly and/or annual report to CMS:
   i. Enrollee Service Costs
      a. The enrollee cost for each of the top ten enrollees who received the most costly services across all ECMs cumulatively:
      b. The 90% percentile cumulative cost for an enrollee in ECM
      c. The 75% percentile cumulative cost for an enrollee in ECM
      d. The 50% percentile cumulative cost for an enrollee in ECM
      e. The 25% percentile cumulative cost for an enrollee in ECM
      f. The 10% percentile cumulative cost for an enrollee in ECM.
   ii. Incentive Payments. The state will provide a report on the amount and how incentive funds were dispersed to PHPs, LPEs, and pilot providers.
   iii. ECM Capacity Building. The state will provide a report on the amount of capacity building provided to each LPE, the time frame the funding was provided, and what the funding was used for.

28. **Close-Out Operational Report**. Within 120 calendar days prior to the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft final report must comply with the most current Guidance from CMS.
b. The state must 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 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 23.

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

a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on the evaluation.
b. CMS will provide updates on any amendments or concept papers under review, 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.

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

X. EVALUATION OF THE DEMONSTRATION

31. Independent Evaluator. Upon approval of the demonstration, the state must 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 independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved, draft 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. Evaluation Budget. A budget for the evaluation must 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.

33. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state may choose to submit one evaluation design inclusive of the demonstration and SUD, or a separate evaluation design focused on SUD. If the state chooses to submit two evaluation designs, the SUD evaluation design is subject to the same terms and conditions listed below which apply to the overall demonstration evaluation. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. 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 state must use an independent evaluator to develop the draft Evaluation Design.

34. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) 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 to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

35. **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 must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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 must be posted to the state's website with the application for public comment.
    a. The interim evaluation report must 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 must 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 of these STCs.

37. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, November 1, 2019 – October 31, 2024, 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 must 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. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

39. **Public Access**. The state must 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 days of approval by CMS.

40. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS must 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. Prior to release of these reports, articles or other publications, CMS must be provided a copy including any associated press materials. CMS must 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.

XI. GENERAL FINANCIAL REQUIREMENTS

This project is approved for title XIX expenditures applicable to services rendered during the demonstration period.

41. **Reporting Expenditures under the Demonstration.** The following describes the reporting of expenditures subject to the Budget Neutrality agreement:

    a. Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the BN expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11W00313/4) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered, and by the Waiver Names identified in subparagraph (d).

b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments must be reported as otherwise instructed in the State Medicaid Manual.

c. Pharmacy Rebates. Pharmacy rebates must be reported on Form CMS 64.9 Base, and not allocated to any Form 64.0 or 64.9 Waiver.

d. Use of Waiver Forms. For each demonstration year, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be completed, using the waiver names listed below. Expenditures must be allocated to these forms based on the guidance which follows.

   i. ABD: *Expenditures for Medical assistance services provided to ABD eligibles not identified as excluded in Table 1, not SUD IMD expenditures.*

   ii. TANF Adult: *Expenditures for Medical assistance services provided to TANF Adult eligibles not identified as excluded in Table 1, not SUD IMD expenditures.*

   iii. TANF Child: *Expenditures for Medical assistance services provided to TANF Child eligibles not identified as excluded in Table 1, not SUD IMD expenditures.*

   iv. INN/TBI: *Expenditures for Medical assistance services provided to INN/TBI eligibles not identified as excluded in Table 1, not SUD IMD expenditures.*

   v. SUD IMD MC TANF and Related Adults: *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible TANF and Related Adults enrolled in managed care during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.*

   vi. SUD IMD MC ABD: *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible ADB individuals enrolled in managed care during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.*

   vii. SUD IMD MD Innovations/TBI: *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible Innovations/TBI individuals enrolled in managed care during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.*

   viii. SUD IMD FFS: *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible individuals enrolled in fee-for-service during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.*

   ix. ECM Service: *Expenditures for ECM pilot services payments.*

e. Demonstration Years. There are two separate and distinct programs operating during different demonstration years under this comprehensive demonstration, but each for only 5 years. The SUD component will operate in demonstration years 1 through 5 (January 1, 2019 through October 31, 2023. The managed care component including the ECM pilot

will operate in demonstration years 2 through 6 (November 1, 2019 through October 31, 2024).

