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

September 16, 2022

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

Dear Mr. Richard:

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 Act. Approval of this demonstration amendment will expand eligibility for the state's existing demonstration initiative called "Healthy Opportunities Pilots" to individuals covered in the state's Separate Children's Health Insurance Program (S-CHIP), and will authorize Title XXI expenditure authority. This amendment is effective as of the date of this approval.

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 CHIP state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable to expenditures under the demonstration.

Consistent with CMS's requirements for monitoring and evaluation of section 1115 demonstrations, and as outlined in the demonstration STCs, the state is required to continue conducting systematic monitoring and a robust evaluation of its North Carolina Medicaid Reform Demonstration, per applicable CMS guidance and technical assistance. Overall, the evaluation must produce a thorough assessment of whether the demonstration initiatives are effective in producing the desired outcomes for its beneficiaries and the state's Medicaid and CHIP programs. As such, the state is required to review and revise the Evaluation Design to incorporate this amendment, as appropriate. The state must also ensure the demonstration's monitoring reports reflect any changes to the demonstration, as approved in this amendment. The demonstration's monitoring and evaluation 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.

Extent and Scope of Demonstration

North Carolina requested a demonstration amendment to expand eligibility for the Healthy Opportunities Pilots (formerly known as Enhanced Case Management) to S-CHIP beneficiaries. The Healthy Opportunities Pilots establish a public-private regional pilot program in three locations throughout the state, with a focus on providing information, benefits, and services to improve health and lower costs. The pilot program is structured to employ evidence-based interventions for Medicaid beneficiaries addressing housing instability, transportation insecurity, food insecurity and interpersonal safety and toxic stress. In order to qualify for pilot services, beneficiaries must be Medicaid managed care enrollees, live in a pilot region, and must meet at least one health needs criteria and at least one risk criteria, as described in the STCs. Because S-CHIP beneficiaries are not Medicaid enrollees they are not eligible to receive pilot services.

This amendment will add S-CHIP beneficiaries ages 6-19, with family incomes up to 211 percent of the federal poverty level (FPL) into the demonstration solely for the purpose of receiving services offered through the Healthy Opportunities Pilots. North Carolina expects that the average monthly enrollment among S-CHIP members would be approximately 800 to 1,200 individuals.

Components of the Proposal Still Under Review

The amendment application also includes several proposed modifications to the demonstration. The amendment seeks to alter the dates of the demonstration, adjust which population will not or must be covered under the Behavioral Health Intellectual/Development Disability Tailored plans, modify implementation details related to the Healthy Opportunities Pilots, and exclude the COVID-19 group from mandatory managed care. These provisions are not being approved at this time, but remain under review for possible future approval.

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 several comments on the amendment during the public notice process but did not receive any specifically related to adding S-CHIP beneficiaries to the demonstration.

CMS received two comments during the federal comment period, February 2, 2022 through March 4, 2022. One comment was not relevant to the S-CHIP proposal. The other comment was supportive of the S-CHIP proposal, citing the importance of addressing social determinants of health, like food insecurity and housing, to improve health outcomes.

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 S-CHIP beneficiaries.

Other Information

The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. Your project officer for this demonstration is Ms. 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. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

[redacted]

Deputy Administrator and Director

Enclosure

cc: Robert Townes, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: **11W00313/4**

TITLE: **North Carolina Medicaid Reform Demonstration**

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

All requirements of the Medicaid program 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**

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 enrolled in a PHP who meet the eligibility criteria specified in the special terms and conditions. The expenditure authority will expire on October 31, 2024.

Title XIX Requirements not applicable to the 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**

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 C: Evaluation Design
Attachment D: SUD Implementation Plan Protocol
Attachment E: SUD Monitoring Protocol
Attachment F: SUD Health Information Technology (Health IT) Protocol
Attachment G: Healthy Opportunities Pilot Program Eligibility and Services

II. PROGRAM DESCRIPTION AND OBJECTIVES

In September 2015, the state passed legislation to transition its Medicaid (Title XIX) program and title XXI funded 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 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, substance use disorder, and intellectual and developmental disability (I/DD), and for children in foster care and North Carolina former foster care youth.
- The implementation of Medicaid 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 Substance Use Disorder (SUD)

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

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 Pilots, previously known as the Enhanced Case Management and Other Services Pilot program.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
2. **Compliance with Medicaid and 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; managed care organization (MCO) reports; state quality assurance monitoring; and any other documentation that validates the quality of care provided or corrective action taken under the demonstration.

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

Management standard questions. If title XXI funding is used in the demonstration, a CHIP Allotment Neutrality worksheet must be included.

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

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

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

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

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

b. Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid 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 comply with all notice requirements found in 42 CFR §431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, State Health Official Letter #10-008.

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

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

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

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

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

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

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR section 431.408(b), State Medicaid Director Letter #01-024, and contained in the state's approved Medicaid 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, the 1915(c) waiver. This demonstration affects all eligibility groups other than those listed in Table 1A and Table 1B. STC 19 applies to eligibility groups eligble for the demonstration and listed in Table 1A, but not in Table 1B. Table 1B lists an eligibility group that is only eligible for the Healthy Opportunities Pilots, STC 21 P.

TABLE 1A: GROUPS EXCLUDED FROM ENROLLMENT IN PHPs

GROUP NAME	CITATIONS
Duals Eligible for Cost-Sharing Assistance • Qualified Medicare Beneficiaries • Qualified Disabled and Working Individuals • Specified Low Income Medicare Beneficiaries • Qualifying Individuals	• 1902(a)(10)(E) • 1905(p)
Duals Eligible for Full Medicaid, except those enrolled in BH I/DD tailored plans	• 1902(e)(8) • 1905(p)(1) • 1935(c)(6)

GROUP NAME	CITATIONS
Medically Needy • Medically Needy Pregnant Women except those covered by Innovations or TBI waivers • Medically Needy Children under 18 except those covered by Innovations or TBI waivers • Medically Needy Children Age 18 through 20 except those covered by Innovations or TBI waivers • Medically Needy Parents and Other Caretaker Relatives except those covered by Innovations or TBI waivers • Medically Needy Aged, Blind, or Disabled except those covered by Innovations or TBI waivers • Medically Needy Blind or Disabled Individuals Eligible in 1973 except those covered by Innovations or TBI waivers	• 1902(a)(10)(C)
Presumptively Eligible • Presumptively Eligible Pregnant Women • Presumptively Eligible MAGI Individuals	• 1902(a)(47) • 1920 • 1920A • 1920B • 1920C
Individuals Participating in the Program of All-Inclusive Care for the Elderly (PACE)	• 1905(a)(26) • 1934
Individuals Receiving Refugee Medical Assistance	• 8 USC § 1522 • 45 CFR Part 400
Individuals Participating in the NC Health Insurance Premium Payment (HIPP) program except those covered by Innovations or TBI waivers	State Plan Eligibility
Individuals with Limited or no Medicaid Coverage (e.g., eligible for emergency services only)	See Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996
Individuals Eligible for Family Planning Services	• 1902(a)(10)(A)(ii)(XXI) • 42 CFR 435.214
Prison Inmates *(Inpatient stays only)*	• Clause (A) following 1905(a)(29)(A) • 42 CFR 435.1009, 1010
Medicaid-only Beneficiaries Receiving Long-Stay Nursing Home Services	State Plan Eligibility
Community Alternatives Program for Children (CAP/C)	1915(c) waiver

GROUP NAME	CITATIONS
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: GROUPS INCLUDED IN THE HEALTHY OPPORTUNITIES PILOTS ONLY

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

V. DEMONSTRATION PROGRAMS AND BENEFITS

19. **Opioid Use Disorder/Substance Use Disorder Program.** 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)	

SUD BENEFIT	***MEDICAID AUTHORITY***	***EXPENDITURE AUTHORITY***
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
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)	

SUD BENEFIT	*MEDICAID AUTHORITY*	*EXPENDITURE AUTHORITY*
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(g) and Attachment F; and

x. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient

facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

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

c. **Mid-Point Assessment.** The state must conduct an independent Mid-Point Assessment by DY 3 (November 1, 2021) of the demonstration. The state must require that the assessor collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The state must require that the assessment include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan Protocol, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol. The state must require that the assessment include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The state must require that the Mid-Point Assessment must also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the state must require the assessor 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 General Reporting Requirements and X Evaluation of the Demonstration of the STCs.

e. **SUD Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, the Evaluation Design, including the SUD program with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

   i. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval 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 documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component must have at least one evaluation question and hypothesis. The hypothesis testing 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.

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

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

1. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."
2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

[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*.
[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.

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

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

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

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

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

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

VI. COST SHARING

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

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

POPULATIONS	DY 2-3[4]	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)[5]	BH I/DD tailored plan
Legal aliens eligible to enroll in BH I/DD tailored plans	Medicaid fee-for-service	BH I/DD tailored plan
Children under age three eligible to enroll in BH I/DD tailored plans	Medicaid fee-for-service (Children 0-3 of age are exempt from LME-MCOs)	BH I/DD tailored plan
Beneficiaries dually eligible for Medicare and Medicaid and enrolled in BH I/DD tailored plans	Medicaid fee-for-service/LME-MCO	Medicaid fee-for-service/BH I/DD tailored plan[6]
Innovations waiver enrollees[7]	Medicaid fee-for-service/LME-MCO	BH I/DD tailored plan
Traumatic Brain Injury waiver enrollees[8]	Medicaid fee-for-service/LME-MCO	BH I/DD tailored plan

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

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:
    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 21(h), that will account for service needs and the following diagnosis categoies:
        i. Serious Mental Illness;
        ii. Serious Emotional Disturbance;
        iii. Severe Substance Use Disorder; 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 2 MCOs. A beneficiary who does not make an MCO selection at the time of application may be auto-assigned to a MCO by the state consistent with 42 C.F.R. § 438.54(d)(5). Upon enrollment, whether by auto-assignment or enrollee selection, the state or its designee must send a notice to enrollees confirming their enrollment in the plan. Pursuant to 42 C.F.R. § 438.56, beneficiaries must have 90 days to change plans after initial enrollment and at least once every 12 months thereafter.

H. **BH I/DD Tailored Plan Enrollment and Specialized Plan for Children in Foster Care and Formerly in Foster Care Enrollment.** 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**. Beneficiaries eligible for the BH I/DD Plan, Specialized Plan for Children in Foster Care and Formerly in Foster Care may disenroll from either a BH I/DD Tailored Plan or specialized plan pursuant to STC 19(g) into a Standard Plan, but will lose access to the specialized services offered under those specialized plans. An eligible beneficiary must have the option to re-enroll in a BH I/ DD Tailored Plan or the Specialized Plan for Children in Foster Care and Formerly in Foster Care at any time following the beneficiary's voluntary disenrollment.

J. **BH I/DD Tailored Plans Benefits**. Specialized behavioral health services, including Innovations and TBI waiver services and services covered under 1915(b)(3) 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 will implement Managed Care in two state regions by November 2019 and the remaining four regions must be implemented by February 2020. The state will implement each plan type according to the following schedule:

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

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

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

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

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

   i. Eligibility. Under the demonstration, there is no change in Medicaid 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.

   ii. HCBS Authority. The 1915(c) waivers of NC-0423.R02.00 and NC-1326.R00.00 will continue to be the authority under which HCBS operates until such time the State Medicaid Agency requests and receives approval of an 1115 amendment to incorporate the 1915(c) services into the section 1115 demonstration. The state must follow the section 1915(c) amendment process to make alterations to its HCBS waivers. The state must notify CMS demonstration staff in writing of any proposed amendments to the 1915(c) waivers concurrently with the submission of the 1915(c) amendment.

P. **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 21(P)(vi)(d) below), to establish the public-private

regional Healthy Opportunities Pilot program (the "pilot program") in two to four regions of the state to serve approximately 25,800 to 51,200 Medicaid, M-CHIP, and S-CHIP beneficiaries throughout the state during the demonstration approval period of November 1, 2019 through October 31, 2024. The $650 million is the total expenditure authority for the Healthy Opportunity Pilots; however, the state is only granted $118 million in Title XXI expenditure authority. The state cannot spend over $650 million for the Healthy Opportunities Pilot over the course of the five-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 eligible enrollees to determine if the target population criteria is met related to the following four risk factors of the pilot: housing instability, food insecurity, transportation insecurity, and interpersonal violence/toxic stress. The state must require that each participating PHP determines the services to be provided and will review the plan of care with the enrollee after the assessment is complete. Following implementation of the pilot program, the state must require that each participating PHP: review the pilot services the enrollee is receiving every three months to verify the services are meeting the needs of the enrollee; and reassess the enrollee's eligibility in the pilot program every six months.

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

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

ii. Enrollees Determined Ineligible. The state must require that enrollees determined ineligible must have the opportunity to request to have their eligibility status be reassessed when there is an indication the enrollee's health status or social risk

factors have changed. Upon a determination of ineligibility, the state must require that PHP will communicate to the enrollee the process to request a reassessment. Eligibility reassessments will consist of utilizing the same tools and staff previously used to evaluate the enrollee in the initial assessment.

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

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

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

   a. Developing, contracting with, and managing a network of pilot providers to deliverHealthy Opportunity Pilot program services, including community-based organizations (CBOs), social service agencies and healthcare providers.
   b. Convening pilot providers and PHPs to establish a governance structure consistent with state guidelines, and determine operational roles, responsibilities and procedures.
   c. Developing an infrastructure for reimbursing and tracking reimbursement to pilot providers and payment protocols and procedures.
   d. Working in collaboration with PHPs, pilot providers, and other stakeholders to determine locally available and appropriate Healthy Opportunity Pilot program services based on the pilot provider network.

e. Providing technical assistance to PHPs, pilot providers, and other stakeholders on Healthy Opportunity Pilot program services and sharing best practices across regions.
f. Working in collaboration with PHPs to track provision of Healthy Opportunity Pilot program services and data collection to report on metrics needed for rapid cycle evaluation and summative evaluation.
g. Participation in "learning communities" to ensure that the pilot regions are sharing and adopting best practices throughout the duration of the five-year demonstration period of November 1, 2019 through October 31, 2024.

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

vi. Pilot Funding Flow. The state must distribute funding for pilot-related authorized services and capacity building.
a. Pilot Services Payment. The state must distribute funding to the PHPs from a PHP specific capped allocation based on the volume and cost of pilot services delivered to its pilot-enrolled beneficiaries inclusive of a PHP administrative fee. The administrative fee will be determined by the state and will be a component of pilot service payments, but the majority of the service payment must be used to pay for the delivery of pilot services. The state must require that the PHPs distribute the payments to the LPE. The state must require the PHPs to implement the requirement that the LPE distribute the funds to a network of providers authorized to deliver pilot services based on standards and requirements set forth by the state.
i. The state must require that the PHP, in collaboration with the LPE, track and report the services provided to beneficiaries, ensuring accountability for service delivery and payment, monitoring against fixed allotments, and bundled services updates.
ii. The state must develop a methodology for PHP funding allocation based on the regional participants and establish reporting requirements.

iii. The state must conduct periodic audits of payments to verify accurate reporting and spending.
iv. The state must conduct quarterly reviews of PHP spending against capped funds.
v. FFP will be based on the aggregated amounts actually paid by the state to providers, LPEs, and PHPs for authorized pilot purposes, as defined in these STCs.

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

c. Incentive Payments to PHPs for Pilot Services. Any incentive payments that meet the definition of incentive arrangement under 42 CFR 438.6(a) must meet the requirements of 42 CFR 438.6(b). To the extent that the state directs managed care plans under this pilot program to pay providers, such arrangements will be consistent with 42 CFR 438.6(c). The state must work with CMS to identify all 438.6(c) payments prior to the start of the pilot program and prior to the submission of their rates and contracts as required under 42 CFR 438.4 and 438.5.

d. Capacity Building. The state must provide funding to the LPEs to build capacity. Capacity building for HOP will be considered an administrative cost

and must be capped and time limited. The pilot funding is capped at $100 million for pilot regions that begin their first pilot year in the time period between November 1, 2019 through October 31, 2021. LPEs will be eligible for capacity building funding for up to two years after their contractual effective date. Unspent capacity building funding must be used for authorized HOP purposes only. The state must notify CMS prior to shifting capacity building funding to any other authorized purposes.

i. The state must require that the LPE may use this capacity building funding only to:
    a. Through collaboration with stakeholders (PHPs, social services agencies, Community Based Organizations), develop necessary infrastructure/systems to prepare providers to deliver authorized services, receive payment, and reporting of information for managing patient care, monitoring outcomes, and ensuring program integrity.
    b. Providing technical assistance and collaboration with stakeholders.

e. Pathway to Value-Based Payments. The state must establish an incentive payment fund to incorporate value-based payments to incentivize the delivery of high-quality care by increasingly linking payments for pilot program services to health and socioeconomic outcomes based on the pilot services provided during the demonstration and gathering the required data and experience needed for more complex risk-based models. The funding for the incentive payment fund must be a subset of the $650 million authorized for the Healthy Opportunities Pilot program.

i. Pilot Year 1: Incentives for meeting pilot implementation measures. A pilot's first year will begin the state's collaboration with the LPEs and PHPs for launching the pilots, including establishing a pilot provider network, providing training to providers and care management staff, and establishing payment and reporting processes. The state must require that the PHPs and LPEs complete all of these activities before any PHPs begin delivering pilot services; however, LPEs may continue to expand their provider networks, provide ongoing training, and refine their payment and reporting process after they begin delivering services. To ensure the pilots launch in a timely manner, the state must establish an incentive payment fund to provide rewards for achieving or surpassing specific metrics. Incentive payments for PHPs must reflect their key role in standing up and implementing the pilots (e.g., Completing implementation of a robust pilot-specific training series for care managers in pilot region(s); and Completion of readiness testing on data collection and reporting systems to support oversight and evaluation). The state must require that incentive payments for LPEs are only made if the LPE meets key metrics and timelines established through the contracting process related to establishing provider networks, payment and reporting systems, and training.

ii. Pilot Year 2: Incentives for meeting service delivery performance metrics. During a pilot's second year, participating PHPs must begin enrolling beneficiaries and delivering pilot services. Incentive payments must be provided to PHPs and LPEs based on role specific criteria.

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

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

iv. Pilot Year 4: Withholds for exceeding health and utilization outcome benchmarks. In a pilot's fourth year, the state must begin withholding a

share of the LPE payments contingent on achieving specific targets for their enrollees' healthcare utilization and health outcomes.

a. The state must require that LPE benchmarks be designed to take into account the eligible populations, services provided and related outcome measures, for example reductions in hospital admissions related to uncontrolled diabetes in adults and pediatric pilot enrollees receiving medically tailored meal services. At a minimum, the outcome measures selected for the LPE withhold design must align with the state's Medicaid Managed Care Quality Measures, to which the PHPs are being held accountable through robust requirements, incentives and withholds in the Medicaid managed care program. By combining the PHPs' and LPEs' goals, the entities have aligned financial incentives to deliver high-quality medical, behavioral and social services that improve beneficiaries' health.
b. Pilot providers will receive a percentage of the LPE's earned withhold payments based on the LPE's state approved plan for sharing any earned withhold payments with pilot providers that have contributed to the improvements in outcomes by delivering high-quality services.
c. The state must require that the PHPs withhold payments in a pilot's fourth year must be linked to their capacity to exceed expectations related to data collection and reporting requirements that support the state's rapid cycle assessments, including timeliness of reporting and accuracy standards.

