DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

July 7, 2023

Jay Ludlam
Deputy Secretary for North Carolina Medicaid
North Carolina Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-2001

Dear Jay Ludlam:

The Centers for Medicare & Medicaid Services (CMS) is approving an amendment to the section 1115(a) demonstration titled, "North Carolina Medicaid Reform Demonstration" (Project Numbers 11-W-00313/4 and 21-W-00070/4) (the "demonstration"), in accordance with section 1115(a) of the Social Security Act (the Act). Approval of this demonstration amendment will adjust which populations will, will not, or must be covered under the Behavioral Health Intellectual/Development Disability (BH I/DD) Tailored Plans, expand access to the Healthy Opportunities Pilot (HOP) Program, and modify certain implementation details relating to the HOP Program. This amendment is effective as of the date of this approval and will remain in effect throughout the demonstration approval period, which is set to expire October 31, 2024.

CMS's approval of this section 1115(a) demonstration, as amended, is subject to the limitations specified in the attached waiver and expenditure authorities, special terms and conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable to expenditures under the demonstration.

Extent and Scope of Demonstration

Behavioral Health Intellectual/Development Disability Tailored Plans
Upon implementation of the BH I/DD tailored plans on October 1, 2023, these plans will provide integrated physical health, behavioral health, I/DD, traumatic brain injury (TBI), and pharmacy services to enrollees. The BH/IDD Tailored Plans were initially scheduled to launch in Demonstration Year 3, and implementation has since been delayed in light of the timing of the state budget and additional time needed for providers to transition into the program.

This amendment grants two changes with regards to the BH I/DD Tailored Plans. First, in order to ensure that BH I/DD beneficiaries who receive specialized behavioral health services are able to preserve access and not lose those services upon entering a residential setting, this amendment

will require enrollment into tailored BH I/DD plans for certain populations with no opt-out option.

Currently, BH I/DD eligible beneficiaries will default into a BH I/DD tailored plan and will be allowed to opt-out of the tailored plan and into a standard plan. Following the launch of the standard plans on July 1, 2021, North Carolina distributed notices to BH I/DD tailored plan-eligible populations informing them that they would remain in the current fee-for-service (FFS) delivery system (and behavioral health Local Management Entity/Managed Care Organizations [LME-MCO] when applicable) prior to BH I/DD tailored plan launch, but had the option to enroll in a standard plan. After receiving these notices, many individuals—including some in residential settings that are not covered under standard plans—voluntarily opted to enroll in standard plans, resulting in individuals losing coverage for needed residential treatment services. North Carolina was able to mitigate this issue by requiring that these individuals consult with a choice counselor before opting to change delivery systems.

Under managed care rules, beneficiaries ordinarily must have a choice of at least two managed care organizations (MCOs). Under this amendment, CMS is granting expenditure authority to limit individuals to a mandated single specialty health plan. For beneficiaries who reside in an intermediate care facilities, these individuals will be enrolled in a BH I/DD tailored plan with no opt-out option if they meet the following criteria: have intellectual disabilities (ICF-IID), participate in North Carolina's Transitions to Community Living Initiative, are enrolled in the Innovations or TBI 1915(c) waiver, live in a state-funded residential treatment facility (i.e., individuals receiving services to support them in their residence/housing setting, including services provided in group homes or other non-independent settings such as Group Living, Family Living, Supported Living, and Residential Supports). These individuals will have the choice to enroll in a standard plan only if they elect to no longer use the residential services not covered by standard plans. This approach will help ensure that beneficiaries retain access to critical services that enable them to live safely in their current residence that will only be offered through this BH I/DD managed care product.

To ensure a smooth transition for this vulnerable population, the special terms and conditions (STC) include guardrail requirements for a transition of care protocol to ensure continuity of care for members, assurances of adequate capacity and services, quarterly appeals and grievance reports, and requirements of choice for primary care providers. Most importantly, on October 1, 2023 and monthly for six months following the launch of the Tailored Plan program, the state must submit a report detailing the total percentage of members who experienced a disruption in primary care across all primary care providers. If the total percentage of member disruption is greater than 10 percent, CMS will request the state submit a corrective action plan. In addition, CMS reserves the right to extend the transition of care protocol by an additional six months if the October 1, 2023 report, and subsequent reports, show there is inadequate access for beneficiaries. These STCs will help ensure beneficiaries are not negatively impacted by limiting choice under the demonstration.

Second, this amendment will remove dually eligible individuals with significant behavioral health and I/DD needs from the demonstration, with the exception of dually eligible individuals enrolled in the state's Innovations and TBI 1915(c) waiver programs. In recent months, North Carolina has determined that it will continue to offer the state's existing behavioral health

delivery system, namely behavioral health limited benefit prepaid inpatient health plans called LME/MCOs which are authorized via the state's 1915(b) waiver, after the launch of BH I/DD Tailored Plans, instead of phasing out these prepaid inpatient health plans as initially contemplated. North Carolina believes that dually eligible individuals will be best served by remaining in their existing behavioral health and I/DD delivery system. This change will align coverage for these individuals with other dual eligible enrollees (i.e., those without significant behavioral health needs or an I/DD).

Healthy Opportunities Pilot Program
The HOP program is a public-private *regional* program located in three regions within the state with a focus on providing information, benefits, and services to improve health and lower costs. The pilot programs employ evidence-based interventions for Medicaid beneficiaries to address housing instability, transportation insecurity, food insecurity and interpersonal safety and toxic stress. Currently, in order to qualify for pilot services, beneficiaries must be enrolled in a "Prepaid Health Plan" (PHP),[1] live in one of the three pilot regions, and must meet at least one health needs criteria and at least one risk factor, as described in the STCs.

This amendment approves three changes to better manage and expand the HOP program. First, North Carolina will give all non-PHP managed care entities (MCEs) in the state that have any share of their business in the pilot regions an opportunity to administer HOP services. Any non-PHP MCE that meets readiness criteria (as determined by the state Department of Health and Human Services (DHHS)) and is approved by the state to participate in the HOP program will be permitted to manage a budget for HOP services and coordinate HOP services for its enrollees (i.e., to play the same role that is currently played by the PHPs). Approval may be based on both the non-PHP MCE's readiness and the state's capacity to monitor and oversee another participating MCE's performance. Primary Care Case Management Entities (PCCM-Es) and Prepaid Inpatient Health Plans (PIHPs) are currently the only types of MCEs other than PHPs operating in North Carolina, and both types of entities will have this opportunity to participate in the HOP program. Should other non-PHP MCEs participate in North Carolina's Medicaid program in the future and have any share of their business in the pilot regions, those entities would have a similar opportunity to participate. As is required by federal law and reflected in STC 1, when setting readiness criteria, determining whether an MCE has demonstrated readiness to participate, and granting approval for an MCE to participate, the state must comply with all applicable federal law relating to non-discrimination, including but not limited to the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Section 1557 of the Patient Protection and Affordable Care Act. The state must notify CMS when it approves a new non-PHP MCE to administer HOP services and must update its Evaluation Design to account for new populations served by a newly approved non-PHP MCE, if applicable. This amendment will have the effect of expanding eligibility for HOP services to a wider range of full-benefit enrollees residing in pilot regions, provided that they meet the health needs criteria and have at least one risk factor, and are able to enroll in a PHP or a non-PHP MCE that the state has approved to administer a HOP.

[1] North Carolina's PHPs are managed care organizations (MCOs) as defined under 42 CFR 438.2. The following PHPs are offered in North Carolina: Standard Plans, Behavioral Health Intellectual/Developmental Disability Tailored Plans and the Children and Families Specialty Plan.

The Program of All-Inclusive Care for the Elderly (PACE) population will not be able to receive HOP services under this amendment. During the PACE enrollment process, PACE participants must agree that the PACE organization will be their sole service provider, and that they will receive all their care and services from the PACE organization and their network providers. The PACE regulations at 42 CFR 460.154(i) state that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. Additionally, PACE offers services similar to the HOP services, if the services are determined necessary by the PACE organization's interdisciplinary team to improve and maintain the participant's overall health status. Therefore, CMS has excluded the PACE population from enrollment in the HOP.

Second, this amendment will extend the timeframe that HOP capacity building funds are available. In the existing demonstration, CMS approved the use of a portion of pilot funding for capacity building in order to ensure network leads (NLs) and human service organizations (HSOs) could successfully execute their pilot-related responsibilities. However, the capacity building funds are currently only available for the first 24 months of a NL's contract with the state. With this amendment, capacity building funding will be available for the remainder of the current demonstration period to support HSOs and NLs. This change will support HSOs as they work to increase pilot enrollment, support HSOs that are phasing into the pilot program, support network sustainability and retention of HSOs, and support NLs continuing to refine their networks. The amount of funding authorized for capacity building will not change with this approval.

Finally, with this amendment the HOP funds flow, pathway to value-based payments, and HOP program integrity has been largely moved from the STCs into a protocol, Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol, which CMS is concurrently approving with this demonstration amendment. Moving certain operational details from the STCs into a protocol, while maintaining appropriate requirements and goals in the STCs, will help the state maintain an agile approach to the evolution of HOP design, as contemplated in the Rapid Cycle Assessment approach to evaluation.

Budget Neutrality

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstration is likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs in that state likely would have been without the demonstration. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid

expenditures that could have occurred absent the demonstration (the "without waiver" (WOW) costs).

Under this approval, CMS is departing from the budget neutrality approach described in the 2018 SMD Letter. CMS is revising the approach to adjusting the budget neutrality calculation in the middle of a demonstration approval period. Historically, CMS has limited its review of state requests for "mid-course" budget neutrality adjustments to situations that necessitate a corrective action plan, in which projected expenditure data indicate a state is likely to exceed its budget neutrality expenditure limit. CMS has updated its approach to mid-course corrections in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (e.g., expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (e.g., unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (e.g., a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

Components of the Proposal CMS is Not Approving

North Carolina requested that the Optional COVID-19 Group be excluded from mandatory managed care. However, fee-for-service is the default delivery system for this population; therefore, the state does not need section 1115 authority to implement this change. Additionally, North Carolina requested the ability to modify the needs- and risk-based eligibility criteria for the HOP through the amendment. However, the STCs do not lay out the specific criteria for the HOP as this is outlined in Attachment G and can be updated at any time. CMS provided technical assistance to the state and Attachment G was updated with additional criteria on September 28, 2022. Finally, North Carolina requested to amend some components of its demonstration by either extending the end date of the demonstration to June 30, 2026 (from October 31, 2024) or shifting the start date of the demonstration (except for the SUD component) to June 2021, to allow for a five years of performance. The state withdrew this request on December 2, 2022.

Monitoring and Evaluation

Consistent with CMS's requirements for monitoring and evaluation of section 1115 demonstrations, and as outlined in the demonstration's STCs, the state is required to continue conducting systematic monitoring and a robust evaluation of its Medicaid Reform Demonstration, per applicable CMS guidance and technical assistance. Throughout the life-cycle of the demonstration approval period, monitoring will support tracking the state's progress towards its demonstration goals, and such monitoring will accommodate new policy areas such as those approved with this amendment. Overall, the evaluation must produce a thorough assessment of whether the demonstration initiatives are effective in producing the desired outcomes for beneficiaries and the state's Medicaid program. As such, the state is required to

review and revise the Evaluation Design to incorporate this amendment, as appropriate. The demonstration's monitoring and evaluation approaches also must accommodate data collection and analyses stratified by key subpopulations of interest—to the extent feasible—to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration, including this amendment, might support bridging any such inequities.

Consideration of Public Comments

North Carolina provided public notice for the amendment submission in accordance with the processes described in the September 27, 1994 Federal Register notice (59 FR 49249) as generally acceptable methods of state public notice for demonstration amendments. CMS generally considers a state to have provided acceptable public notice for a demonstration amendment if the state follows one or more (if the state desires) of the processes described in the 1994 Federal Register notice.

The state conducted a public notice and comment period on the draft amendment proposal from November 18, 2021 through December 27, 2021. North Carolina also completed tribal consultation in accordance with section 1902(a)(73) of the Act by providing a summary to tribal leaders and designees on October 26, 2021. North Carolina received comments from a variety of stakeholders during the public notice period, including consumer advocates, providers, health plans, and others. North Carolina reported that the comments were generally supportive of the amendment or sought clarification on various requests proposed in the amendment.

CMS received two comments during the federal comment period, open February 2, 2022 through March 4, 2022. One commenter was supportive of the proposal, reiterating support for mandatory managed care plans, the demonstration's substance use disorder component and the expansion of the HOP services to additional populations.

The second comment included a signed letter from various organizations opposing the amendment due to the lack of plan choice and insufficient network adequacy for the BH I/DD tailored plan beneficiaries. The aim of the state's approach of limiting BH I/DD tailored plan beneficiaries using residential services within the BH I/DD tailored plan is to preserve access to critical residential services for these beneficiaries that are not available under the standard plan. These individuals will have the choice to enroll in a standard plan if they opt to no longer use residential services. Additionally, the STCs include beneficiary protections which include requirements for a transition of care protocol to ensure continuity of care for members, assurances of adequate capacity and services, quarterly appeals and grievance reports, and requirements of choice for primary care providers. To further address the commenters concerns, CMS has required that, on October 1, 2023, and monthly for six months following the launch of the Tailored Plan program, the state must submit a report detailing the total percentage of members who experienced a disruption in primary care across all primary care providers. The state will have to assure greater than 90 percent of individuals will not receive a disruption of care, and should there be a disruption of care for 10 percent or great of individuals, CMS will require the state submit a corrective action plan. Managed care plans must continue medically necessary services for members in an ongoing course of treatment without any form of prior approval and without regard to whether such services are provided by in-network or out-of-network providers for at least six months, unless the member/family has opted to discontinue

such services or selects a provider that is in network. In addition, CMS reserves the right to extend the transition of care protocol by an additional six months if the March 1, 2024 report, and subsequent reports, show there is not adequate access for beneficiaries. These additional STCs seek to ensure beneficiaries are not negatively impacted by limiting choice under the demonstration.

The comment letter also asked CMS to require the state to allow mandatory enrollees who cannot access the services and providers to disenroll from managed care and opt back into FFS and the LME system. CMS points out that mandatory managed care enrollment was approved with the initial demonstration approval in October 2018.

After careful review of the public comments submitted during the federal comment period and the information received from the state, CMS has concluded that the demonstration, as amended, is likely to advance the objectives of Medicaid by providing additional services to Medicaid beneficiaries and ensuring that vulnerable beneficiaries have access to and are receiving appropriate services in managed care.

Other Information

This 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. Shelby Higgins. She is available to answer any questions concerning your amendment. Ms. Higgins's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Shelby.Higgins@cms.hhs.gov
Phone: (443) 926-6513

If you have questions regarding this approval, please contact Ms. Mehreen Rashid, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (443) 257-5069.

Sincerely,

Daniel Tsai
Deputy Administrator and Director

Enclosure

cc: Robert Townes, State Monitoring Lead, CMS Managed Care Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: **11W00313/4 and 21W00070/4**

TITLE: **North Carolina Medicaid Reform Demonstration**

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

All requirements of the Medicaid program and the Children's Health Insurance Program (CHIP) 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 (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 enable necessary to enable the state to implement the Healthy Opportunities 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 under this demonstration, regardless of eligibility category.

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11W00313/4 and 21W00070/4**

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 or section 2107(e)(2)(A) of the Act, incurred from November 1, 2019 to October 31, 2024 unless otherwise specified, shall be regarded as expenditures for the state's title XIX and title XXI state plans.

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.

Title XIX Expenditure Authority:

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. **Healthy Opportunities Pilot Program**. Effective November 1, 2019, expenditures not to exceed $650 million to conduct the Healthy Opportunities Pilot program in two to four regions of the state to improve health-related needs for Medicaid eligible individuals who meet the eligibility criteria specified in the special terms and conditions. The expenditure authority will expire on October 31, 2024. The only expenditures permitted after October 31, 2024, are claims runout, incentive payments for prior periods of performance, and administrative activities to close out the value-based payment portion of the Healthy Opportunities Pilot Program.

3. **Behavioral Health/Intellectual Developmental Disability Tailored Plans.** Effective July 7, 2023, expenditures under contracts with managed care entities that do not meet the requirements in 1903(m)(2)(A) and 1932(a) of the Act as implemented in 42 CFR 438.52(a),), to the extent necessary to allow the state to limit the choice to a single BH I/DD tailored health plan in each county for individuals meeting one of the following criteria:

a. Reside in an intermediate care facility for individuals with intellectual disabilities (ICF-IID)
b. Participate in North Carolina's Transitions to Community Living Initiatives
c. Enrolled in the Innovations or Traumatic Brain Injury 1915(c) waiver
d. Medicaid-enrolled beneficiaries who receive services/supports in state-funded residential treatment (i.e., individuals receiving services to support them in their residence/house setting, including services provided in group homes or non-independent settings such as group living, family living, supported living, and residential supports).

Title XIX Requirements not applicable to the Healthy Opportunities Pilot Program.

All title XIX requirements that are waived for Medicaid eligible groups are also not applicable to the Healthy Opportunities 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 Healthy Opportunities Pilot program.

Title XXI Expenditure Authority:

1. **Healthy Opportunities Pilot Program**. Effective November 1, 2019, expenditures not to exceed $118 million to conduct the Healthy Opportunities Pilot program in two to four regions of the state to improve health-related needs for Medicaid-Expansion Children's Health Insurance Program (M-CHIP) eligible children who meet the eligibility criteria specified in the special terms and conditions. Effective September 16, 2022, this expenditure authority also applies to Separate Children's Health Insurance Program (S-CHIP) eligible children who meet the eligibility criteria specified in the special terms and conditions for the Healthy Opportunities Pilot program. The expenditure authority will expire on October 31, 2024.

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

NUMBER: **11W00313/4 and 21W00070/4**

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:	SUD Implementation Plan Protocol
Attachment E:	SUD Monitoring Protocol (reserved)
Attachment F:	SUD Health Information Technology (Health IT) Protocol
Attachment G:	Healthy Opportunities Pilot Program Eligibility and Services
Attachment H:	Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol
Attachment I:	Monitoring Protocol for Other Policies (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

In September 2015, the state passed legislation to transition its Medicaid (Title XIX) program and Medicaid-expansion Children's Health Insurance Program (M-CHIP) (Title XXI) care delivery system to a Medicaid managed care program and delegate direct management of medical services and financial risks to Managed Care Organizations (MCO) 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 and M-CHIP 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 M-CHIP; 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, SUD, and intellectual and developmental disability (I/DD), and for children in foster care and North Carolina former foster care youth.
- The implementation of Medicaid and M-CHIP 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 and M-CHIP 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 and M-CHIP 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 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.

On September 16, 2022, North Carolina amended the demonstration to add its Separate Children's Health Insurance Program (S-CHIP) as an eligible population to receive the Healthy Opportunities Pilot(s) (HOP), previously known as the Enhanced Case Management and Other Services Pilot program.

On July 7, 2023, North Carolina amended the demonstration to adjust which populations will, will not, or must be covered under the Behavioral Health Intellectual/Development Disability (BH I/DD) Tailored Plans, expand access to the HOP, and modify certain implementation details relating to the HOP. As of July 7, 2023, BH I/DD Tailored Plans and the Specialized Plan for Children in Foster Care and Formerly in Foster Care have not yet launched. Standard Plans launched on July 1, 2021 and the HOP program launched on March 15, 2022.

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, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Section 1557 of the Patient Protection and Affordable Care Act.
2. **Compliance with Medicaid and Children's 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 and CHIP 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; 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 or CHIP 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1) or for children in CHIP consider eligibility for other insurance affordability programs under 42 CFR 457.350. For individuals determined ineligible for Medicaid and CHIP, the state must redetermine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements for Medicaid found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214 or for CHIP found at 42 CFR 457.340(e) including information about a right to a review consistent with 42 CFR 457.1180. In addition, the state must assure all applicable Medicaid appeal and hearing rights are afforded to Medicaid beneficiaries in the demonstration as outlined in 42 CFR part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230.

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 or CHIP 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 or CHIP program – including public benefit or service programs; procedures for obtaining Medicaid or CHIP 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, including M-CHIP, or, where applicable, a 1915(c) waiver. This demonstration fully applies to all eligibility groups other than those listed in Table 1A and Table 1B. All beneficiaries in Table 1A and Table 1B are excluded from enrollment in PHPs under the demonstration.

TABLES 1A, 1B, AND 1C: ELIGIBLITY GROUPS EXCLUDED FROM ENROLLMENT IN PHPs THROUGH THE DEMONSTRATION, AND EXCLUDED FROM MOST DEMONSTRATION COMPONENTS

TABLE 1A: FULL BENEFIT MEDICAID BENEFICIARIES IN THIS TABLE ARE ELIGIBLE FOR SUD (STC 19) AND HOP (IF THEY MEET THE HOP CRITERIA AND ARE SERVED BY A HOP ADMINISTRATOR CONSISTENT WITH STC 21T))

GROUP NAME	CITATIONS
Duals Eligible for Full Medicaid, except those who are enrolled in the state's Innovations and TBI 1915(c) waiver programs. which qualifies the beneficiary for enrollment in the BH I/DD tailored plans	
Medically Needy • Medically Needy Pregnant Individuals 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)
Individuals Participating in the NC Health Insurance Premium Payment (HIPP) program except those covered by Innovations or TBI waivers	1906
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)

TABLE 1B: S-CHIP BENEFICIARIES IN THIS TABLE ARE ELIGIBLE FOR HOP (IF THEY MEET THE HOP CRITERIA AND ARE SERVED BY A HOP ADMINISTRATOR CONSISTENT WITH STC 21T)

GROUP NAME	CITATIONS
Separate Children's Health Insurance Program (S-CHIP)	Title XXI

TABLE 1C: EXCLUDED FROM THIS DEMONSTRATION ENTIRELY

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)(i) • 1905(p)(1) • 1902(a)(10)(E)(ii) • 1902(a)(10)(E)(iii) • 1902(a)(10)(E)(iv)
Individuals with Limited or no Medicaid Coverage (e.g., eligible for emergency services only)	• 1903(v)(2) and (3)
Individuals Eligible for Family Planning Services	• 1902(a)(10)(A)(ii)(XXI) • 42 CFR 435.214
Incarcerated Individuals *(Inpatient stays only)*	• Clause (A) following 1905(a)(29)(A) • 42 CFR 435.1009, 1010
Presumptively Eligible • Presumptively Eligible Pregnant Individuals • 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

V. DEMONSTRATION PROGRAMS AND BENEFITS

19. <u>Opioid Use Disorder/Substance Use Disorder Program.</u> Effective upon CMS's 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
Medically Managed Intensive Inpatient	State Plan (Individual services covered)	Services provided to individuals in an IMD

SUD BENEFIT	*MEDICAID AUTHORITY*	*EXPENDITURE AUTHORITY*
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 will 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(f) 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. Progress on the performance measures identified in the SUD Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the SUD Monitoring Protocol must include:

i. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 19(a).

ii. A description of 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 26 of the demonstration; and

iii. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will 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.

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 to 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 (Monitoring and Reporting Requirements) and IX (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 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.

   i. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 days after receipt of CMS's comments, if any. Upon CMS approval of the draft Evaluation Design, the document will be included as Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 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. 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 if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.

   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 Reports) of these STCs, the evaluation deliverables 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 will 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 HealthIT.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

g. 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.

h. 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).

i. 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. Cost Sharing. 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. Managed Care Organizations (MCO). 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 and M-CHIP 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[4]

POPULATIONS	DY 2-3[5]	DY 4-6
Medicaid and M-CHIP 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 and M-CHIP 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)[6]	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 enrolled in BH I/DD tailored plans	Medicaid fee-for-service/LME-MCO	Medicaid fee-for-service/BH I/DD tailored plan[7]

[4]As of July 7, 2023, BH I/DD Tailored Plans and the Specialized Plan for Children in Foster Care and Formerly in Foster Care have not yet launched. Standard Plans launched on July 1, 2021.

[5] Populations enrolling in BH I/DD tailored plans may not be included in the demonstration besides the SUD component until demonstration year 3, when BH I/DD tailored plans are scheduled to begin.

[6] LME-MCOs are limited benefit prepaid inpatient health plans.

[8] All Innovations waiver enrollees including certain children in foster care, NC 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,

POPULATIONS	DY 2-3[5]	DY 4-6
Innovations waiver enrollees[8]	Medicaid fee-for-service/LME-MCO	BH I/DD tailored plan
Traumatic Brain Injury waiver enrollees[9]	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 are those 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 will provide CMS with a minimum of 60 days to review and approve changes.