f. Budget Neutrality Specifications Manual. The state must create and maintain a Budget neutrality Specifications Manual that describes in detail how the state compiles data on actual expenditures and member months related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64 and in member month reports, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual must be made available to CMS on request.

g. The demonstration years for managed care component and the Enhanced Case Management and Other Services Pilot Program are as follows:

Demonstration Year 2	*11/1/2019-10/31/2020*	*12 Months*
Demonstration Year 3	*11/1/2020-10/31/2021*	*12 Months*
Demonstration Year 4	*11/1/2021-10/31/2022*	*12 Months*
Demonstration Year 5	*11/1/2022-10/31/2023*	*12 Months*
Demonstration Year 6	*11/1/2023-10/31/2024*	*12 Months*

h. The SUD component demonstration years are as follows:

Demonstration Year 1	*1/1/2019-10/31/2019*	*10 Months*
Demonstration Year 2	*11/1/2019-10/31/2020*	*12 Months*
Demonstration Year 3	*11/1/2020-10/31/2021*	*12 Months*
Demonstration Year 4	*11/1/2021-10/31/2022*	*12 Months*
Demonstration Year 5	*11/1/2022-10/31/2023*	*12 Months*

42. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in Section IX. CMS will provide technical assistance, upon request.

43. Quarterly annuals: The state must provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided through this demonstration under the Medicaid program, including those provided through the demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

FFP will be provided for expenditures net of collections in the form of pharmacy rebates, cost sharing, or third party liability.

44. **Expenditures Subject to the Budget Neutrality Agreement.** For the purpose of this section, the term "expenditures subject to the budget neutrality agreement" means expenditures for the EGs outlined in Section XII, Monitoring Budget Neutrality for the Demonstration, except where specifically exempted. For clarity, populations listed in Table 1, services excluded from managed care and populations in geographic regions where managed care has not yet been implemented are not subject to budget neutrality limits, except with respect to the SUD IMD budget neutrality cap. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or 64.9P Waiver. Disproportionate share hospital payments, behavioral health health homes payments, and graduate medical education payments are not expenditures under the demonstration and are therefore excluded from budget neutrality.

45. Administrative Costs. The state must separately track and report additional administrative costs that are directly attributable to the demonstration, using separate CMS-64.10 waiver and 64.10 waiver forms. Expenditures must be allocated to these forms based on the guidance which follows:

a. ECM Capacity Building: *Expenditures for ECM capacity building payments.*
b. ADM: *All other additional administrative costs that are directly attributable to the demonstration (for information only, excluded from budget neutrality).*

46. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

47. Reporting Member Months. The following describes the reporting of member months for demonstration populations.

a. For the purpose of calculating the BN expenditure limit and for other purposes, the state must provide to CMS, as part of the BN Monitoring Tool required under STC 42, the actual number of eligible member months for each MEG described in subparagraph D below. The state must submit a statement accompanying the BN Monitoring Tool, which certifies the accuracy of this information. To permit full recognition of "in-process" eligibility, reported counts of member months may be subject to revision. The member-months reported should only be for title XIX Medicaid populations (i.e., not title XXI M-CHIP or S-CHIP) not identified as excluded in Table 1.

b. The term "eligible member/months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member/months.

c. The state must report separate member month totals for individuals enrolled in the North Carolina Medicaid Reform Demonstration and the member months must be subtotaled according to the MEGs defined in STC 47(d) below.

d. The required member month reporting MEG is:

i. **SUD IMD MC TANF and Related Adults:** SUD IMD MC TANF and Related Member Months are months of TANF and Related Adults Medicaid eligibility enrolled in managed care during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

ii. **SUD IMD MC ABD:** SUD IMD MC ABD Member Months are months of ABD Medicaid eligibility enrolled in managed care during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

iii. **SUD IMD MC Innovations/TBI**: SUD IMD MC Innovations/TBI Member Months are months of Innovations/TBI Medicaid eligibility enrolled in managed care during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MED, as applicable.