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

a. LPEs are eligible to receive shared savings from the PHP under the following circumstances:
    i. The LPE continues to meet the health and utilization benchmarks outlined in Pilot Year 4.
    ii. There is a reduction in average total cost of care per beneficiary. This measure must be:
        - Based on the costs of a subset of pilot enrollees whose services are likely to result in decreased medical expenses in the short-term (e.g., homeless adults with multiple chronic conditions or high ED or hospital admission utilizations who receive housing services). This assures that LPEs are not penalized for delivering effective, evidence-based interventions that result in a financial return on investment over the longer-term (i.e., children who have experienced three categories of adverse childhood experiences who receive home-based visiting services to strengthen stronger and healthier parental relationships).

- Assessed in comparison with a comparable control group.

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

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

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

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

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

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

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

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

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

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

ii. Visit Verification Procedures
    1. In accordance with the state's Medicaid program integrity requirements, the state must require the PHPs regularly validate services, including those delivered through the pilots, that were rendered as provided and properly billed and documented by pilot providers through conducting visit verification procedures on a random sample of claims/invoices. Verification procedures may include:

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

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

c. Ensuring action is taken to address identified non-compliance

i. Recoupment of Overpayments. Under the state's Medicaid program integrity requirement, the state must require the PHPs to monitor payments and identify issues of overpayment. PHPs and LPEs must regularly monitor their payments to Pilot Providers to identify potential overpayments. If an overpayment is discovered, the PHP or LPE must calculate the payback amount and return the overpayment no later than sixty (60) days from the date the overpayment was identified.

ii. Suspension, Withhold, Sanctions and Termination Activities due to Findings of Fraud or Abuse. In accordance with the state's Medicaid program integrity requirements:

1. The state reserves the right to direct a PHP to impose a payment suspension or withhold on any provider, including pilot providers and LPEs, due to potential or actual instances of fraudulent behavior.
2. The state, PHPs and LPEs will have the right to terminate a pilot provider for reasons related to substantiated fraudulent behavior.
3. The state will have the right to impose other sanctions or intermediate sanctions on, or require a corrective action plan from a PHP, LPE, or pilot provider.
4. LPEs must submit monthly reports to the state on all pilot provider terminations or non-renewals due to fraudulent behavior, including terminations and non-renewals initiated by the LPE, a PHP or the state.

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

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

VIII. GENERAL REPORTING REQUIREMENTS

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

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

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

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

   i. CMS may decline the extension request.

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

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

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

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

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

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

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

25. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and

c. Submit deliverables to the appropriate system as directed by CMS.

26. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 23.

IX. MONITORING

27. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) compiled Annual Monitoring Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Monitoring Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90) calendar days following the end of the DY. The 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. Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing 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 of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

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

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

f. 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 HOPs 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 PHPs, LPEs, and pilot providers.
   iii. HOP Capacity Building. The state will provide a report on the amount of capacity building provided to each LPE, the time frame the funding was provided, and what the funding was used for.

28. **Close-Out Operational Report**. Within 120 calendar days 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. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 36 and 37, respectively.

c. The state must present to and participate in a discussion with CMS on the Close-Out report.
d. The state must take into consideration CMS's comments for incorporation into the final Close-Out Report.
e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.
f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 23.

29. Monitoring Calls. CMS will convene periodic conference calls with the state.
a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on the evaluation.
b. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The state and CMS will jointly develop the agenda for the calls.

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

X. EVALUATION OF THE DEMONSTRATION

31. Independent Evaluator. Upon approval of the demonstration, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved, draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

32. Evaluation Budget. A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

33. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state may choose to submit one Evaluation Design inclusive of the demonstration and SUD, or a

separate Evaluation Design focused on SUD. If the state chooses to submit two Evaluation Designs, the SUD Evaluation Design is subject to the same terms and conditions listed below which apply to the overall demonstration evaluation. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

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.

34. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.

35. **Evaluation Questions and Hypotheses.** Consistent with attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF). Furthermore, the evaluation should accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or 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.

36. **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 that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. 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. If the state is not requesting an extension for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit a revised Interim Evaluation Report sixty (60) calendar days after receiving CMS's comments on the draft Interim Evaluation Report. The state must post the final Interim Evaluation Report to the state's website within thirty (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.

37. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, November 1, 2019 – October 31, 2024, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

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

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

39. **Public Access**. The state must post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.

40. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS must be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS must be

provided a copy including any associated press materials. CMS must be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS

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

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

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

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

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

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

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

    ii. TANF and Related Adult: *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.*

    iii. TANF and Related Child: *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.*

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

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

vi. SUD IMD MC ABD: *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible 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.*

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

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

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

e. Demonstration Years. There are two separate and distinct programs operating during different demonstration years under this comprehensive demonstration, but each for only 5 years. The SUD component will operate in demonstration years 1 through 5 (January 1, 2019 through October 31, 2023. The managed care component including the HOP pilot will operate in demonstration years 2 through 6 (November 1, 2019 through October 31, 2024).

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

g. The demonstration years for managed care component and the 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*

h. The SUD component demonstration years are as follows:

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

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

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

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

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

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

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

46. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar

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

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

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

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

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

d. The required member month reporting MEG is:

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

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

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

iv. **SUD IMD FFS:** SUD IMD Member Months are months of Medicaid eligibility enrolled in fee for service during which the individual is an inpatient in an IMD under

terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

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

vi. **TANF and Related Adults:** TANF Adult member months are months of Medicaid eligibility for an individual receiving coverage within the temporary assistance for needy families program and other non-ABD adults.

vii. **TANF and Related Children:** TANF Child member months are months of Medicaid eligibility for a child only receiving coverage within the temporary assistance for needy families program and other non-ABD children.

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

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

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

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

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

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

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

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

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

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

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

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

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

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

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

55. Calculation of the Budget Neutrality Limit and How It Is Applied. For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each EG (shown on the table in STC 57) by the corresponding actual member months total, and summing the results of those calculations.

The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by Composite Federal Share, which is defined in STC 59 below.

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

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

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

58. **Supplemental Tests.**

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

these services. Therefore, a separate expenditure cap is established for SUD IMD services, to be known as Supplemental Budget Neutrality Test 1.

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

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

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

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

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

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

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

MEG	DY 02 Total	DY 03 Total	DY 04 Total	DY 05 Total	DY 06 Total

Healthy Opportunities Pilot	$110,000,000	$110,000,000	$110,000,000	$110,000,000	$110,000,000

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

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

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

59. Composite Federal Share Ratios. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported through the MBES/CBES and summarized on Schedule C, with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections and pharmacy rebates, by total computable demonstration expenditures for the same period as reported on the same forms. There are three Composite Federal Share Ratios for this demonstration: Composite Federal Share 1 is based on the expenditures reported under the following Waiver Names: ABD, TANF and related Adults, TANF and Related Child, and INN/TBI. Composite Federal Share 2 is based on the following Waiver Names: SUD IMD MC TANF and Related Adults, SUD IMD MC ABD, SUD IMD MC Innovations/TBI, and, SUD IMD FFS. Composite Federal Share 3 is based on the following Waiver Name: HOP Service. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed upon method.

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

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

62. Managed Care and Healthy Opportunities Pilot Program component

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

SUD Component of the Demonstration

Year	Cumulative target definition	Percentage
DY 1	Cumulative budget neutrality cap plus:	3.0 percent
DY 2	Cumulative budget neutrality cap plus:	2.0 percent
DY 3	Cumulative budget neutrality cap plus:	1.0 percent
DY 4	Cumulative budget neutrality cap plus:	0.5 percent
DY 5	Cumulative budget neutrality cap plus:	0.0 percent

XIII. MONITORING ALLOTMENT NEUTRALITY

63. 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.

64. 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.

65. 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 idenfitied in these STCs) are subject to the title XXI 10 percent administrative cap described in section 2105(c)(2)(A) of the Act.

66. 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 iendified 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.

67. 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 21P 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 21P. 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.

68. 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 64.9P W.

XIV. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Date	Deliverable	STC
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Plan Protocol	STC 19
150 days after SUD program approval date	SUD Monitoring Protocol	STC 19
180 days after approval date	Evaluation Design	STC 34
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 35
October 31, 2023, or with extension application	Draft Interim Evaluation Report	STC 36
60 days after receipt of CMS comments	Revised Interim Evaluation Report	STC 36
Within 18 months after October 31, 2024	Summative Evaluation Report	STC 37
60 days after receipt of CMS comments	Revised Summative Evaluation Report	STC 37
Monthly Deliverables	Monitoring Call	STC 29
Quarterly Deliverables Due 60 days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 27
	Quarterly Expenditure Reports	STC 43

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-demo/evaluationreports/evaluation-designs-and-reports/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

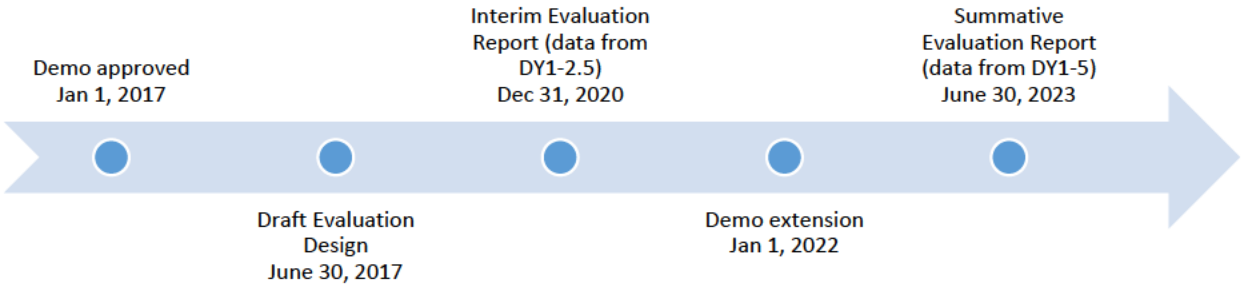
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

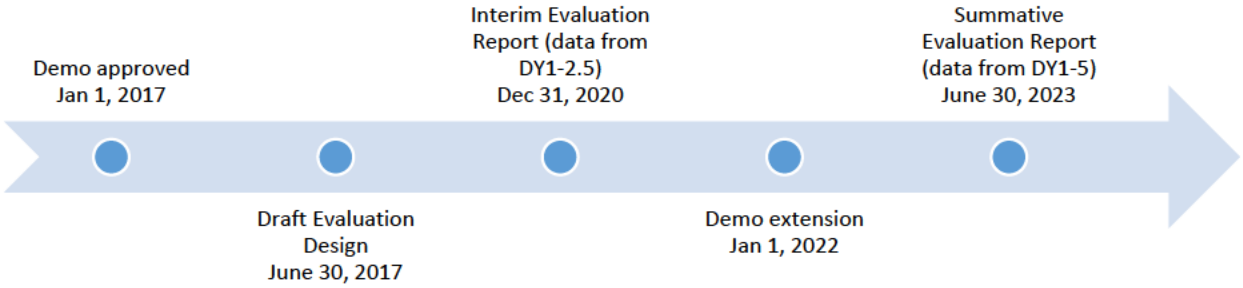
The format for the Evaluation Design is as follows:

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;

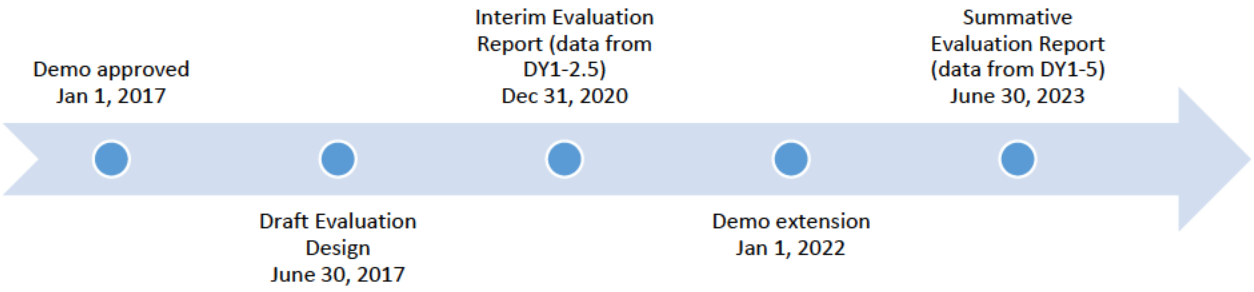
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;

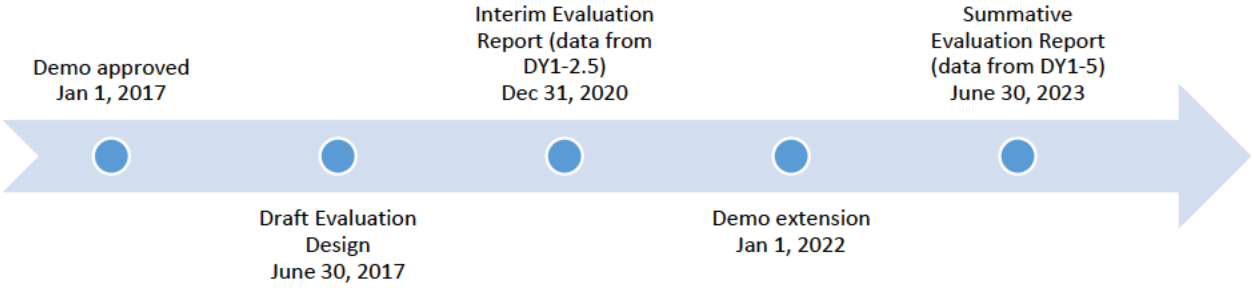
I. Lessons Learned and Recommendations; and

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.


Demo approved
Jan 1, 2017
Draft Evaluation
Design
June 30, 2017
Interim Evaluation
Report (data from
DY1-2.5)
Dec 31, 2020
Demo extension
Jan 1, 2022
Summative
Evaluation Report
(data from DY1-5)
June 30, 2023


Demo approved
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Draft Evaluation
Design
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Interim Evaluation
Report (data from
DY1-2.5)
Dec 31, 2020
Demo extension
Jan 1, 2022
Summative
Evaluation Report
(data from DY1-5)
June 30, 2023

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: Reserved for Evaluation Design

North Carolina Medicaid Reform Demonstration
Updated Evaluation Design Report:
Incorporating CMS Feedback Received on June 17, 2019 and October 24, 2019
November 7, 2019

A. General Background Information

North Carolina's 1115 waiver entitled "North Carolina Medicaid Reform Demonstration" was approved by the Centers for Medicare & Medicaid Services (CMS) on October 24, 2018. This evaluation embeds two major elements of the demonstration: components related to the Medicaid and Health Choice delivery system in NC and components to address the State's needs related to the opioid use epidemic and general substance use treatment needs. The Substance Use Disorder (SUD) component began on July 1, 2019 and will expire on October 31, 2023. The remaining components of the waiver will begin no sooner than February 1, 2020 and will expire on October 31, 2024.

Plans for the waiver were initiated in 2015, when the NC General Assembly enacted Session Law 2015-245 to move the state's Medicaid and Health Choice programs away from reimbursing providers directly through fee for service payments to a system of paying private health plans on a capitated basis. The purpose of the NC 1115 Waiver is to improve Medicaid beneficiary health outcomes through the implementation of a new delivery system, to enhance the viability and sustainability of the NC Medicaid program by maximizing the receipt of high-value care, and to reduce substance use disorders statewide.

There are several large components to NC's 1115 demonstration, which are listed in Table 1. First, the State intends to transition most NC Medicaid and Health Choice enrollees into a capitated model of care from the fee-for-service system that exists in the state currently. This will be done in phases, by eligible populations. The first group will transition to Prepaid Health Plans (PHPs) beginning February 1, 2019. This group will consist of individuals statewide, who are not excluded from enrollment in PHPs and do not qualify for one of the behavioral health intellectual / developmental disability tailored plans ("BH I/DD Tailored Plans") or specialized foster care plans, described below. Later in the demonstration, Medicaid enrollees with severe behavioral health conditions, intellectual or developmental disabilities, and/or traumatic brain injuries who meet criteria established by the Department of Health and Human Services and current and former foster care youth[1] will be enrolled in separate capitated plans with specialized features that are customized for the needs of each of these groups. While most Medicaid enrollees will be covered under a capitated plan under the demonstration, several groups are excluded from participation, including Medicaid enrollees dually eligible for

[1] Medicaid only beneficiaries in foster care under age 21, children in adoptive placements and former foster youth who aged out of care up to age 26

Medicare[2], Medicaid enrollees who are eligible through the Medically Needy program, those with limited eligibility such as through family planning waivers, those presumptively eligible for Medicaid, and prison inmates receiving Medicaid covered inpatient services. In addition, Medicaid-only beneficiaries receiving long-stay nursing home services and Community Alternatives Program for Children and Community Alternatives Program for Disabled Adults enrollees are also excluded.

Table 1: Major components of the 1115 waiver demonstration and implemention dates

Component	Current implementation date	Description of Implementation	Medicaid and Health Choice Beneficiaries affected
Enhancement of benefits related to substance use disorder (SUD) treatments	July 1, 2019		All receiving SUD services
Standard Plans (SPs)	February 1, 2020	Statewide implementation	All standard plan enrollees[3]
Advanced Medical Homes	February 1, 2020	Many primary care practices are already certified as AMH; Others will become certified after PHP launch	All receiving primary care from an AMH
Enhanced Case Management and Other Services (ECMOS) Pilots	Late 2020	Pilots will begin delivering services to eligible PHP enrollees in selected regions	PHP enrollees in selected pilot regions in need of pilot services (only SP enrollees affected at launch)
Behavioral Health and Intellectual/Developmental Disability Tailored Plans and Statewide Foster Care Plan	2021		All enrollees in a BH I/DD Tailored Plan or the

[2] Dual eligibles will enroll in BH I/DD Tailored Plans at their launch for BH and I/DD services only and that medically needy and HIPP beneficiaries who are enrolled in the Innovations waiver will enroll in BH I/DD Tailored Plans at their launch.

[3] Does not include indiiduals who qualify for a BH I/DD Tailored Plan or the Statewide Foste Care Plan or those excluded from managed care (e.g., Dual eligible, Medically Need, those receiving limited benefits). Eligibility criteria for BH I/DD Tailored Plans can be found here. DHHS is in the process of establishing eligibility criteria for the Statewide Foster Care Plan.

Component	Current implementation date	Description of Implementation	Medicaid and Health Choice Beneficiaries affected
			Statewide Foster Care Plan[4]
Health Homes	2021	On launch of BH I/DD Tailored Plans	Those eligible for a TP who are in a participating practice

The second major component of the 1115 waiver demonstration involves the enhancement of benefits related to substance use disorder services, allowing the state to leverage federal financial participation for additional services to treat opioid use disorders and other substance use disorders. These newly covered services include services for substance use disorders (SUDs) provided to Medicaid enrollees who are short-term residents in residential and inpatient treatment facilities that previously were excluded from federal Medicaid payments because of the institution for mental diseases (IMD) exclusion, as well as other improvements in access to and standards of SUD care. The expansions in covered SUD services could affect all Medicaid and Health Choice enrollees with SUDs by increasing the covered treatment options available, but also by increasing access to SUD services broadly (new as well as existing services), potentially creating more capacity in service provision due to shifts to more appropriate care.