E. The state is authorized to contract with 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:

except one exception. American Indians/Alaska Natives enrolled in the Innovations waiver who are exempt from mandatory PHP enrollment, but may opt to enroll in PHPs, can remain enrolled in Medicaid fee-for-services/LME-MCO at the end of DY 3.

[8] All Innovations waiver enrollees including certain children in foster care, NC 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, except one exception. American Indians/Alaska Natives enrolled in the Innovations waiver who are exempt from mandatory PHP enrollment, but may opt to enroll in PHPs, can remain enrolled in Medicaid fee-for-services/LME-MCO at the end of DY 3.

[9] All TBI waiver enrollees including children in foster care, NC HIPP program participants, medically needy beneficiaries, and beneficiaries who are dually eligible for Medicare and Medicaid 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, with one exception. American Indians/Alaska Natives enrolled in the TBI waiver, who are exempt from mandatory PHP enrollments but may opt to enroll in PHPs, can remain enrolled Medicaid fee-for-services/LME-MCO at the end of DY 3.

a. Standard Plans that serve Medicaid and M-CHIP 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. At a minimum, the state will 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 state will develop clear eligibility criteria for BH I/DD Tailored Plans, consistent with STC 21H, that will account for service needs and the following diagnosis categories:
    i. Serious Mental Illness;
    ii. Serious Emotional Disturbance;
    iii. Severe SUD; and
    iv. I/DD and/or TBI.
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 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 will be given an opportunity to select an MCO at the time of application. Beneficiaries must have the choice of at least two 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.** Beneficiary eligibility for BH I/DD Tailored Plans and Specialized Plan for Children in Foster Care will be determined through the use of available information and data (e.g., historical claims and

encounters). Enrollees eligible for a BH I/DD Tailored Plan or Specialized Plan may be auto-enrolled into that plan. Auto-assignment must be 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**.
    a. Beneficiaries eligible for the BH I/DD Tailored Plan (with the exception of beneficiaries who meet the criteria in STC 21I (b) or) 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 21H 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.
    b. Beneficiaries who meet one of the below criteria may disenroll from a BH I/DD Tailored Plan if they receive residential services offered by the BH I/DD Tailored Plan that are not covered in a standard plan:
        i. Reside in an intermediate care facility for individuals with intellectual disabilities (ICF-I/DD)
        ii. Participate in North Carolina's Transitions to Community Living
        iii. Enrolled in the Innovations or Traumatic Brain Injury 1915(c) waiver,
        iv. Receive services/supports in state-funded residential treatment (i.e., individuals receiving services to support them in their residence/house setting, including services provided in group homes or non-independent settings such as group living, family living, supported living, and residential supports).
    c. Beneficiaries unable to disenroll from the BH I/DD Tailored Plan in STC 21I(b) must receive notices. The notice should include an explanation as to why the enrollees are unable to opt out of the BH I/DD tailored plan and explain how the beneficiary can opt out of the residential services and opt out of the BH I/DD tailored plan.

J. **BH I/DD Tailored Plans Benefits**. Specialized behavioral health services, including Innovations and TBI waiver services and services covered under 1915(b)(3) and/or 1915(i) will be available through BH I/DD Tailored Plans and not through Standard 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 has authority to implement Managed Care in two state regions by November 2019 and the remaining four regions

by February 2020. The state plans to implement each plan type according to the following schedule[10]:

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. **Continuity of Care during the Transition Period for Managed Care Plans.** The state's contracts with all managed care plans must require a transition of care protocol to ensure continuity of care for members. Managed care plans must continue medically necessary services for members in an ongoing course of treatment without any form of prior approval and without regard to whether such services are provided by in-network or out-of-network providers for at least six months, unless the member/family has opted to discontinue such services or selects a provider that is in network. To ensure continuity of care and allow the member to keep their current primary care provider (PCP), beginning in DY 5, if the managed care plan does not have a member's PCP in its network on the date when the member is assigned a PCP prior to the launch of the managed care program, the managed care plan is required to offer to execute a contract or a single case agreement to that PCP . Upon BH I/DD Tailored Plan launch and monthly for six months following the launch of the BH I/DD Tailored Plan program, the state must submit a report detailing the total percentage of members who experienced a disruption in primary care across all primary care providers, meaning that their historical primary care provider is not in-network for their BH I/DD Tailored Plan. If the total percentage of members with PCP disruption is greater than 10%, CMS will request the state submit a corrective action plan. In addition, CMS reserves the right to extend the transition of care protocol by an additional six months if the initial report, and subsequent reports, show there is not adequate access for beneficiaries. Any notice of extension of transition of care protocols shall be communicated no less than 60 days prior to anticipated expiration of the protocols.

N. **Assurances of Adequate Capacity and Services for Managed Care Plans.** For all managed care plans that furnish services to Medicaid beneficiaries enrolled in the managed care programs authorized by this 1115(a) demonstration, the state must submit the Assurance of Compliance detailed in 42 CFR § 438.207(d) using the Access Reporting Template provided by CMS. Before implementation, each BH I/DD Tailored Plan and Specialized Plan for Children in Foster Care and Formerly in Foster Care must provide adequate assurances that it has sufficient capacity to serve the expected enrollment in its service area and offers an adequate range of preventive, primary,

[10]As of July 7, 2023, BH I/DD Tailored Plans and the Specialized Plan for Children in Foster Care and Formerly in Foster Care have not yet launched. Standard Plans launched on July 1, 2021.

specialty, and acute services for the anticipated number of enrollees in the service area. The state must verify these assurances by reviewing demographic, utilization and enrollment data for enrollees in the demonstration as well as:

a. The number and types of preventive, primary, specialty, and acute providers available to provide covered services to the demonstration population;
b. The number of providers accepting the new demonstration population; and
c. The geographic location of providers, as shown through GeoAccess or similar software.

O. **Timing of Submission of Assurances of Adequate Capacity and Services.** The state must begin submitting the Access Reporting Templates for all managed care plans that furnish services to Medicaid beneficiaries enrolled in the managed care programs authorized by this 1115(a) demonstration by October 1, 2023. For the initial submissions in DY 5, the state must tailor Access Reporting Template submissions based on operational readiness and data availability. For submissions in DY 6, the state must provide the complete set of data outlined in the Access Reporting Template for all managed care plans that furnish services to Medicaid beneficiaries enrolled in the managed care programs authorized by this 1115(a) demonstration. The state must publish these reports on its public website.

P. **Quarterly Appeals and Grievance Report for Managed Care Plans.** CMS reserves the right to request quarterly appeals and grievance data for all programs authorized under this 1115(a) demonstration. The state must submit 60 days after the end of each quarter, appeals and grievance data for all managed care plans that furnish services to Medicaid beneficiaries enrolled in the managed care programs authorized by this 1115(a) demonstration launching on or after October 1, 2023. The state must submit the data for four quarters. If additional data is needed after that period, CMS shall provide the state with at least 60 days notices of the extension of the reporting. In effectuating this requirement, the state must utilize the Appeals and Grievance Reporting Template provided by CMS.

Q. **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).

R. **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.

S. **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.

a. Eligibility. Under the demonstration, there is no change in Medicaid or M-CHIP 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.[11]

b. 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 operate 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.

T. **Healthy Opportunities 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 21T(vii)(c) below), to establish the public-private regional Healthy Opportunities Pilot (HOP) program (the "pilot program") in two to four regions of the state serving Medicaid, M-CHIP, and S-CHIP beneficiaries during the demonstration approval period of November 1, 2019 through October 31, 2024. The $650 million is the total expenditure authority for the HOP; however, the state is only granted $118 million in Title XXI expenditure authority. The state cannot spend over $650 million for the HOP over the course of the 5-year demonstration through both Title XIX and XXI. The pilot regions must have specific target populations of high-need Medicaid and CHIP beneficiaries within their geographic region, and the state will 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 beneficiaries to determine if they meet HOP eligibility criteria related to the following four risk factors of the pilot: housing instability, food insecurity, transportation insecurity, and interpersonal violence/toxic stress. The HOP Administrator (as described in STC 21.T.vi below) determines the HOP services to be provided to each eligible beneficiary. Following implementation of the pilot program, the HOP Administrator must review the pilot services an eligible beneficiary is receiving every 3 months to verify the services are meeting the needs of the beneficiary, and must reassess the beneficiary's eligibility in the pilot program every 6 months.

The state must submit to CMS a plan to incorporate pilot interventions that were tested during the pilot evaluation process into the state's Medicaid and CHIP program throughout the state at the conclusion of the 5-year demonstration.

i. Eligible Beneficiaries. Medicaid and CHIP beneficiaries who reside in a pilot region, are able to enroll in a PHP or an approved non-PHP HOP Administrator, and meet HOP eligibility criteria are eligible for HOP services. Individuals must be assessed for HOP services by the HOP Administrator to determine their eligibility for HOP services based on meeting one needs-based criterion and having one risk factor, as outlined in Attachment G. The HOP program is a voluntary pilot

[11] American Indians/Alaska Natives, who are exempt from mandatory PHP enrollment but may opt to enroll in PHPs, can also obtain Innovations or TBI waiver services through LME-MCOs, North Carolina's PIHPs.

program. Once a beneficiary is enrolled in an MCE serving as the HOP Administrator and is determined eligible for HOP program services, the HOP Administrator must seek consent from the beneficiary to enroll the beneficiary in the HOP program. After receiving the beneficiary's consent, the HOP Administrator may enroll that beneficiary in the HOP program. The enrollee will have the option to opt out and disenroll from the HOP program at any time. If an eligible beneficiary opts against enrolling in, or voluntarily disenrolls from, the HOP program, that beneficiary (if still eligible) must have the option to enroll or re-enroll in the HOP program at any time during the 6-month period following the most recent determination that the beneficiary is (or remains) eligible for HOP services. Beneficiaries who do not opt out will remain enrolled in the HOP program until they no longer meet the eligibility criteria and/or do not require pilot services to address an unmet need as determined in a pilot eligibility reassessment. Subject to all applicable federal and state non-discrimination laws, the HOP Administrator will be permitted to set enrollment caps in its pilot region(s), following review and approval by the state, if the HOP Administrator has limited funding capacity to serve all eligible beneficiaries.

ii. Beneficiaries Determined Ineligible. The state must require that beneficiaries determined ineligible have the opportunity to request reassessment of their eligibility status when there is an indication the beneficiary's health status or social risk factors have changed. Upon a determination of ineligibility, the HOP Administrator will communicate to the beneficiary the process to request a reassessment. Eligibility reassessments will utilize the same tools 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 Network Leads (NL)[12] in two to four regions within the state by November 4, 2019. NLs 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 that all pilot enrollees have a care plan that tracks the enrollee's non-medical needs. The HOP Administrator will reimburse for 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 involvement and lower healthcare costs. The services that can be provided in this pilot program are outlined in Attachment G . The state must ensure that individuals eligible for HOP do not obtain HOP services that are duplicative with those they are eligible to obtain under the state plan, 1915(c) waivers, or any other approved Medicaid authority outside of this 1115 demonstration. Any HOP services provided that are duplicative will result in a recoupment of FFP for the duplicative HOP service. 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

[12] Previously referred to as the "Lead Pilot Entity" or "LPE."

deleted, the number of pilot participants impacted by the proposed service change(s), and the financial impact on the demonstration from 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. Network Leads (NLs). The state must select a NL for each pilot region through a competitive procurement process to serve as the regional pilot coordinator, and be accountable for the pilot operations. The NL will support the HOP Administrator in its region in identification of eligible pilot enrollees . The NL will develop the network of participating Human Services Organizations (HSOs) delivering pilot services which helps to ensure the enrollee receives services based on identified care needs. The state must require that the NL's key responsibilities include:
    a. Developing, contracting with, and managing a diverse network of HSOs to deliver pilot services, including community-based organizations (CBOs), social service agencies, and healthcare providers.
    b. Establishing a governance structure consistent with state guidelines, and determine operational roles, responsibilities, and procedures.
    c. Tracking reimbursement to HSOs in accordance with payment protocols and procedures.
    d. Working in collaboration with the HOP Administrator, HSOs, and other stakeholders to determine locally available and appropriate HOP services based on the HSO network.
    e. Providing technical assistance to HOP Administrators, HSOs, and other stakeholders on HOP services and sharing best practices across regions.
    f. Working in collaboration with HOP Administrators to track provision of HOP services and data collection to report on metrics needed for rapid cycle assessments, and other monitoring and evaluation activities outlined in Sections VIII (Monitoring and Reporting Requirements) and IX (Evaluation of the Demonstration) of these STCs.
    g. Participation in "learning communities" to ensure that the pilot regions are sharing and adopting best practices throughout the duration of the demonstration period.

vi. HOP Administrator. A HOP Administrator is defined as any managed care entity, subject to STCs 21T.vi.b and 21T.vi.c. The HOP Administrator will serve as a point of contact with the state. The HOP Administrator will execute many of its member-facing pilot-related responsibilities in partnership with employed care managers and local contracted care management entities.
    a. The key responsibilities of the HOP Administrator in the pilot program, as appropriate (and the key responsibilities of its care managers, as appropriate) include:
        - Screening Medicaid and CHIP beneficiaries to identify those who are eligible for receiving services through this pilot program.

- Obtaining consent for enrollment in the pilot program and enrolling individuals who consent.
- Determining and authorizing the specified HOP program services that are necessary and appropriate for enrolled beneficiaries.
- Developing and reviewing a care plan that tracks the enrollee's non-medical needs.
- Working in collaboration with the NL to track the provision of HOP program services and to pay HSOs for delivering authorized pilot services.
- Managing budgets and submitting any enrollment restrictions to the state for approval.
- Participation in "learning communities" to ensure that pilots are sharing and adopting best practices throughout the duration of the demonstration period.

b. PHPs that serve as the HOP Administrator. Under the oversight of the state's Medicaid managed care program, the state shall require that all PHPs[13] that have any share of their business within any of the 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 who are enrolled in the PHP, within state guidelines and these STCs. The BH I/DD Tailored Plans and Formally in Foster Care, which will be implemented on or after DY 5, will be required to participate in the pilot program only after the state determines their readiness to cover HOP services. BH I/DD Tailored Plans must be actively providing HOP services by one year after the BH I/DD Tailored Plan launch.

c. Other Non-PHP Managed Care Entities (MCEs) that serve as the HOP Administrator. Under the oversight of the state's Medicaid managed care program, the state may allow any other non-PHP MCE with any share of its business within any of the pilot regions, including Primary Care Case Management Entities (PCCM-Es), Primary Care Case Managers (PCCMs), Prepaid Inpatient Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs), to become an HOP Administrator, provided the non-PHP MCE demonstrates a readiness to participate in the HOP program and receives approval from the North Carolina DHHS to participate in the program. Approval may only be based on both the non-PHP MCE's readiness and the state's capacity to monitor and oversee another participating MCE's performance. Approved non-PHP HOP Administrators, like PHP HOP Administrators, are responsible for authorizing the provision of all pilot services to beneficiaries who are eligible for those services and who are enrolled in (or able to enroll in) the MCE, within state guidelines and these STCs. The state must notify CMS when it approves a new non-PHP HOP Administrator and must update its Evaluation Design to account for the new populations served by the new HOP Administrator, if applicable.

[13] North Carolina's PHPs are managed care organizations as defined under 42 CFR 438.2. The following PHPs are offered in North Carolina: Standard Plans, Behavioral Health Intellectual/Developmental Disability Tailored Plans and the Specialized Plan for Children in Foster Care and Formerly in Foster Care.

vii. Pilot Funding Flow. The state must distribute funding for pilot-related authorized services and capacity building. Key pilot funding flow elements are described in detail in Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol. Pilot funding streams will include:

a. Pilot Services Payment. The state must distribute the specific capped allocation to each HOP Administrator which considers regional Medicaid/CHIP enrollment to support the delivery of authorized pilot services to the HOP Administrator's enrollees who are eligible for the pilot services, inclusive of an administrative fee. The majority of the cumulative service payment must be used to pay for the delivery of pilot services. HOP Administrators must use the allocation only for the pilot specified purposes and must return all unused pilot funds to the state.

i. The state must require that the HOP Administrator, in collaboration with the NL, 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 HOP Administrator funding allocation based on the enrolled beneficiaries 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 HOP Administrator spending against capped funds.

v. FFP will be based on the aggregated amounts actually paid by the state to providers, NLs, and HOP Administrators for authorized pilot purposes, as defined in these STCs.

b. Service Reimbursement. The state must develop a pilot service fee schedule and submit to CMS for approval no later than September 1, 2019. Failure to submit this deliverable to CMS will result in a funding deferral. Furthermore, FFP is not available until the fee schedule is approved.

c. Capacity Building. The state must provide funding to the NLs to build capacity. Capacity building for the pilot will be considered an administrative cost and must be capped at $100 million. Unspent capacity building funding must be used for authorized HOP purposes only. The state must notify CMS prior to shifting capacity building funding to any other authorized purposes.

i. The NL may use this capacity building funding only for the following purposes:

a. Through collaboration with stakeholders (HOP Administrators, social services agencies, Community Based Organizations):

i. developing necessary infrastructure/systems to prepare providers to deliver authorized services,

ii. receive payment,

iii. report information for managing patient care,

iv. track progress in Pilot implementation,

v. collect all applicable data to support monitoring beneficiary take-up and health and quality of care outcomes, and
vi. ensuring program integrity, including distributing capacity building funding to contracted HSOs to enable Pilot participation.

b. Providing technical assistance and collaboration with stakeholders.

d. Pathway to Value-Based Payments. The state must establish an incentive payment program to incorporate value-based payments to incentivize the delivery of high-quality care by increasingly linking payments to pilot entities to health and socioeconomic outcomes based on the pilot services provided. The funding for the value-based payment program must be a subset of the $650 million authorized for the Healthy Opportunities Pilot program. The state's approach to pilot value-based payments is defined further in Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol.

e. Pilot Evaluation. The state must evaluate the HOP in alignment with section IX (Evaluation of the Demonstration) of these STCs. The HOP Administrator, NLs, and HSOs are required to meet evaluation and reporting requirements to track and document the effectiveness of the interventions. 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.

vii. 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 tested pilot program services into its Medicaid program.

viii. Healthy Opportunities Pilot Program Integrity. The state must maintain program integrity standards in the pilot program, including:

a. Quarterly accounting on delivered pilot services. The state must ensure that there is quarterly accounting on pilot services delivered based on a payment and reporting system and defined roles and responsibilities for the HOP Administrators, NLs, and HSOs. Additional detail on quarterly accounting and specific roles and responsibilities is available in Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol.

b. Audit Processes. The HOP Administrators in collaboration with NLs will be required to ensure Medicaid and CHIP payments are for services covered under this pilot program that were actually provided and properly billed and documented by HSOs through the processes including invoice analysis and visit verification procedures. Additional detail on pilot-related audit processes is described in Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol.

c. Ensuring action is taken to address identified non-compliance. The state must ensure that appropriate action is taken to address non-compliance by pilot-participating entities (HOP Administrators, NL, HSOs) including by conducting audits, recouping any overpayments, and by imposing suspensions, withholds, sanctions or treatments due to findings of fraud or abuse. Additional detail on pilot-related audit processes is described in Attachment H: Healthy Opportunities Pilot Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol .

ix. Pilot Termination. The state may suspend or terminate the entire pilot program, any pilot region, or an NL, HOP Administrator, or HSO in any pilot region, if corrective action has been imposed and poor performance continues. The state must notify CMS when any such entity 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. MONITORING AND 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. A deferral shall not exceed the value of the federal amount for the demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) 30 calendar days after the deliverable was due, if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) 30 calendar days after CMS has notified the state in writing that the deliverable was not accepted due to being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.
b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. The extension request must explain the reason why the required deliverable was not submitted, the steps that the state has taken to address such issue, and state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action

plan, still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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 $5,000,000 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. **Monitoring Protocol for Other Policies.** The state must submit to CMS a Monitoring Protocol for Other Policies no later than 150 calendar days after approval of the demonstration amendment. The state must submit a revised Monitoring Protocol within 60 days after receipt of CMS's comments, if any. Once approved, the Monitoring Protocol will be incorporated into the STCs as Attachment I. At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, as applicable. CMS will provide the state with a set of metrics including, but not limited to, enrollment, access to care, and quality of care and health outcomes. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, English

language proficiency, primary language, disability status, and geography) and demonstration component.

27. **Monitoring Reports.** The state must submit three Quarterly Monitoring Reports and one compiled Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The compiled Annual Monitoring Report (including the fourth-quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The monitoring 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. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the monitoring reports must document any policy or administrative difficulties in operating the demonstration. The Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. In addition, the reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed. 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 reports 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 applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress toward meeting the demonstration's milestones and/or goals and must cover all key policies under this demonstration. Additionally, per 42 CFR 431.428, the monitoring reports must document the impact of the demonstration on beneficiaries' outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals. The required monitoring and performance metrics must be included in the monitoring reports, and will follow the framework provided by CMS to support federal tracking and analysis.

    c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements, Section X 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(f).

f. HOP 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 HOP cumulatively:
      b. The 90 percentile cumulative cost for an enrollee in HOP
      c. The 75 percentile cumulative cost for an enrollee in HOP
      d. The 50 percentile cumulative cost for an enrollee in HOP
      e. The 25 percentile cumulative cost for an enrollee in HOP
      f. The 10 percentile cumulative cost for an enrollee in HOP.
   ii. Incentive Payments. The state will provide a report on the amount and how incentive funds were dispersed to HOP Administrators, NLs, and HSOs.
   iii. HOP Capacity Building. The state will provide a report on the amount of capacity building provided to each NLs, the time frame the funding was provided, and what the funding was used for.

28. **Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.
   a. The draft Close-Out Report must comply with the most current guidance from CMS.
   b. The state will present to and participate in a discussion with CMS on the Close-Out report.
   c. The state must take into consideration CMS's comments for incorporation into the final Close-Out Report.
   d. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's 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 ongoing demonstration operations. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
   b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
   c. The state and CMS will jointly develop the agenda for the calls.

30. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within 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.

31. **Corrective Action Plan Related to Demonstration Monitoring**. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 13. CMS will withdraw an authority, as described in STC 13, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

IX. EVALUATION OF THE DEMONSTRATION

32. **Independent Evaluator.** The state must use 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.

33. **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 that 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.

34. **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.

35. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than one hundred eighty (180) days after the effective date of these STCs. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs and any other relevant CMS guidance. 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. 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 Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined culturally appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic)—as these implementation strategies help create strong comparison groups and facilitate robust evaluation.

    The state is strongly encouraged to use the expertise of an independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 37 and 38.

36. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. 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 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation 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 if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.

    For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component, as applicable. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring

reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described in STCs 36 and 37.

37. Evaluation Questions and Hypotheses. Consistent with attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

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). The evaluation must study outcomes, including various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Furthermore, the evaluation should accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography) to the extent feasible, to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support bridging any such inequities.

As noted above, for any amendment to the demonstration, the state will be required to update the approved Evaluation Design or submit a new Evaluation Design to accommodate the amendment component, as appropriate.

38. Interim Evaluation Report. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the Interim 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 or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report may include an evaluation of the authority, to be collaboratively determined by CMS and the state.

c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted or 1 year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted must be included. For demonstration phase-outs prior to the expiration of the

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

d. The state must submit a revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any. The state must post the final Interim Evaluation Report to the state's website within 30 calendar days of CMS approval.

e. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.

39. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.

b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

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

41. **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.

42. Additional Publications and Presentations. For a period of 12 months following CMS approval of deliverables, CMS must be notified prior to presentation of these reports or their findings, including in related publications (e.g., 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 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.

43. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A correction action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 13. CMS

further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

X. GENERAL FINANCIAL REQUIREMENTS

44. Allowable Expenditures. This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

45. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

46. Sources of Non-Federal Share. As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.

b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.

c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

47. State Certification of Funding Conditions. As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.

d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

48. Financial Integrity for Managed Care Delivery Systems. As a condition of demonstration approval, the state attests to the following, as applicable:

a. All risk-based MCO, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

49. Requirements for Health Care-Related Taxes and Provider Donations. As a condition of demonstration approval, the state attests to the following, as applicable:

a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).

b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).

c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.

d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).

e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.

50. State Monitoring of Non-federal Share. If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 23. This report must include:

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;

b. Number of providers in each locality of the taxing entities for each locality tax;

c. Whether or not all providers in the locality will be paying the assessment for each locality tax;

d. The assessment rate that the providers will be paying for each locality tax;

e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;

f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

51. 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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in Section XI:

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

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

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

52. Program Integrity. The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

53. Medicaid Expenditure Groups. Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 4: Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
ABD	Main	X		X	Expenditures for Medical assistance services provided to ABD eligibles not identified as excluded in Table 1A, not SUD IMD expenditures.
TANF and Related Adults	Main	X		X	Expenditures for Medical assistance services provided to TANF Adult eligibles and other non-ABD adults not identified as excluded in Table 1, not SUD IMD expenditures.