iv. **SUD IMD FFS:** SUD IMD Member Months are months of Medicaid eligibility enrolled in fee for service during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

v. **ABD:** ABD member months are months of Medicaid eligibility for an individual that is Aged, Blind or Disabled.

vi. **TANF and related Adults:** TANF Adult member months are months of Medicaid eligibility for an individual receiving coverage within the temporary assistance for needy families program.

vii. **TANF and related Children:** TANF Child member months are months of Medicaid eligibility for a child only receiving coverage within the temporary assistance for needy families program.

viii. **INN/TBI:** INN/TBI member months are months of Medicaid eligibility for an individual receiving coverage under the 1915(c) waiver.

ix. **Enhanced Case Management and Other Services Pilot:** Enhanced Case Management and Other Services Pilot member months are months of Medicaid eligibility for an individual receiving pilot services within the Enhanced Case Management and Other Services program.

48. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit, and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing

Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

49. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding. CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the limits described in Section XII:

    a. Administrative costs, including those associated with the administration of the demonstration;

    b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

    c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

50. **Sources of Non-Federal Share.** The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

    a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.

    b. Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

    c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provision, as well as the approved Medicaid state plan.

51. **State Certification of Funding Conditions.** Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes—including health care provider-related taxes—fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

52. **Program Integrity.** The state must have a process in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

53. Limit on Title XIX. The state must be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using a per capita cost method. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in Section VII.

54. Risk. The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk for the number of participants in the demonstration population. By providing FFP without regard to enrollment for all demonstration populations, CMS will not place the state at risk for changing economic conditions. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

55. Calculation of the Budget Neutrality Limit and How It Is Applied. For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each EG (shown on the table in STC 57) by the corresponding actual member months total, and summing the results of those calculations. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by Composite Federal Share, which is defined in STC 59 below.

56. Impermissible Taxes or Donations. CMS reserves the right to adjust the budget neutrality ceiling to be consistent with enforcement of laws and policy statements, including regulations and letters regarding impermissible provider payments, health care related taxes, or other payments (if necessary adjustments must be made). CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

57. Main Budget Neutrality Test. The trend rates and per capita cost estimates for each EG for each year of the demonstration are listed in the table below. *The PMPM cost estimates are based on actual Medicaid PMPM costs from Calendar Year 2010-2015, trended forward using trends based on the lower of state historical trends from Calendar Year 2010-2015 and the FFY 2018 President's Budget trends.* The demonstration expenditures subject to the main budget neutrality limit are those reported under the following Waiver Names:

ABD, TANF and Related Adult, TANF and Related Child, INN/TBI, and ECM Capacity Building.

MEG	Trend Rate	DY 02 PMPM	DY 03 PMPM	DY 04 PMPM	DY 05 PMPM	DY 06 PMPM
ABD	4.47%	$1,991.86	$2,099.07	$2,230.85	$2,330.60	$2,434.81
TANF and Related Adult	4.8%	$664.91	$706.93	$761.10	$797.63	$835.92
TANF and Related Child	1.83%	$244.73	$253.06	$265.50	$270.36	$275.31
INN/TBI	3.92%	N/A	$7,350.26	$7,638.41	$7,937.87	$8,249.06

58. Supplemental Tests.

A. **Supplemental Budget Neutrality Test 1: Substance Use Disorder Expenditures.** As part of the SUD initiative, the state may receive FFP for the continuum of services to treat OUD and other SUDs, provided to Medicaid enrollees in an IMD. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical. The state may only claim FFP via demonstration authority for the services listed in Table B that will be provided in an IMD. However, the state must not be allowed to obtain budget neutrality "savings" from these services. Therefore, a separate expenditure cap is established for SUD IMD services, to be known as Supplemental Budget Neutrality Test 1.

i. The MEG listed in the table below is/are included in SUD IMD Supplemental BN Test.