A third major component of NC's demonstration is the Advanced Medical Home (AMH) program. Building on its well-established primary care case-management program, the AMH will be used as a primary mechanism for delivering and coordinating care management services under managed care. PHPs will be required to deliver care management services and are mandated to contract with all "Tier 3" AMHs (further described below) for the provision of care management to many enrollees. The Department expects that 22 percent of beneficiaries will receive care management services through AMHs or PHPs (https://files.nc.gov/ncdma/Care-Management-Rate-Memo-20190724.pdf). These individuals will be identified by risk stratification tools, which are further described below. Providers can continue to receive fees as they did under the primary care case management program or can take on additional care management responsibilities in exchange for higher levels of reimbursement to be negotiated with the PHPs. The AMH program distinguishes practices by tiers, according to their care management responsibilities. As defined in the AMH manual for primary care providers (https://files.nc.gov/ncdma/documents/Providers/Programs_Services/amh/AMH_Provider-Manual_08272018.pdf): "In AMH Tier 1 and 2 practices, PHPs will retain primary responsibility for care management, and practices will be required to closely coordinate and interact with each PHP with which they have a contract. AMH Tier 3 is a more advanced phase for practices

[4] Eligibility criteria for BH I/DD Tailored Plans can be found here. DHHS is in the process of establishing eligibility criteria for the Statewide Foster Care Plan.

ready to take on care management responsibility, either alone or as part of a network of practices affiliated with a Clinically Integrated Network (CIN). PHPs will provide oversight for care management delivered in or on behalf of Tier 3 practices, but will otherwise delegate day to day care management responsibilities to the Tier 3 AMH practice or the system or CIN/partners with which they are affiliated." The distinction between Tier 1 and Tier 2 practices follows the same distinction from the current primary care case management program, with Tier 2 practices required to contract with a regional network, on top of the Tier 1 practice requirements such as after-hours availability and panel size. PHPs are required to contract with 100% of Tier 3 AMH practices in their service area. As of March 2019, there are already almost 2,800 practices which have been certified as AMHs, and almost 1,500 of these have been certified as AMH Tier 3 practices. The majority of PHP enrollees are expected to be served in an AMH of level 1-3.

Finally, NC's demonstration permits DHHS to establish a limited number of Enhanced Case Management and Other Services (ECMOS) Pilots in a subset of regions. These pilots will offer reimbursement for evidence-based, non-medical interventions that address housing, transportation, food, and interpersonal safety and toxic stress that are traditionally not covered by Medicaid. North Carolina will be able to evaluate the impact of the provision of these services on enrollees' health outcomes and healthcare costs. The Pilots will be evaluated in a separate evaluation plan, although Pilot participants will be identified in some of the analyses for the overall waiver.

B. Evaluation Hypotheses and Research Questions

There are three stated goals of the demonstration:

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

The primary and secondary drivers, or pathways through which these goals will be achieved, are diagrammed below. Goal 3 is additionally broken out in more detail in the subsequent figure.

The primary drivers for both Goals 1 and 2 include an increased use of alternative payment models, providing care with a whole person orientation, enhanced access to care, and more use of evidence-based practices and medicines.

The use of alternative payment models is expected to increase through the use of prepaid health plans and provider-led entities (PHPs/PLEs), rather than the current Medicaid system. Contracts with PHPs/PLEs were developed assuming a slower growth rate, which thus incentivizes the plans to manage costs. PHPs and PLEs are permitted to use APMs to pay providers, which differs from the current design. Additionally, PHPs have more ability to place incentives upon providers to meet quality expectations. Likewise, the PHPs and PLEs are held

to quality expectations and other oversight/compliance by the State; this puts more emphasis on quality and value than existed prior to the waiver.

It is well known that medical care is only responsible for a fraction of a person's health; other factors like social determinants of health and the environment are also considerable drivers. An increased emphasis on a whole person orientation will improve beneficiary outcomes. A number of managed care initiatives specifically address social determinants of health; these include the ECMOS Pilots (and the spread of learning from those pilots), the resource platform linking needs to local assets, and mandated screening for patients' SDOH-related needs.

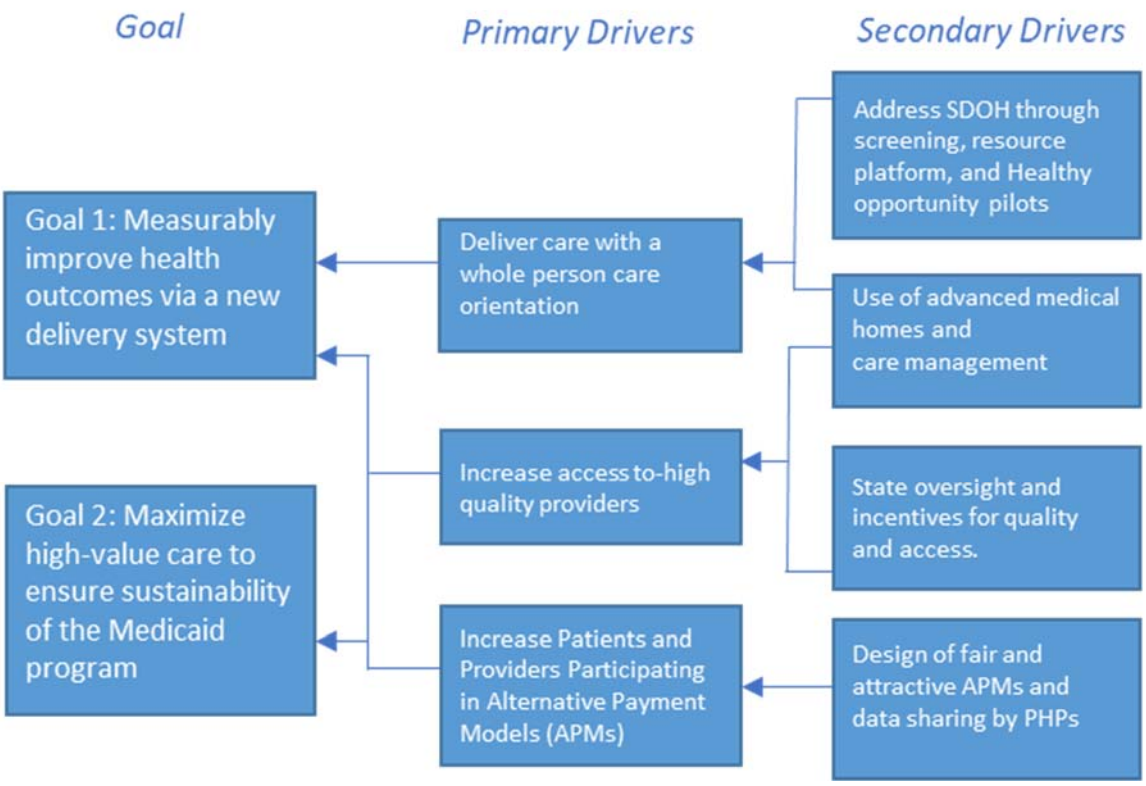
Multiple secondary drivers will improve the use of evidence-based practices (EBP). This driver is deliberately worded to account for both the recommendation of EBPs by providers as well as the ability and willingness of patients to participate in the EBP - ability to access recommended care (e.g. transportation needs met), trust in the provider's recommendation through shared decision-making, and adherence to the recommended treatment (e.g. medication). Some of the secondary drivers are focused on the provider side (e.g. quality improvement activity and shared data/transparency) while others are more focused on the patient and family (patient engagement, use of advanced medical homes). Likewise, oversight of the PHPs and providers will increase the practice of EBPs, and access to the resource platform will attenuate social barriers inhibiting patients' abilities to access evidence-based practices.

Finally, these primary drivers also improve the ability of patients to access care more generally. These will improve provider satisfaction and willingness to treat and manage Medicaid beneficiaries. As providers become more satisfied with the Medicaid program, more providers will be willing to manage Medicaid beneficiaries and many will increase the number of Medicaid beneficiaries they are able to manage.

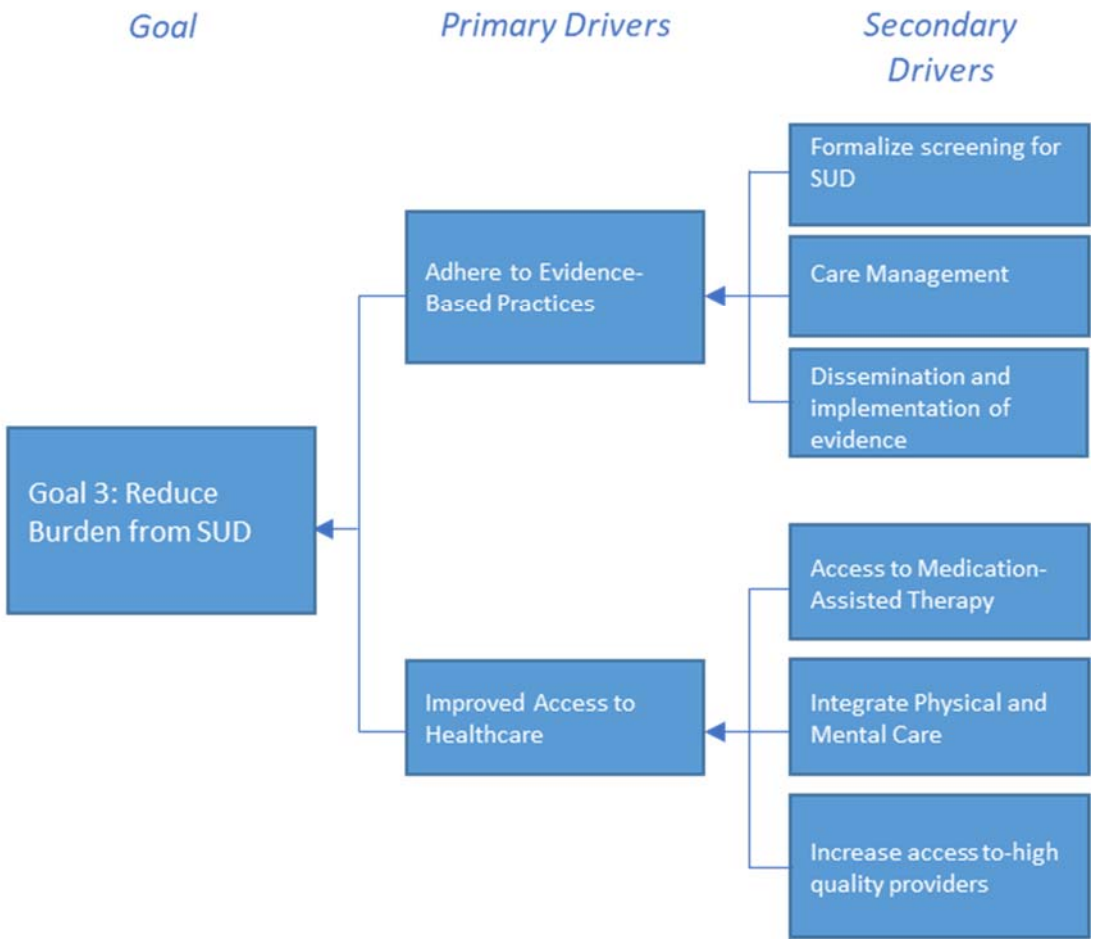
Goal 3 is "reduce substance use disorder." In the driver diagrams below, we provide additional detail on this goal - reduce the burden of substance use disorder, including mortality and morbidity. The primary design of the SUD element of the waiver is to more effectively provide beneficiaries with substance use disorders the high-quality care they need and reduce the long-term use of opiods.

The Goal 3-specific Driver Diagram focuses on drivers uniquely leading to Goal 3. Secondary drivers of better management, integration between physical and behavioral health, patient satisfaction with SUD treatment and an increase in MAT prescribers lead to treatment being provided in the most appropriate care setting, adherence to medications and SUD services (including, as above, the notion that providers need to be recommending EBPs as well), and improving rates of treatment and engagement with SUD treatment and providers.

DRIVER DIAGRAM: GOALS 1 & 2



DRIVER DIAGRAM: GOAL 3



Each of the three goals leads to a number of hypotheses which will be tested in the demonstration evaluation through the related research questions. These include:

Goal 1: Measurably improve health outcomes via a new delivery system

Hypothesis 1.1 The implementation of Medicaid managed care will increase access to health care and improve the quality of care and health outcomes.

Research question 1.1.a Does the implementation of standard plans increase access to health care for those in the target population?

Research question 1.1.b Does the implementation of standard plans improve the quality of health care received by the target population?

Research question 1.1.c Does the implementation of standard plans improve health outcomes for those in the target population?

Research question 1.1.d Does the implementation of BH I/DD Tailored Plans increase access to health care for those in the target population?

Research question 1.1.e Does the implementation of BH I/DD Tailored Plans improve the quality of health care received by the target population?

Research question 1.1.f Does the implementation of BH I/DD Tailored Plans improve health outcomes for those in the target population?

Research question 1.1.g Does the implementation of specialized foster care plans increase access to health care for those in the target population?

Research question 1.1.h Does the implementation of specialized foster care plans improve the quality of health care received by the target population?

Research question 1.1.i Does the implementation of specialized foster care plans improve health outcomes for those in the target population?

Hypothesis 1.2: The implementation of Medicaid managed care will increase the rate of use of behavioral health services at the appropriate level of care and improve the quality of behavioral health care received.

Research question 1.2.a Does the implementation of standard plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?

Research question 1.2.b Does the implementation of standard plans improve the quality of behavioral health care received for those in the target population?

Research question 1.2.c Does the implementation of BH I/DD Tailored Plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?

Research question 1.2.d Does the implementation of BH I/DD Tailored Plans improve the quality of behavioral health care received for those in the target population?

Research question 1.2.e Does the implementation of specialized foster care plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?

Research question 1.2.f Does the implementation of specialized foster care plans improve the quality of behavioral health care received for those in the target population?

Hypothesis 1.3: The implementation of Medicaid managed care will increase the use of medication-assisted treatment (MAT) and other opioid treatment services and decrease the long-term use of opioids.

Research question 1.3.a Does the implementation of standard plans increase the use of MAT for those in the target population?

Research question 1.3.b Does the implementation of standard plans increase the use of non-medication opioid treatment services for those in the target population?

Research question 1.3.c Does the implementation of standard plans decrease the probability of long-term use of opioids?

Research question 1.3.d Does the implementation of BH I/DD Tailored Plans increase the use of MAT for those in the target population?

Research question 1.3.e Does the implementation of BH I/DD Tailored Plans increase the use of non-medication opioid treatment services for those in the target population?

Research question 1.3.f Does the implementation of BH I/DD Tailored Plans decrease the probability of long-term use of opioids?

Research question 1.3.g Does the implementation of specialized foster care plans increase the use of MAT for those in the target population?

Research question 1.3.h Does the implementation of specialized foster care plans increase the use of non-medication opioid treatment services for those in the target population?

Research question 1.3.i Does the implementation of specialized foster care plans decrease the probability of long-term use of opioids?

Hypothesis 1.4: Implementation of Advanced Medical Homes (AMHs) and Health Homes (HHs) will increase the delivery of care management services and will improve quality of care and health outcomes.

Research question 1.4.a Does the implementation of AMHs and HHs increase the probability of receiving care management services?

Research question 1.4.b Does the implementation of AMHs and HHs improve the quality of care received?

Research question 1.4.c Does the implementation of AMHs and HHs improve health outcomes?

Hypothesis 1.5: The implementation of Medicaid managed care will reduce disparities (increase equity) in the quality of care received across rurality, age, race/ethnicity and disability status.

Research question 1.5.a Does the implementation of standard plans increase equity in the quality of care for those in the target population?

Research question 1.5.b Does the implementation of BH I/DD Tailored Plans increase equity in the quality of care for those in the target population?

Research question 1.5.c Does the implementation of specialized foster care plans increase equity in the quality of care for those in the target population?

Goal 2: Maximize high-value care to ensure sustainability of the Medicaid program

Hypothesis 2.1: The implementation of Medicaid managed care will decrease the use of emergency departments for non-urgent use and hospital admissions for ambulatory sensitive conditions.

Research question 2.1.a Does the implementation of standard plans decrease the use of emergency departments for non-urgent use?

Research question 2.1.b Does the implementation of standard plans decrease the use of hospital admissions for ambulatory sensitive conditions?

Research question 2.1.c Does the implementation of BH I/DD Tailored Plans decrease the use of emergency departments for non-urgent use?

Research question 2.1.d Does the implementation of BH I/DD Tailored Plans decrease the use of hospital admissions for ambulatory sensitive conditions?

Research question 2.1.e Does the implementation of specialized foster care plans decrease the use of emergency departments for non-urgent use?

Research question 2.1.f Does the implementation of specialized foster care plans decrease the use of hospital admissions for ambulatory sensitive conditions?

Hypothesis 2.2: The implementation of Medicaid managed care will increase the number of enrollees receiving care management, overall and during transitions in care.

Research question 2.2.a Does the implementation of standard plans increase the number of enrollees receiving care management?

Research question 2.2.b Does the implementation of standard plans increase the number of enrollees receiving care management during transitions in care?

Research question 2.2.c Does the implementation of BH I/DD Tailored Plans increase the number of enrollees receiving care management?

Research question 2.2.d Does the implementation of BH I/DD Tailored Plans increase the number of enrollees receiving care management during transitions in care?

Research question 2.2.e Does the implementation of specialized foster care plans increase the number of enrollees receiving care management?

Research question 2.2.f Does the implementation of specialized foster care plans increase the number of enrollees receiving care management during transitions in care?

Hypothesis 2.3: The implementation of Medicaid managed care will reduce Medicaid program expenditures.

Research question 2.3.a Does the implementation of standard plans reduce Medicaid program expenditures?

Research question 2.3.b Does the implementation of BH I/DD Tailored Plans reduce Medicaid program expenditures?

Research question 2.3.c Does the implementation of specialized foster care plans reduce Medicaid program expenditures?

Hypothesis 2.4: The implementation of Medicaid managed care will increase provider satisfaction and participation in the Medicaid program.

Research question 2.4.a Does the implementation of standard plans increase provider satisfaction?

Research question 2.4.b Does the implementation of standard plans increase provider participation in the Medicaid program?

Research question 2.4.c Does the implementation of BH I/DD Tailored Plans increase provider satisfaction?

Research question 2.4.d Does the implementation of BH I/DD Tailored Plans increase provider participation in the Medicaid program?

Research question 2.4.e Does the implementation of specialized foster care plans increase provider satisfaction?

Research question 2.4.f Does the implementation of specialized foster care plans increase provider participation in the Medicaid program?

Goal 3: Reduce Substance Use Disorder (SUD)

Hypothesis 3.1: Expanding coverage of SUD services to include residential services furnished in IMDs as part of a comprehensive strategy for treating SUD will result in improved care quality and outcomes for patients with SUD.

Research question 3.1.a Does the expanded coverage of SUD services increase the quality of care for patients with SUD?

Research question 3.1.b Does the expanded coverage of SUD services improve outcomes for people with SUD?

Hypothesis 3.2: Expanding coverage of SUD services to include residential services furnished in institutions for mental diseases (IMDs) as part of a comprehensive strategy for treating SUD will increase the use of MAT and other appropriate opioid treatment services and decrease the long-term use of prescription opioids.

Research question 3.2.a Does the expanded coverage of SUD services increase the use of MAT?

Research question 3.2.b Does the expanded coverage of SUD services increase the use of non-medication opioid treatment services at the appropriate level of care?