Table 4: Master MEG Chart					
MEG	**Which BN Test Applies?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
TANF and Related Children	Main	X		X	Expenditures for Medical assistance services provided to TANF Child eligible and other non-ABD children not identified as excluded in Table 1, not SUD IMD expenditures.
INN/TBI	Main	X		X	Expenditures for Medical assistance services provided to INN/TBI eligibles not identified as excluded in Table 1, not SUD IMD expenditures.
SUD IMD MC TANF and Related	Hypo	X		X	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.
SUD IMD MC ABD	Hypo	X		X	Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible ABD individuals enrolled in managed care during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.
SUD IMD MC Innovations/ TBI	Hypo	X		X	Expenditures for all otherwise-allowable Medicaid services

Table 4: Master MEG Chart					
MEG	**Which BN Test Applies?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
					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.
SUD IMD FFS	Hypo	X		X	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.
HOP Services	Hypo		X	X	Expenditures for the Healthy Opportunities Pilots service payments.
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.
HOP Capacity Building	Main		X	X	Expenditures for HOP capacity building payments.

54. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00313/4 and 21-W-00070/4). Separate reports must be submitted by MEG (identified by Waiver Name) and

Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b (in lieu of lines 9 or 10c), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. **Pharmacy Rebates.** Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the MEG Charts and in the STCs in Section XI, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in Section VIII, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible

member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

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

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
ABD	ABD member months are months of Medicaid eligibility for an individual that is Aged, Blind or Disabled.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	11/1/19	10/31/24
TANF and Related Adult	TANF Adult member months are months of Medicaid eligibility for an individual receiving coverage within the temporary assistance for needy families program and other non-ABD adults.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	11/1/19	10/31/24
TANF and Related Child	TANF Child member months are months of Medicaid eligibility for a child only receiving coverage within the temporary assistance for needy families program and other non-ABD children.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	11/1/19	10/31/24

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
INN/TBI	INN/TBI member months are months of Medicaid eligibility for an individual receiving coverage under the 1915(c) waivers.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	11/1/19	10/31/24
SUD IMD MC TANF	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.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/19	10/31/23

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
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.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/19	10/31/23

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
SUD IMD 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 MEG, as applicable.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/19	10/31/23

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
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.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/19	10/31/23
HOP Service	Expenditures for the Healthy Opportunities Pilots service payments.		Follow standard CMS 64.9 or 64.10 Category of Service Definitions		MAP	N	11/1/19	10/31/24
ADM	All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.		Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	11/1/19	10/31/24

Table 5: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	**Detailed Description**	**Exclusions**	**CMS-64.9 or 64.10 Line(s) To Use**	**How Expend. Are Assigned to DY**	**MAP or ADM**	**Report Member Months (Y/N)**	**MEG Start Date**	**MEG End Date**
HOP Capacity Building	Expenditures for HOP capacity building payments.		Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	11/1/19	10/31/24

55. Demonstration Years. The demonstration years for managed care component and the Healthy Opportunities 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*

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*

56. 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 the demonstration's actual expenditures to the budget neutrality expenditure limits described in Section XI. CMS will provide technical assistance, upon request.[14]

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

58. Future Adjustments to Budget Neutrality. CMS reserves the right to adjust the budget neutrality expenditure limit:

a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or

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

other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

59. Budget Neutrality Mid-Course Correction Adjustment Request. No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process.** In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 59(c). If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for

anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:

i. Provider rate increases that are anticipated to further strengthen access to care;

ii. CMS or state technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;

iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;

iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;

v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;

vi. High cost innovative medical treatments that states are required to cover; or,

vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

60. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of a Main Budget Neutrality Test, a Hypothetical Budget Neutrality Test, and a Capped Hypothetical Budget Neutrality Test as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

61. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 4, Master MEG Chart and Table 5 MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at

risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

62. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

63. **Main Budget Neutrality Test.** The Main Budget Neutrality Test allows the state to show that approval of the demonstration has not resulted in Medicaid costs to the federal government that are greater than what the federal government's Medicaid costs would likely have been absent the demonstration, and that federal Medicaid "savings" have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as "WOW Only" or "Both" are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of the limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test.

Table 6: Main Budget Neutrality Test

MEG	PC or Agg	WOW Only, WW Only, or BOTH	Trend Rate	DY 2	DY 3	DY 4	DY 5	DY 6
ABD	PC	Both	4.47 %	$1,991.86	$2,099.07	$2,173.97	$2,305.84	$2,434.81

Table 6: Main Budget Neutrality Test								
MEG	**PC or Agg**	**WOW Only, WW Only, or BOTH**	**Trend Rate**	**DY 2**	**DY 3**	**DY 4**	**DY 5**	**DY 6**
TANF and Related Adult	PC	Both	4.8%	$664.91	$706.93	$730.28	$784.17	$835.92
TANF and Related Child	PC	Both	1.83 %	$244.73	$253.06	$253.77	$265.38	$275.31
INN/TBI	PC	Both	3.92 %	N/A	$7,350.26	$7,638.41	$7,937.87	$8,249.06
HOP Capacity Building	Agg	WW	0%	$100,000,000	Carryover only	Carryover only	Carryover only	Carryover only

64. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

65. Hypothetical Budget Neutrality Test 1: Substance Use Disorder Expenditures. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7: Hypothetical Budget Neutrality Test 1 – SUD Expenditures

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5
SUD IMD MC TANF and Related Adults	PC	Both	4.8%	N/A	$2,479.75	$2,598.78	$2,723.52	$2,854.25
SUD IMD MC ABD	PC	Both	4.5%	N/A	$3,424.34	$3,577.46	$3,737.42	$3,904.53
SUD IMD MC Innovations/ TBI	PC	Both	3.9%	N/A	N/A	$7,474.12	$7,767.13	$8,071.63
SUD IMD FFS	PC	Both	4.6%	$13,893.55	$14,478.29	$15,144.30	$15,840.93	$16,569.62

66. Hypothetical Budget Neutrality Test 2: Healthy Opportunities Pilots Expenditures. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 8: Hypothetical Budget Neutrality Test 2 – Healthy Opportunities Pilots Expenditures							
MEG	**PC or Agg**	**WOW Only, WW Only,**	**DY 2 Total**	**DY 3 Total**	**DY 4 Total**	**DY 5 Total**	**DY 6 Total**
Healthy Opportunities Pilots	Agg	Both	$110,000,000	$110,000,000	$110,000,000	$110,000,000	$110,000,000

67. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

68. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 11/1/2019 to 10/31/2024. If at the end of the demonstration approval period the Main Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

69. Corrective Action Plan. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 9: SUD Component of the Demonstration Budget Neutrality Test Corrective Action Plan Calculation		
Demonstration Year	**Cumulative Target Definition**	**Percentage**
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

Table 10: Managed Care and Healthy Opportunities Pilot Component of the Demonstration Budget Neutrality Test Corrective Action Plan Calculation		
Demonstration Year	**Cumulative Target Definition**	**Percentage**
DY 2	Cumulative budget neutrality limit plus:	2.0 percent
DY 2 through DY 3	Cumulative budget neutrality limit plus:	1.5 percent
DY 2 through DY 4	Cumulative budget neutrality limit plus:	1.0 percent
DY 2 through DY 5	Cumulative budget neutrality limit plus:	0.5 percent
DY 2 through DY 6	Cumulative budget neutrality limit plus:	0.0 percent

XII. MONITORING ALLOTMENT NEUTRALITY FOR THE DEMONSTRATION

70. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement. The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

a. Tracking Expenditures: In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 and CMS 64 reporting instructions as outlined in section 2115 of the State Medicaid Manual.

b. Use of Waiver Forms: Title XXI demonstration expenditures will be reported on the following separate forms designated for M-CHIP (i.e., Forms 64.21U Waiver and/or CMS-64.21UP Waiver) and S-CHIP (i.e., Forms CMS-21 Waiver and/or CMS-21P Waiver), identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The state must submit separate CMS-21 and CMS-64.21U waiver forms for each title XXI demonstration population.

c. Claiming Period: All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the CMS-21 and CMS-64.21U waiver forms, net expenditures related to dates of service during the operation of the demonstration.

71. Standard CHIP Funding Process. The standard CHIP funding process will be used during the demonstration. North Carolina will continue to estimate matchable CHIP expenditures on the quarterly Forms CMS-21B for S-CHIP and CMS-37 for M-CHIP. On these forms estimating expenditures for the title XXI funded demonstration populations, the state shall separately identify estimates of expenditures for each applicable title XXI demonstration population. CMS will 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 report demonstration expenditures through Form CMS-21W and/or CMS-21P Waiver for the S-CHIP population and report demonstration expenditures for the M-CHIP population through Form 64.21U Waiver and/or CMS-64.21UP Waiver. Expenditures reported on the waiver forms must be identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). CMS will reconcile expenditures reported on the CMS-21W/CMS-21P Waiver and the CMS 64.21U Waiver/CMS-64.21UP Waiver forms with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

72. Title XXI Administrative Costs. Administrative costs will not be included in the allotment neutrality limit. All administrative costs (i.e., costs associated with the title XXI state plan and the title XXI funded demonstration populations identified in these STCs) are subject to the title XXI 10 percent administrative cap described in section 2105(c)(2)(A) of the Act.

73. Limit on Title XXI Funding. North Carolina will be subject to a limit on the amount of federal title XXI funding that the state may receive on eligible CHIP state plan populations and the CHIP demonstration populations described in STC 21 during the demonstration period. Federal title XXI funds for the state's CHIP program (i.e., the approved title XXI state plan and the demonstration populations identified in these STCs) are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.

74. Exhaustion of Title XXI Funds for S-CHIP Population. If the state exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the state must continue to provide coverage to the approved title XXI separate state plan population. However, because the S-CHIP demonstration population described in STC 21T only receives benefits that are additional to full title XXI state plan benefits, if the state exhausts the available title XXI allotment, the state may discontinue coverage for the S-CHIP demonstration population described in STC 21T. North Carolina must submit a notice process for CMS review and concurrence describing how the state will notify beneficiaries if it expects to exhaust its title XXI federal allotment within the demonstration year and therefore decides to reduce or discontinue the additional benefits for the remainder of the allotment year.

75. Exhaustion of Title XXI Funds for M-CHIP Population. If the state has exhausted title XXI funds, expenditures for this population as approved within the CHIP state plan, may be claimed as title XIX expenditures, as approved in the Medicaid state plan. The state must notify CMS in writing at least 90 days prior to an expected change in claiming of expenditures for the M-CHIP population. The state shall report demonstration expenditures for these individuals, identified as "M-CHIP," on the Forms CMS 64.9W and/or CMS 64.9PW.

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 36
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 36
October 31, 2023, or with extension application	Draft Interim Evaluation Report	STC 38
60 days after receipt of CMS comments	Revised Interim Evaluation Report	STC 38
Within 18 months after October 31, 2024	Summative Evaluation Report	STC 39
60 days after receipt of CMS comments	Revised Summative Evaluation Report	STC 39
Monthly Deliverables	Monitoring Call	STC 29
Quarterly Deliverables Due 60 days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 27
	Quarterly Expenditure Reports	STC 54
Annual Deliverables - Due 90 days after end of each 4th quarter	Annual Monitoring Reports	STC 27
September 1, 2019	Healthy Opportunities Pilot Service Reimbursement: Fee For Service Schedule/Cost-Based Reimbursement Sets	STC 21
	Healthy Opportunities Pilot 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.

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups, identifying causal inferences, phasing implementation to support evaluation, and designing and administering beneficiary surveys are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/index.html. If the state needs additional technical assistance using this outline or developing the Evaluation Design, the state should contact the demonstration team.

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**.**

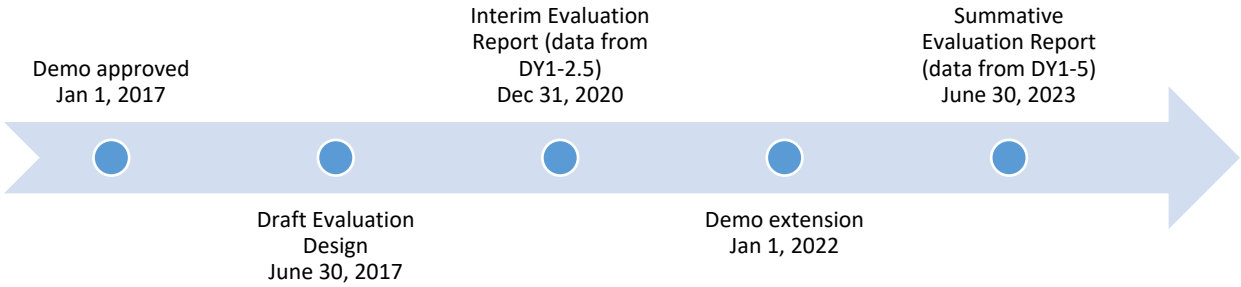
The format for the Evaluation Design is as follows:

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline for a 5-year demonstration). 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, using references where appropriate.

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) *Methodological 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 Attachment

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;

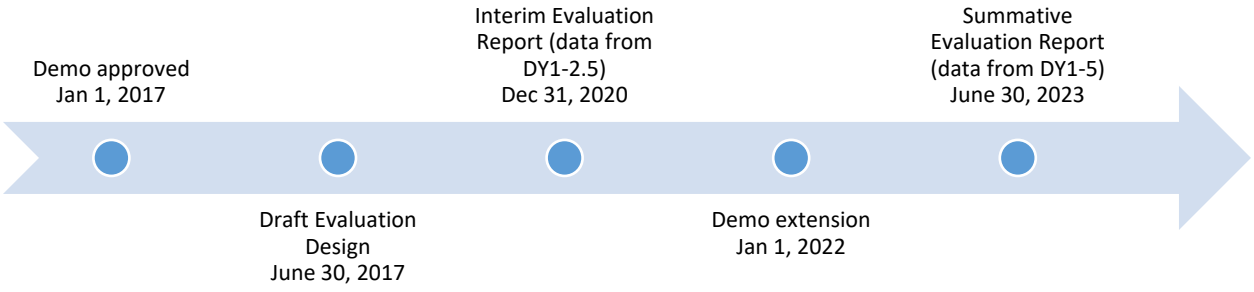
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;

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 for a 5-year demonstration. 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. *Methodological Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?

2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.

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

4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?

5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.

6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

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

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

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

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

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

    a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

I. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C: Evaluation Design

ATTACHMENT D: SUD Implementation Plan Protocol

North Carolina

Substance Use Disorder Implementation Plan Protocol

March 8, 2019

NC DHHS Division of Health Benefits

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Introduction

Like many states, North Carolina is facing an opioid crisis that has rapidly intensified in recent years. Opioid overdose deaths in North Carolina have increased from just over 100 deaths in 1999 to 1,384 in 2016, including a 39% increase in overdose deaths from 2015-2016.[15,16] Since 1999, over 13,000 North Carolinians have died from an opioid overdose. Despite significant efforts to turn the tide on the opioid crisis—including launching North Carolina's Opioid Action Plan, passing the bipartisan Strengthen Opioid Misuse Prevention (STOP) Act, and making changes to North Carolina's Medicaid program—the number of people dying from opioid overdoses each month continues to increase.

As part of its commitment to expand access to treatment for substance use disorders (SUDs), North Carolina's Department of Health and Human Services (the Department) is pursuing a Section 1115 demonstration to strengthen its SUD delivery system by:

- Expanding its SUD benefits to offer the complete American Society of Addiction Medicine (ASAM) continuum of SUD services;
- Obtaining a waiver of the Medicaid institution for mental diseases (IMD) exclusion for SUD services;
- Ensuring that providers and services meet evidence-based program and licensure standards;
- Building SUD provider capacity;
- Strengthening care coordination and care management for individuals with SUDs; and
- Improving North Carolina's prescription drug monitoring program (PDMP).

The following implementation plan provides an overview of North Carolina's current Medicaid SUD delivery system and then details North Carolina's strategic vision for comprehensive SUD delivery reform across six milestones identified by the Centers for Medicare & Medicaid Services (CMS).

Department Overview

The Department includes the following divisions that have significant roles in the delivery and regulation of SUD services for Medicaid enrollees:

- **Division of Health Benefits (North Carolina Medicaid).** The division within the Department responsible for implementing Medicaid transformation and managing the North Carolina (NC) Medicaid and Health Choice (CHIP) programs.
- **Division of Mental Health/Developmental Disabilities/Substance Abuse Services (DMH/DD/SAS).** The division that serves as the single state authority for the Substance Abuse and Mental Health Services Administration (SAMHSA) and administers state-funded mental health, developmental disability and substance abuse services.
- **Division of Health Services Regulation (DHSR).** The division that certifies and monitors healthcare providers.

[15] North Carolina's Opioid Action Plan, 2017-2021. Available at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%208-22-2017.pdf.
[16] North Carolina Opioid Overdose Factsheet, June 2017. Available at https://files.nc.gov/ncdhhs/Opioid_Overdose_Factsheet_FINAL_06_27_17.pdf.

- **Division of State Operated Health Care Facilities (DSOHF).** The division that oversees and manages state-operated health care facilities that treat adults and children with mental illness, SUDs, intellectual and developmental disabilities (I/DDs) and neuro-medical needs.

Current SUD Delivery System

Today, North Carolina Medicaid contracts with seven local management entities–managed care organizations (LME-MCOs), which are prepaid inpatient health plans, to provide mental health, substance use, and I/DD services for Medicaid enrollees located within their catchment areas. Medicaid enrollees obtain physical health services, pharmacy, and most long-term services and support (LTSS) through Medicaid fee-for-service. Additionally, DMH/DD/SAS contracts with the LME-MCOs to manage state and federal block grant-funded mental health, I/DD and SUD services to serve the uninsured and underinsured populations living within their catchment areas. Certain populations that are excluded from LME-MCO enrollment, such as NC Health Choice or legal aliens, receive SUD services through Medicaid fee-for-service. NC Medicaid contracts with a vendor to perform utilization management functions for fee-for-service behavioral health services.

Medicaid Delivery System Transformation

In September 2015, the North Carolina General Assembly (General Assembly) enacted North Carolina Session Law 2015-245, which was amended by Session Laws 2016-121, 2017-57 and 2018-48, directing the transition of North Carolina's Medicaid program from a predominantly fee-for-service model to managed care beginning in 2019. Consistent with best practices, the Department will create integrated managed care products that cover the full spectrum of physical health, behavioral health, LTSS and pharmacy services for all enrollees. North Carolina will permit two types of prepaid health plan (PHPs) products: standard plans and behavioral health and intellectual and developmental disability (BH I/DD) tailored plans. The majority of Medicaid and NC Health Choice enrollees, including adults and children with lower-intensity behavioral health needs, will receive integrated physical health, behavioral health and pharmacy services through standard plans when managed care launches in November 2019. Individuals with significant behavioral health disorders, I/DDs, or traumatic brain injury (TBI) will be enrolled by July 2021 in BH I/DD tailored plans, which will be specialized managed care products that target the needs of these populations.

Both standard plans and BH I/DD tailored plans will cover SUD treatment and withdrawal management services, but the BH I/DD tailored plans will cover a more expansive set of SUD services targeting individuals with significant SUD needs. LME-MCOs will continue to provide all covered SUD treatment services for Medicaid enrollees in the period following approval of the state's 1115 demonstration until standard plan implementation in November 2019. Upon standard plan implementation and until the anticipated launch of BH I/DD tailored plans in July 2021, LME-MCOs will provide SUD services for Medicaid enrollees who are eligible to enroll in the BH I/DD tailored plans or who are delayed or excluded from managed care. Throughout the managed care transition and afterward, the Department will continue to provide the complete array of Medicaid-covered SUD treatment and withdrawal

services in fee-for-service for populations that will phase into managed care in later years of implementation or that will be exempt or excluded from managed care.[17]

[17] Federally recognized tribal members may choose to remain in the fee-for-service system and are not mandated to participate in managed care at any point, unless the mandate is for an Indian Managed Care Entity (IMCE).

Milestone 1: Access to Critical Levels of Care for SUD

North Carolina's Medicaid State Plan covers a wide range of SUD services for enrollees across outpatient, residential and inpatient care settings. While North Carolina's Medicaid program currently covers most services in the ASAM continuum of care, the state seeks to complete its coverage of the ASAM continuum by adding ASAM levels 3.1 (clinically managed low-intensity residential treatment services), 3.3 (clinically managed population-specific high-intensity residential programs), 2-WM (ambulatory withdrawal management with extended on-site monitoring) and 3.2-WM (clinically managed residential withdrawal management) to its State Plan, and expanding coverage of existing services such as ASAM levels 3.5 (clinically managed high-intensity residential services) and 3.7 (medically monitored intensive inpatient services) to include adolescents. The table below provides an overview of North Carolina Medicaid coverage for each ASAM level of care, as well as proposed changes.

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
0.5	Early intervention	Screening, brief intervention and referral for treatment (SBIRT)	Physicians and physician extenders only	Currently covered for all	Expansion of providers that are eligible for reimbursement	Fee-for service, standard plans and BH I/DD tailored plans
1	Outpatient services	Psychiatric and biopsychosocial assessment; medication management; individual, group and family therapies; psychotherapy for crisis; and psychological testing for eligible enrollees based on clinical severity and function Service includes assisting the individual to achieve changes in	Direct-enrolled licensed behavioral health providers	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
		his or her substance use or addictive behaviors, serving as a step down from a more intensive level of care, care for an individual in the early stages of change, and care for ongoing monitoring and disease management				
2.1	Intensive outpatient services (substance abuse intensive outpatient program)	Structured program delivering 9–19 hours of services per week to meet complex needs of people with addiction and co-occurring conditions	DHSR-licensed facilities	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service and BH I/DD tailored plans
2.5	Partial hospitalization services (substance abuse comprehensive outpatient treatment)	Structured program delivering 20 or more hours of clinically intensive programming per week, with a planned format of individualized services	DHSR-licensed facilities	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans
3.1	Clinically managed low-intensity residential treatment services	SUD halfway-house services; supportive living environment with 24-hour staff and integration with clinical services; at least five hours of low-intensity treatment per week or more intensive outpatient care as indicated	DHSR-licensed facilities	No coverage	Will be covered for all enrollees meeting medical necessity criteria	Fee-for service and BH I/DD tailored plans

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
3.3	Clinically managed population-specific high-intensity residential programs	Clinically managed high-intensity SUD residential service for adults with cognitive impairment, including developmental delays, provided in a structured recovery environment	DHSR-licensed facilities	No coverage	Will be covered for all enrollees meeting medical necessity criteria	Fee-for service and BH I/DD tailored plans
3.5	Clinically managed high-intensity residential services (substance abuse non-medical community residential treatment)	Clinically managed high-intensity SUD residential services provided in a structured recovery environment	DHSR-licensed facilities	Currently covered for pregnant and parenting women	Will be covered for all enrollees, including adults and adolescents meeting medical necessity criteria	Fee-for service and BH I/DD tailored plans
3.7	Medically monitored intensive inpatient services (substance abuse medically monitored community residential treatment)	Medically monitored SUD inpatient treatment service with a structured regimen of 24-hour physician-directed evaluation, observation, medical monitoring and addiction treatment	DHSR-licensed specialty units in a community or psychiatric hospital	Currently covered for adult enrollees meeting medical necessity criteria	Will be covered for all enrollees, including adults and adolescents meeting medical necessity criteria	Fee-for service and BH I/DD tailored plans
4	Medically managed intensive inpatient services (inpatient behavioral health services)	Medically managed intensive inpatient services with 24-hour nursing care and daily physician care for severe, unstable problems in ASAM dimension: (1) acute intoxication and/or withdrawal potential; (2)	DHSR-licensed psychiatric hospitals and licensed community hospitals	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
		biomedical conditions and complications; or (3) emotional, behavioral or cognitive conditions and complications Counseling services also available				
OTP	Opioid treatment program (outpatient opioid treatment)	Service includes methadone or buprenorphine administration for treatment or maintenance; NC Medicaid is exploring creating an integrated service package that includes counseling and case management and other supportive services such as lab work in addition to methadone or buprenorphine	DHSR-licensed facilities	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans
1-WM	Ambulatory withdrawal management without extended on-site monitoring (ambulatory detoxification)	An organized outpatient withdrawal management service under the direction of a physician providing medically supervised evaluation, detoxification and referral services to treat mild withdrawal symptoms	DHSR-licensed facilities	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans
2-WM	Ambulatory withdrawal management with extended on-site monitoring	An organized outpatient withdrawal management service under the direction of a physician providing medically supervised evaluation, detoxification and referral services to treat	DHSR-licensed facilities	No coverage	Will be covered for all enrollees meeting medical necessity criteria	Fee-for service, standard plans and BH I/DD tailored plans

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
		moderate withdrawal symptoms with extended on-site monitoring				
3.2-WM	Clinically managed residential withdrawal	An organized, clinically managed residential withdrawal management service for individuals who are experiencing moderate withdrawal symptoms and who require 24-hour supervision, observation and support; uses physician-approved protocols to identify individuals who require medical services beyond the capacity of the facility and to transfer these individuals to the appropriate levels of care	DHSR-licensed facilities	No coverage	Will be covered for all enrollees meeting medical necessity criteria	Fee-for service, standard plans and BH I/DD tailored plans
3.7-WM	Medically monitored inpatient withdrawal management (non-hospital medical detoxification)	An organized, medically monitored inpatient withdrawal management service under the supervision of a physician that provides 24-hour observation, monitoring and treatment for individuals who are experiencing severe withdrawal symptoms and require 24-hour nursing care	DHSR-licensed facilities	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans

ASAM Level of Care	Service Title	Description	Provider	Current Coverage	Future Coverage	Future Medicaid Delivery System
n/a	Medically supervised or alcohol and drug abuse treatment center (ADATC) detoxification crisis stabilization	An organized, medically monitored withdrawal management service under the supervision of a physician that provides 24 hour supervision in a permanent facility with inpatient beds; individuals served are often in crisis due to co-occurring severe mental disorders and in need of short term, intensive evaluation, treatment intervention or behavioral management to stabilize the acute or crisis situation	DHSR-licensed facilities	Currently covered for adult beneficiaries meeting medical necessity criteria	Will be incorporated into ASAM 4.0-WM	Fee-for service, standard plans and BH I/DD tailored plans
4-WM	Medically managed intensive inpatient withdrawal (inpatient behavioral health services)	An organized, medically managed inpatient service under the supervision of a physician that provides 24-hour, medically directed evaluation and withdrawal management for individuals who are experiencing severe, unstable withdrawal and require an acute care setting	Licensed psychiatric hospitals and licensed community hospitals	Currently covered for all enrollees meeting medical necessity criteria	No change expected	Fee-for service, standard plans and BH I/DD tailored plans

The current North Carolina Medicaid coverage of ASAM-level SUD services, proposed changes and an implementation timeline are described in detail below. LME-MCOs currently are required to follow the Department's service definitions as described in the state's clinical coverage policies. Following managed care implementation, standard plans and BH I/DD tailored plans will be subject to these provisions in the clinical coverage policies when they launch on November 1, 2019, and July 1, 2021, respectively. The Department's service definitions will continue to apply to fee-for-service populations following the managed care transition.