SUD MEG	Trend Rate	DY 01 PMPM	DY 02 PMPM	DY 03 PMPM	DY 04 PMPM	DY 05 PMPM
SUD IMD MC TANF and Related Adults	4.8%	N/A	$2,479.75	$2,598.78	$2,723.52	$2,854.25
SUD IMD MC ABD	4.5%	N/A	$3,424.34	$3,577.46	$3,737.42	$3,904.53
SUD IMD MC Innovations/TBI	3.9%	N/A	N/A	$7,474.12	$7,767.13	$8,071.63
SUD IMD FFS	4.6%	$13,893.55	$14,478.29	$15,144.30	$15,840.93	$16,569.62

ii. SUD IMD expenditures cap is calculated by multiplying the projected PMPM for each of the SUD IMD MEGs, each DY, by the number of actual eligible SUD IMD member months for the same MEG/DY—and summing the products together across MEGS and all DYs. The federal share of the SUD IMD expenditure cap(s) is/are obtained by multiplying those caps by the Composite Federal Share 2 (see STC 59).

iii. SUD IMD Supplemental BN Test(s) is/are a comparison between the federal share of SUD IMD expenditure cap(s) and total FFP reported by the state for the SUD IMD MEG.

iv. If total FFP for hypothetical groups should exceed the federal share of the expenditure limit in Supplemental Budget Neutrality Test 1, the difference must be reported as a cost against the budget neutrality limit described in STC 57.

B. **Supplemental Budget Neutrality Test 2: Enhanced Case Management and Other Services Pilot.** The demonstration will provide support to establish an Enhanced Case Management and Other Services pilot program in two to four areas of the state by providing pilot program services and capacity building. Funding for this program will be hypothetical, and a separate expenditure cap is established for ECM expenditures, to be known as Supplemental Budget Neutrality Test 2.

i. The MEG listed in the table below is/are included in ECM Supplemental BN Test(s).

MEG	DY 02 Total	DY 03 Total	DY 04 Total	DY 05 Total	DY 06 Total
Enhanced Case Management and Other Services Pilot	$110,000,000	$110,000,000	$110,000,000	$110,000,000	$110,000,000

ii. ECM expenditures cap consists of the total computable dollar limits presented in the above table, summed across all DYs. The federal share of the ECM expenditure cap is obtained by multiplying those caps by Composite Federal Share 3 (see STC 59).

iii. ECM Supplemental BN Test(s) is/are a comparison between the federal share of ECM expenditure cap(s) and total FFP reported by the state for the ECM Service MEG.

iv. If total FFP for ECM group should exceed the federal share of the expenditure limit in Supplemental Budget Neutrality Test 2, the difference must be reported as a cost against the budget neutrality limit described in STC 57.

59. Composite Federal Share Ratios. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported through the MBES/CBES and summarized on Schedule C, with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections and pharmacy rebates, by total computable demonstration expenditures for the same period as reported on the same forms. There are

four Composite Federal Share Ratios for this demonstration: Composite Federal Share 1 is based on the expenditures reported under the following Waiver Names: ABD, TANF and related Adults, TANF and Related Child, and INN/TBI. Composite Federal Share 2 is based on the following Waiver Names: SUD IMD MC TANF and Related Adults, SUD IMD MC ABD, SUD IMD MC Innovations/TBI, and, SUD IMD FFS. Composite Federal Share 3 is based on the following Waiver Name: ECM Service. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed upon method.

60. Exceeding Budget Neutrality. The budget neutrality limits calculated in STCs 57 and 58 must apply to actual expenditures for demonstration services as reported by the state under section XI of these STCs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds must be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test must be based on the time period through the termination date.

61. Enforcement of Budget Neutrality. If the state exceeds the calculated cumulative target limit by the percentage identified below for any of the DYs, the state must submit a corrective action plan to CMS for approval.