Research question 3.2.c Does the expanded coverage of SUD services decrease the probability of long-term use of opioids?

Hypothesis 3.3: Expanding coverage of SUD services will result in no changes in total Medicaid and out-of-pocket costs for people with SUD diagnoses, increases in Medicaid costs on SUD IMD services, increases in SUD pharmacy, outpatient, and rehabilitative costs, and decreases in acute care crisis-oriented, inpatient, ED, long-term care and other SUD costs.

Research question 3.3a Does the expanded coverage of SUD services change total Medicaid costs?

Research question 3.3b Does the expanded coverage of SUD services change out-of-pocket costs to Medicaid enrollees with an SUD diagnosis?

Research question 3.3c Does the expanded coverage of SUD services increase Medicaid costs on SUD IMD services, SUD pharmacy, outpatient, and rehabilitative costs?

Research question 3.3d Does the expanded coverage of SUD services decrease Medicaid costs on acute care crisis-oriented, inpatient, ED, long-term care and other SUD costs?

Research question 3.3e Does the expanded coverage of SUD services decrease Medicaid spending on non-SUD services for people with an SUD diagnosis?

Evaluation Questions

With the Demonstration goals, hypotheses, and research questions specified, a series of metrics were generated during the Evaluation Proposal Development period. The Evaluation will assess the degree to which the Demonstration was effective in achieving its goals and will examine the processes, facilitators and barriers experienced during the Demonstration period using these metrics.

The sections and tables below detail the quantitative measures to be used to test each hypothesis, the source or custodian of each measure, the sample or population to which the measure is relevant, and the proposed data sources. Measures were generated from the required PHP Quality Metrics, as specified in the RFP for PHPs, Section VII, Attachment E, page 37), the Quality Strategy, the SUD guidance document, and other public sources. Several of these measures will be employed for multiple hypotheses, to examine the effect of different components of the waiver on outcomes or in different Medicaid populations.The data sources and analytic methods are further described below.

Goal 1: Measurably improve health outcomes via a new delivery system

Hypothesis 1.1 The implementation of Medicaid managed care will increase access to care, the quality of care, and health outcomes.

Table 1.1: Measures related to Hypothesis 1.1, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.1.a Does the implementation of standard plans increase access to health care for those in the target population?					
Getting Care Quickly	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q4 & Q6	Outcome
Getting Needed Care	NQF #: 0006 / AHRQ	Respondents who always desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Use of primary care services	Quality Strategy Objective 2.3	Coded as receiving primary care	In PHP population	Claims / Encounter data	Process
Adolescent Well-Care	NCQA – HEDIS 17168	Received a well-child visit	Adolescents age 12-21 in PHP population	Claims / Encounter data	Process
Children and Adolescents' Access to Primary Care Practitioners (4 measures)	NQF#: 2371 / NCQA - HEDIS	Coded as receiving primary care	Children ages 12 months – 19 years in PHP population	Claims / Encounter data	Process
(Any) Annual Dental Visits	NQF#: 1388/ NCQA - HEDIS	Coded as receiving 1+ outpatient dental visit	Beneficiaries ages 2-20 years of age with dental coverage included in the PHP contract	Claims / Encounter data	Process
Dental Sealants for Children at Elevated Caries Risk	NQF#: 2508/ NCQA – HEDIS / ADA on Behalf of the Dental Quality Alliance	Coded as receiving dental sealants	Beneficiaries age 6-9 at Elevated Caries Risk in PHP population	Claims / Encounter data	Process
Up to date on Childhood Immunizations	NQF#: 0038 / NCQA - HEDIS	Received all immunizations suggested per age	Children who turned age 2 in PHP population	Claims / Encounter Data; Immunization Data	Process
Immunizations for Adolescents (2 measures)	NQF#: 1407 / NCQA - HEDIS	Adolescents age 13 who had specified vaccine by their 13th birthday	Medicaid enrolled adolescents in PHP population	Claims / Encounter Data; Immunization Data	Process
Research question 1.1.b Does the implementation of standard plans improve the quality of health care received by the target population?					

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Customer Service	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome
Rating of Health Plan	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q26	Outcome
Rating of all Health Care	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q8	Outcome
Rating of Personal Doctor	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q16	Outcome
Adult BMI Assessment	NQF#: 0023 / NCQA - HEDIS	Coded as having BMI assessment	Beneficiaries 18-74 with an outpatient visit in PHP population	Claims / Encounter Data; PHP data	Process
Weight Assessment and Counseling for Nutrition and Physical Activity for Children/ Adolescents	NQF#: 0024/ NCQA - HEDIS	Coded as having Weight Assessment and Counseling for Nutrition and Physical Activity	Beneficiaries 3-17 in PHP population who had an outpatient visit with a PCP or OB/GYN	Claims / Encounter Data; PHP data	Process
Tobacco Use screening and follow-up	NQF# 2600	Coded as having received tobacco use screening	Adults age 18+ in target population	Claims / Encounter data	Process
Breast Cancer Screening	NQF#: 2372 / NCQA - HEDIS	Coded as receiving breast cancer screening	Women 50-74 years of age in PHP population	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Cervical Cancer Screening	NQF#: 0032 / NCQA - HEDIS	Coded as receiving cervical cancer screening	Women 21-64 years of age in PHP population	Claims / Encounter Data	Process
Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Coded as receiving Medicaid-paid flu vaccine	Adults age 18-64 in PHP population	Claims / Encounter Data	Process
Appropriate Testing (for strep) for Children with Pharyngitis	NQF#: 0002 / NCQA - HEDIS	Coded as receiving a strep test	Children age 3-18 in PHP population diagnosed with pharyngitis and dispensed an antibiotic	Claims / Encounter Data	Process
Appropriate Treatment for Children with Upper Respiratory Infection	NQF#: 0069 / NCQA - HEDIS	Coded as receiving appropriate treatment	Children 3 months – 18 years in PHP population given a diagnosis of URI	Claims / Encounter Data	Process
Medication Management for People with Asthma	NQF#: 1799 / NCQA - HEDIS	Coded as receiving medication management	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Asthma Medication Ratio	NQF#: 1800 / NCQA - HEDIS	Medication ratio >=50%	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Avoidance of Antibiotic Treatment in Adults with Acute	NQF#: 0058 / NCQA - HEDIS	Coded as not receiving antibiotics	Adults age 18-64 in PHP population with a diagnosis of	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Bronchitis			acute bronchitis		
Annual Monitoring for Patients on Persistent Medications	NQF#: 2371 / NCQA - HEDIS	Coded as receiving 1+ monitoring visit each year	Beneficiaries age 18+ in PHP population who received at least 180 days of outpatient medication for selected conditions	Claims / Encounter Data	Process
Pharmacotherapy Management of COPD Exacerbation (2 measures)	NQF#: 2856 / NCQA - HEDIS	Coded as receiving pharmacotherapy management	Beneficiaries age 40+ in PHP population with an acute inpatient discharge or ED visit	Claims / Encounter Data	Process
Statin Therapy for Patients with Diabetes (2 measures)	NQF#: 0547 / NCQA - HEDIS	Coded as receiving statin therapy	Beneficiaries age 40-75 in PHP population with diabetes and without atherosclerotic cardiovascular disease	Claims / Encounter Data	Process
Statin Therapy for Patients with Cardiovascular Disease (2 measures)	NQF#: 0543 / NCQA - HEDIS	Coded as receiving statin therapy	Men age 21-75 and women age 40-75 in PHP population with atherosclerotic cardiovascular disease	Claims / Encounter Data	Process
Visits in the First 15 Months of Life	NQF#: 1392 / NCQA - HEDIS	Received well-child visits	Children at age 15 months	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			in PHP population		
Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life+	NQF#: 1516 / NCQA - HEDIS	Received well-child visits	Children age 3-6 in PHP population	Claims / Encounter Data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Received concurrent prescriptions for opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice in PHP population with two or more prescriptions of opioids with a days supply of over 15 days	Claims / Encounter data	Process
Use of Imaging Studies for Low Back Pain	NQF#: 0052 / NCQA - HEDIS	Coded as receving 1+ imaging procedure	Beneficiaries with a diagnosis of low back pain in PHP population	Claims / Encounter data	Process
Chlamydia Screening in Women	NQF#: 0033 / NCQA - HEDIS	Coded as receiving chlamydia screening	Women 16-24 years of age in PHP population identified as sexually active	Claims / Encounter Data	Process
Screening for pregnancy risk	NC Administrative Measure	Coded as receiving screening for pregnancy risk	Women in PHP population with a viable pregnancy	Claims / Encounter data	Process
Frequency of Prenatal Care (>=81% of expected	NQF#: 1391 / NCQA - HEDIS	Coded as receiving >=81% of expected visits	Women in PHP population with births	Claims / Encounter data; Birth	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
visits)			covered by Medicaid	Certificate Data	
Prenatal and Postpartum Care+	NQF#: 1517 / NCQA - HEDIS	Coded as receiving prenatal and postpartum visits	Women with live births	Claims / Encounter data; Birth Certificate Data	Process
Pregnant smokers screened and treated for tobacco use	NC Modified measure	Coded as screened and treated	Pregnant tobacco users in PHP population	Birth certificate / Claims / Encounter data	Process
Research question 1.1.c Does the implementation of standard plans improve health outcomes for those in the target population?					
All-Cause Hospital Readmission	NQF#: 1768 / NCQA - HEDIS	Readmission within 30 days of discharge	Inpatient hospital stays for beneficiaries age 18+ in PHP population	Claims / Encounter Data	Outcome
30-day hospital readmission rate following hospitalization for SUD	--	Readmission within 30 days of discharge	Hospital stays in PHP population with a diagnosis of SUD (generally) or OUD (specifically)	Claims / Encounter data	Outcome
Comprehensive Diabetes Care: HbA1c poor control (>9.0) +	NQF#: 0059 / NCQA - HEDIS	Coded as having HbA1c poor control (>9.0)+	Beneficiaries age 18-75 in PHP population with a diabetes diagnosis	Claims / Encounter Data; PHP data	Outcome
Comprehensive Diabetes Care (9 measures)	NQF#: 0061, 0575, 0055 / NCQA - HEDIS	Coded as receiving various measures of	Beneficiaries age 18-75 in PHP	Claims / Encounter	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
		comprehensive care	population with a diabetes diagnosis	Data ; PHP data	
Diabetes Short-term Complication Admission Rate	PQI-01, PDI-15	Coded as having an admission for short-term complications	Beneficiaries in PHP population with a diabetes diagnosis	Claims / Encounter data	Outcome
Controlling High Blood Pressure	NQF#: 0018 / NCQA - HEDIS	Coded as having controlled BP	Beneficiaries age 18-85 in PHP population with a diagnosis of HTN	Claims / Encounter Data ; PHP data	Outcome
COPD or Asthma in Older Adult Admissions	PQI-05	Discharges for asthma or COPD	Adult beneficiaries age 40+ in PHP population	Claims / Encounter data	Outcome
Heart Failure Admissions	PQI-08	Discharges for heart failure	Adult beneficiaries in PHP population	Claims / Encounter data	Outcome
Receipt of Preventative Dental Services	NQF#: 1334 / CMS-416	Receipt of a preventative dental service	Beneficiaries ages 1-20 in PHP population enrolled at least 90 days and eligible for EPSDT	Claims / Encounter data	Outcome
Asthma Admissions in Younger Adults	PQI-15	Hospitalized for asthma	Young adult beneficiaries in PHP population	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Gastroenteritis Admissions	PDI-15	Hospitalized for gastroenteritis	Children in PHP population	Claims / Encounter data	Outcome
Urinary Tract Infection Admissions	PDI-18	Hospitalized for UTI	Children in PHP population	Claims / Encounter data	Outcome
Death rate by group (e.g., SUD, SMI)	--	Died	Adult beneficiaries in PHP population; by key diagnostic group	Claims / Encounter data linked with death certificate data	Outcome
Live Births Weighing Less than 2500 Grams +	NQF#: 1382 / CDC (NC Modification)	Birthweight less than 2500 grams	Live births / live births covered by a PHP since 16 weeks	Birth Certificate / Medicaid eligibility	Outcome
Infant Mortality		Infant death	Live births in PHP population	Birth Certificate / Death Certificate data	Outcome
Healthy Days		Number of self-reported healthy days in month	Medicaid enrollees in PHP population and/or those Based on FPL	BRFSS	Outcome
Tobacco Use Rate (multiple measures)	Public Health Measures	Evidence of tobacco use	Medicaid enrollees in PHP population	BRFSS / CAHPS	Outcome
Overweight / Obesity Rate	--	Coded as over weight / obese	Medicaid enrollees in PHP population and/or those Based on FPL	BRFSS / CAHPS	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Death rate post prison release	--	Died	Adult beneficiaries in PHP population released from prison	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	Outcome
Research question 1.1.d Does the implementation of tailored plans increase access to health care for those in the target population?					
Getting Care Quickly	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q4 & Q6	Outcome
Getting Needed Care	NQF #: 0006 / AHRQ	Respondents who always desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome
Use of primary care services	Quality Strategy Objective 2.3	Coded as receiving primary care	Enrollees in TP population	Claims / Encounter data	Process
Adolescent Well-Care	NCQA – HEDIS 17168	Received a well-child visit	Adolescents age 12-21 in TP population	Claims / Encounter data	Process
Children and Adolescents' Access to Primary Care Practitioners (4 measures)	NQF#: 2371 / NCQA - HEDIS	Coded as receiving primary care	Children ages 12 months – 19 years in TP population	Claims / Encounter data	Process
(Any) Annual Dental Visits	NQF#: 1388/ NCQA - HEDIS	Coded as receiving 1+ outpatient dental visit	Beneficiaries ages 2-20 years of age in TP population with dental coverage	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			included in the TP contract		
Dental Sealants for Children at Elevated Caries Risk	NQF#: 2508/ NCQA – HEDIS / ADA on Behalf of the Dental Quality Alliance	Coded as receiving dental sealants	Beneficiaries age 6-9 in TP population at elevated caries risk	Claims / Encounter data	Process
Up to date on Childhood Immunizations	NQF#: 0038 / NCQA - HEDIS	Received all immunizations suggested per age	Children who turned age 2 in TP population	Claims / Encounter Data; Immunization Data	Process
Immunizations for Adolescents (2 measures)	NQF#: 1407 / NCQA - HEDIS	Adolescents age 13 who had specified vaccine by their 13th birthday	Medicaid enrolled adolescents in TP population	Claims / Encounter Data; Immunization Data	Process
Research question 1.1.e Does the implementation of BH I/DD Tailored Plans improve the quality of health care received by the target population?					
Customer Service	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome
Rating of Health Plan	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q26	Outcome
Rating of all Health Care	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q8	Outcome
Rating of Personal Doctor	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q16	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Adult BMI Assessment	NQF#: 0023 / NCQA - HEDIS	Coded as having BMI assessment	Beneficiaries 18-74 with an outpatient visit in TP population	Claims / Encounter Data; PHP data	Process
Weight Assessment and Counseling for Nutrition and Physical Activity for Children/ Adolescents	NQF#: 0024/ NCQA - HEDIS	Coded as having Weight Assessment and Counseling for Nutrition and Physical Activity	Beneficiaries 3-17 in TP population who had an outpatient visit with a PCP or OB/GYN	Claims / Encounter Data; PHP data	Process
Tobacco Use screening and follow-up	NQF# 2600	Coded as having received tobacco use screening	Adults age 18+ in target population	Claims / Encounter data	Process
Breast Cancer Screening	NQF#: 2372 / NCQA - HEDIS	Coded as receiving breast cancer screening	Women 50-74 years of age in TP population	Claims / Encounter Data	Process
Cervical Cancer Screening	NQF#: 0032 / NCQA - HEDIS	Coded as receiving cervical cancer screening	Women 21-64 years of age in TP population	Claims / Encounter Data	Process
Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Coded as receiving Medicaid-paid flu vaccine	Adults age 18-64 in TP population	Claims / Encounter Data	Process
Appropriate Testing (for strep) for Children with Pharyngitis	NQF#: 0002 / NCQA - HEDIS	Coded as receiving a strep test	Children age 3-18 in TP population diagnosed with pharyngitis and dispensed an antibiotic	Claims / Encounter Data	Process
Appropriate Treatment for Children with Upper Respiratory Infection	NQF#: 0069 / NCQA - HEDIS	Coded as receiving appropriate treatment	Children 3 months – 18 years in TP population given a	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			diagnosis of URI		
Medication Management for People with Asthma	NQF#: 1799 / NCQA - HEDIS	Coded as receiving medication management	Beneficiaries age 5-64 in TP population with persistent asthma	Claims / Encounter Data	Process
Asthma Medication Ratio	NQF#: 1800 / NCQA - HEDIS	Medication ratio >=50%	Beneficiaries age 5-64 in TP population with persistent asthma	Claims / Encounter Data	Process
Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	NQF#: 0058 / NCQA - HEDIS	Coded as not receiving antibiotics	Adults age 18-64 in TP population with a diagnosis of acute bronchitis	Claims / Encounter Data	Process
Annual Monitoring for Patients on Persistent Medications	NQF#: 2371 / NCQA - HEDIS	Coded as receiving 1+ monitoring visit each year	Beneficiaries age 18+ in TP population who received at least 180 days of outpatient medication for selected conditions	Claims / Encounter Data	Process
Pharmacotherapy Management of COPD Exacerbation (2 measures)	NQF#: 2856 / NCQA - HEDIS	Coded as receiving pharmacotherapy management	Beneficiaries age 40+ in TP population with an acute inpatient discharge or ED visit	Claims / Encounter Data	Process
Statin Therapy for Patients with Diabetes (2 measures)	NQF#: 0547 / NCQA - HEDIS	Coded as receiving statin therapy	Beneficiaries age 40-75 in TP population with diabetes	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			and without atherosclerotic cardiovascular disease		
Statin Therapy for Patients with Cardiovascular Disease (2 measures)	NQF#: 0543 / NCQA - HEDIS	Coded as receiving statin therapy	Men age 21-75 and women age 40-75 in TP population with atherosclerotic cardiovascular disease	Claims / Encounter Data	Process
Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life+	NQF#: 1516 / NCQA - HEDIS	Received well-child visits	Children age 3-6 in PHP population	Claims / Encounter Data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Received concurrent prescriptions for opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice in TP population with two or more prescriptions of opioids with a days supply of over 15 days	Claims / Encounter data	Process
Use of Imaging Studies for Low Back Pain	NQF#: 0052 / NCQA - HEDIS	Coded as receving 1+ imaging procedure	Beneficiaries with a diagnosis of low back pain in TP population	Claims / Encounter data	Process
Chlamydia Screening in Women	NQF#: 0033 / NCQA - HEDIS	Coded as receiving chlamydia screening	Women 16-24 years of age in TP population	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			identified as sexually active		
Screening for pregnancy risk	NC Administrative Measure	Coded as receiving screening for pregnancy risk	Women in TP population with a viable pregnancy	Claims / Encounter data	Process
Frequency of Prenatal Care (>=81% of expected visits)	NQF#: 1391 / NCQA - HEDIS	Coded as receiving >=81% of expected visits	Women in TP population with births covered by Medicaid	Claims / Encounter data; Birth Certificate Data	Process
Prenatal and Postpartum Care+	NQF#: 1517 / NCQA - HEDIS	Coded as receiving prenatal and postpartum visits	Women with live births	Claims / Encounter data; Birth Certificate Data	Process
Pregnant smokers screened and treated for tobacco use	NC Modified measure	Coded as screened and treated	Pregnant tobacco users in TP population	Birth certificate / Claims / Encounter data	Process
Research question 1.1.f Does the implementation of BH I/DD Tailored Plans improve health outcomes for those in the target population?					
All-Cause Hospital Readmission	NQF#: 1768 / NCQA - HEDIS	Readmission within 30 days of discharge	Inpatient hospital stays for beneficiaries age 18+ in TP population	Claims / Encounter Data	Outcome
30-day hospital readmission rate following hospitalization for SUD	--	Readmission within 30 days of discharge	Hospital stays in TP population with a diagnosis of SUD (generally) or OUD (specifically)	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Comprehensive Diabetes Care: HbA1c poor control (>9.0) +	NQF#: 0059 / NCQA - HEDIS	Coded as having HbA1c poor control (>9.0)+	Beneficiaries age 18-75 in TP population with a diabetes diagnosis	Claims / Encounter Data; PHP data	Outcome
Comprehensive Diabetes Care (9 measures)	NQF#: 0061, 0575, 0055 / NCQA - HEDIS	Coded as receiving various measures of comprehensive care	Beneficiaries age 18-75 in TP population with a diabetes diagnosis	Claims / Encounter Data ; PHP data	Outcome
Diabetes Short-term Complication Admission Rate	PQI-01, PDI-15	Coded as having an admission for short-term complications	Beneficiaries in TP population with a diabetes diagnosis	Claims / Encounter data	Outcome
Controlling High Blood Pressure	NQF#: 0018 / NCQA - HEDIS	Coded as having controlled BP	Beneficiaries age 18-85 in TP population with a diagnosis of HTN	Claims / Encounter Data ; PHP data	Outcome
COPD or Asthma in Older Adult Admissions	PQI-05	Discharges for asthma or COPD	Adult beneficiaries in TP population	Claims / Encounter data	Outcome
Heart Failure Admissions	PQI-08	Discharges for heart failure	Adult beneficiaries in TP population	Claims / Encounter data	Outcome
Receipt of Preventative Dental Services	NQF#: 1334 / CMS-416	Receipt of a preventative dental service	Beneficiaries ages 1-20 in TP population enrolled at least 90 days	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			and eligible for EPSDT		
Asthma Admissions in Younger Adults	PQI-15	Hospitalized for asthma	Young adult beneficiaries in TP population	Claims / Encounter data	Outcome
Gastroenteritis Admissions	PDI-15	Hospitalized for gastroenteritis	Children in TP population	Claims / Encounter data	Outcome
Urinary Tract Infection Admissions	PDI-18	Hospitalized for UTI	Children in TP population	Claims / Encounter data	Outcome
Death rate by group (e.g., SUD, SMI)	--	Died	Adult beneficiaries in TP population; by key diagnostic group	Claims / Encounter data linked with death certificate data	Outcome
Live Births Weighing Less than 2500 Grams +	NQF#: 1382 / CDC (NC Modification)	Birthweight less than 2500 grams	Live births / live births covered by a TP since 16 weeks	Birth Certificate / Medicaid eligibility	Outcome
Infant Mortality		Infant death	Live births in TP population	Birth Certificate / Death Certificate data	Outcome
Healthy Days		Number of self-reported healthy days in month	Medicaid enrollees in TP population and/or those Based on FPL	BRFSS	Outcome
Tobacco Use Rate (multiple measures)	Public Health Measures	Evidence of tobacco use	Medicaid enrollees in TP population	BRFSS / CAHPS	Outcome
Overweight / Obesity Rate	--	Coded as over weight / obese	Medicaid enrollees in TP population and/or those	BRFSS / CAHPS	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			Based on FPL		
Death rate post prison release	--	Died	Adult beneficiaries in TP population released from prison	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	Outcome
Research question 1.1.g Does the implementation of specialized foster care plans increase access to health care for those in the target population?					
Getting Care Quickly	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q4 & Q6	Outcome
Getting Needed Care	NQF #: 0006 / AHRQ	Respondents who always desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome
Use of primary care services	Quality Strategy Objective 2.3	Coded as receiving primary care	In SP population	Claims / Encounter data	Process
Adolescent Well-Care	NCQA – HEDIS 17168	Received a well-child visit	Adolescents age 12-21 in SP population	Claims / Encounter data	Process
Children and Adolescents' Access to Primary Care Practitioners (4 measures)	NQF#: 2371 / NCQA - HEDIS	Coded as receiving primary care	Children ages 12 months – 19 years in SP population	Claims / Encounter data	Process
(Any) Annual Dental Visits	NQF#: 1388/ NCQA - HEDIS	Coded as receiving 1+ outpatient dental visit	Beneficiaries ages 2-20 years of age with dental coverage	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			included in the SP contract		
Dental Sealants for Children at Elevated Caries Risk	NQF#: 2508/ NCQA – HEDIS / ADA on Behalf of the Dental Quality Alliance	Coded as receiving dental sealants	Beneficiaries age 6-9 at Elevated Caries Risk in SP population	Claims / Encounter data	Process
Up to date on Childhood Immunizations	NQF#: 0038 / NCQA - HEDIS	Received all immunizations suggested per age	Children who turned age 2 in SP population	Claims / Encounter Data; Immunization Data	Process
Immunizations for Adolescents (2 measures)	NQF#: 1407 / NCQA - HEDIS	Adolescents age 13 who had specified vaccine by their 13th birthday	Medicaid enrolled adolescents in SP population	Claims / Encounter Data; Immunization Data	Process
Research question 1.1.h Does the implementation of specialized foster care plans improve the quality of health care received by the target population?					
Customer Service	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q9 & Q18	Outcome
Rating of Health Plan	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q26	Outcome
Rating of all Health Care	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q8	Outcome
Rating of Personal Doctor	NQF #: 0006 / AHRQ	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q16	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Adult BMI Assessment	NQF#: 0023 / NCQA - HEDIS	Coded as having BMI assessment	Beneficiaries 18+ with an outpatient visit in SP population	Claims / Encounter Data; PHP data	Process
Weight Assessment and Counseling for Nutrition and Physical Activity for Children/ Adolescents	NQF#: 0024/ NCQA - HEDIS	Coded as having Weight Assessment and Counseling for Nutrition and Physical Activity	Beneficiaries 3-17 in SP population who had an outpatient visit with a PCP or OB/GYN	Claims / Encounter Data; PHP data	Process
Tobacco Use screening and follow-up	NQF# 2600	Coded as having received tobacco use screening	Adults age 18+ in target population	Claims / Encounter data	Process
Breast Cancer Screening	NQF#: 2372 / NCQA - HEDIS	Coded as receiving breast cancer screening	Women 50-74 years of age in PHP population	Claims / Encounter Data	Process
Cervical Cancer Screening	NQF#: 0032 / NCQA - HEDIS	Coded as receiving cervical cancer screening	Women 21-64 years of age in PHP population	Claims / Encounter Data	Process
Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Coded as receiving Medicaid-paid flu vaccine	Adults age 18-64 in PHP population	Claims / Encounter Data	Process
Appropriate Testing (for strep) for Children with Pharyngitis	NQF#: 0002 / NCQA - HEDIS	Coded as receiving a strep test	Children age 3-18 in PHP population diagnosed with pharyngitis and dispensed an antibiotic	Claims / Encounter Data	Process
Appropriate Treatment for Children with Upper	NQF#: 0069 / NCQA - HEDIS	Coded as receiving appropriate treatment	Children 3 months – 18 years in PHP population	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Respiratory Infection			given a diagnosis of URI		
Medication Management for People with Asthma	NQF#: 1799 / NCQA - HEDIS	Coded as receiving medication management	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Asthma Medication Ratio	NQF#: 1800 / NCQA - HEDIS	Medication ratio >=50%	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	NQF#: 0058 / NCQA - HEDIS	Coded as not receiving antibiotics	Adults age 18-64 in SP population with a diagnosis of acute bronchitis	Claims / Encounter Data	Process
Annual Monitoring for Patients on Persistent Medications	NQF#: 2371 / NCQA - HEDIS	Coded as receiving 1+ monitoring visit each year	Beneficiaries age 18+ in SP population who received at least 180 days of outpatient medication for selected conditions	Claims / Encounter Data	Process
Visits in the First 15 Months of Life	NQF#: 1392 / NCQA - HEDIS	Received well-child visits	Children at age 15 months in SP population	Claims / Encounter Data	Process
Well-Child Visits in the Third, Fourth,	NQF#: 1516 / NCQA - HEDIS	Received well-child visits	Children age 3-6 in SP population	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Fifth, and Sixth Years of Life+					
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Received concurrent prescriptions for opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice in SP population with two or more prescriptions of opioids with a days supply of over 15 days	Claims / Encounter data	Process
Use of Imaging Studies for Low Back Pain	NQF#: 0052 / NCQA - HEDIS	Coded as receving 1+ imaging procedure	Beneficiaries with a diagnosis of low back pain in SP population	Claims / Encounter data	Process
Chlamydia Screening in Women	NQF#: 0033 / NCQA - HEDIS	Coded as receiving chlamydia screening	Women 16-24 years of age in SP population identified as sexually active	Claims / Encounter Data	Process
Screening for pregnancy risk	NC Administrative Measure	Coded as receiving screening for pregnancy risk	Women in SP population with a viable pregnancy	Claims / Encounter data	Process
Frequency of Prenatal Care (>=81% of expected visits)	NQF#: 1391 / NCQA - HEDIS	Coded as receiving >=81% of expected visits	Women in SP population with births covered by Medicaid	Claims / Encounter data; Birth Certificate Data	Process
Prenatal and Postpartum Care+	NQF#: 1517 / NCQA - HEDIS	Coded as receiving prenatal and postpartum visits	Women with live births	Claims / Encounter data; Birth Certificate Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Pregnant smokers screened and treated for tobacco use	NC Modified measure	Coded as screened and treated	Pregnant tobacco users in PHP population	Birth certificate / Claims / Encounter data	Process
Research question 1.1.i Does the implementation of specialized foster care plans improve health outcomes for those in the target population?					
All-Cause Hospital Readmission	NQF#: 1768 / NCQA - HEDIS	Readmission within 30 days of discharge	Inpatient hospital stays for beneficiaries age 18+ in SP population	Claims / Encounter Data	Outcome
30-day hospital readmission rate following hospitalization for SUD	--	Readmission within 30 days of discharge	Hospital stays in SP population with a diagnosis of SUD (generally) or OUD (specifically)	Claims / Encounter data	Outcome
Comprehensive Diabetes Care: HbA1c poor control (>9.0) +	NQF#: 0059 / NCQA - HEDIS	Coded as having HbA1c poor control (>9.0)+	Beneficiaries age 18-75 in SP population with a diabetes diagnosis	Claims / Encounter Data; PHP data	Outcome
Comprehensive Diabetes Care (9 measures)	NQF#: 0061, 0575, 0055 / NCQA - HEDIS	Coded as receiving various measures of comprehensive care	Beneficiaries age 18+ in SP population with a diabetes diagnosis	Claims / Encounter Data ; PHP data	Outcome
Diabetes Short-term Complication Admission Rate	PQI-01, PDI-15	Coded as having an admission for short-term complications	Beneficiaries in SP population with a	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			diabetes diagnosis		
Controlling High Blood Pressure	NQF#: 0018 / NCQA - HEDIS	Coded as having controlled BP	Beneficiaries age 18+ in SP population with a diagnosis of HTN	Claims / Encounter Data ; PHP data	Outcome
COPD or Asthma in Older Adult Admissions	PQI-05	Discharges for asthma or COPD	Adult beneficiaries in SP population	Claims / Encounter data	Outcome
Heart Failure Admissions	PQI-08	Discharges for heart failure	Adult beneficiaries in SP population	Claims / Encounter data	Outcome
Receipt of Preventative Dental Services	NQF#: 1334 / CMS-416	Receipt of a preventative dental service	Beneficiaries ages 1-20 in SP population enrolled at least 90 days and eligible for EPSDT	Claims / Encounter data	Outcome
Asthma Admissions in Younger Adults	PQI-15	Hospitalized for asthma	Young adult beneficiaries in SP population	Claims / Encounter data	Outcome
Gastroenteritis Admissions	PDI-15	Hospitalized for gastroenteritis	Children in SP population	Claims / Encounter data	Outcome
Urinary Tract Infection Admissions	PDI-18	Hospitalized for UTI	Children in SP population	Claims / Encounter data	Outcome
Death rate by group (e.g., SUD, SMI)	--	Died	Adult beneficiaries in SP population; by	Claims / Encounter data linked with death	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			key diagnostic group	certificate data	
Live Births Weighing Less than 2500 Grams +	NQF#: 1382 / CDC (NC Modification)	Birthweight less than 2500 grams	Live births / live births covered by a SP since 16 weeks	Birth Certificate / Medicaid eligibility	Outcome
Infant Mortality		Infant death	Live births in SP population	Birth Certificate / Death Certificate data	Outcome
Death rate post prison release	--	Died	Adult beneficiaries in SP population released from prison	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	Outcome