Federal law prohibits federal financial participation (FFP) for services delivered to individuals ages 21 to 64 residing in IMDs. An IMD is defined as a hospital, nursing facility or other institution with more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care or related services. One of the primary goals of the SUD-related portion of the 1115 demonstration is to waive this restriction and expand access to SUD treatment for individuals residing in IMDs. As detailed below, providers delivering the following types of services may be considered IMDs:

- ASAM level 3.1: Clinically managed low-intensity residential treatment services
- ASAM level 3.3: Clinically managed population-specific high-intensity residential programs
- ASAM level 3.5: Clinically managed high-intensity residential services
- ASAM level 3.7: Medically monitored intensive inpatient services
- ASAM level 4: Medically managed intensive inpatient services
- ASAM level 3.2-WM: Clinically managed residential withdrawal
- ASAM level 3.7-WM: Medically monitored inpatient withdrawal management
- Medically supervised or ADATC detoxification crisis stabilization
- ASAM level 4-WM: Medically managed intensive inpatient withdrawal

In addition, North Carolina has obtained approval to obtain FFP upon approval of this SUD Implementation Plan Protocol for the following non-residential services delivered to individuals residing in IMDs.

- ASAM level 2.1: Substance abuse intensive outpatient program
- ASAM level 2.5: Substance abuse comprehensive outpatient treatment program
- Opioid treatment program
- Office-based opioid treatment program

Level of Care: 0.5 (Early Intervention)

Current State

The Department provides coverage for several individual services around early intervention, including smoking cessation counseling and SBIRT. Physicians and physician extenders are the only providers who can currently bill LME-MCOs or Medicaid fee-for-service for these services. These services are available to all Medicaid-eligible enrollees without prior authorization.

Future State

North Carolina's Medicaid program plans to expand the types of providers that can bill this service to include direct-enrolled licensed behavioral health providers by updating the state's Medicaid management information system (MMIS) to add the taxonomies of the providers who would be eligible to bill these CPT codes. Additionally, NC Medicaid will post a Medicaid Bulletin informing the behavioral health providers of this change and any relevant clinical and billing criteria.

Summary of Actions Needed

- Implement MMIS modifications: September 2018 – April 2020

Level of Care: 1 (Outpatient Services)

Current State

The Department covers Medicaid-funded outpatient behavioral health services provided by direct-enrolled providers. These services are intended to determine an enrollee's SUD treatment needs and to provide the necessary treatment. Services focus on reducing symptoms of SUD and other BH disorders in order to improve the enrollee's functioning in familial, social, educational or occupational domains. Outpatient behavioral health services are available to eligible enrollees and often involve the participation of family members, significant others and legally responsible person(s) as applicable, unless contraindicated. Based on collaboration between the practitioner and the enrollee, and others as needed, the enrollee's needs and preferences determine the treatment goals and frequency, as well as measurable and desirable outcomes. Outpatient behavioral health services include:

- Comprehensive clinical assessment (CCA)
- Medication management
- Individual, group and family therapies
- Psychotherapy for crisis
- Psychological testing

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-C, Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers, located here: https://files.nc.gov/ncdma/documents/files/8C_0.pdf.

Future State

The Department will amend the current Medicaid clinical coverage policies 8-A Diagnostic Assessment and 8-C to ensure a determination of ASAM level of care is included in the assessment information of enrollees diagnosed with SUDs. Enrollees with a SUD need will need to meet ASAM level 1 criteria to obtain this service.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policies 8-A Diagnostic Assessment and 8-C to reflect ASAM criteria: September 2018 – April 2020
- Submit SPA for 8A Diagnostic Assessment: September 2018 – April 2020

Level of Care: 2.1 (Intensive Outpatient Services)

Current State

The Department provides Medicaid coverage for substance abuse intensive outpatient program (SAIOP) services, which include structured individual and group SUD services that are provided in an outpatient program designed to assist adult and adolescent enrollees in beginning recovery and learning skills for recovery maintenance. The program is offered at least three hours a day, at least three days a week (no more than 19 hours of structured services per week), with no more than two consecutive days between offered services. SAIOP services include a structured program consisting of, but not limited to, the following services: individual, group and family counseling and support; biochemical assays to identify recent drug use; strategies for relapse prevention to include community and social support systems in treatment; life skills training; crisis contingency planning; disease management; and case management activities. Enrollees must meet the ASAM level 2.1 criteria to demonstrate medical necessity for these services.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here: https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

The Department will amend the current Medicaid clinical coverage policy 8-A to include the structured programming time frame of six to 19 hours for adolescents, reflect the 2013 ASAM criteria, require the presence of a full-time licensed professional, and permit this service to be reimbursed for individuals residing in an IMD. DHSR will update licensure rule 10A NCAC 27G .4400.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to reflect 2013 ASAM criteria, add parameters for adolescents, require the presence of a full-time licensed professional, and permit the service to be reimbursed in an IMD: September 2018 – October 2020
- Update MMIS to permit this service to be reimbursed for individuals residing in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 – October 2020
- Revise licensure rule: September 2018 – October 2022
- Revise LME-MCO contracts: September 2018 – October 2020

Level of Care: 2.5 (Partial Hospitalization Services)

Current State

The Department provides Medicaid coverage for substance abuse comprehensive outpatient treatment (SACOT), a time-limited periodic service with a multifaceted treatment approach for adults who require structure and support to achieve and sustain recovery. SACOT is a service that emphasizes the following: reduction in use of substances or continued abstinence; the negative consequences of substance use; the development of a social support network and necessary lifestyle changes; educational skills;

vocational skills that focus on substance use as a barrier to employment; social and interpersonal skills; improved family functioning; understanding of addictive disease; and the continued commitment to a recovery and maintenance program. Enrollees must meet the ASAM level 2.5 criteria to demonstrate medical necessity for this service.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here: https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

The Department will update the current Medicaid clinical coverage policy 8-A to align with the 2013 ASAM criteria, require the presence of a full-time licensed professional and permit this service to be reimbursed for individuals residing in an IMD. The Department will also work with DHSR to update licensure rule 10A NCAC 27G .4500.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to align with ASAM criteria, require the presence of full-time licensed professional, and permit this service to reimbursed in an IMD: September 2018 – October 2020
- Update MMIS to permit this service to be reimbursed for individuals residing in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 – October 2020
- Revise licensure rule: September 2018 – October 2022
- Revise LME-MCO contracts: September 2018 – October 2020

Level of Care: 3.1 (Clinically Managed Low-Intensity Residential Treatment Services)

Current State

North Carolina's Medicaid program does not currently cover ASAM level 3.1 clinically managed low-intensity residential treatment services, also called substance abuse halfway-house services. However, DMH/DD/SAS covers substance abuse halfway-house services under ASAM level 3.1 in its state-funded service array. Additionally, North Carolina has a current licensure rule under 10A NCAC 27G .5600 for the services provided in this type of facility.

Future State

The Department will submit a state plan amendment (SPA) to add substance abuse halfway-house services to its State Plan for all enrollees. North Carolina is has obtained expenditure authority to deliver the service to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for substance abuse halfway-house services provided to individuals residing in IMDs.

The Department will promulgate a new Medicaid clinical coverage policy for substance abuse halfway-house services. This service will provide a supportive living environment with 24-hour staff and at least five hours of low-intensity treatment per week (i.e., individual, group and/or family therapies; psycho-education) or a more intensive level of outpatient care such as ASAM 2.1 as medically necessary. Additionally, DHSR will work to create a new stand-alone licensure rule to align with ASAM criteria. Enrollees will need to meet the ASAM level 3.1 criteria to access these services.

Summary of Actions Needed

- Develop a Medicaid clinical coverage policy: September 2018 – October 2020
- Create a licensure rule waiver process: September 2018 – October 2020
- Create licensure rule: September 2018 – October 2022
- Implement MMIS modifications: September 2018 – October 2020
- Submit SPA: September 2018 – October 2020

Level of Care: 3.3 (Clinically Managed Population-Specific High-Intensity Residential Programs)

Current State

The Department does not currently cover ASAM level 3.3 clinically managed population-specific high-intensity residential programs in Medicaid.

Future State

The Department will submit a SPA to add clinically managed population-specific high-intensity residential programs to its State Plan for all enrollees meeting the medical necessity criteria. North Carolina has obtained expenditure authority to deliver the service to individuals receiving the service in facilities that meet the definition of an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, and the finalization of new licensure rules, North Carolina will be able to provide Medicaid reimbursement for clinically managed population-specific high-intensity residential services provided to individuals residing in IMDs.

The Department will promulgate a new Medicaid clinical coverage policy that will reflect the 2013 ASAM criteria for this level of care. These programs will provide clinically managed high-intensity SUD residential services in a structured recovery environment to adults with cognitive impairment, including developmental delays. Additionally, working across divisions, the Department will create a licensure rule for this service. Enrollees will need to meet the ASAM level 3.3 criteria to access these services.

Summary of Actions Needed

- Develop a Medicaid clinical coverage policy: September 2018 – October 2020
- Create a licensure rule waiver process: September 2018 – October 2020
- Create licensure rule: September 2018 – October 2022
- Implement MMIS modifications: September 2018 – October 2020
- Submit SPA: September 2018 – October 2020

Level of Care: 3.5 (Clinically Managed High-Intensity Residential Services)

Current State

The Department currently covers ASAM level 3.5 clinically managed high-intensity residential services for pregnant and parenting women at facilities that do not meet the definition of an IMD. Clinically managed high-intensity residential services, also called non-medical community residential treatment (NMCRT), is a 24-hour, professionally supervised residential recovery program that provides trained staff to work intensively with adults with SUDs who provide or have the potential to provide primary care for their minor children.

NMCRT rehabilitation facilities provide planned programs of professionally directed evaluation, care and treatment for the restoration of functioning of enrollees with an addiction disorder. These programs include assessment, referral, individual and group therapy, family therapy, recovery skills training, disease management, symptom monitoring, medication monitoring and self-management of symptoms, after-care, follow-up, access to preventive and primary healthcare including psychiatric care, and case management activities. NMCRT facilities do not provide 24-hour medical nursing or monitoring. Enrollees must meet the ASAM level 3.5 criteria to demonstrate medical necessity for these services.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here: https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

North Carolina has obtained expenditure authority to deliver these services to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to reimburse NMCRT provided to Medicaid enrollees in IMDs.

The Department will revise the current Medicaid clinical coverage policy 8-A to reflect the 2013 ASAM criteria, add adolescents who meet medical necessity as a population eligible to receive this service, include IMDs as eligible service providers, and extend coverage for treatment services provided in a therapeutic community. Working across divisions, the Department will revise the licensure rules 10A NCAC 27G .4100 and 10A NCAC 27G .4300 and create a new licensure rule for both adults and adolescents. The Department will also need to submit a SPA in light of the changes to this clinical coverage policy.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to reflect 2013 ASAM criteria, add adolescents as a population eligible to receive service, include IMDs as eligible service providers, and extend coverage for treatment services provided in a therapeutic community: September 2018 – October 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 – October 2020

- Revise existing licensure rules and create new licensure rules: September 2018 – October 2022
- Revise LME-MCO contracts: September 2018 – October 2020
- Submit SPA: September 2018 – October 2020

Level of Care: 3.7 (Medically Monitored Intensive Inpatient Services)

Current State

The Department currently covers ASAM level 3.7 medically monitored intensive inpatient services for adults only at facilities that do not meet the definition of an IMD. Medically monitored intensive inpatient service providers, also called medically monitored community residential treatment (MMCRT) providers, are non-hospital rehabilitation facilities for adults, with 24-hour medical or nursing monitoring, that provide a planned program of professionally directed evaluation, care and treatment for the restoration of functioning of enrollees with alcohol and other drug problems or addiction. Enrollees must meet the ASAM level 3.7 criteria to demonstrate medical necessity for these services.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here: https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

North Carolina has obtained expenditure authority to deliver these services to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for MMCRT delivered to individuals residing in IMDs. North Carolina is planning to make these services available to both adolescents and adults who demonstrate medical necessity.

The Department will revise the current Medicaid clinical coverage policy 8-A to reflect the 2013 ASAM criteria, add adolescents who meet medical necessity as a population eligible to receive this service and add IMDs as eligible service providers. Working across divisions, the Department will create a new licensure rule for this level of care that aligns with the ASAM criteria. The Department will also need to submit a SPA in light of the changes to this clinical coverage policy.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to reflect ASAM criteria, add adolescents as a population eligible to receive service, and include IMDs as eligible service providers: September 2018 – October 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 – October 2020
- Revise and create licensure rules: September 2018 – October 2022
- Revise LME-MCO contracts: September 2018 – October 2020
- Submit SPA: September 2018 – October 2020

Level of Care: 4 (Medically Managed Intensive Inpatient Services)

Current State

Since July 2016, LME-MCOs have had the authority to reimburse for inpatient services delivered in an IMD in lieu of settings covered by the NC State Plan.

North Carolina Medicaid currently provides coverage for ASAM level 4 medically managed intensive inpatient services at facilities that do not meet the definition of an IMD. Medically managed intensive inpatient services are behavioral health services provided in a hospital setting 24 hours a day along with supportive nursing and medical care provided under the supervision of a psychiatrist or a physician. These services are designed to provide continuous treatment for enrollees with acute psychiatric or substance use problems. They are appropriate for enrollees whose acute biomedical, emotional, behavioral and cognitive problems are so severe that they require primary medical and nursing care. Enrollees who are admitted with an SUD must meet the ASAM level 4 criteria to demonstrate medical necessity for these services.

Additional coverage, code and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-B, Inpatient Behavioral Health Services, located here: https://files.nc.gov/ncdma/documents/files/8B.pdf.

Future State

North Carolina has obtained expenditure authority to deliver these services to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for medically managed intensive inpatient services delivered to individuals residing in IMDs.

The Department will revise the current Medicaid clinical coverage policy 8-B to reflect the 2013 ASAM criteria and include IMDs as eligible service providers for SUD treatment. Working across divisions, the Department will revise the 10A NCAC 27G .6000 licensure rule to align with ASAM criteria.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-B to reflect ASAM criteria and include IMDs as eligible service providers for SUD treatment: September 2018 – July 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Revise LME-MCO contracts: September 2018 – July 2020

Level of Care: OTP (Opioid Treatment Programs)

Current State

The Department currently covers office-based opioid treatment and opioid treatment programs at the ASAM OTP level of care.

Office-Based Opioid Treatment: Use of Buprenorphine and Buprenorphine-Naloxone

The clinical coverage policy 1A-41 for office-based opioid treatment outlines the requirements for providers who prescribe buprenorphine and the buprenorphine-naloxone combination product for the treatment of opioid use disorders (OUDs) in office-based settings. The Drug Addiction Treatment Act of 2000 (DATA 2000) permits providers who meet certain qualifications to dispense or prescribe narcotic medications that have a lower risk of abuse, such as buprenorphine and the buprenorphine-naloxone combination product, and that are approved by the Food and Drug Administration (FDA) for OUDs in settings other than an OTP, such as a provider's office. This program allows enrollees who need the opioid agonist treatment to receive this treatment in a qualified provider's office, provided certain conditions are met.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy 1A-41, Office-Based Opioid Treatment: Use of Buprenorphine and Buprenorphine-Naloxone, located here: https://files.nc.gov/ncdma/documents/files/1A-41_4.pdf?ANpMLgJ7MIhEyt4r38bYvXinBFTk1h23.

Outpatient Opioid Treatment

Outpatient opioid treatment is a service designed to offer the enrollee an opportunity to effect constructive changes in his or her lifestyle by receiving, via a licensed OTP, methadone or other drugs approved by the FDA for the treatment of an OUD, in conjunction with rehabilitation and medical services. North Carolina Medicaid covers methadone- and buprenorphine-assisted treatment at this service level. Enrollees must meet the ASAM OTP criteria to demonstrate medical necessity for this service.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhance Mental Health and Substance Use Services, located here: https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

The Department will revise the current Medicaid clinical coverage policy 8-A to reflect that the 2013 ASAM criteria, permit this service to be reimbursed in an IMD, and to develop an integrated service model for outpatient opioid treatment that includes medication, medication administration, counseling, laboratory tests and case management activities. Working across divisions, the Department will revise the 10A NCAC 27G .3600 licensure rule.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to reflect ASAM criteria, permit service to be reimbursed in an IMD, and create integrated service model: September 2018 – April 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 – April 2020
- Revise licensure rule: September 2018 – October 2022
- Submit SPA: September 2018 – April 2020

- Revise LME-MCO contracts: September 2018 – April 2020

Level of Care: 1-WM (Ambulatory Withdrawal Management Without Extended On-Site Monitoring)

Current State

The Department currently provides coverage for ASAM level 1-WM ambulatory withdrawal management without extended on-site monitoring. Ambulatory detoxification is an organized outpatient service delivered by trained clinicians who provide medically supervised evaluation, detoxification and referral services in regularly scheduled sessions. The services are designed to treat the enrollee's level of clinical severity, to achieve safe and comfortable withdrawal from mood-altering drugs (including alcohol), and to effectively facilitate the enrollee's transition into ongoing treatment and recovery. Enrollees must meet the ASAM level 1-WM criteria to demonstrate medical necessity for this service.

Additional coverage and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here**:** https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

The Department will need to submit a SPA for 1-WM ambulatory withdrawal management services to reflect the proposed changes to the service based on the ASAM criteria. The Department will promulgate a new Medicaid clinical coverage policy that will reflect the ASAM criteria for this level of care and will work with DHSR to revise the 10A NCAC 27G .3300 licensure rule

Summary of Actions Needed

- Develop new Medicaid clinical coverage policy to align with ASAM criteria: September 2018 – July 2020
- Develop a licensure rule waiver process: September 2018 – July 2020
- Revise licensure rules: September 2018 – October 2022
- Submit SPA: September 2018 – July 2020
- Revise LME-MCO contracts: September 2018 – July 2020

Level of Care: 2-WM (Ambulatory Withdrawal Management With Extended On-Site Monitoring)

Current State

The Department does not currently provide coverage for ASAM level 2-WM ambulatory withdrawal management with extended on-site monitoring.

Future State

The Department will need to submit a SPA for ambulatory withdrawal management services to reflect that, going forward, the state will cover ambulatory withdrawal management with extended on-site monitoring for all enrollees who meet the medical necessity criteria. The Department will promulgate a new Medicaid clinical coverage policy that will reflect the 2013 ASAM criteria for this level of care. This

service will provide enrollees with an organized outpatient withdrawal management service under the direction of a physician providing medically supervised evaluation, detoxification and referral services to treat moderate withdrawal symptoms with extended on-site monitoring. Enrollees must meet the ASAM level 2-WM criteria to demonstrate medical necessity for this service. Additionally, NC Medicaid will work with DHSR to revise the 10A NCAC 27G .3300 licensure rule to include ambulatory withdrawal management with extended on-site monitoring.

Summary of Actions Needed

- Develop a Medicaid clinical coverage policy: September 2018 – July 2020
- Develop a licensure rule waiver process: September 2018 – July 2020
- Create licensure rule: September 2018 – October 2022
- Implement MMIS modifications: September 2018 – July 2020
- Submit SPA: September 2018 – July 2020
- Revise LME-MCO contracts: September 2018 – July 2020

Level of Care: 3.2-WM (Clinically Managed Residential Withdrawal)

Current State

Federal restrictions preclude the Department from obtaining FFP for withdrawal services delivered in an IMD to Medicaid enrollees between the ages of 21 and 64.

North Carolina Medicaid does not currently provide coverage for ASAM level 3.2-WM clinically managed residential withdrawal.

Future State

The Department will submit a SPA to add clinically managed residential withdrawal services to its State Plan. North Carolina is also seeking expenditure authority to deliver the service to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, and the finalization of new licensure rules, North Carolina will be able to provide Medicaid reimbursement for clinically managed residential withdrawal services, also called social setting detoxification services, that are delivered to individuals residing in IMDs.

The Department will promulgate a new Medicaid clinical coverage policy that will reflect the 2013 ASAM criteria for this level of care and include IMDs as eligible providers. This policy will provide adults with an organized clinically managed residential withdrawal service that offers 24-hour supervision, observation and support for enrollees who are experiencing moderate withdrawal symptoms and who require 24-hour support utilizing physician-approved protocols. Enrollees must meet the ASAM level 3.2-WM criteria to demonstrate medical necessity for this service.
Working across divisions, the Department will revise the 10A NCAC 27G .3200 licensure rule.

Summary of Actions Needed

- Develop a Medicaid clinical coverage policy: September 2018 – July 2020
- Develop a licensure rule waiver process: September 2018 – July 2020

- Revise licensure rule: September 2018 – October 2022
- Implement MMIS modifications: September 2018 – July 2020
- Submit SPA: September 2018 – July 2020
- Revise LME-MCO contracts: September 2018 – July 2020

Level of Care: 3.7-WM (Medically Monitored Inpatient Withdrawal Management)

Current State

The Department currently covers ASAM level 3.7-WM medically monitored inpatient withdrawal management services at facilities that do not meet the definition of an IMD. Non-hospital medical detoxification, the Department's name for this service, is an organized service delivered by medical and nursing professionals, which provides 24-hour, medically supervised evaluation and withdrawal management in a permanent facility affiliated with a hospital or in a free-standing facility. Services are delivered under a defined set of physician-approved policies and physician-monitored procedures and clinical protocols. Enrollees must meet the ASAM level 3.7-WM criteria to demonstrate medical necessity for this service.

Additional coverage, code and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here**:** https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

North Carolina has obtained expenditure authority to deliver the service to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for medically monitored inpatient withdrawal management services delivered to individuals residing in IMDs.