62. Managed Care and Enhanced Case Management and Other Services Pilot Program component

Year	Cumulative target definition	Percentage
DY 2	Cumulative budget neutrality cap plus:	3.0 percent
DY 3	Cumulative budget neutrality cap plus:	2.0 percent
DY 4	Cumulative budget neutrality cap plus:	1.0 percent
DY 5	Cumulative budget neutrality cap plus:	0.5 percent
DY 6	Cumulative budget neutrality cap plus:	0.0 percent

SUD Component of the Demonstration

Year	Cumulative target definition	Percentage
DY 1	Cumulative budget neutrality cap plus:	3.0 percent
DY 2	Cumulative budget neutrality cap plus:	2.0 percent
DY 3	Cumulative budget neutrality cap plus:	1.0 percent
DY 4	Cumulative budget neutrality cap plus:	0.5 percent

DY 5	Cumulative budget neutrality cap plus:	0.0 percent

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Date	Deliverable	STC
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Plan Protocol	STC 19
150 days after SUD program approval date	SUD Monitoring Protocol	STC 19
180 days after approval date	Evaluation Design	STC 34
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 35
November 1, 2021, or with renewal application	Draft Interim Evaluation Report	STC 36
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 36
Within 18 months after October 31, 2022	Summative Evaluation Report	STC 37
60 days after receipt of CMS comments	Final Summative Evaluation Report	STC 37
Monthly Deliverables	Monitoring Call	STC 29
Quarterly Deliverables Due 60 days after end of each quarter, except 4th quarter	Quarterly Progress Reports	STC 27
	Quarterly Expenditure Reports	STC 43
Annual Deliverables - Due 90 days after end of each 4th quarter	Annual Reports	STC 27
July 1, 2019	Enhanced Case Management and Other Services Service Reimbursement: Fee For Service Schedule/Cost-Based Reimbursement Sets	STC 21
	Enhanced Case Management and Other Services Service Reimbursement: Bundled Payments	STC 21

ATTACHMENT A

Developing the Evaluation Design

Introduction

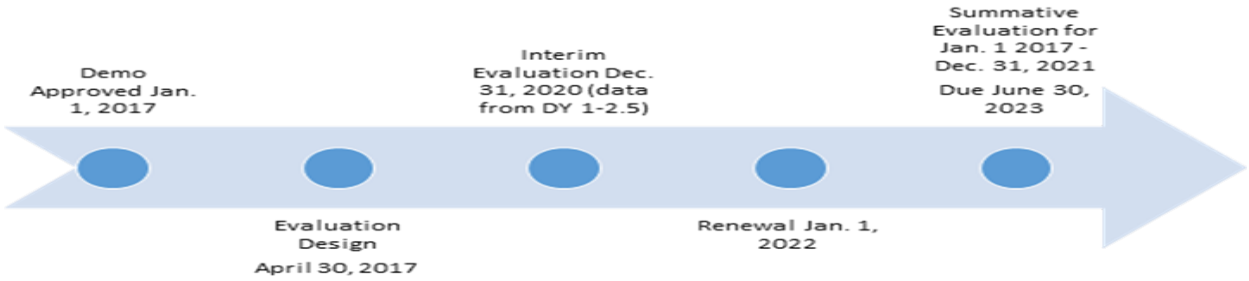
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about 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 could benefit from improved 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**.**

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
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 thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

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

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

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

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

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

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

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

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

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

E. 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 "No Conflict of Interest" 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 Interim and Summative Evaluation Reports

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 provide 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 could benefit from 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. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. 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 Guidance

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 Guidance 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;

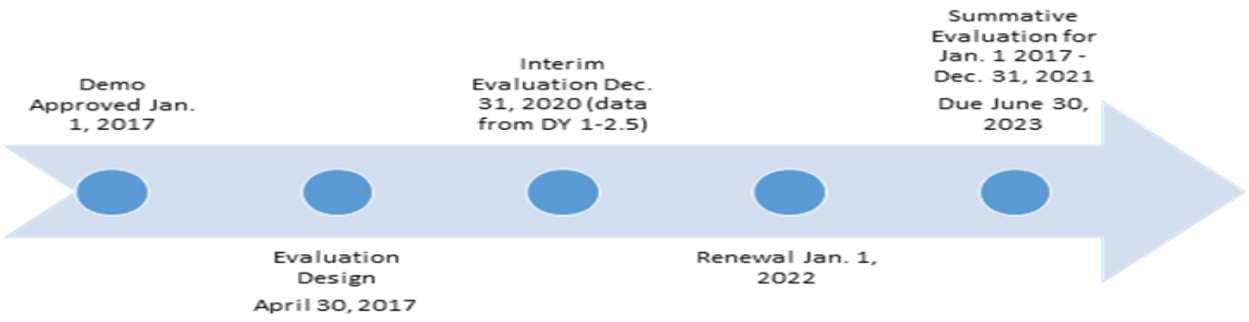
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;