* Claims / Encounter data refers to fee-for-service (FFS) claims data prior to Nov 1, 2021 as well as remaining populations or services subject to FFS payments after Nov 1, 2021; LME/MCO encounter data; PHP encounter data; and State Operated Facilities (IMD) utilization data. + priority measures are those measures which PHPs are required to monitor in the Quality Strategy and may be used for an annual disparity report and may be published annually on DHHS's website.

Hypothesis 1.2: The implementation of Medicaid managed care will increase the rate of use of behavioral health services at the appropriate level of care and improve the quality of behavioral health care received.

Table 1.2: Measures related to Hypothesis 1.2, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.2.a Does the implementation of standard plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?					
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Initiation of SUD treatment	Adolescent and adult beneficiaries with a new episode of SUD	Claims / Encounter data	Process
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a supply of over 15 days	Claims / Encounter data	Process
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 1.2.b Does the implementation of standard plans improve the quality of behavioral health care received for those in the target population?					
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a supply of over 15 days	Claims / Encounter data	Process
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 1.2.c Does the implementation of BH I/DD Tailored Plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?					
Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	PDC >=80% and at least two Rx claims	Adults with an administrative diagnosis of Schizophrenia; during time periods not hospitalized	Claims / Encounter data*	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Use of behavioral health care for people with SMI or SUD	--	Evidence of behavioral health care use	Children, Adults in target population	Claims / Encounter data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Initiation of SUD treatment	Adolescent and adult beneficiaries with a new episode of SUD	Claims / Encounter data	Process
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			supply of over 15 days		
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 1.2.d Does the implementation of BH I/DD Tailored Plans improve the quality of behavioral health care received for those in the target population?					
Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	PDC >=80% and at least two Rx claims	Adults with an administrative diagnosis of Schizophrenia; during time periods not hospitalized	Claims / Encounter data*	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a supply of over 15 days	Claims / Encounter data	Process
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 1.2.e Does the implementation of specialized foster care plans increase the rate of use of behavioral health services at the appropriate level of care for those in the target population?					
Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	PDC >=80% and at least two Rx claims	Adults with an administrative diagnosis of Schizophrenia; during time periods not hospitalized	Claims / Encounter data*	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Use of behavioral health care for people with SMI or SUD	--	Evidence of behavioral health care use	Children, Adults in target population	Claims / Encounter data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Initiation of SUD treatment	Adolescent and adult beneficiaries with a new episode of SUD	Claims / Encounter data	Process
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			supply of over 15 days		
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 1.2.f Does the implementation of specialized foster care plans improve the quality of behavioral health care received for those in the target population?					
Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	PDC >=80% and at least two Rx claims	Adults with an administrative diagnosis of Schizophrenia; during time periods not hospitalized	Claims / Encounter data*	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process
Depression screening among those with SUD	NQMC: 004006	Evidence of depression screening	Beneficiaries with SUD	Claims / Encounter data	Process
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a supply of over 15 days	Claims / Encounter data	Process
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process

* Claims / Encounter data refers to fee-for-service (FFS) claims data prior to Nov 1, 2021 as well as remaining populations or services subject to FFS payments after Nov 1, 2021; LME/MCO encounter data; PHP encounter data; and State Operated Facilities (IMD) utilization data. + priority measures are those measures which PHPs are required to monitor in the Quality Strategy and may be used for an annual disparity report and may be published annually on DHHS's website.

Hypothesis 1.3: The implementation of Medicaid managed care will increase the use of Medication-assisted treatment (MAT) and other opioid treatment services and decrease the long-term use of opioids.

Table 1.3: Measures related to Hypothesis 1.3, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.3.a Does the implementation of standard plans increase the use of MAT for those in the target population?					
Use of pharmacotherapy for opioid use disorder (OUD)	NQF 3400	Use of MAT	Beneficiaries with OUD	Claims / Encounters	Outcome
Number of providers with DEA DATA 2000 waivers	--		NC licensed providers	NC Licensure data / DEA DATA 2000 waiver data	Process
Number of providers with DEA DATA 2000 waivers who have written prescriptions for Medicaid enrollees for MAT	--		NC licensed providers with DEA waivers	CSRS / Medicaid claims	Process
Research question 1.3.b Does the implementation of standard plans increase the use of non-medication opioid treatment services for those in the target population?					
Percent of SUD diagnosed beneficiaries who receive an SUD treatment service	--	Evidence of psychosocial service for SUD	Adults with a current diagnosis of SUD	Claims / Encounters	Outcome
Research question 1.3.c Does the implementation of standard plans decrease the probability of long-term use of opioids?					
Long-Term Use of Opioids		TBD	Beneficiaries with opioid use	Claims / Encounters	Outcome
Use of Opioids at High Dosage in Persons without Cancer	NQF#:2940/ PQA	Evidence of opioid use of greater than 120mg for 90 consecutive days or longer	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			supply is greater than or equal to 15.		
Use of Opioids from Multiple Providers in Persons Without Cancer	NQF#:2950/ PQA	Evidence of opioid prescription claims from 4 or more prescribers AND 4 or more pharmacies	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.	Claims / Encounter data	Outcome
Reduced incarceration for drug-related charges	--		Adults with SUD	DOC data	Outcome
Research question 1.3.d Does the implementation of BH I/DD Tailored Plans increase the use of MAT for those in the target population?					
Use of pharmacotherapy for opioid use disorder (OUD)	NQF 3400	Use of MAT	Beneficiaries with OUD	Claims / Encounters	Outcome
Number of providers with DEA DATA 2000 waivers	--		NC licensed providers	NC Licensure data / DEA DATA 2000 waiver data	Process
Number of providers with DEA DATA 2000 waivers who have written prescriptions for Medicaid enrollees for MAT	--		NC licensed providers with DEA waivers	CSRS / Medicaid claims	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.3.e Does the implementation of BH I/DD Tailored Plans increase the use of non-medication opioid treatment services for those in the target population?					
Percent of SUD diagnosed beneficiaries who receive an SUD treatment service	--	Evidence of psychosocial service for SUD	Adults with a current diagnosis of SUD	Claims / Encounters	Outcome
Research question 1.3.f Does the implementation of BH I/DD Tailored Plans decrease the probability of long-term use of opioids?					
Long-Term Use of Opioids		TBD	Beneficiaries with opioid use	Claims / Encounters	Outcome
Use of Opioids at High Dosage in Persons without Cancer	NQF#:2940/ PQA	Evidence of opioid use of greater than 120mg for 90 consecutive days or longer	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.	Claims / Encounter data	Outcome
Use of Opioids from Multiple Providers in Persons Without Cancer	NQF#:2950/ PQA	Evidence of opioid prescription claims from 4 or more prescribers AND 4 or more pharmacies	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.	Claims / Encounter data	Outcome
Reduced incarceration for	--		Adults with SUD	DOC data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
drug-related charges					
Research question 1.3.g Does the implementation of specialized foster care plans increase the use of MAT for those in the target population?					
Use of pharmacotherapy for opioid use disorder (OUD)	NQF 3400	Use of MAT	Beneficiaries with OUD	Claims / Encounters	Outcome
Research question 1.3.h Does the implementation of specialized foster care plans increase the use of non-medication opioid treatment services for those in the target population?					
Percent of SUD diagnosed beneficiaries who receive an SUD treatment service	--	Evidence of psychosocial service for SUD	Adults with a current diagnosis of SUD	Claims / Encounters	Outcome
Research question 1.3.i Does the implementation of specialized foster care plans decrease the probability of long-term use of opioids?					
Long-Term Use of Opioids		TBD	Beneficiaries with opioid use	Claims / Encounters	Outcome
Use of Opioids at High Dosage in Persons without Cancer	NQF#:2940/ PQA	Evidence of opioid use of greater than 120mg for 90 consecutive days or longer	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.	Claims / Encounter data	Outcome
Use of Opioids from Multiple Providers in Persons Without Cancer	NQF#:2950/ PQA	Evidence of opioid prescription claims from 4 or more prescribers AND 4 or	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days,	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
		more pharmacies	for which the sum of the days supply is greater than or equal to 15.		
Reduced incarceration for drug-related charges	--		Adults with SUD	DOC data	Outcome

* Claims / Encounter data refers to fee-for-service (FFS) claims data prior to Nov 1, 2021 as well as remaining populations or services subject to FFS payments after Nov 1, 2021; LME/MCO encounter data; PHP encounter data; and State Operated Facilities (IMD) utilization data. + priority measures are those measures which PHPs are required to monitor in the Quality Strategy and may be used for an annual disparity report and may be published annually on DHHS's website. CSRS refers to data from the Controlled Substances Reporting System.