The Department will revise the current clinical coverage policy 8-A to reflect the 2013 ASAM criteria and include IMDs as eligible service providers. Working across divisions, the Department will revise the 10A NCAC 27G .3100 licensure rule.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-A to reflect ASAM criteria and include IMDs as eligible service providers: September 2018 – July 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Develop a licensure rule waiver process: September 2018 –July 2020
- Revise licensure rule: September 2018 – October 2022
- Submit SPA: September 2018 – July 2020
- Revise LME-MCO contracts: September 2018 – July 2020

Level of Care: Medically Supervised or ADATC Detoxification Crisis Stabilization

Current State

The Department currently covers medically supervised or ADATC detoxification crisis stabilization services. Medically supervised or ADATC detoxification crisis stabilization is an organized service, delivered by medical and nursing professionals, that provides for 24-hour medically supervised evaluation and withdrawal management in a licensed permanent facility with 16 beds or less. Services are delivered under a defined set of physician-approved policies and physician-monitored procedures and clinical protocols. Beneficiaries are often in crisis due to co-occurring severe substance related mental disorders (e.g. acutely suicidal or severe mental health problems and co-occurring SUD) and are in need of short term intensive evaluation, treatment intervention or behavioral management to stabilize the acute or crisis situation.

Additional coverage, code and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-A, Enhanced Mental Health and Substance Abuse Services, located here**:** https://files.nc.gov/ncdma/documents/files/8A_1.pdf.

Future State

North Carolina has obtained expenditure authority to deliver the service to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for medically supervised or ADATC detoxification crisis stabilization services delivered to individuals residing in IMDs.

Coverage for detoxification services delivered in ADATCs will be incorporated into the Medicaid and Health Choice Clinical Coverage Policy 8-B for Inpatient Behavioral Health Services, which will be updated to align with 2013 ASAM level 4.0-WM criteria and include IMDs as eligible service providers. .

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-B to reflect ASAM criteria: September 2018 – July 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019

Level of Care: 4-WM (Medically Managed Intensive Inpatient Withdrawal)

Current State

Federal restrictions preclude the Department from obtaining FFP for medically managed intensive inpatient withdrawal services delivered in an IMD to Medicaid enrollees between the ages of 21 and 64. Since July 2016, LME-MCOs have had the authority to reimburse for inpatient services delivered to individuals residing in an IMD in lieu of services or settings covered by the Medicaid State Plan.

The Department currently provides Medicaid coverage for ASAM level 4-WM medically managed intensive inpatient withdrawal services at facilities that do not meet the definition of an IMD. Inpatient

behavioral health services provide treatment in a hospital setting 24 hours a day. Supportive nursing and medical care are provided under the supervision of a psychiatrist or a physician. This service is designed to provide continuous treatment for enrollees with acute psychiatric or substance use problems. It is appropriate for enrollees whose acute biomedical, emotional, behavioral and cognitive problems are so severe that they require primary medical and nursing care. Enrollees must meet the ASAM level 4-WM criteria to demonstrate medical necessity for this service.

Additional coverage, code and billing details can be found in Medicaid and Health Choice Clinical Coverage Policy No. 8-B, Inpatient Behavioral Health Services, located here**:** https://files.nc.gov/ncdma/documents/files/8B.pdf.

Future State

North Carolina has obtained expenditure authority to deliver this service to individuals ages 21 to 64 residing in an IMD. Following CMS approval of NC's 1115 demonstration, SPA and SUD Implementation Plan Protocol, North Carolina will be able to provide Medicaid reimbursement for medically managed intensive inpatient withdrawal services to individuals residing in IMDs.

The Department will revise the current clinical coverage policy 8-B to reflect the 2013 ASAM criteria and include IMDs as eligible service providers. Working across divisions, the Department will revise the 10A NCAC 27G .6000 licensure rule.

Summary of Actions Needed

- Amend current Medicaid clinical coverage policy 8-B to reflect ASAM criteria and include IMDs as eligible service providers: September 2018 – July 2020
- Implement MMIS modifications to permit this service to be reimbursed in an IMD: September 2018 – April 2019
- Revise LME-MCO contracts: September 2018 – July 2020

Summary of Actions Needed Across All Service Levels

Action	Implementation Timeline
Current Services[18]	
Revise Medicaid clinical coverage policies to reflect 2013 ASAM criteria and expand coverage to adolescents, as indicated	September 2018 – October 2020
Develop a licensure rule waiver process to incorporate ASAM criteria	September 2018 – October 2020
Revise licensure rules to align with ASAM criteria	September 2018 – October 2022
Implement MMIS modifications	September 2018 – October 2020
Submit SPAs, as necessary	September 2018 – October 2020
Revise LME-MCO contracts	September 2018 – October 2020
New Services	
Standard and BH I/DD Tailored Plan Services	
Develop Medicaid clinical coverage policies	September 2018 – July 2020
Develop a licensure rule waiver process	September 2018 – July 2020
Create licensure rules	September 2018 – October 2022
Implement MMIS modifications	September 2018 – July 2020
Submit SPAs	September 2018 – July 2020
Revise LME-MCO contracts	September 2018 – July 2020
BH I/DD Tailored Plan Services Only	
Develop Medicaid clinical coverage policies	September 2019 – October 2020
Create licensure rules	September 2020 – October 2020
Implement MMIS modifications	September 2019 – October 2020
Submit SPAs	September 2019 – October 2020

Milestone 2: Use of Evidence-Based SUD-Specific Patient Placement Criteria

North Carolina has robust, evidence-based policies in place to ensure that enrollees have access to appropriate SUD services according to their diagnosis and ASAM level of care determination. Over the course of the 1115 demonstration, North Carolina will strengthen its assessment and person-centered planning policies, which are prerequisites for obtaining most SUD services, by requiring that all SUD providers conducting assessments document their training with respect to the ASAM criteria.

Enrollee Assessments

Current State

As part of its Medicaid 8-A and 8-C clinical coverage policies, NC Medicaid requires behavioral health providers to complete an assessment before an enrollee can receive behavioral health services, except for selected crisis services. Providers use their clinical expertise to choose between two types of assessments:

[18] For some services, actions will be complete prior to October 2020 as detailed earlier in this section.

1. **Diagnostic assessments:** NC Medicaid requires that a team of at least two licensed professionals interview and assess an enrollee and, based on the assessment, write a joint report recommending the services appropriate for the enrollee. For enrollees with SUDs, at a minimum this team must include (1) a certified clinical supervisor or licensed clinical addiction specialist; and (2) a medical doctor (MD), doctor of osteopathy (DO), nurse practitioner (NP), physician assistant (PA) or licensed psychologist. The clinical coverage policy for diagnostic assessments recommends a level of placement using the ASAM criteria for enrollees with SUD diagnoses, but does not require its use.
2. **Comprehensive clinical assessments (CCA):** Licensed professionals perform the CCA, a clinical evaluation that provides the necessary data and recommendations that form the basis of the enrollee's treatment or person-centered plan, as described in the next section. NC Medicaid does not have a prescribed format for the CCA; providers can tailor the CCA based on the enrollee's clinical presentation.

Diagnostic assessments and CCAs must include the following elements:

- Description of the presenting problems, including source of distress, precipitating events, and the associated problems or symptoms.
- Chronological general health and behavioral health history (including both mental health and substance abuse) of the enrollee's symptoms, treatment and treatment response.
- Current medications (for both physical and psychiatric treatment).
- A review of the biological, psychological, familial, social, developmental and environmental dimensions to identify strengths, needs and risks in each area.
- Evidence of the enrollee's and the legally responsible person's (if applicable) participation in the assessment.
- Analysis and interpretation of the assessment information with an appropriate case formulation.
- DSM-5 diagnosis, including mental health, SUDs or intellectual/developmental disabilities, as well as physical health conditions and functional impairment.
- Recommendations for additional assessments, services, support or treatment based on the results of the CCA.
- Signature of the licensed professional completing the assessment and the date.

Future State

The Department will update clinical coverage policies 8-A and 8-C to require an ASAM determination as part of the diagnostic assessment and CCA. The Department will require all professionals administering diagnostic assessments and CCAs to obtain training in the ASAM criteria.

Upon their launch in 2019 and 2021, respectively, standard plans and BH I/DD tailored plans will be required to follow the provisions related to behavioral health assessments included in Medicaid clinical coverage policies 8-A and 8-C.

Summary of Actions Needed

- Revise clinical coverage policies to require that (1) an ASAM determination is part of the diagnostic assessment and CCA and (2) licensed providers providing SUD services or

assessments document their training with respect to the ASAM criteria: September 2018 – April 2020
- Contractually require standard plans to comply with the provisions related to behavioral health assessments included in Medicaid clinical coverage policies 8-A and 8-C: Completed
- Contractually require BH I/DD tailored plans to comply with the provisions related to behavioral health assessments included in Medicaid clinical coverage policies 8-A and 8-C: September 2018-July 2021

Person-Centered Plan

Current State

Person-centered planning is a guiding principle that must be embraced by all who are involved in the SUD service delivery system. Person-centered thinking and individualized service planning are the hallmarks of the provision of high-quality services in meeting the unique needs of each person served. Each plan is driven by the individual, utilizing the results and recommendations of a comprehensive clinical assessment, and is individually tailored to the preferences, strengths and needs of the person seeking services.

As detailed in the clinical coverage policies for behavioral health services, a person-centered plan is required in order for an enrollee to receive the covered SUD treatment services listed in Milestone 1, with the exception of all detoxification services, outpatient treatment and early intervention services. When a person-centered plan is not required, a plan of care, service plan or treatment plan, consistent with and supportive of the service provided and within professional standards of practice, is required on or before the day the service is delivered. The person-centered plan must be developed and written by a qualified professional or a licensed professional according to the requirements of the specific policy and in collaboration with the individual receiving services, family members (when applicable) and other service providers, in order to maximize unified planning. The person responsible for developing the person-centered plan should present the results and recommendations of the plan as an integral part of the person-centered planning discussions and should incorporate them into the plan as appropriate and as agreed upon by the individual and/or his or her legally responsible person.

The person-centered plan is effective for the 12-month period following the date the qualified or licensed professional signs it, unless there is a change that requires an updated plan. The person-centered plan includes service orders for behavioral health services other than ASAM level 1.0 (outpatient services) that demonstrate medical necessity and are based on an assessment of each enrollee's needs. Service orders are valid for one year from the date of the person-centered plan. At least annually, the LME-MCOs must review medical necessity for the services, and providers must issue a new service order for services to continue. An event such as a hospitalization may trigger a new assessment and a person-centered plan revision.

Future State

Upon their launch in 2019 and 2021, respectively, standard plans and BH I/DD tailored plans will be required to follow the person-centered planning provisions included in current Medicaid clinical coverage policies prior to authorizing SUD services. As noted above, the Medicaid clinical coverage

policies will continue to apply to SUD services delivered through fee-for-service. This means that the process described above related to the development and use of the person-centered plan will continue to occur as it does today.

Summary of Actions Needed

- Contractually require standard plans to comply with the provisions related to person-centered planning included in Medicaid clinical coverage policies 8-A and 8-C: Completed
- Contractually require BH I/DD tailored plans to comply with the provisions related to person-centered planning included in Medicaid clinical coverage policies 8-A and 8-C: September 2018-July 2021

Utilization Management

Current State

NC Medicaid requires LME-MCOs to establish a utilization management program that includes a written plan that addresses procedures used by LME-MCOs to review and approve requests for medical services, and that identifies the clinical criteria used by LME-MCOs to evaluate the medical necessity of the service being requested. Additionally, LME-MCOs are required to ensure consistent application of the review criteria and consult with requesting providers when appropriate. LME-MCOs must conduct an annual appraisal that assesses adherence to the utilization management plan and identifies the need for changes. LME-MCOs are permitted to establish utilization management requirements for behavioral health services that are different from, but not more restrictive than, Medicaid State Plan requirements. NC Medicaid requires LME-MCOs to use the ASAM criteria to determine medical necessity of SUD services.

NC Medicaid requires providers, except those in outpatient, SAIOP and SACOT programs, to obtain prior approval from an enrollee's LME-MCO before providing certain SUD services. For all services, the LME-MCOs performs utilization management. The LME-MCOs follow the requirements listed below, although they have the flexibility to establish their own utilization management criteria, provided they are not more restrictive than the requirements listed below.

For populations receiving SUD services through fee-for-service, the NC Medicaid's behavioral health vendor performs utilization management, which includes prior authorization for selected services, in accordance with NC Medicaid's clinical coverage policy requirements detailed below. The vendor does not have the flexibility to establish its own utilization management criteria.

Medicaid clinical coverage policies:

- **ASAM Level 1: Outpatient services.** For children and adolescents under the age of 21, initial coverage is limited to 16 unmanaged outpatient visits per year, with additional visits requiring prior authorization. For adult enrollees, coverage is limited to eight unmanaged outpatient visits per year, with additional visits requiring prior authorization.
- **ASAM Level 2.1: SAIOP.** The initial 30 calendar days of treatment do not require a prior authorization. Services provided after this initial 30-day "pass-through" period require authorization from the LME-MCO or the Department's approved behavioral health vendor. This

pass-through is available only once per treatment episode and only once per state fiscal year. The amount, duration and frequency of SAIOP services must be included in an enrollee's authorized person-centered plan. Services may not be delivered less frequently than noted in the structured program set forth in the service description described in Milestone 1. Reauthorization shall not exceed 60 calendar days. Under exceptional circumstances, one additional reauthorization up to two weeks can be approved. All utilization review activity shall be documented in the enrollee's person-centered plan.

- **ASAM Level 2.5: SACOT.** The initial 60 calendar days of treatment do not require a prior authorization. Services provided after this initial 60-day pass-through period require authorization from the LME-MCO or the Department's approved behavioral health vendor. This pass-through is available only once per treatment episode and only once per state fiscal year. The amount, duration and frequency of SACOT services, as well as all utilization review activities, must be included in an enrollee's authorized person-centered plan. Reauthorization shall not exceed 60 calendar days.
- **ASAM Levels 3.5 and 3.7: NMCRT and MMCRT.** Authorization by the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization shall not exceed 10 days, and reauthorization shall not exceed 10 days. This service and all utilization review activity shall be included in the enrollee's person-centered plan. Utilization management must be performed by the LME-MCO or the Department's approved behavioral health vendor.
- **ASAM Level 4: Medically managed intensive inpatient services.** Authorization from the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization is limited to seven calendar days.
- **Outpatient opioid treatment.** Authorization by the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization shall not exceed 60 days. Reauthorization shall not exceed 180 days. All utilization review activity shall be documented in the enrollee's person-centered plan.
- **ASAM Level 1-WM: Ambulatory detoxification.** Authorization by the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization is limited to seven days. Reauthorization is limited to three days, as there is a 10-day maximum for this service. This service must be included in an enrollee's person-centered plan.
- **ASAM Level 3.7-WM: Medically monitored inpatient withdrawal management.** Authorization by the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization shall not exceed 10 days. Reauthorization shall not exceed 10 days. This service must be included in an enrollee's person-centered plan. All utilization review activity shall be documented in the enrollee's person-centered plan.
- **Medically supervised or ADATC detoxification crisis stabilization.** Authorization by the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization shall not exceed 5 days. This is a short-term service that cannot be billed for more than 30 days in a 12-month period. All utilization review activity shall be included in an enrollee's person-centered plan.
- **ASAM Level 4-WM: Medically managed withdrawal management services.** Authorization from the LME-MCO or the Department's approved behavioral health vendor is required. Initial authorization is limited to seven calendar days.

Future State

For all newly added SUD services—halfway house for individuals with an SUD, clinically managed population-specific high-intensity residential services, ambulatory detoxification services with extended

on-site monitoring, and social setting detoxification services—the Department will establish prior authorization and utilization management requirements consistent with ASAM standards of care to ensure the appropriateness of patient placement. The clinical coverage policies for these new services will include these prior authorization and utilization management requirements. As described in Milestone 1, the Department will submit SPAs to add these four services to its Medicaid State Plan.

Following the managed care transition in November 2019, and consistent with its utilization management approach for LME-MCOs, the Department will permit standard plans and BH I/DD tailored plans (beginning at their launch in July 2021) to establish utilization management requirements for behavioral health services that are different from, but not more restrictive than, Medicaid State Plan requirements. Standard plans and BH I/DD tailored plans will be required to use the ASAM criteria to review the medical necessity of SUD services versus a "fail first" approach and will ensure that patient placements are appropriate as detailed in the LME-MCO and PHP contracts.

Approximately one to two years following BH I/DD tailored plan launch, the Department will solicit feedback from enrollees and providers, as well as standard plans and BH I/DD tailored plans, on utilization management approaches for SUD services, to determine whether to allow plans greater flexibility to establish their own utilization management approach. The clinical coverage policies will continue to apply to the fee-for-service population.
The Department understands the importance of ensuring that the length of SUD treatment authorized is aligned with an individual's specific needs. The National Institute on Drug Abuse (NIDA) notes that a program of fewer than 90 days of residential or outpatient treatment has shown limited or no effectiveness and recommends a 12-month minimum length of treatment for methadone maintenance.[19] Individuals with SUDs may require treatment that continues over a period of years and for multiple episodes. Client retention and engagement in treatment are critical components of recovery.

Summary of Actions Needed

Action	Implementation Timeline
Revise clinical coverage policies to require that (1) an ASAM determination is part of the diagnostic assessment and CCA and (2) licensed providers providing SUD services or assessments document their training with respect to the ASAM criteria	September 2018 – April 2020
Submit SPAs as needed to reflect updated utilization management requirements	September 2018 – October 2020
Update LME-MCO contracts, as necessary	September 2018 – October 2020
Require standard plans to follow clinical coverage policies 8-A and 8-C	Completed

[19] National Institute on Drug Abuse. (n.d.). 7: Duration of treatment. Retrieved April 12, 2018, from https://www.drugabuse.gov/publications/teaching-packets/understanding-drug-abuse-addiction/section-iii/6-duration-treatment.

Require BH I/DD tailored plans to follow clinical coverage policies 8-A and 8-C	September 2018 – July 2021

Milestone 3: Use of Nationally Recognized SUD-Specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

DHSR licenses and regulates outpatient, residential and inpatient SUD providers. The current licensure rules for SUD treatment providers include standards around the services that must be offered, program hours and staff credentials. Today, the degree of alignment between licensure rules for SUD providers and the ASAM criteria varies across provider type. The Department, through cross-division collaboration, intends to update nearly all of the licensure rules for SUD providers to align with the 2013 ASAM criteria and ensure that residential treatment providers either provide medication-assisted treatment (MAT) on-site or facilitate access to off-site MAT providers within a specified distance. The Department will also conduct more robust monitoring of SUD treatment providers to ensure compliance with the ASAM criteria.

Provider Licensure

Current State

Today, DHSR's Mental Health Licensure & Certification Section (MHLC) licenses and regulates non-acute residential facilities and outpatient programs pursuant to NC General Statute 122C. DHSR's Acute and Home Care Section licenses and regulates hospitals and psychiatric hospitals that provide acute inpatient and withdrawal management services. Four outpatient services and five residential services that provide an ASAM level of care are considered to be non-acute residential facilities and outpatient programs. With the exception of ASAM level 2.1 (substance abuse intensive outpatient program) and 2.5 (substance abuse comprehensive outpatient program) providers, none of the licensure rules for covered SUD treatment providers, including residential treatment providers, were written to reflect the ASAM criteria. The table below displays the SUD outpatient programs and the residential and inpatient services that North Carolina Medicaid covers today or intends to add to the State Plan; North Carolina's administrative rule that applies to each service; and the alignment between the current provider qualifications and the ASAM criteria.

The licensing standards for each covered service are memorialized in the 10 NCAC 27G Administrative Code, located here: http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2027%20-%20mental%20health,%20community%20facilities%20and%20services/subchapter%20g/subchapter%20g%20rules.pdf.

ASAM Level of Care	ASAM Title for Level of Care	North Carolina Licensure Rule	Section of NC Administrative Code (10A NCAC 27G)	Current Provider Qualifications
Outpatient Services				
2.1	Intensive outpatient services	Substance abuse intensive outpatient program	.4400	Reflect ASAM criteria with regard to types of services offered, hours of clinical care for adults and credentials of staff
2.5	Partial hospitalization services	Substance abuse comprehensive outpatient treatment	.4500	Reflect ASAM criteria with regard to types of services offered, hours of clinical care for adults and credentials of staff
OTP	Opioid treatment program	Outpatient opioid treatment	.3600	Do not reflect ASAM criteria
1-WM	Ambulatory withdrawal management without extended on-site monitoring	Outpatient detoxification for substance abuse	.3300	Do not reflect ASAM criteria
2-WM	Ambulatory withdrawal management with extended on-site monitoring	N/A	N/A	New service; will require revision of the .3300 licensure rule
Residential Services				
3.1	Clinically managed low-intensity residential treatment services	Supervised-living halfway house	.5600	Will require new stand-alone licensure rule
3.2-WM	Clinically managed residential withdrawal	Social setting detoxification for substance abuse	.3200	Do not reflect ASAM criteria
3.3	Clinically managed population-specific high-intensity residential programs	N/A	N/A	New service; will require new licensure rule

ASAM Level of Care	ASAM Title for Level of Care	North Carolina Licensure Rule	Section of NC Administrative Code (10A NCAC 27G)	Current Provider Qualifications
3.5	Clinically managed high-intensity residential services	Residential recovery programs for individuals with substance abuse disorders and their children Therapeutic community Non-medical community residential treatment services (adults and adolescents)	.4100 .4300 N/A	Do not reflect ASAM criteria Do not reflect ASAM criteria New service; will require new licensure rule
3.7	Medically monitored intensive inpatient services	Residential treatment for individuals with substance abuse disorders	.3400	Do not reflect ASAM criteria
3.7-WM	Medically managed inpatient withdrawal	Non-hospital medical detoxification	.3100	Do not reflect ASAM criteria
N/A	Medically supervised or ADATC detoxification crisis stabilization	N/A	N/A	Do not reflect ASAM criteria
Inpatient Services				
4	Medically managed intensive inpatient services	Psychiatric hospital Psychiatric unit, hospital	.6000 10A NCAC 13B .5200	Do not reflect ASAM criteria
4-WM	Medically managed intensive inpatient withdrawal	Psychiatric hospital	.6000 10A NCAC 13B	Do not reflect ASAM criteria

ASAM Level of Care	ASAM Title for Level of Care	North Carolina Licensure Rule	Section of NC Administrative Code (10A NCAC 27G)	Current Provider Qualifications
		Psychiatric unit, hospital		

Future State

DHSR, in collaboration with other divisions of the Department, will develop a licensure rule waiver process to expedite the process of aligning its provider qualifications for SUD outpatient programs and residential treatment services with ASAM criteria within the next 24 months. DHSR will also leverage the state's administrative rulemaking process to update its licensure rules for SUD outpatient programs and residential treatment services to align with the ASAM criteria. DHSR will continue to evaluate whether it needs to revise its licensure rules for inpatient services to align with ASAM criteria. When developing licensure rules for new services or new populations that will be able to access a service (e.g., adolescents), DHSR will ensure that they reflect ASAM's specifications regarding service definitions, hours of clinical care provided and program staff credentialing.

Summary of Actions Needed

- Develop a licensure rule waiver process to incorporate ASAM criteria: September 2018 – October 2020
- Revise existing licensure rules to align provider qualifications with 2013 ASAM criteria: September 2018 – October 2022

Monitoring of SUD Treatment Providers

Current State

To ensure that high-quality SUD treatment services are delivered in accordance with state licensure rules, DHSR regularly monitors outpatient OTPs and residential treatment providers. DHSR's monitoring of residential and OTP providers includes annual surveys, complaint investigations and follow-up surveys to determine compliance with the North Carolina administrative rules regarding services offered, hours of clinical care and program staffing. DHSR does not conduct annual surveys of outpatient treatment providers other than OTPs, but investigates complaints and conducts follow-up surveys to ensure that the provider has addressed the cited deficiencies.

Future State

DHSR will incorporate questions assessing compliance with the ASAM criteria, as memorialized in the state's updated licensure rules, into its annual surveys of licensed SUD treatment providers. In addition, DHSR will begin surveying ASAM level 2.1, 2.5 and 1-WM providers annually for compliance with the licensure rules. DHSR, in collaboration with other divisions of the Department, will train its inspectors to ensure they are equipped on how to monitor providers for compliance with ASAM standards. As part of these education efforts, DHSR will also revise its Survey Process Guide, which includes written

instructions for surveyors regarding how to consistently assess compliance with administrative rules. These actions are expected to be completed by October 2020.