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 to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



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 guidance) 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.

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

B. 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.

C. 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?

D. 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.

E. 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?

E. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C: Reserved for Evaluation Design

ATTACHMENT D: Reserved for SUD Implementation Plan Protocol

ATTACHMENT E: Reserved for SUD Monitoring Protocol

ATTACHMENT F
SUD Health Information Technology (Health IT)

SUD Health Information Technology (Health IT). The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This "SUD Health IT Plan," or assurance, will be included as a section of the state's "Implementation Plan" (see STC 19(a)) to be approved by CMS. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.

a. The SUD Health IT section of the Implementation plan will include implementation milestones and dates for achieving them.

b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

c. The SUD Health IT Plan will describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP)[9]

d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[10] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

e. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[11]

g. In developing the Health IT Plan, states shall use the following resources.

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[9] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[10] *Ibid*.

[11] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

i. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."

ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

iii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

h. The state will include in its Monitoring Protocol (see STC 19(b)) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or state defined metrics to be approved in advance by CMS.

i. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (see STC 28).

j. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

i. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

ii. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

Attachment G: Enhanced Case Management and Other Services Pilot Program Eligibility and Services

Beneficiaries eligible for enhanced case management pilot services (as described in Table 3) are enrolled in a PHP (either in a standard plan, BH I/DD tailored plan, or specialized plan) and must also meet at least one needs-based criteria (as described in Table 1) and at least one risk factor (as described in Table 2).

Eligible Enrollees

Table 1: Needs-Based Criteria

Eligibility Category	Age	Needs-Based Criteria (at least one, per eligibility category)
Adults	22+	• 2 or more chronic conditions. Chronic conditions that qualify an individual for pilot enrollment include: BMI over 25, blindness, chronic cardiovascular disease, chronic pulmonary disease, congenital anomalies, chronic disease of the alimentary system, substance use disorder, chronic endocrine and cognitive conditions, chronic musculoskeletal conditions, chronic neurological disease and chronic renal failure, in accordance with Social Security Act section 1945(h)(2). • Repeated incidents of emergency department use (defined as more than four visits per year) or hospital admissions.
Pregnant Women	n/a	• Multifetal gestation • Chronic condition likely to complicate pregnancy, including hypertension and mental illness • Current or recent (month prior to learning of pregnancy) use of drugs or heavy alcohol • Adolescent ≤ 15 years of age • Advanced maternal age, ≥ 40 years of age • Less than one year since last delivery • History of poor birth outcome including: preterm birth, low birth weight, fetal death, neonatal death
Children	0-3	• Neonatal intensive care unit graduate • Neonatal Abstinence Syndrome • Prematurity, defined by births that occur at or before 36 completed weeks gestation • Low birth weight, defined as weighing less than 2500 grams or 5 pounds 8 ounces upon birth • Positive maternal depression screen at an infant well-visit
	0-21	• One or more significant uncontrolled chronic conditions or one or more controlled chronic conditions that have a high risk of becoming uncontrolled due to unmet social need, including: asthma, diabetes, underweight or overweight/obesity as defined by having a BMI of $<5^{th}$ or $>85^{th}$ %ile for age and gender, developmental delay, cognitive

		impairment, substance use disorder, behavioral/mental health diagnosis (including a diagnosis under DC: 0-5), attention-deficit/hyperactivity disorder, and learning disorders • Experiencing three or more categories of adverse childhood experiences (e.g. Psychological, Physical, or Sexual Abuse, or Household dysfunction related to substance abuse, mental illness, parental violence, criminal behavioral in household) • Enrolled in North Carolina's foster care or kinship placement system