Hypothesis 1.4: Implementation of Advanced Medical Homes will increase the delivery of care management services and will improve quality of care and health outcomes.

Table 1.4: Measures related to Hypothesis 1.4, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.4.a Does the implementation of AMHs and HHs increase the probability of receiving care management services?					
Number / % of practices on the PHP panel that attest to being a level 3 AMH	--	AMH Tier 3 providers	Providers	PHP Network data	Process
Number of enrollees attributed to an Advanced Medical Home	Quality Strategy Objective 2.2	Enrollees attributed to an AMH	All	Claims and Encounters	Process
Number of	--	Evidence of care	All	Care management databases	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
enrollees receiving care management		management receipt			
Research question 1.4.b Does the implementation of AMHs and HHs improve the quality of care received?					
Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Coded as receiving Medicaid-paid flu vaccine	Adults age 18-64 in PHP population	Claims / Encounter Data	Process
Medication Management for People with Asthma	NQF#: 1799 / NCQA - HEDIS	Coded as receiving medication management	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Asthma Medication Ratio	NQF#: 1800 / NCQA - HEDIS	Medication ratio >=50%	Beneficiaries age 5-64 in PHP population with persistent asthma	Claims / Encounter Data	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process
Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Evidence of receipt of advice or treatments to quit	Adults who are current tobacco users	Claims / Encounters; PHP data; CAHPS	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Beneficiaries age 6+ who were hospitalized for treatment of selected mental illnesses	Claims / Encounter data	Process
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life+	NQF#: 1516 / NCQA - HEDIS	Received well-child visits	Children age 3-6 in PHP population	Claims / Encounter Data	Process
Up to date on Childhood Immunizations	NQF#: 0038 / NCQA - HEDIS	Received all immunizations suggested per age	Children who turned age 2 year	Claims / Encounter Data; Immunization Data	Process
Immunizations for Adolescents (2 measures)	NQF#: 1407 / NCQA - HEDIS	Adolescents age 13 who had specified vaccine by their 13th birthday	Medicaid enrolled adolescents	Claims / Encounter Data; Immunization Data	Process
Weight Assessment and Counseling for Nutrition and Physical Activity for Children/ Adolescents	NQF#: 0024/ NCQA - HEDIS	Coded as having Weight Assessment and Counseling for Nutrition and Physical Activity	Beneficiaries 3-17 in PHP population who had an outpatient visit with a PCP or OB/GYN	Claims / Encounter Data; PHP data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Cervical Cancer Screening	NQF#: 0032 / NCQA - HEDIS	Coded as receiving cervical cancer screening	Women 21-64 years of age in PHP population	Claims / Encounter Data	Process
Comprehensive Diabetes Care: HbA1c poor control (>9.0) +	NQF#: 0059 / NCQA - HEDIS	Coded as having HbA1c poor control (>9.0)+	Beneficiaries age 18-75 in PHP population with a diabetes diagnosis	Claims / Encounter Data; PHP data	Outcome
Research question 1.4.c Does the implementation of AMHs and HHs improve health outcomes?					
All-Cause Hospital Readmission	NQF#: 1768 / NCQA - HEDIS	Readmission within 30 days of discharge	Inpatient hospital stays for beneficiaries age 18+ in PHP population	Claims / Encounter Data	Outcome
Controlling High Blood Pressure	NQF#: 0018 / NCQA - HEDIS	Coded as having controlled BP	Beneficiaries age 18-85 in PHP population with a diagnosis of HTN	Claims / Encounter Data ; PHP data	Outcome
Diabetes Short-term Complication Admission Rate	PQI-01, PDI-15	Coded as having an admission for short-term complications	Beneficiaries in PHP population with a diabetes diagnosis	Claims / Encounter data	Outcome
COPD or Asthma in Older Adult Admissions	PQI-05	Discharges for asthma or COPD	Adult beneficiaries age 40+ in PHP population	Claims / Encounter data	Outcome
Heart Failure Admissions	PQI-08	Discharges for heart failure	Adult beneficiaries	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
			in PHP population		
Asthma Admissions in Younger Adults	PQI-15	Hospitalized for asthma	Young adult beneficiaries in PHP population	Claims / Encounter data	Outcome
Gastroenteritis Admissions	PDI-15	Hospitalized for gastroenteritis	Children in PHP population	Claims / Encounter data	Outcome
Urinary Tract Infection Admissions	PDI-18	Hospitalized for UTI	Children in PHP population	Claims / Encounter data	Outcome

Hypothesis 1.5: The implementation of Medicaid managed care will reduce disparities in the quality of care received.

Table 1.5: Measures related to Hypothesis 1.5, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.5.a Does the implementation of standard plans increase equity in the quality of care for those in the target population?					
Appropriate Treatment for Children with Upper Respiratory Infection	NQF#: 0069 / NCQA - HEDIS	Coded as receiving appropriate treatment	Children 3 months – 18 years in PHP population given a diagnosis of URI	Claims / Encounter Data	Process
Dental Sealants for Children at Elevated Caries Risk	NQF#: 2508/ NCQA – HEDIS / ADA on Behalf of the Dental Quality Alliance	Coded as receiving dental sealants	Beneficiaries age 6-9 at Elevated Caries Risk in PHP population	Claims / Encounter data	Process
Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Coded as receiving Medicaid-paid flu vaccine	Adults age 18-64 in PHP population	Claims / Encounter Data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 1.5.b Does the implementation of BH I/DD Tailored Plans increase equity in the quality of care for those in the target population?					
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Initiation of SUD treatment	Adolescent and adult beneficiaries with a new episode of SUD	Claims / Encounter data	Process
Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	PDC >=80% and at least two Rx claims	Adults with an administrative diagnosis of Schizophrenia; during time periods not hospitalized	Claims / Encounter data*	Process
Research question 1.5.c Does the implementation of specialized foster care plans increase equity in the quality of care for those in the target population?					
Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Evidence of outpatient visit in the appropriate time frame	Children newly prescribed ADHD medications	Claims / Encounter data	Process
Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Beneficiaries who remained on antidepressant treatment	Beneficiaries age 18 and older who filled at least one prescription for antidepressant medication	Claims / Encounter Data	Process

Hypothesis 2.1: The implementation of Medicaid managed care will decrease the use of emergency departments for non-urgent use and hospital admissions for ambulatory sensitive conditions.

Table 2.1: Measures related to Hypothesis 2.1, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 2.1.a Does the implementation of standard plans decrease the use of emergency departments for non-urgent use?					
Number of ED visits	NCQA - HEDIS	Use of ED visits	All	Claims / Encounters	Outcome
Avoidable or preventable emergency department visits	NYU / Billings algorithm	Evidence of an avoidable ED visit	All	Claims / Encounters	Outcome
Research question 2.1.b Does the implementation of standard plans decrease the use of hospital admissions for ambulatory sensitive conditions?					
Number of hospital admissions	--	Hospital Admissions	All	Claims / Encounters	Outcome
Number of hospital days	--	Hospital Days	All	Claims / Encounters	Outcome
Hospital admissions for ambulatory sensitive conditions; avoidable or preventable inpatient hospitalizations	AHRQ PQI and PDI	Evidence of ASHA	All	Claims / Encounters	Outcome
Research question 2.1.c Does the implementation of BH I/DD Tailored Plans decrease the use of emergency departments for non-urgent use?					
Number of ED visits	NCQA - HEDIS	Use of ED visits	All	Claims / Encounters	Outcome
Avoidable or preventable emergency department visits	NYU / Billings algorithm	Evidence of an avoidable ED visit	All	Claims / Encounters	Outcome
Research question 2.1.d Does the implementation of BH I/DD Tailored Plans decrease the use of hospital admissions for ambulatory sensitive conditions?					
Number of hospital admissions	--	Hospital Admissions	All	Claims / Encounters	Outcome
Number of hospital days	--	Hospital Days	All	Claims / Encounters	Outcome
Hospital admissions for ambulatory sensitive conditions; avoidable or preventable inpatient hospitalizations	AHRQ PQI and PDI	Evidence of ASHA	All	Claims / Encounters	Outcome
Research question 2.1.e Does the implementation of specialized foster care plans decrease the use of emergency departments for non-urgent use?					

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Number of ED visits	NCQA - HEDIS	Use of ED visits	All	Claims / Encounters	Outcome
Avoidable or preventable emergency department visits	NYU / Billings algorithm	Evidence of an avoidable ED visit	All	Claims / Encounters	Outcome
Research question 2.1.f Does the implementation of specialized foster care plans decrease the use of hospital admissions for ambulatory sensitive conditions?					
Number of hospital admissions	--	Hospital Admissions	All	Claims / Encounters	Outcome
Number of hospital days	--	Hospital Days	All	Claims / Encounters	Outcome
Hospital admissions for ambulatory sensitive conditions; avoidable or preventable inpatient hospitalizations	AHRQ PQI and PDI	Evidence of ASHA	All	Claims / Encounters	Outcome

Hypothesis 2.2: The implementation of Medicaid managed care will increase the number of enrollees receiving care management, overall and during transitions in care.
(Note that Hypothesis 1.4 focuses on the role AMHs specifically, whereas this Hypothesis focuses on access to care management generally and during transitions in care.)

Table 2.2: Measures related to Hypothesis 2.2, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 2.2.a Does the implementation of standard plans increase the number of enrollees receiving care management?					
Coordination of Care (consumer perceptions)	NQF #: 0006	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q22&Q23	Outcome
Time to SDOH Screening from PHP attribution	--	Number of days from enrollment to SDOH screening	PHP enrollees	Claims / Encounter data ; PHP data; NCcare360	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 2.2.b Does the implementation of standard plans increase the number of enrollees receiving care management during transitions in care?					
Enrollees Receiving Care Management during transitions in care	--	Evidence of care management	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data; care management data systems	Process
Medication Reconciliation Post-Discharge	ACO-12	Evidence of medication reconcillation	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data	Process
Research question 2.2.c Does the implementation of BH I/DD Tailored Plans increase the number of enrollees receiving care management?					
Coordination of Care (consumer perceptions)	NQF #: 0006	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q22&Q23	Outcome
Time to SDOH Screening from PHP attribution	--	Number of days from enrollment to SDOH screening	PHP enrollees	Claims / Encounter data ; PHP data; NCcare360	Process
Research question 2.2.d Does the implementation of BH I/DD Tailored Plans increase the number of enrollees receiving care management during transitions in care?					
Enrollees Receiving Care Management during transitions in care	--	Evidence of care management	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data; care management data systems	Process
Medication Reconciliation Post-Discharge	ACO-12	Evidence of medication reconcillation	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data	Process
Research question 2.2.e Does the implementation of specialized foster care plans increase the number of enrollees receiving care management?					

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Coordination of Care (consumer perceptions)	NQF #: 0006	Respondents who always received the desired care or service	Respondents to the CAHPS survey*	CAHPS Q22&Q23	Outcome
Time to SDOH Screening from PHP attribution	--	Number of days from enrollment to SDOH screening	PHP enrollees	Claims / Encounter data ; PHP data; NCcare360	Process
Research question 2.2.f Does the implementation of specialized foster care plans increase the number of enrollees receiving care management during transitions in care?					
Enrollees Receiving Care Management during transitions in care	--	Evidence of care management	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data; care management data systems	Process
Medication Reconciliation Post-Discharge	ACO-12	Evidence of medication reconcillation	Beneficiaries discharges from a long hospital, rehab, or residential care	Claims / Encounter data	Process

Note: A measure of care management use is under development and expected to be added as an additional metric for this outcome.

Hypothesis 2.3: The implementation of Medicaid managed care will reduce Medicaid program expenditures.

Table 2.3: Measures related to Hypothesis 2.3, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 2.3.a Does the implementation of standard plans reduce Medicaid program expenditures?					
Total Expenditures to the Medicaid program and components	--	Total Medicaid expenditures	PHP enrollees	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Out-of-pocket costs to Medicaid enrollees	--	OOP expenditures	PHP enrollees	Claims / Encounter data	Outcome
Costs of Medicaid funded services and components	--	Value of Medicaid services, using FFS weights	PHP enrollees	Claims / Encounter data	Outcome
Research question 2.3.b Does the implementation of BH I/DD Tailored Plans reduce Medicaid program expenditures?					
Total Expenditures to the Medicaid program and components	--	Total Medicaid expenditures	TP enrollees	Claims / Encounter data	Outcome
Out-of-pocket costs to Medicaid enrollees	--	OOP expenditures	TP enrollees	Claims / Encounter data	Outcome
Costs of Medicaid funded services and components	--	Value of Medicaid services, using FFS weights	TP enrollees	Claims / Encounter data	Outcome
Research question 2.3.c Does the implementation of specialized foster care plans reduce Medicaid program expenditures?					
Total Expenditures to the Medicaid program and components	--	Total Medicaid expenditures	PHP enrollees	Claims / Encounter data	Outcome
Out-of-pocket costs to Medicaid enrollees	--	OOP expenditures	PHP enrollees	Claims / Encounter data	Outcome
Costs of Medicaid funded services and components	--	Value of Medicaid services, using FFS weights	PHP enrollees	Claims / Encounter data	Outcome

Hypothesis 2.4: The implementation of standard and tailored plans will increase provider satisfaction and participation in the Medicaid program

Table 2.4: Measures related to Hypothesis 2.4, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 2.4.a Does the implementation of standard plans increase provider satisfaction?					
Overall Provider Satisfaction	UNC*	Measures of Satisfaction	Medicaid Providers	Provider Survey	Outcome

Research question 2.4.b Does the implementation of standard plans increase provider participation in the Medicaid program?					
Provider participation in Medicaid (several measures, by quantity of participation, and by provider type)	UNC*	Number of Medicaid enrollees	Medicaid Providers	Claims / Encounter	Outcome
Research question 2.4.c Does the implementation of BH I/DD Tailored Plans increase provider satisfaction?					
Overall Provider Satisfaction	UNC*	Measures of Satisfaction	Medicaid Providers	Provider Survey	Outcome
Research question 2.4.d Does the implementation of BH I/DD Tailored Plans increase provider participation in the Medicaid program?					
Provider participation in Medicaid (several measures, by quantity of participation, and by provider type)	UNC*	Number of Medicaid enrollees	Medicaid Providers	Claims / Encounter	Outcome
Research question 2.4.e Does the implementation of specialized foster care plans increase provider satisfaction?					
Overall Provider Satisfaction	UNC*	Measures of Satisfaction	Medicaid Providers	Provider Survey	Outcome
Research question 2.4.f Does the implementation of specialized foster care plans increase provider participation in the Medicaid program?					
Provider participation in Medicaid (several measures, by quantity of participation, and by provider type)	UNC*	Number of Medicaid enrollees	Medicaid Providers	Claims / Encounter	Outcome

* Measures under development by Evaluation Team and/or other contractors

Hypothesis 3.1: Expanding coverage of SUD services to include residential services furnished in institutions for mental disease (IMD) as part of a comprehensive strategy will result in improved care quality and outcomes for patients with SUD.

Table 3.1: Measures related to Hypothesis 3.1, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 3.1.a Does the expanded coverage of SUD services increase the quality of care for patients with SUD?					
Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Initiation of SUD treatment	Adolescent and adult beneficiaries with a new episode of SUD	Claims / Encounter data	Process
Continuity of Pharmacotherapy with OUD	NQF#: 3175	MAT use of 180+ days	Those with a diagnosis of OUD and MAT	Claims / Encounter data	Process
Percent of diagnosed beneficiaries who receive a treatment service	--	Evidence of an SUD treatment service	Those with a current diagnosis of SUD	Claims / Encounter data	Process
Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Contemporaneous use of opioids and benzodiazepines	Adults without a cancer diagnosis and not in hospice with two or more prescriptions of opioids with a supply of over 15 days	Claims / Encounter data	Process
Research question 3.1.b Does the expanded coverage of SUD services improve outcomes for people with SUD?					
Percent of SUD diagnosed beneficiaries who receive a SUD treatment service	--	Evidence of psychosocial service for SUD	Adults with a current diagnosis of SUD	Claims / Encounters	Outcome
Death rate from overdose	--		Adult beneficiaries with SUD diagnoses	Claims / Encounter data linked with death certificate data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Death rate from overdose post-release	--		Adult beneficiaries released from prison	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	Outcome

Hypothesis 3.2: Expanding coverage of SUD services to include residential services furnished in IMDs as part of a comprehensive strategy for treating SUD will increase the use of MAT and other opioid treatment services and decrease the long-term use of opioids.

In contrast to Hypothesis 1.2, this hypothesis and Hypothesis 3.1 examine the use of SUD services and quality of care as a result of changes in the SUD delivery system rather than the implementation of managed care. This distinction will be further described in the Methods sections below.