Summary of Actions Needed

- Revise DHSR MHLC's annual survey process to provide the ability to assess compliance with 2013 ASAM standards: September 2018 – October 2020

Requirement That Residential Treatment Providers Offer MAT On-Site or Facilitate Access to Off-Site Providers

Current State

DMH/DD/SAS currently requires state-funded ASAM level 3.5 (clinically managed high-intensity residential services) providers, many of which may be Medicaid providers as well, to provide MAT on-site or coordinate care with a licensed OTP or office-based opioid treatment (OBOT) provider. ASAM level 3.7 (medically monitored intensive inpatient services) providers are not subject to a similar requirement, although some ASAM 3.7 providers may offer MAT on-site if the individual was receiving MAT prior to seeking care at the residential facility and/or if the physicians at the facility have completed buprenorphine training required under DATA 2000.

To ensure that all residential treatment providers either offer MAT on-site or facilitate access to MAT off-site, North Carolina is conducting two different assessments of MAT capacity. First, the state is working to identify which residential treatment providers offer MAT on-site today. Second, the state is plotting the locations of licensed OBOT providers and OTPs that currently provide MAT services and comparing them to the locations of residential treatment providers to understand access to OBOT and OTP.

Future State

The Department will require residential treatment providers that do not provide MAT on-site to have the ability to link individuals to a licensed OBOT or OTP located within a minimum number of miles or minutes. The Department will develop this requirement based on the results of its analysis of the geographic locations of residential treatment providers compared with OBOT providers and OTPs. This standard may vary for residential treatment facilities located in urban and rural areas of the state. To ensure provider compliance with this requirement, the Department will conduct outreach and additional training, as well as provide technical assistance to residential treatment providers.

Summary of Actions Needed

- Develop requirement for residential treatment providers to be able to refer patients to MAT within a minimum number of miles or minutes: September 2018 – October 2020

Summary of Actions Needed

Action	Implementation Timeline
Develop a licensure rule waiver process to incorporate ASAM criteria	September 2018 – October 2020
Revise existing licensure rules to align provider qualifications with 2013 ASAM criteria	September 2018 – October 2022
Revise DHSR MHLC's annual survey process to provide the ability to assess compliance with 2013 ASAM standards	September 2018 – October 2020
Develop requirement for residential treatment providers to be able to refer patients to MAT within a minimum number of miles or minutes	September 2018 – October 2020

Milestone 4: Sufficient Provider Capacity at Critical Levels of Care, Including for Medication-Assisted Treatment for OUD

Today, LME-MCOs manage SUD provider networks and are required to comply with NC Medicaid choice and time and distance standards for all covered Medicaid services. Rural areas, in particular, face ongoing staffing shortages at critical levels of SUD care, including with respect to OTPs and residential treatment services. To ensure that Medicaid enrollees, whether they receive services through the LME-MCOs or fee-for-service, have access to SUD treatment providers at critical levels of care, the Department will conduct an assessment of all Medicaid-enrolled providers. As part of this assessment, the Department will identify providers that are accepting new patients. The Department will use the results of the assessment to target network development efforts for LME-MCOs, standard plans and BH I/DD tailored plans.

Current State

The Department tasks the LME-MCOs with overseeing the development and management of a qualified SUD provider network in accordance with community needs. LME-MCOs are responsible for the enrollment, disenrollment, credentialing, and assessment of qualifications and competencies of providers, in accordance with applicable state and federal regulations. The LME-MCOs are subject to the following network adequacy standards for Medicaid covered behavioral health services:

Provider Type	Urban Standard	Rural Standard[20]
Outpatient Services[21]	≥ 2 providers of each outpatient service within 30 minutes or 30 miles of residence	≥ 2 providers of each outpatient service within 45 minutes or 45 miles of residence
Location-Based Services[22]	≥ 2 providers of each location-based service within 30 minutes or 30 miles of residence	≥ 2 providers of each location-based service within 45 minutes or 45 miles of residence
Crisis Services[23]	≥ 1 provider of each crisis service within each LME-MCO region	
Specialized Services[24]	≥ 1 provider of each service within each LME-MCO region	
Inpatient Services	≥ 1 provider of each service within each LME-MCO region	

LME-MCOs endeavor to ensure that enrollees have a choice of providers within time and distance requirements set forth by the Department. LME-MCOs must ensure a provider directory is made available to the enrollees to support their selection of a provider. In the event of limited services, LME-MCOs may request an exception for a specific access-to-care gap. The Department determines whether to grant an exception by examining service utilization, provider availability and the LME-MCO's plan for ensuring enrollees have access to the required service. In addition, the LME-MCO must have a plan for meeting the network adequacy requirement in the future.

Each LME-MCO is required to conduct an annual gap analysis and needs assessment of its provider network that incorporates data analysis of access to and choice of providers, as well as input from enrollees, family members, providers and other stakeholders. LME-MCOs review all services, identify service gaps, and prioritize strategies to address any gaps or weaknesses identified. The assessment takes into consideration the characteristics of the population in the entire catchment area and includes input from individuals receiving services and their family members, the provider community, local public agencies, and other local system stakeholders. Each LME-MCO assesses the adequacy, accessibility, and availability of its current provider network and creates a network development plan to meet identified community needs, following the Department's published gap analysis requirements.
Notwithstanding the LME-MCOs' robust time and distance standards, there are gaps in provider access in rural areas of North Carolina across all ASAM levels. Recent gap analyses have

[20] For the purposes of the state's network adequacy standards, "urban" is defined as "non-rural counties," or counties with an average population density of 250 or more people per square mile. This includes 20 counties categorized by the North Carolina Rural Economic Development Center (the Rural Center) as "regional cities or suburban counties" or "urban counties." These 20 counties include 59% of the state's population. "Rural" is defined as counties with a population density below 250 people per square mile. Per the Rural Center, 80 counties in North Carolina meet this definition; these counties are home to 41% of the state's population. See more at http://www.ncleg.net/documentsites/committees/BCCI-6678/4-6-16/NCRC3%20Rural_Center_Impacts_Report.pdf4-6-16.pdf.

[21] Outpatient services include behavioral health services provided by direct enrolled providers such as psychiatrists.

[22] Location-based services include ASAM levels 2.1 (SAIOP), 2.5 (SACOT) and OTPs.

[23] Detoxification services include ASAM levels 1-WM (ambulatory detoxification services without extended on-site monitoring), and 3.7-WM (non-hospital medical detoxification). For medically supervised or ADATC detoxification crisis stabilization, each LME-MCO is required to contract with all three ADATCs in the state.

[24] Specialized services include ASAM levels 3.5 (NMCRT) and 3.7 (MMCRT).

highlighted gaps in access to OTPs, ASAM level 2.5 (SACOT) providers, residential treatment programs and withdrawal management services.

To ensure that enrollees in fee-for-service have sufficient access to services, NC Medicaid enrolls any willing provider, reviews the adequacy of its network on a service-level basis, and collaborates with stakeholders to expand its network for services where shortages exist.

Future State

Within 12 months of the demonstration approval, the Department will complete its statewide assessment of the availability of enrolled Medicaid and state-funded providers, which will include identifying those who are accepting new patients at the critical levels of care. This assessment will also identify providers delivering state-funded services at ASAM level 3.1 (substance abuse halfway house) and ASAM level 3.2-WM (social setting detoxification services), which will be added to the Medicaid service array.

Summary of Actions Needed

Conduct an assessment of all Medicaid-enrolled providers, to include the identification of providers that are accepting new patients at the critical levels of care: September 2018 – October 2019

Network Adequacy Standards for LME-MCOs, Standard Plans and BH I/DD Tailored Plans

As described above, LME-MCOs are subject to a strong set of SUD network adequacy standards today. Standard plans and BH I/DD tailored plans will also be expected to maintain and monitor a robust network of SUD providers beginning at their launches in November 2019 and July 2021, respectively. The Department will develop a monitoring system to ensure compliance with all applicable network adequacy standards for LME-MCOs, standard plans and BH I/DD tailored plans. In alignment with the final federal Medicaid managed care rule, the Department will monitor the following indicators from the report "Promoting Access in Medicaid and CHIP Managed Care: A Toolkit for Ensuring Provider Network Adequacy and Service Availability." North Carolina will also use consumer experience to verify and monitor access to care and adjust time and distance standards, if necessary. The state will monitor appropriate service use through performance measure indicators that align with HEDIS measures.

Indicators of Provider Network Adequacy and Service Availability

Availability	Accessibility	Accommodation	Acceptability	Realized Access
Provider Capacity	**Timely Access to Care**	**Cultural Competency & Operating Hours**	**Customer Service**	**Appropriate Service Use**
Number of providers accepting new Medicaid enrollees	Percentage of consumers living within 30 minutes/30 miles for urban and 45 minutes/45 miles for rural areas	Availability and delivery of services in a culturally competent manner regardless of cultural and ethnic backgrounds; disabilities; and	Consumer perception of care surveys Number of appeals, grievances and complaints	Critical performance indicators: Follow-up after care Readmissions

Availability	Accessibility	Accommodation	Acceptability	Realized Access
Provider Capacity	**Timely Access to Care**	**Cultural Competency & Operating Hours**	**Customer Service**	**Appropriate Service Use**
	Percentage of consumers able to be seen within maximum wait time for emergent, urgent and routine care	gender, sexual orientation or gender identity		Initiation and engagement Physical healthcare visits

As part of its managed care design process, the Department has developed the following time and distance standards for proposed SUD services that will be covered by standard plans. These services include one of the new services at ASAM level 2-WM (ambulatory detoxification with extended on-site monitoring). The Department will develop network adequacy standards for BH I/DD tailored plans in the coming year.

Standard Plan Network Adequacy Standards for Behavioral Health Services

Provider Type	Urban Standard	Rural Standard
Outpatient Services[25]	≥ 2 providers of each outpatient service within 30 minutes or 30 miles of residence	≥ 2 providers of each outpatient service within 45 minutes or 45 miles of residence
Location-Based Services[26]	≥ 2 providers of each location-based service within 30 minutes or 30 miles of residence	≥ 2 providers of each location-based service within 45 minutes or 45 miles of residence
Crisis Services[27]	≥ 1 provider of each crisis service within each standard plan region	
Inpatient Services	≥ 1 provider of each crisis service within each standard plan region	

Building Capacity for New Services

The state intends to support LME-MCOs, standard plans and BH I/DD tailored plans in building network capacity for new or expanded services that will be covered through fee-for-service as well.

- **Expand service offerings to include ASAM level 2-WM.** The Department plans to work with the LME-MCOs to encourage their ASAM level 1-WM providers to expand their service offerings to include ASAM level 2-WM.

[25] Outpatient services include behavioral health services provided by direct-enrolled providers such as psychiatrists.
[26] Location-based services include ASAM levels 2.1 (SAIOP), 2.5 (SACOT) and OTPs.
[27] Crisis services include ASAM levels 1-WM (ambulatory detoxification services without extended on-site monitoring), 2-WM (ambulatory detoxification with extended on-site monitoring), and 3.7-WM (non-hospital medical detoxification). For medically supervised or ADATC detoxification crisis stabilization, the standard plan will be required to contract with all three ADATCs in the state.

- **Leverage state-funded networks for ASAM levels 3.1, 3.7 and 3.2-WM.** The Department plans to work with LME-MCOs to enroll in Medicaid their current state-funded providers for ASAM levels 3.1 and 3.2-WM, in order to build Medicaid provider networks for these services. In addition, the state will work with LME-MCOs to enroll in Medicaid their state-funded providers serving adolescents for ASAM level 3.7 (medically monitored community residential treatment).
- **Engage with stakeholders for ASAM level 3.3.** To build sufficient networks for ASAM level 3.3 (clinically managed population-specific high-intensity residential programs), the state will engage with disability advocates representing individuals with TBI or I/DD as well as LME-MCOs, in order to identify providers that may be interested in offering this service.
- **Provide training for new Medicaid SUD providers.** The Department will educate and require the LME-MCOs, standard plans and BH I/DD tailored plans to provide training for new Medicaid SUD providers, to orient them to Medicaid and managed care, including topics such as utilization management, credentialing and billing.

Strategies to Ensure Adequate Capacity Post-Managed Care Transition

While standard plans and BH I/DD tailored plans will be required to meet minimum standards set by the Department, they will be given sufficient flexibility to innovate to improve quality and efficiency of care. In the event a service gap is identified, the standard plan or BH I/DD tailored plan may request an exception for a specific access-to-care gap in a specific region, consistent with current LME-MCO practice. The Department will determine if an exception is granted by looking at service utilization, the availability of providers, history of complaints, and the plan's short- and long-term plans for meeting ASAM level of care needs.

Standard plans and BH I/DD tailored plans will be allowed to develop their own telemedicine policies to ensure access to needed services, consistent with departmental guidance and approval. However, plans will not be permitted to use telemedicine to meet the state's network adequacy standards (unless the state has approved a request for an exception that involves telemedicine). When a Medicaid enrollee requires a medically necessary service that is not available within a standard plan's or BH I/DD tailored plan's network, the plan may offer the service, if applicable and clinically appropriate, through telemedicine, in addition to providing access to an out-of-network provider of the needed service. In these instances, the enrollee will have a choice between out-of-network provider and telemedicine and will not be forced to receive services through telemedicine. Medicaid enrollees receiving services through fee-for-service will be able to access telemedicine services consistent with the Department's clinical coverage policies. The Department is also exploring additional ways to leverage telemedicine for SUD treatment. As discussed in greater detail in Milestone 5 below, the state is supporting an expansion of Project Extension for Community Healthcare Outcomes (ECHO) to expand access to MAT in underserved and rural communities.

Standard plans and BH I/DD tailored plans will be required to submit an Access Plan annually to the Department, which will be reviewed and monitored by department staff. The Access Plan will demonstrate that the plans have the capacity to serve the expected enrollment in their service area in accordance with the Department's network requirements and network adequacy standards. NC Medicaid will review each Access Plan to ensure the standard plan or BH I/DD tailored plan meets all the

expectations and requirements and provides a reasonable approach to a plan's oversight and management of its providers and networks.

NC Medicaid will continue to ensure that it is has an adequate network of SUD providers in its fee-for-service program.

Expanding Access to MAT

The state has identified approximately 800 certified OBOT providers across North Carolina, and is working to determine the composition of active and non-active MAT prescribers. A robust network of active OBOT providers can complement the growing network of 65 OTPs licensed across the state. To build the network of active OBOT providers, the state intends to provide ongoing training programs and technical support to prescribers on the following:

Implementing safe prescribing practices.
Collaborating with pharmacists as part of a care team.
Incorporating component services including counseling into the practice.
Billing the PHP for component services (e.g., prescription, laboratory and counseling services).

Summary of Actions Needed

Action	Implementation Timeline
Conduct an assessment of all Medicaid-enrolled providers, to include the identification of providers that are accepting new patients at the critical levels of care	September 2018 – October 2019
Work to build Medicaid provider networks for new Medicaid levels of care	September 2018 – October 2020
Develop BH I/DD tailored plan network adequacy standards for SUD treatment services, taking into account results of provider assessment	September 2018 – October 2019

Milestone 5: Implementation of Comprehensive Strategies to Address Prescription Drug Abuse and Opioid Use Disorders

North Carolina has intensified its efforts over the past year to address the opioid crisis. As described below, the state developed and is making progress on an Opioid Action Plan outlining statewide goals and priorities for tackling the epidemic. Recent state legislation implementing opioid prescribing guidelines and expanding access to naloxone, Medicaid pharmacy program initiatives, the state's requirements for PHPs and a federal 21st Century Cures Act grant of $31 million have also bolstered North Carolina's efforts.

The North Carolina Opioid Action Plan

In June 2017, North Carolina announced North Carolina's Opioid Action Plan, which outlines the key actions the state and its partners are taking to combat the epidemic and calls for measuring and

assessing the effectiveness of the strategies. The Opioid Action Plan was developed through collaboration among state agencies and various health, law enforcement, education, business, nonprofit and government partners. It aims to reduce opioid addiction and overdose deaths in the period from 2017 to 2021 by implementing the following key strategies:

- Create a coordinated infrastructure between the state, stakeholders and local coalitions.
- Reduce oversupply of prescription opioids.
- Reduce diversion of prescription drugs and flow of illicit drugs.
- Increase community awareness and prevention.
- Make naloxone widely available, and link overdose survivors to care.
- Expand treatment and recovery-oriented systems of care.
- Measure impact and revise strategies based on results.

The Department has thus far conducted numerous activities in support of the Opioid Action Plan. In October 2017, the Department purchased nearly 40,000 units of nasal naloxone to make the overdose reversal drug more widely available and thus help reduce the number of unintentional opioid-related deaths. The naloxone has been distributed to partners across the state that work with individuals at high risk of opioid overdose, including OTPs and other treatment providers, EMS agencies, Oxford House, and other community partners. The Department established a North Carolina Payers Council to bring together healthcare payers across the state to partner on benefit design, member services, and pharmacy policies to reduce opioid overuse and overdose. The Department also made important changes to the Medicaid program in order to increase access to treatment by removing prior-approval requirements for suboxone.

Strengthen Opioid Misuse Prevention Act

In June 2017, North Carolina's General Assembly passed and Governor Roy Cooper signed the STOP Act, North Carolina Session Law 2017-57, Senate Bill 257. The STOP Act seeks to reduce drug addiction and overdoses through smarter prescribing practices by doctors and dentists, restrictions on pharmacies dispensing opioids, expanding the availability of naloxone, and strengthening the state's Controlled Substance Reporting System (CSRS). STOP Act provisions apply broadly across the state; they are not specific to the Medicaid program.[28] North Carolina will require standard plans and BH I/DD tailored plans to incorporate STOP Act requirements into their opioid misuse programs. Key provisions, most of which became effective immediately, include:

Prescriber Provisions

- **Reduce unused, misused and diverted pills with five-day limit on initial prescriptions for acute pain.** A prescriber may not prescribe more than a five-day supply of a controlled substance (or a seven-day supply after surgery) when first treating a patient for acute pain, effective January 1, 2018.[29]
- **Reduce doctor shopping and improve care with required scan of state prescription database.** Before prescribing controlled substances, a doctor, dentist or other prescriber must check the CSRS

[28] STOP Act, https://www.ncleg.net/gascripts/billlookup/billlookup.pl?Session=2017&BillID=H243.

[29] This requirement does not apply to cancer care, palliative care, hospice care or MAT for substance use disorders.

to learn of a patient's other prescriptions, effective upon completion of certain upgrades to the CSRS.[30]

- **Reduce fraud through e-prescribing.** A prescriber must electronically prescribe controlled substances to reduce fraud stemming from stolen prescription pads or forged prescriptions—except for drugs administered by the prescriber or drugs administered in a healthcare or residential facility, effective January 1, 2020.
- **Reduce diversion of veterinary drugs.** Veterinarians who dispense controlled substances must register and report to CSRS to enable detection of drug diversion by pet owners, effective January 1, 2019.
- **Tighter supervision.** PAs and NPs must consult their supervising physicians the first time they prescribe controlled substances and every 90 days thereafter, effective July 1, 2017.

Pharmacy Provisions

- **Implement universal registration and reporting.** All pharmacies dispensing controlled substances must register for and report to CSRS—consistent with the current practice of most pharmacies.
- **Enable near-time reporting to detect and stop doctor-shopping.** Pharmacies dispensing controlled substances must report to CSRS within 24 hours of each transaction—down from the current requirement of 72 hours but consistent with the current practice of many pharmacies, effective September 1, 2017.
- **Detect fraud, misuse and diversion.** Pharmacies must consult the CSRS before dispensing a controlled substance when there is reason to suspect fraud, misuse or diversion, and must consult the prescriber when there is reason to believe the prescription is fraudulent or duplicative. Pharmacies are required to remedy missing or incomplete data upon request, effective upon completion of certain upgrades to the CSRS.

Provisions Expanding Access to Community-Based Treatment and Naloxone

- **Improve health and save money by investing in local treatment and recovery services.** The STOP Act appropriates $10 million for FY 2017-18 and $10 million for FY 2018-19 for community-based treatment and recovery services for substance use disorders, including MAT.
- **Reverse overdoses and save lives.** The STOP Act facilitates wider distribution of the overdose-reversal drug naloxone by clarifying that standing orders cover not only individuals at risk, family members, law enforcement and local health departments, but also community health groups. In addition, the act underscores that no state funds may be used to support needle exchange programs, but that does not preclude a local government from supporting such a program in its community.

Other Provisions

- **Stronger oversight.** The Department will audit doctor, dentist and other prescriber use of the CSRS and will report violations to the appropriate licensing boards, effective upon completion of certain upgrades to the CSRS.
- **Better data use.** The STOP Act expands use of data to detect and prevent fraud and misuse.
- **More secure funding.** The STOP Act creates a non-reverting special revenue fund to support the CSRS.

[30] This scan is allowed but not required for cancer treatment, palliative care, hospice care, drugs administered in a healthcare or residential facility, or prescriptions for five or fewer days (or seven or fewer days after surgery).

Medicaid Pharmacy Program

The NC Medicaid pharmacy program has worked to (1) update clinical coverage criteria for the use of opioids for pain management based on the Centers for Disease Control and Prevention (CDC) guideline "Prescribing Opioids for Chronic Pain"; (2) align clinical coverage criteria for prescription of opioids with strategies targeted toward reducing the oversupply of prescription opioids available for diversion and misuse; (3) strengthen its enrollee lock-in program; and (4) expand access to suboxone.[31] The Medicaid pharmacy program has also adopted the STOP Act provisions, as applicable.

In 2010, North Carolina established the NC Medicaid Enrollee Lock-In Program to establish a "prescription gatekeeper" for enrollees deemed to have potential for misuse of their prescription benefits.[32] In March 2017, the state strengthened its Medicaid lock-in program by increasing the number of enrollees subject to the lock-in from 200 to 600 per month and by lengthening the duration of enrollment in the program to two years. Next, in May 2017, Medicaid increased the early refill threshold for all opioids and benzodiazepine prescriptions from 75% to 85%, meaning that an enrollee cannot refill a prescription for one of these drugs until less than 15% of his or her current supply remains.

Effective June 1, 2018, NC Medicaid limited the prior authorization threshold for opioids to 90 mg of morphine equivalents per day. In addition, NC Medicaid began to require prior approval for opioid prescriptions exceeding the maximum daily dosage; for opioid prescriptions that are for longer than five or seven days, consistent with the STOP Act; or for any non-preferred opioid product.[33] The state requires opioid prescribers to consult the CSRS, review the CDC chronic pain guidelines for prescribing opioids and, if applicable, explain the need to exceed daily dosage limits prior to prescribing opioids. Finally, the Medicaid program eliminated the prior authorization requirements for suboxone as of November 1, 2017, to provide timely access to opioid withdrawal treatment.

New Medicaid Managed Care Provisions

North Carolina recognizes that a strong partnership with standard plans and BH I/DD tailored plans is necessary to build on its ongoing efforts to combat the opioid epidemic. To that end, the Department will require its PHPs to implement a comprehensive opioid misuse prevention program. To monitor potential abuse or inappropriate utilization of prescription medications, the Department will give plans the choice of either participating in the NC Medicaid Enrollee Lock-In Program or develop their own lock-in program consistent with state law and subject to Department approval. PHPs will provide care coordination for enrollees in the lock-in program in conjunction with the enrollee's primary care provider. Plans will be required to report to the Department lock-in program outcomes including, but not limited to, changes in emergency department visits and changes in opioid misuse, to inform monitoring efforts and identify the need for further interventions.

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[31] NC Division of Medical Assistance. Outpatient Pharmacy Prior Approval Criteria Opioid Analgesics, available at https://www.nctracks.nc.gov/content/dam/jcr:45fd795f-2681-4fab-b59c-07b350801d6b/Criteria-Opioid%20Analgesics%2090mme%20and%20III%20and%20IV.pdf.

[32] Today, the program restricts enrollees who meet at least one of the following criteria to a single prescriber and pharmacy: enrollees with six claims of opiates, benzodiazepines and certain anxiolytics; beneficiaries receiving prescriptions for these drugs from more than three prescribers in two consecutive months; or referral from a provider, NC Medicaid or Community Care of North Carolina (CCNC). NCHC enrollees are not subject to lock-in provisions. Source: NC Outpatient Pharmacy Clinical Coverage Policy.

[33] North Carolina Medicaid Pharmacy Newsletter, June 2017.

Additionally, plans will be required to implement a maximum morphine milligram equivalent dose for opioid prescriptions as point-of-service edits, as well as drug utilization review programs to address opioid misuse.