Table 2: Risk Factors

Risk Factor	Definition
Homelessness and housing insecurity	Homelessness, as defined in 42 C.F.R. § 254b(h)(5)(A), and housing insecurity, as defined based on questions used to establish housing insecurity in the Accountable Health Communities Health Related Screening Tool.[12]
Food insecurity	As defined by the US Department of Agriculture commissioned report on Food Insecurity in America:[13] • Low Food Security: reports of reduced quality, variety, or desirability of diet. Little or no indication of reduced food intake. • Very low food security: Reports of multiple indications of disrupted eating patterns and reduced food intake
Transportation insecurity	Defined based on questions used to establish transportation insecurities in the Accountable Health Communities Health Related Screening Tool.[14]
At risk of, witnessing, or experiencing interpersonal violence	Defined based on questions used to establish interpersonal violence in the Accountable Health Communities Health Related Screening Tool.[15]

[12] The Accountable Health Communities Health-Related Social Needs Screening Tool. Available: https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf

[13] National Research Council. (2006). Food Insecurity and Hunger in the United States: An Assessment of the Measure. Panel to Review the U.S. Department of Agriculture's Measurement of Food Insecurity and Hunger, Gooloo S. Wunderlich and Janet L. Norwood, Editors, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Available: https://www.nap.edu/download/11578

[14] The Accountable Health Communities Health-Related Social Needs Screening Tool. Available: https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf

[15] *Ibid*.

Enhanced Case Management and Other Services Pilot Program Services

Table 3: Enhanced Case Management Pilot and Other Services

Service Sub-Category	Enhanced Case Management and Other Services Pilot Program Services
Housing	
Tenancy Support and Sustaining Services	• Assisting the individual with identifying preferences related to housing (e.g., type, location, living alone or with someone else, identifying a roommate, accommodations needed, or other important preferences) and needs for support to maintain community integration • Supports to assist the individual in budgeting for housing/living expenses, including financial literacy education on budget basics and locating community based consumer credit counseling bureaus. • Assisting the individual to connect with social services to help with finding housing necessary to support individual in meeting their medical care needs. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan. • Assisting the individual with housing application and selection process, including filling out housing applications and obtaining and submitting appropriate documentation • Assisting the individual to develop a housing support plan based on upon the functional needs assessment, including establishing measurable goal(s) as part of the overall person centered plan • Developing a crisis plan, which must identify prevention and early intervention services if housing is jeopardized • Participating in the person centered plan meetings to assist the individual in determination or with revisions to housing support plan • Assisting the individual to review, update and modify his or her housing support and crisis plan on a regular basis to reflect current needs and address existing or recurring housing retention barriers • Assisting the individual to complete reasonable accommodation requests as needed to obtain housing • Supporting individuals in the development of independent living skills, such as skills coaching, financial counseling and anger management • Connecting the individual to education and training on tenants' and landlords' role, rights, and responsibilities • Assisting in reducing risk of eviction by providing services such as services that help the beneficiary improve his or her conflict resolution skills, coaching, role-playing and communication strategies targeted towards resolving disputes with landlords and neighbors; communicate with landlords and neighbors to reduce the risk of eviction; address biopsychosocial behaviors that put housing at risk; and provide ongoing support with activities related to household management • Assessing potential health risks to ensure living environment is not adversely affecting occupants' health