Table 3.2: Measures related to Hypothesis 3.2, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 3.2.a Does the expanded coverage of SUD services increase the use of MAT?					
Number of providers with DEA DATA 2000 waivers	--		NC licensed providers	NC Licensure data / DEA DATA 2000 waiver data	Process
Number of providers with DEA DATA 2000 waivers who have written prescriptions for Medicaid enrollees for MAT	--		NC licensed providers with DEA waivers	CSRS / Medicaid claims	Process
Percent of enrollees diagnosed with	CMS	Receipt of MAT	Enrollees age 12 and above with OUD diagnosis	Claims / Encounter data	Process

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
OUD receiving MAT			and/or opioid poisoning code		
Research question 3.2.b Does the expanded coverage of SUD services increase the use of non-medication opioid treatment services at the appropriate level of care?					
Percent of enrollees diagnosed with OUD receiving non-medication opioid treatment services	--	Evidence of psychosocial service for OUD	Enrollees age 12 and above with OUD diagnosis and/or opioid poisoning code	Claims / Encounter data	Process
ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Evidence of 1+ ED visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
IP visits for SUD and specifically for OUD	--	Evidence of 1+ IP visits for SUD	Children age 12 and over and adults with SUD	Claims / Encounter data	Process
Research question 3.2.c Does the expanded coverage of SUD services decrease the probability of long-term use of opioids?					
Long-Term Use of Opioids		TBD	Beneficiaries with opioid use	Claims / Encounters	Outcome
Use of Opioids at High Dosage in Persons without Cancer	NQF#:2940/ PQA	Evidence of opioid use of greater than 120mg for 90 consecutive days or longer	Adults without Cancer, with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.	Claims / Encounter data	Outcome

Hypothesis 3.3: Expanding coverage of SUD services will result in no changes in total Medicaid costs for people with SUD diagnoses, increases in Medicaid costs on SUD IMD services, increases in SUD pharmacy, outpatient, and rehabilitative costs, and decreases in acute care crisis-oriented, inpatient, ED, long-term care and other SUD costs.

Table 3.3: Measures related to Hypothesis 3.3, by Research Question

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 3.3a Does the expanded coverage of SUD services change total Medicaid costs?					
Total Expenditures to the Medicaid program	--	Total Medicaid expenditures	People with SUD diagnoses	Claims / Encounter data	Outcome
Costs of Medicaid funded services	--	Value of Medicaid services, using FFS weights	People with SUD diagnoses	Claims / Encounter data	Outcome
Research question 3.3b Does the expanded coverage of SUD services change out-of-pocket costs to Medicaid enrollees with an SUD diagnosis?					
Out-of-pocket costs to Medicaid enrollees	--	OOP expenditures	People with SUD diagnoses	Claims / Encounter data	Outcome
Research question 3.3c Does the expanded coverage of SUD services increase Medicaid costs on SUD IMD services, SUD pharmacy, outpatient, and rehabilitative costs?					
Expenditures to the Medicaid program components	--	Total Medicaid expenditures	People with SUD diagnoses	Claims / Encounter data	Outcome
Costs of Medicaid funded services components	--	Value of Medicaid services, using FFS weights	People with SUD diagnoses	Claims / Encounter data	Outcome
Research question 3.3d Does the expanded coverage of SUD services decrease Medicaid costs on acute care crisis-oriented, inpatient, ED, long-term care and other SUD costs?					
Expenditures to the Medicaid program components	--	Total Medicaid expenditures	People with SUD diagnoses	Claims / Encounter data	Outcome
Costs of Medicaid funded services components	--	Value of Medicaid services, using FFS weights	People with SUD diagnoses	Claims / Encounter data	Outcome

Measure	Measure custodian	Numerator	Denominator	Data Sources	Process / Outcome
Research question 3.3e Does the expanded coverage of SUD services decrease Medicaid spending on non-SUD services for people with an SUD diagnosis?					
Expenditures to the Medicaid program components	--	Total Medicaid expenditures	People with SUD diagnoses	Claims / Encounter data	Outcome
Costs of Medicaid funded services components	--	Value of Medicaid services, using FFS weights	People with SUD diagnoses	Claims / Encounter data	Outcome

C. Methodology

1. Evaluation Design

The evaluation will use a mixed-methods approach to testing the evaluation hypotheses. The quantitative analyses will use a difference-in-differences approach to the extent possible, as described below. This approach will be informed by the qualitative analyses by triangulating results from provider interviews and surveys and discussing preliminary results with providers and other stakeholders.

2. Qualitative Evaluation Plan

a. Purpose

The qualitative evaluation will examine perspectives from primary care and specialist providers including family medicine, internal medicine, pediatrics, and Ob/Gyn, behavioral health specialists, community based organizations (CBOs) (e.g., focusing on food and transportation accessibility), including those in Pilot networks, and in Pilot regions, as well as others, state health agency officials, and Prepaid Health Plans (PHPs) impacted by the NC Medicaid transformation. This examination will reveal detailed insights into the transformation that are not easily captured through claims and surveys; for example, how providers are preparing for the transformation and what can be done to improve their satisfaction with the Medicaid program. In addition to having standalone value, the qualitative evaluation, when combined with claims and survey analysis, enables a mixed methods evaluation design. A key strength of the mixed methods design is that it allows us to triangulate quantitative and qualitative approaches, thereby leveraging the strengths while minimizing the weaknesses of each. Quantitative approaches allow for establishing trends and levels of metrics and statistical significance of relationships between variables, whereas qualitative findings allow for in-depth exploration of how activities are performed and why relationships between variables exist.

Analyses of the qualitative data, along with particular stories contained in that data set, may provide additional hypotheses to test using the quantitative data sources and will be useful for developing explanations for the patterns we find in the quantitative analyses. Similarly, relationships observed among variables in the quantitative data analyses may be useful when inferring the extent to which findings from the qualitative analyses are likely to be generalizable.

In this evaluation, the qualitative analysis will enhance claims and survey analyses through collection of additional data from providers as well as data from stakeholders not reached directly by the survey or claims (e.g., health system administrators, support staff, patients). The qualitative evaluation serves both *exploratory* and *explanatory* purposes that will both inform and explain findings from the claims and survey analysis.

The *exploratory* purpose of the qualitative analysis will inform provider satisfaction surveys after waiver implementation has begun and potentially additional outcomes to examine in the claims analysis. For example, themes identified through semi-structured interviews with primary care providers about their satisfaction with the Medicaid program could inform development of survey items about the drivers of provider satisfaction, such as support received from plans, changes in reimbursement, and access to behavioral specialists (increased/decreased).

The *explanatory* purpose of the qualitative evaluation will build upon the initial and subsequent survey and claims analyses by generating explanations for these results that cannot be generated through quantitative analyses alone—typically because quantitative explanatory measures are not available or are insufficient to yield insights on key outcomes of interest. More specifically, the qualitative analysis will examine why hypotheses were or were not supported from quantitative analyses. For example, qualitative analyses will reveal insights into how "successful" providers and/or practices achieved their success. As another example, qualitative analyses could identify strategies for increasing provider satisfaction with Medicaid.

Specifically, the qualitative analysis will focus on exploratory and explanatory evaluation of the hypotheses listed in Table 4:

Table 4: Hypotheses Examined by Qualitative Evaluation

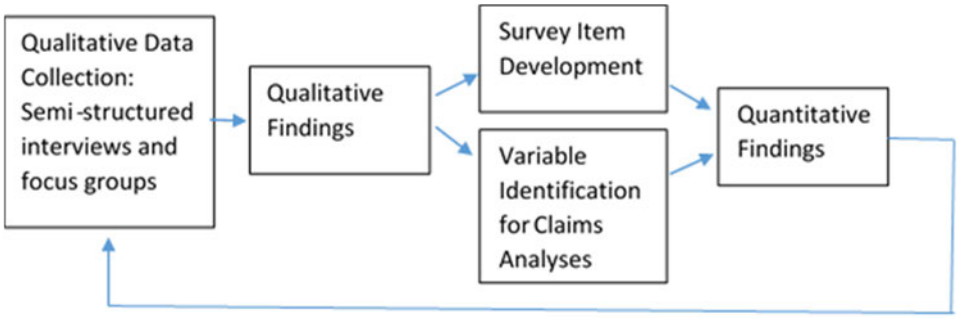
	Stakeholder Interviews				
Hypotheses	**Physician Practices**	**Behavioral Health**	**Community-based organizations**	**State Health Agencies**	**Prepaid Health Plans**
H1.1: *The implementation of Medicaid managed care will*	**X**	**X**			**X**

increase access to care, the quality of care, and health outcomes.			**X**	**X**	
H1.2: *The implementation of Medicaid managed care will increase the rate of use of behavioral health services at the appropriate level of care and improve the quality of behavioral health care received.*	**X**	**X**	**X**	**X**	**X**
H1.4: *Implementation of Advanced Medical Homes will increase the delivery of care management services and will improve quality of care and health outcomes.*	**X**	**X**		**X**	
H2.1*: The implementation of Medicaid managed care will decrease the use of emergency departments for non-urgent use and hospital admissions for ambulatory sensitive conditions.*	**X**	**X**		**X**	**X**
H2.2*: The implementation of Medicaid managed care will increase the number of enrollees receiving care management, overall and during transitions in care.*	**X**	**X**		**X**	**X**
H2.4: *The implementation of Medicaid managed care will increase provider satisfaction and participation in the Medicaid program*	**X**	**X**		**X**	
H3.1*: Expanding coverage of SUD services to include residential services furnished in IMDs as part of a comprehensive strategy for treating SUD will result in*		**X**	**X**		**X**

improved care quality and outcomes for patients with SUD.					
H3.2*: Expanding coverage of SUD services to include residential services furnished in IMDs as part of a comprehensive strategy for treating SUD will increase the use of MAT and other appropriate opioid treatment services and decrease the long-term use of prescription opioids.*		**X**	**X**		**X**

Finally, the qualitative evaluation also will help ensure validity of conclusions through convergence or confirmation of quantitative results (Figure 1). Convergence in the results from the qualitative and quantitative analyses will provide stronger support for our findings, whereas any divergences in the results of the analyses will be useful for tempering interpretations of findings and guiding subsequent research efforts. For example, are quantitative measures of network adequacy and qualitative data on provider perceptions of network adequacy convergent or divergent? Convergence in the results will provide stronger support for the findings, whereas divergence in the results will inform interpretations of findings and suggest areas to examine in more depth in subsequent years of the evaluation.

Figure 1: Integration of Quantitative and Qualitative Methods



b. **Sample**

We will recruit a sample of provider practices to follow during the life of the evaluation. This approach will facilitate a detailed examination into whether/how external circumstances (e.g., support provided by the plans, patient needs, community resources) change over time as well as how providers adjust to the transformation during the early implementation phase and the longer term. Our sample will include approximately 36 physician practices from across the

state, with representation from each of the 6 regions (i.e., approximately 6 practices from each region). Within each region we plan to recruit family medicine, internal medicine, pediatrics, and Ob/Gyn practices. In addition, we will recruit behavioral health specialists and representatives from CBOs from each region that interviewees at the physician practices identify as resources for their Medicaid patients.

Because there is value in assessing perceptions and experiences over time, we plan to interview participants 2-3 times during the project period (e.g. providers every two years, state agencies and health plans every 2-3 years). On average, we will conduct approximately 50 individual interviews in each of the first 6 years of the project, for a total of approximately 314 interviews. The rationale for approximately 50 interviews is that we plan to interview 1 provider and 1 administrative/nursing staff member for each practice and approximately 1 behavioral health and/or CBO representative identified by each practice. We may find a need to interview more than 2 representatives of some practices (e.g., if the practice has many providers). Alternatively, we may not need to interview a behavioral health specialist or CBO representative identified by each practice because some practices may identify the same behavioral health specialists or CBOs as key resources for their patients.

In addition, we will adjust our provider sampling frame to reflect changes in the transformation plan. For example, we will ensure that there is provider representation from each of the tailored plan regions once that element of the transformation plan has been implemented. We will use a purposive sampling approach to account for contextual factors within each region of the state. For example, we may select more practices in some regions than others to account for factors that contribute to the complexity of caring for the Medicaid population (e.g., greater number of plans available) as well as practices that have partnered with CINs as well as those that have not.

In addition to physician practices, behavioral health services, and CBOs, we will conduct interviews with key informants from the state health agencies such as the Division of Health Benefits, the Division of Mental Health, and the Division of Public Health, and representatives from each of the 5 standard plans and from the tailored plans. We anticipate interviewing ~10 individual key informants from the state health agencies at two points during the evaluations—once during the first year of implementation and once approximately 2-3 years after implementation. Similarly, we will interview representatives from the heatlh plans. These interviews may be conducted with individual representatives or small groups (e.g., 2-4 PHP representatives), depending on the preference of the standard and tailored plans. Similar to the state agency interviews, representatives from each plan will be interviewed at two points during the evaluation—once during the first year of implementation and once approximately 2-3 years after implementation. Therefore, we estimate that we will conduct a total of approximately 20 interviews with SP and TP representatives.

Table 5: Qualitative Evaluation Sample Sizes

Stakeholder	Interviews per Wave	Total Interviews	Incentives
Prepaid Health Plans	**~5 Interviews** • Representative from each of 5 PHPs representing all 6 regions • 2 waves of interviews	10	None
Tailored Plans	**~5 Interviews** • Representative from each of the tailored plans • Exact number to be determined based on rollout in 2021 • 2 waves of interviews	10	None
State Health Agencies	**~10 Interviews** • Representatives from DHHS • 2 waves of interviews	20	None
Physician Practices	**~72 Individuals (across 36 practices)** • 1 Physician • 1 Administrator (as appropriate) • 3 waves of interviews	216	$100 per interview
Behavioral Health Specialists	**12-15 Individuals** • 2-3 Behavioral health specialists from each region • 3 waves of interviews	40	$100 per interview
Community Based Organizations	**10 Individuals** • 1-2 Interviews per region • 2 waves of interviews	20	$100 per interview
Total Sample Size = ~ 314			

c. Data Collection

We will conduct semi-structured interviews with representatives from practices, behavioral health specialists, CBOs, and PHPs. Individual interviews will be conducted either in person or via teleconference (e.g., Skype or Zoom). Depending on the practice's or key informant's availability, we will aim to conduct the first round of interviews in-person, in order to establish relationships and increase the likelihood of the practice's participation in future interviews. At least two researchers will attend each in-person interview. The role of the researchers will be to prompt for additional details and to take notes. Each interview will last approximately 45-60 minutes and will be digitally recorded and subsequently transcribed.

We will use an interview guide designed to capture information on such topics as practice-level readiness and capabilities for caring for Medicaid patients, support received from PHPs, and provider satisfaction with the Medicaid program and other key features of the demonstration

components such as the tailored plans and advanced medical homes. Table 6 illustrates potential interview domains that will be explored during interviews with providers and PHPs. Topics and interview questions will be developed and revised based on input from our advisory panel, preliminary findings from the provider satisfaction survey and claims analysis, and developments occurring in the NC Medicaid Transformation program (e.g. rollout of tailored plans in 2021).

Table 6: Example Topics ans Sample Interview Questions

Example Topics	**Sample Interview Question**
Market Context	*Could you tell us about any major changes that have happened in this market in the last year?* *How has the NC Medicaid Transformation affected your local market?*
Practice Readiness and Changes for Medicaid	*Is your practice doing anything differently to prepare for the new Medicaid model?* *What changes in your practice structure, staffing and/or processes have been made since the new Medicaid model was implemented? If none, do you anticipate any changes in the future?*
Medicaid patient load	*What proportion of your practice are Medicaid patients?* *How has the transformation changed the proportion of Medicaid patients in your practice?* *Is your practice doing anything differently to meet the needs of this population?*
Advanced Medical Home & Care Coordination	*What are the core components of your Advanced Medical Home?* *Does your practice have plan to increase AMH level?* *Have there been any changes in the way that care coordination is being provided?*
Information and Support Received from PHP	*What kinds practice support is provided by the prepaid health plans? E.g., reports, quality or risk stratisfication data, incentives?*
Satisfaction with Administrative Process	*Have administrative or business office functions changed since the implementation? E.g. timeliness of payment, appropriateness of payment, ease of working with the PHPs?*
Physician Engagement	*How has the new NC Medicaid model changed your satisfaction or engagement with the Medicaid Program?*
Patient Needs	*In what ways do you think patients are impacted by Medicaid transformation?* *Are there certain patient needs that are not being met?* *Characteristics of patients who are not receiving care they need?* *How has access to behavioral health changed?* *How has access to support for health-related social needs?*

Example Topics	Sample Interview Question
Perceived Effectiveness of Medicaid Program	*How does the new Medicaid model compare to the previous models? (e.g., is care improving for patients? What changes are needed?)* *If there was one thing you could change about the program, what would it be?*
Barriers & Facilitators	*What have been the biggest barriers or challenges facing your practice in the past year related to Medicaid?* *What have you done to remove or address those barriers?* *What factors have been the most helpful in improving your experience with Medicaid this year?*

d. Data Analysis

Following standard qualitative coding techniques, we will code data segments within transcripts using labels that capture ideas contained in the data. Related codes will then be grouped into themes that highlight common perceptions, ideas, or experiences across informants. We will follow an iterative approach to analysis that involves ongoing cycles of reading and coding transcripts, reviewing the literature, and discussing findings among the research team to identify themes. Throughout the process we will use the constant comparative method comparing data with data, data with codes, codes with codes, and codes with themes, in order to construct a detailed framework of perceptions regarding the effectiveness of care coordination strategies. The research team will use a software package (e.g., NVivo version 12) to facilitate the managing and coding of qualitative data.

3. Quantitative Evaluation Plan

The quantitative evaluation plan will focus on the trends in and analysis of the measures outlined in Tables 1.1-3.2. We will use conduct analyses of metrics that are feasible on a monthly basis and reporting results to NC DHHS through a data dashboard to be developed as part of the Evaluation. This approach will allow for the best possible estimates in the shortest possible time, to provide feedback to DHHS and PHPs to allow for short-term quality improvements in plan delivery. We will make appropriate adjustments in the evaluation design if changes in the implementation occur (e.g., using additional time period indicators in the analyses; testing for structural breaks in the parameter estimates). The focus will be on causal modeling of each measure in an attempt to identify changes in the measure due to each aspect of the 1115 waiver. A variety of quantitative techniques will be used as described below.

a. Difference-in-differences analysis

Through the use of a contemporaneous comparison group, described below, and pre-intervention data, many of the models estimated for the evaluation will follow a difference-in-differences approach.

Variables on expenditures and utilization derived from claims data will generally be updated monthly for analysis. Other variables that are from surveys or only available annually will be analyzed on an annual basis. Some metrics that are not relevant monthly, such as quality metrics with annual benchmarks (e.g., the % of eligible women receiving breast cancer screening), will be aggregated to annual measures and analyzed on a rolling basis as appropriate.