Opioid Initiatives Supported by the 21st Century Cures Act Grant

North Carolina is using a $31 million grant received through the 21st Century Cures Act in May 2017 to expand access to prevention, treatment and recovery supports to reduce opioid-related deaths over the next two years.[34] It will also be used to purchase 6,600 naloxone kits statewide to be distributed to law enforcement, paramedics and OTPs. The state expects to serve approximately 1,500 individuals annually over the two-year period through the grant as a whole. In addition to expanding treatment services, funding will be available for prevention, education and outreach; screening/triage/referral; recovery supports; and provider education and development. Two specific examples of current projects funded by this grant follow:

Project Extension for Community Healthcare Outcomes (ECHO) The Department is using its 21st Century Cures Act grant to expand training on MAT and associated barriers for providers and interdisciplinary clinical teams through the University of North Carolina's (UNC) research initiative, Project ECHO, in collaboration with the University of New Mexico Project ECHO. The core goals of the UNC ECHO for MAT demonstration project are to (1) increase understanding about how known barriers to the implementation of MAT in primary care can be overcome; (2) evaluate strategies to overcome those barriers; and (3) simultaneously expand access to MAT in rural and underserved counties, reducing the risk of accidental overdose deaths through a multilayered provider and practice engagement strategy. Additional ECHOs may focus on highlighting best practices and evidence-based care, as well as building treatment capacity for pregnant women or mothers, individuals with OUD who are also HIV positive or hepatitis C positive, and/or for individuals with OUD in North Carolina prisons.

Training on ASAM Levels of Care. During March and April 2018, the state used funds from its 21st Century Cures Act grant to offer and subsidize the cost of eight two-day and four one-day trainings on the ASAM criteria, primarily targeting medical professionals and clinical staff employed at OTPs and OBOT programs across the state. The training provided participants with a comprehensive overview of the ASAM criteria, including:

- Services that are part of the ASAM continuum of care.
- ASAM's six dimensions used to complete a holistic, biopsychosocial assessment that evaluates an individual's substance use and withdrawal history; health history and current physical condition; readiness to change; and emotional, behavioral or cognitive conditions, among others.
- ASAM's continued stay and discharge criteria for residential SUD services.

North Carolina has been a leader in the fight against the opioid crisis. By deploying these initiatives, the state has made and will continue to make progress in curbing this nationwide epidemic.

[34] Governor Cooper Announces $31 Million Grant to Fight Opioid Epidemic in NC.

Summary of Actions Needed

Action	Implementation Timeline
Continue implementation of the STOP Act provisions on an ongoing basis.	September 2018 – October 2020

Milestone 6: Improved Care Coordination and Transitions Between Levels of Care

Care Coordination

Current State

Today, LME-MCOs are responsible for providing care coordination for Medicaid enrollees, including those with special healthcare needs and those who meet the state's definition of being "at risk," but cannot duplicate case management functions that enrollees receive as part of select behavioral health services. The population with special healthcare needs includes the following individuals with SUDs:

- Individuals with an SUD diagnosis and current ASAM patient placement criteria (PPC) of at least level 3.7 or 3.2-WM.
- Adults who reported use of drugs by injection.
- Children with a mental health or SUD diagnosis, who are currently residing or have resided in the past 30 days in a facility operated by the Department of Juvenile Justice or the Department of Corrections, an inpatient hospital setting, a therapeutic group home, or a psychiatric residential treatment facility.
- Individuals with co-occurring SUD and mental illness or I/DD as follows:
    - Individuals with both a mental illness diagnosis and a substance use diagnosis and a current LOCUS/CALOCUS of V or higher, or current ASAM PPC level of 3.5 or higher.
    - Individuals with both an I/DD and an SUD diagnosis and current ASAM PPC level of 3.3 or higher.

Medicaid defines at-risk individuals as those enrollees who:

- Do not appear for scheduled appointments and are at risk for inpatient or emergency treatment.
- Receive a crisis service as their first service, in order to facilitate engagement with ongoing care.
- Are discharged from an inpatient psychiatric unit or hospital, a psychiatric residential treatment facility, or a facility-based crisis or general hospital unit following admission for a mental health, SUD or I/DD condition.

LME-MCOs' care coordination responsibilities for the populations listed above include the following:

- Identifying enrollees' clinical needs.
- Determining level of care through case review.
- Arranging assessments.
- Linking enrollees to necessary psychological, behavioral, educational and physical evaluations.
- Engaging in clinical discussions with enrollees' treatment providers.
- Conducting deliberate organization of care activities.

Facilitating appropriate delivery of healthcare services and connecting enrollees to the appropriate level of care.
Addressing support services and resources.
Assisting enrollees with obtaining referrals and arranging appointments.
Educating enrollees about other available supports as recommended by clinical care coordinators.
Monitoring enrollees' attendance in treatment.
Identifying and addressing enrollees' needs and barriers to treatment engagement.
Developing engagement strategies for individuals with special healthcare needs.
Coordinating and linking all Medicaid-funded services for the enrollee, as appropriate.
Assisting with developing a person-centered treatment plan in consultation with the enrollee and his or her primary care provider.

In addition to the care coordination functions performed by the LME-MCOs, case management is provided as part of select SUD services. In particular, SAIOP and SACOT services include case management components to arrange, link, or integrate across multiple types of SUD services and supports.

The state's fee-for-service behavioral health contractor provides care coordination services to populations excluded from the LME-MCOs. Care coordinators provide the following care coordination functions telephonically:

Information intake;
Evaluation;
Referral to inpatient providers or to appropriate level of care;
Utilization review;
Quality assurance;
Discharge and aftercare planning; and
Monitoring.

Transitions of Care

Current State

Among their care coordination functions, LME-MCOs are required to coordinate and monitor services provided to enrollees during transitions of care. Responsibilities include assisting hospitals, facilities and other institutional providers with discharge planning for short-term and long-term hospital and institutional stays when the admission is primarily based on the enrollee's behavioral health diagnosis. Transitional care coordination performed by LME-MCOs cannot duplicate inpatient facilities' requirements for discharge planning. The inpatient facility must involve the patient, family, staff members and referral sources in discharge planning. If a patient is being referred to another facility for further care, appropriate documentation of the patient's current status must be forwarded with the patient within 48 hours of discharge. The discharge summary must include the reasons for referral, the diagnosis, functional limitations, services provided, the results of services, referral action recommendations, and activities and procedures used by the patient to maintain and improve functioning.

Future State

Upon their launches in 2019 and 2021, respectively, the standard plans and BH I/DD tailored plans will be responsible for care coordination and care management for enrollees with SUDs, including managing transitions between levels of care. LME-MCOs will continue to manage care coordination and care transitions for certain Medicaid enrollees with SUDs until BH I/DD tailored plans launch. For populations that will remain in fee-for-service, the state will develop care coordination protocols that include transitions of care across service levels. In developing the care coordination and care management approaches for these new managed care products, North Carolina has prioritized the establishment of specific requirements related to serving enrollees with SUDs as described below.

Standard Plans: Care Coordination and Care Management

When standard plans launch in November 2019, they will be responsible for overseeing, funding and organizing all aspects of care management in a way that improves health outcomes and manages the total cost of care for their enrollees. They will be required to complete care needs screenings and to perform claims analysis and risk scoring to identify enrollees at risk; stratify their populations by level of need; perform comprehensive assessments for those identified as part of "priority populations"; and perform localized care management at the site of care, in the home or in the community, where face-to-face interaction is possible.

Standard plans will be required to establish policies and procedures to deliver care to and coordinate services for all enrollees regardless of risk or needs. As part of their care coordination for all enrollees, standard plans will be required to do the following:

- Establish policies and procedures for coordination between physical and behavioral health providers, and between mental health and substance use providers.
- Establish policies and procedures to coordinate enrollee transitions from LME-MCOs or Medicaid fee-for-service into standard plans and from one standard plan to another, or between delivery systems.
- Design an evidence-based tool to conduct a care needs screening that can identify enrollees' behavioral health needs, incorporating the ASAM criteria to screen for opioid usage and other SUDs.
- Make best efforts to conduct a care screening of every enrollee within 90 days of enrollment as required by the managed care rule, to identify enrollees with unmet healthcare needs (including SUDs) who may require a comprehensive assessment for care management.

Additionally, standard plans will designate enrollees with SUDs as meeting the state's definition of special healthcare needs, and thereby as a high-priority population for receiving care management. All care management must include coordination of physical health, behavioral health, pharmacy and social services. In addition, the Department will require that all care managers receive training on integrated and coordinated physical and behavioral healthcare, and care managers serving individuals with behavioral health needs will also receive training on behavioral health crisis response.

Standard Plans: Transitions of Care

Among their care coordination responsibilities for all enrollees, including those with SUDs, standard plans will manage transitions of care for all enrollees moving from one clinical setting to another, to

prevent unplanned or unnecessary readmissions, emergency department visits, or adverse outcomes. Following standard plan contracting, standard plans will be required to share with the Department their transitional care management policies and procedures, the experience and qualifications of care managers performing transitional care management, and how their transitional care management approach relates to the staffing and contracting approach for high-need enrollees' care management. In order to identify enrollees in transition who are at risk of readmissions and other poor outcomes, standard plans shall develop a methodology that considers the frequency, duration and acuity of inpatient, skilled nursing facility (SNF), and LTSS admissions or emergency department visits; discharges from inpatient behavioral health services, facility-based crisis services, non-hospital medical detoxification, medically supervised treatment centers or alcohol drug abuse treatment centers; and neonatal intensive care unit (NICU) discharges. In addition, the standard plan may target enrollees for transitional care management by severity of condition, medications and other factors the standard plan may prioritize.

Standard plans will ensure that the entity conducting transitional care management performs the following functions:

- Conducts outreach to the member's advanced medical home/primary care provider and all other medical providers.[35]
- Facilitates clinical handoffs, including those to behavioral health providers.
- Obtains a copy of the discharge plan/summary, and verifies that the enrollee's care manager receives and reviews the discharge plan with the enrollee and the facility.
- Ensures that a follow-up outpatient and/or home visit is scheduled, within a clinically appropriate time window.
- Conducts medication reconciliation and support medication adherence.
- Ensures that a care manager is assigned to manage the transition.
- Rapidly follows up with the enrollee via the assigned care manager following discharge.
- Develop a protocol for determining the appropriate timing and format of such outreach.

BH I/DD Tailored Plans: Care Coordination and Care Management

By design, BH I/DD tailored plans will serve a high-cost population with complex needs. BH I/DD tailored plan enrollees will have a significant need for robust, whole-person care management services that will address their physical health, mental health, substance use, I/DD, TBI, pharmacy, community support and social needs. Specifically, care management for BH I/DD tailored plan enrollees will take into account the following:

- Future BH I/DD tailored plan enrollees are closely engaged with mental health, SUD, I/DD and TBI providers with whom they have frequent interaction and trusting relationships, and conflict-free care management services should be provided at these sites or in primary care settings that have expertise in serving populations with significant BH or I/DD needs to the maximum extent possible.
- Care management services for populations that will enroll in BH I/DD tailored plans, including individuals with SUDs, should generally be more intensive than those provided to the standard plan population and should occur face-to-face for all BH I/DD tailored plan enrollees.

[35] The AMH program will be the framework under which providers can choose to take primary responsibility for care management, either at the individual practice level or in a contractual relationship with a care management/population management entity (e.g., a Clinically Integrated Network)—and receive higher reimbursement for such responsibility—or choose to coordinate with PHPs' care management approaches.

Care managers serving BH I/DD tailored plan enrollees must have specialized expertise, including training in mental health, SUD, I/DD and/or TBI care; experience managing physical and behavioral healthcare and I/DD co-morbidities; and specialized clinical supervision experience to support the coordination of care between physical and behavioral healthcare.

The BH I/DD tailored plan care management model will meet federal standards for health home services, and North Carolina anticipates submitting a health home SPA prior to the BH I/DD tailored plan launch. Health home funds will flow to BH I/DD tailored plans. Given that BH I/DD tailored plans will not launch until July 2021, the Department is still in the process of establishing the full set of BH I/DD care management requirements.

BH I/DD Tailored Plans: Transitions of Care

Among their care management responsibilities, entities delivering health home care management services will be required to provide comprehensive transitional care management services, including all standard plan transitional care services. Additional responsibilities will include:

Instituting evidence-based care transition programs directed toward individuals with mental health disorders SUDs and I/DD.

Developing relationships with local hospitals, nursing homes, SUD residential treatment facilities, SUD rehabilitation providers and inpatient psychiatric facilities to promote smooth care transitions.

Developing working relationships with the justice system and the Division of Social Services to support transitions back to the community.

The Department recognizes the importance of ensuring that standard plan enrollees who meet the BH I/DD tailored plan level of need or require a service that will only be covered by BH I/DD tailored plans are transitioned as quickly and smoothly as possible. To that end, these enrollees will be able to transfer across standard plans and BH I/DD tailored plans throughout the coverage year.

Summary of Actions Needed

Action	Implementation Timeline
Incorporate care management provisions into standard plan contracts	January 2019 – November 2019
Incorporate care management provisions into BH I/DD tailored plan contracts	January 2021 – July 2021
Submit a health home SPA to authorize the creation of behavioral health homes	July 2019 – March 2020

SUD HIT Plan: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
1. Enhanced interstate data sharing in order to better track patient-specific prescription data	▪ North Carolina's PDMP, which is called the CSRS, enables practitioners to see patient prescription history of 24 states, Washington DC, Puerto Rico and the Military Health System using National Associations of Boards of Pharmacy's (NABP) PMP Interconnect (PMPi). The states are: Alabama, Arizona, Arkansas, Connecticut, Delaware, Florida, Georgia, Idaho, Maine, Minnesota, Mississippi, New Jersey, New Mexico, New York, North Dakota, Ohio, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Virginia, and West Virginia.	▪ The state will update its HIT plan as more states are included in PMPi sharing. ▪ By September 2019, 11,250 prescriber and 580 pharmacies will be approved for integration. ▪ Two-way data sharing will be established between North Carolina and all other states.	▪ Review necessary steps to join RxCheck. ▪ Enhance interstate data sharing (ex. KY) through connection with the RxCheck hub, and continue to reach out to remaining states (provided funds are available). **Timeline:** September 2018 – April 2020
2. Enhanced "ease of use" for prescribers and other state and federal stakeholders.	▪ In order to facilitate ease for prescribers, DMH/DD/SAS successfully updated the CSRS platform in September 2018 ▪ North Carolina launched new efforts to integrate CSRS and other states' PDMP data into clinical workflows in November 2018. ▪ At this time, 3,213 prescribers have been approved for integration.	▪ North Carolina has a CSRS integration plan that includes a variety of EHR platforms, including the state's HIE as an option in the event an EHR vendor is not willing to participate. ▪ The state has developed a prioritization matrix based on healthcare entities' geographic location, specialty,	▪ Continue to approve additional prescribers and pharmacies for integration with the CSRS, as well continue its integration efforts with the HIE. **Timeframe:** September 2018 - September 2019

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
	▪ Forty-three pharmacies are currently approved to be integrated. ▪ The state's Health Information Exchange (HIE), NC HealthConnex, is expected to complete integration by September 2019. ▪ The UNC Health Care System integrated independent of the state's effort in the Summer of 2018. ▪ Large pharmacy chains, such as CVS (367 stores), Walmart (229), Kroger (125), Kmart (14), Costco (8), Harris Teeter (8) and Walgreens (474) have integrated independently as well.	past prescribing practices, and overdose rates in their area. ▪ Integration goals are 11,250 prescribers and 580 pharmacies by September 2019. ▪ Ultimately, all NC prescribers and dispensers will have CSRS data integrated into their daily workflows (December 2023, contingent on availability of funds).	
3. Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange.	▪ The Department is working to connect the CSRS with the state's HIE, known as NC HealthConnex. ▪ In May 2018, the Department executed a contract with a vendor to use PMP Gateway to develop an interface between the CSRS and NC HealthConnex.	▪ Transmissions between the CSRS and the HIE will be bi-directional and occur in real time. ▪ The interface with NC HealthConnex is expected to be complete in September 2019, following NC HealthConnex's migration to a new platform.	▪ Complete the interface with HealthConnex in September 2019. **Timeframe**: September 2018 - September 2019
4. Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns (see also "Use of PDMP" #6, below).	▪ On a quarterly basis, DMH/DD/SAS is providing the NC Medical Board, Nursing Board and Board of Pharmacy with advanced analytics collected through the CSRS, based on criteria established by each board aimed at	▪ DMH/DD/SAS plans to partner with additional state licensing boards, such as the NC Board of Podiatry Examiners and the NC State Board of Dental Examiners, to identify prescribers with	▪ Continue to partner with Medical, Nursing and Pharmacy Boards to refine reports. ▪ Establish partnerships with additional state licensing boards.

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
	flagging providers with potentially questionable prescribing patterns. ▪ The licensing boards use these reports to identify prescribers for investigation. ▪ In addition to quarterly reports to the licensing boards, the system utilizes threshold reports to notify prescribers directly when a patient has exceeded established thresholds of a number of prescribers and pharmacies visited in a 90-day period.	questionable prescribing patterns. ▪ DMH/DD/SAS will work with new partners to develop a process for reporting. ▪ Additionally, DMH/DD/SAS will improve reporting sensitivity by improving identity resolution for patients, prescribers and dispensers in the CSRS. ▪ In September 2019, "clinical alerts" will be deployed, which will enable any prescriber to see these threshold alerts when a patient is queried. Current threshold reports are only visible to the practitioner who wrote the prescription.	▪ Deploy clinical alerts in September 2019. **Timeframe**: September 2018 - September 2019
Current and Future PDMP Query Capabilities			
5. Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e., the Entity Resolution [ER] strategy with regard to PDMP queries).	▪ The CSRS' current approach to matching patients with prescriptions to patients in the CSRS involves first examining patients' first and last names, dates of birth, and street addresses. ▪ Based upon that review, the CSRS identifies cases where records with similar names used to fill multiple opioid prescriptions are likely a single	▪ DMH/DD/SAS plans to continue its efforts to improve identity resolution among prescribers, patients and dispensers, including leveraging the HIE's MPI capabilities.	▪ Prescriber and dispenser Entity Resolution is moving forward using DEA and NPI data in routine system auditing in addition to the Entity Resolution plan. ▪ Continue partnership with GDAC and expand scope of work to include

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
	patient, or separates records when it identifies that two different patients have used the same identifying information to fill their prescriptions. ▪ Since 2017, DMH/DD/SAS has partnered with the state's Government Data Analytics Center (GDAC) to facilitate data sharing to improve patient, prescriber and dispenser identity resolution. ▪ The CSRS is also using data from the U.S. Drug Enforcement Agency (DEA) to improve identity resolution for patients, prescribers and dispensers. ▪ Finally, DMH/DD/SAS is working to identify additional data sources that can further improve the resolution of patient identity.		making the business case to other state agencies to obtain permissions and consult with GDAC on defining the methodology for patient and prescriber entity resolution. ▪ Begin discussions with the HIE Authority on additional strategies to coordinate NC HealthConnex and CSRS information. **Timeframe**: September 2018 - September 2021
Use of PDMP – Supporting Clinicians with Changing Office Workflows			
6. Develop enhanced provider workflow/business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance, to address the issues that follow.	▪ DMH/DD/SAS co-chairs the Department's Opioid and Prescription Drug Abuse Advisory Committee (OPDAAC), which is focused on implementing the state's Opioid Action Plan, as described in Milestone 5. ▪ As part of the Opioid Action Plan, the Department aims to expand clinicians' access and use of the CSRS as a tool to combat the opioid epidemic.	▪ All HCEs using EHRs and PMS will have CSRS data integrated into their workflows	▪ Continue to collaborate with vendor to integrate EHR/PMS and CSRS data and acquire additional licenses for pharmacies and prescribers. **Timeframe**: November 2018 - December 2023 (Contingent upon available funds)

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
	▪ The Department recommends that a patient's report is queried within 48 hours of a patient's initial visit. ▪ The CSRS integration plan simplifies providers' abilities to query the report while a patient is in clinic without interrupting the clinician's workflow. ▪ For those entities that are not integrated, state law permits delegate access to the system for querying patients' prescription history on behalf of the practitioner. ▪ Practitioners use the CSRS separate from their EHR and Pharmacy Management Systems (PMS) to acquire patient controlled substance prescription history. ▪ The state is in the process of integrating CSRS and EHR data for individual Healthcare Entities (HCEs)		
7. Develop enhanced supports for clinician review of patient CSRS data prior to prescribing a controlled substance	▪ PDMP users currently use NarxCare analytics, available since September 2018 to review prescription history. ▪ In addition to the information provided in #6, the new CSRS platform includes additional supports for clinical decision-making by providing visualization of the history and overdose risk scores. ▪ The SAMHSA MAT locator is embedded in the system along with links to printable Centers for Disease Control	▪ The state will enhance educational resources available to users on effective NarxCare usage	▪ Extend NarxCare funding to continue availability of NarxCare analytics to CSRS users. **Timeline**: September 2018 - December 2019

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
	and Prevention (CDC) pamphlets to help practitioners discuss topics with their patients. ▪ CSRS also provides a morphine milligram equivalent (MME) or lorazepam milligram equivalent (LME) to assist prescribers in identifying risky behavior.		
Master Patient Index/Identity Management			
8. Enhance patient and prescriber profiles by leveraging other state databases in support of SUD care delivery.	▪ DMH/DD/SAS is in the early stages of Entity Resolution. ▪ The CSRS' current approach to matching patients is detailed above, under #5, "Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP."	▪ Collaborate with GDAC to mirror the current database and use other databases (e.g., Division of Motor Vehicles, Department of Public Safety, HIE Authority) that GDAC has access to, with proper permissions, to better link prescriptions and identify patients and prescribers.	▪ Continue partnership with GDAC and expand scope of work to include making the business case to other state agencies to obtain permissions. ▪ Consult with GDAC on defining the methodology for patient and prescriber Entity Resolution. **Timeframe**: September 2018 - September 2021
Overall Objective for Enhancing PDMP Functionality & Interoperability			
9. Leverage the above functionalities/capabilities/supports (in concert with any other state health IT, technical assistance or workflow effort) to implement effective controls to	▪ DMH/DD/SAS has started a pilot project with NC Medicaid to minimize the risk of inappropriate opioid overprescribing and to ensure that Medicaid does not inappropriately pay for opioids. ▪ Through this pilot, DMH/DD/SAS and NC Medicaid match CSRS data with Medicaid claims data to identify	▪ DMH/DD/SAS and NC Medicaid will work to expand the pilots and run reports analyzing all Medicaid claims for opioid prescriptions on a monthly basis. ▪ Following the managed care transition, standard plans (as	▪ Expand pilots to run reports analyzing all Medicaid claims for opioid prescriptions on monthly basis. ▪ DMH/DD/SAS and NC Medicaid will meet to plan for: (1) cleaning and

	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program Functionalities			
minimize the risk of inappropriate opioid overprescribing and to ensure that Medicaid does not inappropriately pay for opioids.	Medicaid prescribers who may be overprescribing opioids, as well as patients who may be at risk of developing or have OUDs.	of November 2019) and BH I/DD tailored plans (as of July 2021) will be required to submit pharmacy encounter data to the Department on a weekly basis. ▪ Once NC Medicaid receives the encounter data, it will clean and process the data to identify opioid prescriptions and share with DMH/DD/SAS to identify (1) prescribers who are overprescribing opioids, and (2) patients who have or may be at risk of developing OUDs.	processing data received from standard plans and BH I/DD tailored plans, and (2) sharing information on prescribers who may be overprescribing opioids and patients who have or may be at risk of developing OUDs. **Timeframe**: September 2018 - July 2021

10. North Carolina has sufficient health IT infrastructure at every appropriate level (i.e., state, delivery system, health plan/MCO and individual provider) to achieve the goals of this demonstration.

11. North Carolina's SUD Health IT Plan is aligned with the state's broader State Medicaid Health IT Plan (SMHP).

12. The Department will include appropriate standards referenced in the ONC Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B in subsequent PHP contract amendments or PHP re-procurements.

Attachment A, Section II—Implementation Administration

Please provide the contact information for the state's point of contact for the SUD Health IT Plan.

Name and Title: Katherine Nichols, Assistant Director, DMH/DD/SAS
Telephone Number: 919-715-2027
Email Address: Katherine.Nichols@dhhs.nc.gov

Attachment A, Section III—Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

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)[36]

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.[37] 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.[38]

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

    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."

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[36] 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.

[37] *Ibid*.

[38] 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.

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: Healthy Opportunities Pilots Eligibility and Services

Beneficiaries eligible for Healthy Opportunities Pilots services (as described in Table 3) must be eligible for the services via STC 21(T)(i) and meet at least one needs-based criteria (as described in Table 1) and at least one risk factor (as described in Table 2). The state can request changes to Attachment G over the course of the demonstration and CMS will review and approve (if appropriate) all changes within 45 days from submission.