	• Providing services that will assist the individual with moving into stable housing, including arranging the move, assessing the unit's and individual's readiness for move-in, and providing assistance (excluding financial assistance) in obtaining furniture and commodities. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources. • Providing funding related to utility set-up and moving costs provided that such funding is not available through any other program. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources.
Housing Quality and Safety Improvement Services	• Repairs or remediation for issues such as mold or pest infestation if repair or remediation provides a cost-effective method of addressing occupant's health condition, as documented by a health care professional, and remediation is not covered under any other provision such as tenancy law. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources. • Modifications to improve accessibility of housing (e.g., ramps, rails) and safety (e.g., grip bars in bathtubs) when necessary to ensure occupant's health and modification is not covered under any other provision such as the Americans with Disabilities Act.
Legal Assistance	• Assistance with connecting the enrollee to expert community resources to address legal issues impacting housing and thereby adversely impacting health, such as assistance with breaking a lease due to unhealthy living conditions. This pilot service does not include legal representation or payment for legal representation.
Securing House Payments	• Provide a one-time payment for security deposit and first month's rent provided that such finding is not available through any other program. This payment may only be made once for each enrollee during the life of the demonstration, except for state determined extraordinary circumstances such as a natural disaster. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources.
Short-Term Post-Hospitalization	• Post-hospitalization housing for short-term period, not to exceed six [6] months, due to individual's imminent homelessness provided that such a service is not available under any other programs. Temporary housing may not be in a congregate setting. To the extent temporary housing services are available under other programs, this service could cover connecting the individual to such program and helping them secure housing through that program.

Food	
Food Support Services	• Assist the enrollee with applications for SNAP and WIC • Assist the enrollee with identifying and accessing school based food programs • Assist the enrollee with locating and referring enrollees to food banks or community-based summer and after-school food programs • Nutrition counseling and education, including on healthy meal preparation • Providing funding for meal and food support from food banks or other community based food programs, including funding for the preparation, accessibility to, and food for medical condition specific "healthy food boxes," provided that such supports are not available through any other program. Meal and food support services must be provided according to the enrollee's care plan and must not constitute a "full nutritional regimen" (three meals per day per person).
Meal Delivery Services	• Providing funding for targeted nutritious food or meal delivery services for individuals with medical or medically-related special dietary needs provided such funding cannot be obtained through any other source. Meals provided as part of this service must be provided according to the enrollee's care plan and must not constitute a "full nutritional regimen" (3 meals per day, per person).
Transportation	
Non-emergency health-related transportation	• Transportation services to social services that promote community engagement. • Providing educational assistance in gaining access to public or mass transit, including access locations, pilot services available via public transportation, and how to purchase transportation passes. • Providing payment for public transportation (i.e., bus passes or mass transit vouchers) to support the enrollee's ability to access pilot services and other community-based and social services, in accordance with the individual's care plan. • Providing account credits for cost-effective private forms of transportation (taxi, ridesharing) in areas without access to public transit. Pilot transportation services must be offered in accordance with an enrollee's care plan, and transportation services will not replace non-emergency medical transportation as required under 42 CFR 431.53. Whenever possible, the enrollee will utilize family, neighbors, friends, or community agencies to provide transportation services.
Interpersonal Violence (IPV)/Toxic Stress	
Interpersonal Violence-Related Transportation	• Transportation services to/from IPV service providers for enrollees transitioning out of a traumatic situation.
IPV and Parenting	• Assistance with linkages to community-based social service and mental health agencies with IPV expertise.

Support Resources	• Assistance with linking to high quality child care and after-school programs. • Assistance with linkages to programs that increase adults' capacity to participate in community engagement activities. • Providing navigational services focusing on identifying and improving existing factors posing a risk to the safety and health of victims transitioning out of traumatic situations (i.e., obtaining a new phone number, updating mailing addresses, securing immediate shelter and longer-term housing, school arrangements to minimize disruption of school schedule, connecting enrollees to medical-legal partnerships to address overlap between healthcare and legal needs).
Legal Assistance	• Assistance with directing the beneficiary to available legal services within the legal system for interpersonal violence related issues, such as securing a Domestic Violence Protection Order. This pilot service does not include legal representation or payment for legal representation.
Child-Parent Support	• Evidence-based parenting support programs (i.e., Triple P – Positive Parenting Program, the Incredible Years, and Circle of Security International). • Evidence-based home visiting services by licensed practitioners to promote enhanced health outcomes, whole person care and community integration. • Dyadic therapy treatment for children and adolescents at risk for or with an attachment disorder, or as a diagnostic tool to determine an attachment disorder.