Eligible Enrollees

Table 1: Needs-Based Criteria

Eligibility Category	Age	Needs-Based Criteria (at least one, per eligibility category)
Adults	21+	• 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 mental illness, chronic neurological disease, chronic infectious disease, cancer, autoimmune disorders, chronic liver 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. • Former placement in North Carolina's foster care or kinship placement system. • Previously experienced three or more categories of adverse childhood experiences (ACEs).
Pregnant Individuals	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 • Former or current placement in NC's foster care or kinship placement system • Previously experienced or currently experiencing three or more categories of ACEs

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
	0-20	• 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 $>85^{th}$ percentile 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 or previously experienced 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 or formerly enrolled in North Carolina's foster care or kinship placement system

Table 2: Risk Factors

Risk Factor	Definition
Homelessness or housing insecurity	Homelessness, as defined in 42 C.F.R. § 254b(h)(5)(A), or housing insecurity, as defined based on the principles in the questions used to establish housing insecurity in the Accountable Health Communities Health Related Screening Tool or the North Carolina Social Determinants of Health (SDOH) screening tool.[39,40]
Food insecurity	As defined by the US Department of Agriculture commissioned report on Food Insecurity in America:[41] • 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 Or food insecure as defined based on the principles in the questions used to establish food insecurity in the North Carolina Social Determinants of Health (SDOH) screening tool.[42]
Transportation insecurity	Defined based on the principles in the questions used to establish transportation insecurities in the Accountable Health Communities Health Related Screening Tool or the North Carolina SDOH screening tool.[43]
At risk of, witnessing, or experiencing interpersonal violence	Defined based on the principles in the questions used to establish interpersonal violence in the Accountable Health Communities Health Related Screening Tool or the North Carolina SDOH screening tool.[44]

[39] The Accountable Health Communities Health-Related Social Needs Screening Tool. Available https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.
[40] North Carolina's SDOH Screening Questions. Available: https://www.ncdhhs.gov/about/department-initiatives/healthy-opportunities/screening-questions
[41] USDA Economic Research Service [Internet]. Washington: USDA Economic Research Service; [updated 2017 Nov 27]. Definitions of Food Insecurity; [updated 2017 Oct 4; cited 2017 Nov 27]. Available from: https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security/
[42] North Carolina SDOH Screening Tool. Available: https://www.ncdhhs.gov/about/department-initiatives/healthy-opportunities/screening-questions
[43] *Ibid*
[44] *Ibid*.

Healthy Opportunities Pilots Services

Table 3: Healthy Opportunities Pilots Services

Service Sub-Category	Healthy Opportunities Pilots 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 the functional needs assessment, including establishing measurable goal(s) as part of the overall person centered plan. • Developing a crisis plan for an individual, 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 individual 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 individual's health.

	• Assessing potential health risks to ensure living environment is not adversely affecting an individual's 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 essential household items. This pilot service and the assistance and items furnished under this service are coverable only to the extent they are reasonable and necessary as clearly identified through an individual's care plan and the individual 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 individual's care plan and the individual 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 an individual's health condition, as documented by a health care professional, and remediation is not covered under any other program or provision of law, such as tenancy law. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an individual's care plan and the individual 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 an individual's health and the modification is not covered under any other provision such as the Americans with Disabilities Act.
Legal Assistance	• Assistance with connecting the individual 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 an individual's security deposit and first month's rent provided that such funding is not available through any other program. This payment may only be made once for each individual 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 individual's care plan and the individual 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 individual with applications for SNAP and WIC. • Assist the individual with identifying and accessing school based food programs. • Assist the individual with locating and referring individuals to food banks or community-based summer and after-school food programs. • Nutrition counseling and education for the individual, 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" for the individual, provided that such supports are not available through any other program. Meal and food support services must be provided according to the individual'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 involvement for the individual. • Providing educational assistance to the individual 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 individual'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 individual's care plan, and transportation services will not replace non-emergency medical transportation as required under 42 CFR 431.53. Whenever possible, the individual will utilize family, neighbors, friends, or community agencies to provide transportation services.
Interpersonal Violence (IPV)/Toxic Stress	
Interpersonal Violence-Related Transportation	• Transportation services [for who?] to/from IPV service providers for individuals transitioning out of a traumatic situation.

IPV and Parenting	• Assistance with linkages for individuals transitioning out of a traumatic situation to community-based social service and mental health agencies with IPV expertise.
Support Resources	• Assistance with linking the individual to high quality child care and after-school programs. • Assistance with linkages to programs that increase adults' capacity to participate in community involvement 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 individual 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 Maternal, Infant, and Early Home Visiting services 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.

Attachment H
Healthy Opportunities Pilot
Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol

In accordance with North Carolina's Section 1115 Demonstration Waiver and Special Terms and Conditions (STCs 21P.i to 21P.ix.), this protocol outlines key features of Pilot funding mechanics and approach to monitoring and program integrity as required by STC 21P.vii. North Carolina has been authorized for up to $650M in expenditure authority to establish the Healthy Opportunities Pilots in two to five regions of the state. This protocol outlines 1) Pilot Funding Flow and 2) Healthy Opportunities Pilot Program Integrity.

1. **Pilot Funding Flow**. The state must distribute funding for authorized Pilot services and capacity building. The approach to Pilot funds flow is described below.
   a. ***Pilot Service Delivery Allocation***. The state distributes a capped allocation of funding to each HOP Administrator[45] based on a state-developed methodology which considers regional Medicaid/CHIP enrollment to support the delivery of authorized Pilot services to the HOP Administrator's beneficiaries who are eligible for the Pilot services, inclusive of an administrative fee to support the HOP Administrators' and their contracted care managers' Pilot-related operational responsibilities. The majority of the cumulative service payment must be used to pay for the delivery of Pilot services. HOP Administrators must only use the allocation for the Pilot specified purposes and must return all unused Pilot funds to the state.
      i. The HOP Administrator, in collaboration with the Network Lead (NL)[46] tracks and reports the services provided to beneficiaries, ensuring accountability for service delivery and payment, and tracking against its fixed allocation of Pilot funding. To pay for delivered services, HOP Administrators receive Pilot service invoices[47] and distribute funds to Human Services Organizations (HSOs) for the delivery of authorized Pilot services.
      ii. The state conducts periodic audits of payments to verify accurate reporting and spending.
      iii. The state conducts quarterly reviews of HOP Administrator spending against capped funds.
      iv. FFP will be based on the aggregated amounts actually paid by the state to HSOs, NLs, and HOP Administrators for authorized Pilot purposes, as defined in the Pilot STCs.
   b. ***Service Reimbursement Methods.*** The state developed a Pilot service fee schedule and submitted to CMS for approval on August 30, 2019. It was approved in November 2019 and updated in February 2023. The fee schedule provides service definitions and reimbursement rates for each Pilot service. Pilot services are reimbursed through the following payment methods, at a minimum: fee-for-service, cost-based reimbursement and per member per month (PMPM) payments.
      i. Fee for Service (FFS). Some Pilot services are paid on an FFS basis (e.g., targeted

[45] HOP Administrator is defined as any managed care entity providing HOP services during the course of the demonstration.
[46] Previously referred to as the "Lead Pilot Entity" or "LPE."
[47] North Carolina intends to shift Pilot "invoices" to "claims" during the course of the Demonstration.

nutritious food or meal delivery services for individuals with medical or medically-related special dietary needs).

ii. Cost-Based Reimbursement Up to a Capped Amount. Some Pilot services are paid based on the actual billed cost of the service up to a state-defined cap (e.g., cost of public transportation that enables a beneficiary to access Pilot services, expenses related to utility set-up and security deposit).

iii. PMPM Payments. Some bundles of Pilot services are paid for via an assigned PMPM payment rate (e.g., housing navigation, support and sustaining case management services). The PMPM rate reflects the intensity and type of included activities, based on evidence-based averages, but allows for setting and frequency of specific activities to vary based on the beneficiaries' circumstances and local resources. PMPM payments must not include additional fee for service amounts and must be accepted as payment in full.

c. ***Capacity Building.*** The state must provide funding to the Network Leads (NLs)[48] to build their capacity to participate in the Pilot. Capacity building for the Pilot will be considered an administrative cost and must be capped at $100 million. Unspent capacity building funding must be used for authorized Pilot program purposes only.

i. The NL may use this capacity building funding only to:

a. Through collaboration with stakeholders (HOP Administrators, social services agencies, Community Based Organizations), develop necessary infrastructure/systems to prepare HSOs to deliver authorized services, receive payment, report information for managing patient care, track progress in Pilot implementation, collect all applicable data to support monitoring beneficiary take-up and health and quality of care outcomes, and ensuring program integrity, including distributing capacity building funding to contracted HSOs to help them execute preparation for Pilot participation.

b. Providing technical assistance and collaboration with stakeholders.

ii. NLs will be eligible for capacity building funding not to exceed $100M over the course of the demonstration. NLs will distribute a portion of the capacity building dollars to eligible HSOs.

iii. Each NL receives an annual administrative payment from the Department. Capacity building funding is time-limited and covers start-up costs, while administrative payments support ongoing costs associated with Pilot-related operational responsibilities.

d. ***Pathway to Value-Based Payment***. The state must establish an incentive payment program to incorporate value-based payments (VBP) to incentivize the delivery of high-quality services to Pilot enrollees. North Carolina intends to advance the VBP program annually, evolving the use of measurement milestones each year and introducing withholds in addition to incentive payments in the later years of the Pilots. Due to North Carolina's delay implementing the managed care and Healthy Opportunities Pilot components of the demonstration, this protocol is applicable only for the time period from June 1, 2021 through October 31, 2024. The VBP Program for HOP administrators is

[48] Previously referred to as the "Lead Pilot Entity" or "LPE."

currently only available to PHPs[49]. Should North Carolina open the program to the additional managed care entities that serve as HOP Administrators, the state must update the protocol and submit to CMS for review and approval 60 days prior to desired implementation. The funding for the VBP program must be a subset of the $650 million authorized for the Healthy Opportunities Pilot program. Funding available for VBP is a small portion of non-capacity building Pilot funds. The state is allocating up to $10 million across three periods for the VBP program. Actual payment amounts will depend on Pilot entities meeting the specific performance metrics and targets as determined by North Carolina and as described below. Unearned VBP incentive funds will be made available for service delivery funding. North Carolina intends to design the VBP program as follows:

i. **Year-by Year Pilot VBP Program Approach**: VBP payments to participating entities will be linked to meeting performance targets on defined metrics that are commensurate with the pilot launch and implementation stages, as well as entities' operational ability to identify, engage, enroll and deliver high-quality services to meet members' needs and improve health outcomes. The performance targets tied to the VBP payments that participating entities are eligible to receive will evolve and increase over the course of the three VBP periods.
    a. The state defines "VBP periods" to align with Pilot and Medicaid managed care service delivery years to the greatest extent possible, which are distinct from demonstration years, as defined below.
    b. North Carolina intends for the Pilot VBP Program to evolve over the course of the demonstration as follows:
        i. **VBP Period 1 (June 1, 2021 to June 30, 2022):** VBP Period 1 covers 13 months of implementation where Standard Plans and NLs will build capacity and ensure operational readiness to launch the Pilots. It also covers the first four months of service delivery, during which time the majority of Pilot services will launch and Pilot entities will begin enrolling and delivering Pilot services for the first time. Activities tracked toward completion and/or meeting milestones during VBP Period 1 include adapting processes to ensure all aspects of the program are operational, establishing an HSO network, providing training to providers and care management staff, and establishing payment and data and metrics reporting processes.

            In VBP Period 1, Standard Plans and NLs are eligible for incentive payments. Incentive payments for Standard Plans must reflect their key role in standing up and implementing the pilots. The state must require that incentive payments for NLs are only made if the NL meets key metrics and timelines established through the contracting process related to establishing provider networks, payment and reporting systems, and training. The state describes the performance metrics and targets for this Period in **Table 1** below. Once a milestone is met, Standard Plans and NLs submit an invoice

[49] North Carolina's PHPs are MCOs as defined under 42 CFR 438.2. The following PHPs are offered in North Carolina: Standard Plans, Behavioral Health Intellectual/Developmental Disability Tailored Plans and the Children and Families Specialty Plan.

to the state for payment associated with meeting that milestone. The state will split available funds for VBP Period 1 approximately 60/40 between Standard Plans and NLs (respectively) for their corresponding milestones. There are no partial payments for each milestone. The state will report on incentive payments paid out in the Quarterly and Annual Monitoring Reports following distribution of payments.

Table 1: VBP Period 1 Milestones			
Standard Plans			
#	**Milestone**	**Milestone Deadline**	**% Weight**
1	Execute contracts with all Network Leads that are operating in a PHP's region	11/22/2021	30%
2	Successful completion of Division of Health Benefits (DHB) Readiness Review to implement the Pilots	5/13/2022	35%
3	Meet DHB Pilot-related systems integration and end-to-end testing standards related to Pilot eligibility, service authorization, referral, invoice and payment	3/14/2022	35%
Network Leads			
#	**Milestone**	**Milestone Deadline**	**% Weight**
1	Establish an HSO capacity building payment distribution approach	30 days after Network Lead's receipt of the Department's Network Lead-HSO model contract	14.3%
2	Establish reporting processes for contracted HSOs to adhere to	90 days after contract execution	14.3%
3	Disburse first capacity building funds to HSOs	30 days after the Department has approved an individual HSO's capacity building request.	14.3%
4	Receive DHHS approval on HSO Network Report	HSO Network Report must be submitted within 60 days of the Department's approval of	21.4%

		the Network Lead's HSO Network Application and HSO Assessment Process with subsequent Department approval.	
5	Complete implementation year training, technical assistance, and engagement as outlined in the Network Lead's Pilot entity engagement, training, and technical assistance Plan	The day before Pilot service delivery launch	14.3%
6	Pass DHB readiness evaluation, including that the Network Lead's HSO network is prepared to deliver services	**The day before Pilot service delivery launch**	**21.4%**

ii. **VBP Period 2 (July 1, 2022 to June 30, 2023):** VBP Period 2 represents 12 months of Pilot service delivery. During VBP Period 2, the state will advance VBP from distributing incentive payments for meeting implementation milestones to distributing incentive payments for meeting or exceeding pre-established targets on performance metrics. PHPs, specifically Standard Plans, and NLs in collaboration with their contracted care management entities and HSOs, respectively, will be eligible for incentive payments.

In addition, the Behavioral Health and Intellectual/Developmental Disabilities Tailored Plans (henceforth referred to as Tailored Plans or TPs) will launch their Pilot service delivery after the Standard Plans. As such, Tailored Plans will start participation in the Pilot VBP program during VBP Period 2. During this timeframe, TPs will be working on standing up the necessary infrastructure to participate in the Pilot program. For this reason, the TPs will be eligible to earn the same Pilot implementation-related milestones during VBP Period 2 as Standard Plans were eligible to receive during VBP Period 1, as outlined in **Table 2** (e.g., between July 1, 2022 and June 30, 2023, TPs will be eligible to receive incentive payments for the successful completion of a DHB readiness review).

In VBP Period 2, Standard Plans and NLs will be eligible for incentive payments for meeting or exceeding Pilot performance standards related to: (a) enrollment and/or service delivery performance measures and (b) operational performance and financial management measures. The state describes the performance metrics for this Period in **Table 3**. Distribution of incentive payments is contingent upon all Pilot entities across all Pilot regions collectively meeting a minimum overall Pilot enrollment of 8,100 by March 31st, 2023. In the event that this Pilot enrollment threshold is not met, the state has discretion to pause or withhold distribution of VBP payments

for all measures to any and all Pilot entities. The state will distribute funds evenly between Standard Plans and NLs. The state will pay Standard Plans and Network Leads for each milestone that is met by the listed measurement period according to a payment schedule, as determined by the state. If earned, Standard Plans and NLs are contractually required to share a percentage of their earned payments with their contracted care management entities and HSOs, respectively, reflective of the level of effort contributed by each Pilot entity in achieving the milestones, as determined by the state. Once a milestone is met, Standard Plans and NLs submit an invoice to the state for payment associated with meeting that milestone. There will be no partial payments. Earned incentive payments will be distributed after the conclusion of VBP Period 2. If one or more Pilot entities fail to meet milestone(s) and earn payment, the unearned funds will be available for Pilot service delivery. The state will report on incentive payments paid out in the Quarterly and Annual Monitoring Reports following distribution of payments.

Table 2: VBP Period 2 Milestones for Tailored Plans

#	Milestone	Milestone Deadline	% Weight
1	Execute contracts with all Network Leads that are operating in a Tailored Plan's region	12/1/2022	30%
2	Successful completion of Division of Health Benefits (DHB) Readiness Review to implement the Pilots	3/31/2023	35%
3	Meet DHB Pilot-related systems integration related to Pilot eligibility, service authorization, referral, invoice, and payment	3/31/2023	35%

Table 3: VBP Period 2 Milestones

Standard Plans and Local Care Management Entities

#	Milestone	Measurement Period	% Weight
	Pilot Enrollment and Service Delivery Performance Measure		
1	Meet or exceed a Pilot enrollment target, as set by the Department for each Standard Plan	6/30/2023	75%

Operational Performance and Financial Management Measure			
2	75% of HSO invoices are reviewed and paid within 45 calendar days of Standard Plan receipt.	6/30/2023	25%
Network Leads and HSOs			
#	**Milestone**	**Measurement Period**	**% Weight**
Pilot Enrollment and Service Delivery Performance Measure			
1	Meet or exceed delivery of a defined number of total Pilot services, as set by the Department for each Network Lead	6/30/2023	75%
Operational Performance and Financial Management Measure			
2	75% of HSO invoices are submitted to Standard Plans within 45 calendar days of Pilot service completion.	6/30/2023	15%
3	Demonstrate commitment to the long-term sustainability of Network Leads and HSOs in the healthcare delivery system by developing a plan that demonstrates the ways in which the Network Lead intends to have a meaningful role in its community and the health care system beyond the length of the Pilots. VBP in future years may be tied to successfully implementing these plans.	12/31/2022	10%

i. **VBP Period 3 (July 1, 2023 to October 31, 2024):** VBP Period 3 represents 16 months of Pilot service delivery. In VBP Period 3 the state will advance VBP by establishing withholds for exceeding resource outcome benchmarks. Additionally, in a pilot's third year, the state must evaluate whether NLs and Pilot program services are effective in addressing beneficiaries' unmet social needs. Within two weeks of CMS's approval of Attachment H, the state must submit for CMS review and approval an update to the Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol that includes the following:

1. Specific quality measures that will be collected to generate baselines on health outcomes and a description of the data sources and period(s) of

performance for calculating baselines.

2. Milestones that address Pilot enrollees' unmet resource needs (e.g., how many Pilot enrollees who have an unmet resource need have received a Pilot service) and a description of how withholds will be tied to those milestones related to unmet resource needs in VBP Period 3.

The state must propose metrics that meet the requirements above, or will have be required to pause disbursement of all Pilot-related incentive payments related to VBP Period 3 until a protocol is approved. If there is not an approved protocol by January 1, 2024, the state will not be permitted to claim FFP for incentive payments for performance in the entirety of VBP Period 3. CMS commits to reviewing and providing feedback within three weeks of a submission of a protocol from the state.

As part of VBP Period 3, the state will collect and generate baseline data on the selected health outcomes data measures specified in the Funding Mechanics, Pathways to Value Based Payment, and Program Integrity Protocol to be approved by CMS. The state will share baseline findings with all Pilot entities and with CMS prior to the end of the demonstration period.

The state plans to engage Pilot-participating entities in the development of VBP Period 3 milestones to foster a collaborative design process and to socialize these designs with key entities prior to implementation. Pilot-participating entities will provide key "on-the-ground" experiences and insights that will help determine appropriate milestones that advance the goals of the Pilot program.

In addition to incentive payments, the state will apply withholds to Standard Plans and local care management entities for failing to meet minimum measures related to addressing the unmet needs of members. Additionally, Standard Plans and NLs, in collaboration with their contracted care management entities and HSOs, respectively, will remain eligible for incentive payments. If earned, PHPs and NLs will be required to share payments with their contracted care management entities and HSOs, respectively. During VBP Period 3, Local Health Departments, a new local care management entity for the Pilot, will also be eligible for incentive payments.

For Tailored Plans, VBP Period 3 will be the first full 16 months of Pilot service delivery. They will be eligible to earn incentive payments for the same performance-related milestones as the Standard Plans in VBP Period 2. The state will develop specific enrollment targets for Tailored Plans and their contracted local care management entities and provide the funding distribution between Tailored Plans and local care management entities.

2. **Healthy Opportunities Pilot Program Integrity.** North Carolina will monitor and enforce program integrity standards in the Pilot program, across all aspects of the program. In particular, the state will maintain program integrity standards in the Pilot program through the following mechanisms:
    a. **Accounting on delivered Pilot services**
        i. Invoices[50] must be transmitted in accordance with all federal and state privacy and security requirements. Invoices must include the following standardized information[51]:
            1. Beneficiary name and Medicaid/CHIP identification number
            2. Provider organization (HSO) name
            3. Name of service(s) rendered
            4. Date(s) and/or duration of service(s) delivered
            5. Number of unit(s) of service(s) delivered, if applicable
            6. Cost of service(s) delivered
        ii. NL Role. To develop and manage the HSO network, the NL must use an infrastructure allowing:
            1. HSOs to submit invoices for delivering authorized Pilot services.
            2. The NL to submit invoices to the HOP Administrators for reimbursement.
            3. The NL to track payment status to HSOs.
        iii. HOP Administrator Role. HOP Administrators are responsible for paying HSOs for the delivery of Pilot services. HOP Administrators are required to review the invoices submitted by the NL to ensure they contain all of the required elements and that they are for authorized services prior to paying the invoices. HOP Administrators will be required to submit the following information at a minimum annually to the state:
            1. Number of Pilot enrollees who have received a Pilot service
            2. Number of invoices submitted to the HOP Administrator
            3. Number and type of Pilot services delivered
            4. Number of HSOs that delivered Pilot services
            5. Total costs expended in relation to HOP Administrator's capped allocation
    b. **Audit Process.** The HOP Administrator and Network Lead are required to ensure Medicaid payments are made for services covered under this Pilot program that were provided and properly billed and documented by the HSOs through the following processes:
        i. Invoice Analysis. HOP Administrators and NLs are required to analyze invoices submitted by the HSOs to: (1) ensure that they accurately and appropriately represent the delivery of authorized services, and (2) identify irregularities, discrepancies, or outliers requiring further investigation. NLs are required to work with HOP Administrators and HSOs to resolve identified issues.

[50] North Carolina intends to shift Pilot "invoices" to "claims" during the course of the Demonstration.
[51] North Carolina may make adjustments to information required in invoices to ensure compliance with federal or other requirements to preserve member privacy and confidentiality in the context of interpersonal violence related services.

ii. Visit Verification Procedures. In accordance with the state's Medicaid program integrity requirements, NLs are required to regularly validate that services delivered through the Pilots were appropriately rendered and properly billed and documented by HSOs through conducting visit verification procedures on a random sample of claims/invoices. Verification procedures may include:

1. Outreach to beneficiaries to confirm receipt of services
2. Outreach to providers to require documentation of provided services.

As part of the state's overarching oversight strategy, the state will develop a methodology for reviewing and monitoring the NL's visit verification policies including reviewing their procedures related to 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 HOP Administrators and NLs to monitor payments and identify issues of overpayment. HOP Administrators and NLs must regularly monitor their payments to HSOs to identify potential overpayments. If an overpayment is discovered, the HOP Administrator or NL must calculate the overpayment amount and the HSO must return the overpayment within 180 days of notification.

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 HOP Administrator or NL to impose a payment suspension or withhold on any provider, including HSOs and NLs, due to potential or actual instances of fraudulent behavior.
2. The state, HOP Administrators and NLs will have the right to terminate an HSO or 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 HOP Administrator or its contracted care management entities, NL, or HSO.
4. NLs must submit a written report to the Department immediately if it suspects that an HSO may have engaged in fraud, waste and/or abuse and the names of HSOs that have had Pilot service payments suspended or withheld or had their contract terminated. Additionally, NLs must report at a minimum annually to the state on all HSO terminations or non-renewals including those that are due to fraudulent behavior or were initiated by the NL, a HOP Administrator or the state. HOP Administrators must notify the Department within five business days if it

suspects Pilot-related fraud, waste and/or abuse.

iii. Auditing compliance. The state has the discretion to audit HOP Administrators and NLs to ensure their compliance with the Pilot program requirements and take action to address any identified non-compliance.

Reserved for:

ATTACHMENT I
Monitoring Protocol for Other Policies