Analysis models will take the following form:

$$Y_{it} = f(\beta_0 + \beta_1 WaiverParticipant_{it} + \beta_2 Post_t + \beta_3 WaiverParticipant_{it} * Post_t + \beta_4 Z_{it} + \beta_5 Time_t) + \varepsilon_{it}$$

where *i* indexes individuals, *t* indexes time periods, Y are the process and outcome measures specified above, *WaiverParticipant* indicates individuals in the target population for each element of the waiver (e.g., those in the standard plans; those in the tailored plans), *Post* indicates the relevant post implementation period, *Z* are time-varying covariates, *Time* is a time period counter that starts from 1 during the first observation in the analysis period, and ε is the model error term. We will examine both linear models with person-level fixed effects, our preferred specification to control for time-invariant selection differences between treatment and control groups, as well as Generalized Estimating Equation (GEE) models with appropriate distributional and correlation specifications for each outcome measure. Results from all analyses will be converted to average marginal effects, which specify the natural unit increase in the outcome measure due to the implementation of the waiver component (e.g., standard plans, tailored plans, SUD waiver provisions).

b. Regression discontinuity models

PHPs, AMHs, and/or CINs are required to implement a risk stratification system in order to indentify Medicaid and Health Choice enrollees who might benefit from care management. If a single risk score were available across plans and a single threshold for the score were used to indentify candidates for care management, then a regression discontinuity design could be implemented for research questions 1.4 evaluating care management services by examining differences in outcomes for those just below and just above the assignment threshold. However, no single risk scoring tool has been required, which may mean that dozens of different risk scoring systems and thresholds of assignment may be in play. Information on exactly which risk scoring tool will be used by PHPs, AMHs, and CINs may not be available until implementation. We will seek to gather data on these tools from PHP reporting, through

contact with plan administrators, and from DHHS, and if a small number of risk scoring systems are in use on a sufficient number of PHP enrollees to justify the use of an RD design, we will use one to evaluate the effectiveness of care management systems, as described above.

c. Interrupted time-series analysis models

Interrupted time-series (ITS) analysis models will take the following form:

$$Y_{it} = f(\beta_0 + \beta_1 Time_{it} + \beta_2 Post_t + \beta_3 Time_{it} * Post_t + \beta_4 Z_{it} +) + \varepsilon_{it}$$

This analysis is different from difference-in-differences analyses in two ways. First, it only includes intervention observations, from pre- and post- implementation, and thus a *Treatment* indicator is not necessary as it would always equal 1. Second, it specifically tests for changes in the slope of the time trends, in addition to an average shift in the level of the outcome for each measure. We will again generate average marginal effects of the interventions on the level of each outcome and on the trends in the outcomes, but will use GEE and related techniques for modeling outcomes. Because an ITS approach is subject to confounding from events such as the availability of treatments or changes in the health services environment that occur during the post-period, it is not our preferred approach to analysis. However, it may be used for quantitative analyses when a contemporaneous comparison group is not available, such as in analyses of the provider survey. At this writing the provider survey may not contain a pre-intervention assessment due to contract delays, in which case, we would use a modified ITS approach that would examine changes in provider satisfaction over time during the demonstration years and with respect to demonstration milestones.

d. Costs of care

Research questions 2.3 and 3.3 examine the costs care. In a fee-for-service system, identifying costs to the Medicaid program is straightforward through the use of Medicaid expenditures. In capitated systems, there are several complications to this approach. PHPs are expected to continue to pay individual providers on a fee-for-service basis, but expenditure data is not always present in encounter data as it is often perceived as proprietary. This includes the baseline services funded through NC's currently behavioral health carve-out to regional entities, as well as the state-budged IMD services. In addition, the incentives to report accurate expenditure data may be dampened under capitation, although this can be mitigated through auditing or other forms of monitoring. Finally, the costing perspective may change under capitation, since the costs of an additional service to the Medicaid program are zero when the risk for service use is assumed by a PHP. In contrast, the societal cost of service use is non-zero, but should also include other costs not typically available in claims, such as time and transportation costs.

While the gold standard in cost analysis is to take a societal cost perspective, including not only the direct payments for services, but also unreimbursed costs of care as well as time and travel costs for patients, this approach is very resource intensive to do well and requires substantial

primary data collection. Relevant costs for most Medicaid policy analyses include costs to the Medicaid agency (including payments for services under fee-for-service as well as capitation payments), out-of-pocket costs to patients (co-payments), and costs to capitated health plans. We will examine costs from all three of these perspectives for the two cost hypotheses, as the data allows. That is, we will examine costs from the Medicaid agency perspective by aggregating fee-for-service payments for services outside the capitation system with capitation payments, but excluding the cost of services paid by PHPs. These costs are generally expected to decrease under capitation, but may increase with the expanded set of SUD benefits (Hypothesis 3.3). We will examine the out-of-pocket costs to Medicaid beneficiaries, as recorded in claims and encounters. These costs are hypothesized to remain constant. Finally, we will examine the costs of services provided under capitation, which is similar to a PHP perspective, had they been paying for services prior to PHP implementation. This perspective will use a fee-for-service costing approach to actual services use. If PHP expenditures are available in the encounter data, then we will use these expenditures directly, as the fee schedule for HCPCS coded services is not expected to change. If expenditures are not available from PHP encounter data, then we will append the pre-PHP fee-schedule to services delivered after PHP implementation.

Table 7: Summary Design Table for Quantitative Evaluation Metrics

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
Hypothesis 1.1				
RQ1.1.a: Effect of standard plans on access to physical health care RQ1.1.d: Effect of tailored/specialized plans on access to physical health care	Table 1.1	None (Pre/Post)	-CAHPS (5), immunization registry data (11)	Interrupted time series
		In/Out of State Controls	-Claims (1, 27), Encounters (2, 3)	Difference-in-Differences
RQ1.1.b: Effect of standard plans on the quality of care RQ1.1.e: Effect of tailored/specialized plans on the quality of care	Table 1.1	None (Pre/Post)	-CAHPS (5)	Interrupted time series
		In/Out of State Controls	Claims (1, 27), Encounters (2, 3), PHP data (9), Birth Certificate	Difference-in-Differences

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
			data (12), LHD data (25)	
RQ1.1.c: Effect of standard plans on outcomes RQ1.1.f: Effect of tailored/specialized plans on outcomes	Table 1.1	None (Pre/Post)	-CAHPS (5)	Interrupted time series
		In/Out of State Controls	Claims (1, 27), Encounters (2, 3), PHP data (9), Birth Certificate data (12), Death Certficate data (13), BRFSS (14), DOC (19)	Difference-in-Differences
Hypothesis 1.2				
RQ1.2.a: Effect of standard plans on appropriate use of behavioral health services RQ1.2a: Effect of standard plans on quality of behavioral health services RQ1.2c: Effect of tailored/specialized plans on appropriate use of behavioral health services RQ1.2d: Effect of tailored/specialized plans on quality of behavioral health services	Table 1.2	In/Out of State Controls	Claims (1, 27), Encounters (2, 3), PHP data (9), Clinical and diagnositic assessment data (10), NC TOPPS (20), NSDUH (23)	Difference-in-Differences
Hypothesis 1.3				

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
RQ1.3a: Effect of standard plans on Rx for OUD RQ1.3b: Effect of standard plans on Services for OUD RQ1.3c: Effect of standard plans on use of opioids RQ1.3d: Effect of tailored/specialized plans on Rx for OUD RQ1.3e: Effect of tailored/specialized plans on Services for OUD RQ1.3f: Effect of tailored/specialized plans on use of opioids	Table 1.3	In/Out of State Controls	-Claims (1, 27), Encounters (2, 3), DEA data (16), Licensure data (15), CSRS (17), DOC (19)	Difference-in-Differences
Hypothesis 1.4				
RQ1.4a: Effect of AMH on receipt of care management RQ1.4b Effect of AMH on quality RQ1.4c Effect of AMH on outcomes	Table 1.4	In/Out of State Controls; In-state controls will consist of PHP enrollees not in Tier 3 AMHs, if adequately powered.	-Claims (1, 27), Encounters (2, 3), PHP data (9), care management data (8), immunization registry data (11)	Difference-in-Differences
Hypothesis 2.1				
RQ2.1.a: Effect of standard plans on non-urgent ED use RA2.1.b Effect of standard plans on hospital admissions RQ 2.1.c: Effect of tailored/specialized	Table 2.1	In/Out of State Controls	-Claims (1, 27), Encounters (2, 3), PHP data (9), NC Hospital Discharge Data (21)	Difference-in-Differences

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
plans on non-urgent ED use RA2.1.d Effect of tailored/specialized plans on hospital admissions				
Hypothesis 2.2				
RQ2.2.a: Effect of standard plans on care management RQ2.2.c: Effect of tailored/specialized plans on care management	Table 2.2 - consumer perceptions of care coordination	None (Pre/Post)	CAHPS (5)	Interrupted time series
RQ2.2.a: Effect of standard plans on care management RQ2.2.c: Effect of tailored/specialized plans on care management	Table 2.2 - Time to SDOH Screening from PHP attribution	None	-NCcare360 (7)	Descriptive
RQ2.2.a: Effect of standard plans on care management RQ2.2.b: Effect of standard plans on care management during transitions RQ2.2.c: Effect of tailored/specialized plans on care management RQ2.2.d: Effect of tailored/specialized plans on care management during transitions	Table 2.2	In/Out of State Controls	-Claims (1), Encounters (2, 3), PHP data (9), NC Hospital Discharge Data (21)	Difference-in-Differences
Hypothesis 2.3				

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
RQ2.3.a Effect of standard plans on Medicaid expenditures RQ2.3.b Effect of tailored/specialized plans on Medicaid expenditures	Table 2.3	In/Out of State Controls	Claims (1, 27), Encounters (2, 3), MEPS (22)	Difference-in-Differences
Hypothesis 2.4				
RQ2.4.a Effect of standard plans on provider satisfaction RQ2.4.c Effect of tailored/specialized plans on provider satisfaction	Table 2.4	None (Pre/Post or Post-only)	Provider Survey (6)	Interrupted time series
RQ2.4.b Effect of standard plans on provider participation RQ2.4.b Effect of tailored/specialized plans on provider participation	Table 2.4	In/Out of State Controls	Claims (1, 27), Encounters (2, 3),	Difference-in-Differences
Hypothesis 2.5				
RQ 2.5.a Effect of managed care on provider satisfaction	Table 2.5	Pre/Post	Provider survey (6)	Interrupted Time Series
RQ 2.5.b Effect of managed care on provider participation	Table 2.5	In/Out of State Controls	Claims (1, 27), Encounters (2, 3)	Differences-in-differences and Interrupted Time Series
Hypothesis 3.1				
RQ3.1.a Effect of expanded SUD services on quality of care for SUD	Table 3.2	In/Out of State Controls	Claims (1, 27), Encounters (2, 3), IMD data (4), DOC (19), Death	Difference-in-Differences

Abbreviated Research Question	Location of Outcome Measures	Comparison Group	Data Sources (Data source #s from Table 6)	Analytic Methods
RQ3.1.b Effect of expanded SUD services on outcomes for SUD			Certificate data (13)	
Hypothesis 3.2				
RQ3.2.a Effect of expanded SUD services on Rx for OUD RQ3.2.b Effect of expanded SUD services on Sevices for OUD RQ3.2.c Effect of expanded SUD services on opioid use	Table 3.1	In/Out of State Controls	Claims (1, 27), Encounters (2, 3), DEA data (16), Licensure data (15), CSRS (17)	Difference-in-Differences
Hypothesis 3.3				
RQ3.3 a-f Effect of expanded SUD services on total costs and cost components for people with SUD diagnoses	Table 3.3	In/Out of State Controls	Claims (1, 27), Encounters (2, 3), MEPS (22)	Difference-in-Differences

e. Target and Comparison Populations

i. Target Populations

For most quantitative analyses, target populations will be defined from enrollment, claims, and encounter data. Analyses will be conducted at the beneficiary level for most measures, although re-admission analyses will be conducted at the hospital stay level. Many measures examine the full population of Medicaid beneficiaries, which will include those enrolled in Medicaid managed care for the relevant period (month, quarter, or year). Many hypotheses are specific to either populations in tailored plans or in standard plans, and thus target populations will be limited to those enrolled in these plans for the period enrolled. For baseline (pre-implementation, prior to Nov 1, 2019 for standard plans or 2021 for tailored or specialized plans) data, prior to attribution of enrollees to specific PHPs and benefits, we will use the tailored and specialized plan definitions from the Medicaid Managed Care Final Policy

Guidance: Behavioral Health and Intellectual / Developmental Disability Tailored Plan Eligibility and Enrollment document[5], which are based on diagnoses and other information from the claims and enrollment files. Some measures are relevant only for subpopulations, such as beneficiaries with diabetes. We will use diagnoses available in the claims and encounter data, acknowledging that this approach is efficient from an evaluation cost perspective, but will undercount individuals with the diagnosis, since not all diagnoses are recorded in claims; this is especially true for behavioral health diagnoses. This will have the result of biasing the estimation sample towards those with either longer term or more acute illness, but makes the estimates comparable to the numerous other studies that use claims data for identification.

We will conduct a limited number of subpopulation analysis, based on region, age, sex, race/ethnicity, and disability status as well as by key population groups where feasible, in order to contribute to the Disparity Reporting and Tracking from the State's Quality Strategy. We will also stratify some analyses on specific PHPs as motivated by the qualitative and survey analyses in order to between understand differences by characteristic of PHPs (e.g., if some subset of PHPs have a common set of initiatives around tobacco cessation, we will run analyses around tobacco-use outcomes for beneficiaries attributed to these PHPs).

ii. Comparison Populations

Because of the rapid changes in the Medicaid and scientific environments, a contemporaneous control group is desirable. Our quantitative analysis uses several different control groups for analyses, based on data availability and feasibility, as described below. Control groups will be adjusted for differences in observable characteristics through methods such as inverse probability of treatment weights (also referred to as propensity score methods), coarsened exact matching, and/or synthetic control methods.

1. Within-state controls

We will use two sets of within-state controls drawn from the Medicaid and Health Choice population: enrollees that meet the criteria for PHP enrollment before the PHPs are implemented, and enrollees in the Phase II regions, who will have their PHPs coverage delivered with a 4-month lag. The second approach is exploratory only and not critical to the evaluation design, and viable as a control group only for a subset of metrics that are expected to be immediately influenced by managed care implementation (e.g., medications, expenditures).

The groups that are either exempt from managed enrollment or will be enrolled in the behavioral health intellectual / developmental disability tailored or specialized foster care plans by Demonstration Year 3 are not an ideal comparison group, because they consist of individuals who may have distinct patterns of care from those enrolled in managed care, such as Dual-

[5] https://files.nc.gov/ncdhhs/BH-IDD-TP-FinalPolicyGuidance-Final-20190318.pdf

enrollees, those with partial Medicaid benefits, or those with high behavioral health service needs.

We are working towards the inclusion of one additional set of in-state controls, which would be drawn from privately insured NC Blue Cross / Blue Shield (BCBSNC) enrollees, to the extent a similar control group can be identified and with permission from the data custodian. These data have been requested; once they are in hand, we will explore the trends in the outcome variables relevant for those in the standard plans to determine whether the trends in the baseline period are similar between those in the standard plans and BCBSNC enrollees.

2. Out-of-state controls

The Evaluation Team is also exploring the use of comparison Medicaid enrollees from one or more other states' Medicaid programs. While these controls would be ideal to control for changes in national or regional events, such as changes in the labor market that may expand or contract the Medicaid population, changes in the scientific knowledge base and FDA-approved drugs or devices, there are a number of downsides to using out-of-state comparisons. First, it would be ideal to identify one state that has similar levels and trends in outcome metrics during the baseline period and thus serves as a counterfactual to the changes from NC's Medicaid waiver. However, due to the considerable heterogeneity among states in characteristics of their Medicaid programs, provider supply, and patient populations, it is close to impossible to identify a state that meet this requirement. In addition, as described above, the first step in the analysis would be to identify whether the trends in each of the measures specified in Tables 1.1-3.2 above are similar between the intervention and comparison groups. In order to do this, we would need to have the states' data in hand and to run algorithms to generate analytic files from each of these states, not knowing whether the states' data will have similar trends, leading to a non-zero probability of rejection. This is a fairly costly proposition with considerable uncertainty that the investment will pay off, if the trends are not similar. Finally, acquiring another state's data takes relationship-building and a considerable investment in programming effort, as each state's data can differ substantially in format and content. Acquiring data from CMS through MSIS or T-MSIS data sources that are contributed by states and further cleaned by CMS and its subcontractor is being explored as a possibility, although this approach adds a considerable time lag to comparison data, meaning that the full difference-in-differences model described above can only be implemented with a likely 1-3 year lag (e.g., analysis of the first year post-implementation would only be available at least 1-3 years later). Finally, another option under consideration is the use of one or more comparison states through a distributed network approach, which would not allow pool analysis, but would allow the comparison of trends across states in a limited number of outcome measures. AcademyHealth's State University Partnership Learning Network (SUPLN) is investigating the use of a distributed network for our and other states' 1115 waiver evaluations.

In collaboration with NC DHHS, the Evaluation Team is actively involved in discussions with Oklahoma to examine the comparability of Medicaid patterns of utilization

between the two states. Initial comparisons indicate that the relative per enrollee expenditures between the two states are similar, potentially indicating the levels of utilization may also be similar. In addition, conversations with the SUPLN members is progressing as well, as a potential back up plan.

Finally, for national data sets such as the Behavioral Risk Factor Surveillance System (BRFSS), we will draw contemporaneous controls from other states, segmented by their managed care implementation status, thus comparing North Carolina respondents' values to respondents in other states that have and have not yet implemented a capitated managed care program.

d. Evaluation Period

The evaluation study period runs from January 1, 2014 – October 31, 2024, five years prior to Demonstration Year 1, and through the end of the demonstration. There are at least four distinct time periods that we will use for the quantitative evaluation, described below. If the demonstration is altered in a substantial way after its initial approval, these periods may be modified.

We will consider the baseline time period from January 1, 2014-June 30, 2019, prior to expected implementation of the SUD components of the waiver. An additional baseline time period of July 1, 2019 – January 31, 2020 is relevant for the implementation of the standard plans. For most of the analyses for Goals 1 and 2, we will limit the baseline analysis period to be five years prior to PHP implementation, February 1, 2015-January 31, 2020. The third relevant period is during the implementation of standard plans only, beginning February 1, 2020 – June 30, 2021. During this time period, the population that is to be enrolled in tailored and specialized plans will continue to be in fee-for-service coverage for medical care, and will continue to receive behavioral health care and care for I/DD through the LME/MCOs, which will continue to be paid as Prepaid Inpatient Healthcare Plans. Populations excluded from LME-MCOs (e.g., NC Health Choice, children under age 3) will continue to obtain behavioral health services through FFS. During the third evaluation time period, the standard plans will be phased in on a regional basis, with a 4-month lag between implementation in the Phase I regions and implementation in the Phase II regions. In addition, during the third evaluation time period, the ECMOS Pilots will be phased in. Finally, the fourth evaluation time period will reflect the full implementation of the standard, tailored, and specialized plans, and is expected to run from the fall of 2021 – October 31, 2024.

e. ECMOS Pilots and interactions among waiver components

Individuals who are enrolled in a PHP in a selected pilot region and are eligible for pilot services will be potentially affected both by the transition to the PHP as well as by the additional pilot services. In addition, pilot service receipients may be in a practice that is designated as an Advanced Medical Home, and thus may receive care management services from their AMH, PHP, or other local management entity. Fortunately, these events happen at different time

periods at the initial launch of managed care (SP and AMH implementation is Feburary 1, 2019, 2020 while pilot services will begin to be delivered in late 2020 or early 2021). Pilot services will be examined in a separate evaluation and thus the evaluation methods will not be described here. However, pilot enrollees will be included in all analyses of PHP enrollees. In addition, once pilot enrollees can be identified through their receipt of services, we will be able to conduct additional analyses of PHPs and other components of the waiver excluding pilot enrollees in order to be able to tease out the effect of the PHP without the additional effects of pilot services.

Our general strategy allows for isolation of separate effects of many but not all of the waiver components, generally based on temporal separation of waiver components, or on selection criteria for specific components, such as the regional implementation of the pilots or the identification of AMH practices. Some waiver components that will be implemented contemporaneously, such as AMHs that launch at the same time as PHPs, for example, may not allow for identification of separate effects. For example, if most PHP enrollees are also receiving care from an AMH, we may not be able to identify the separate effects due to PHPs independent of AMHs. We will constantly stay up-to-date on waiver and managed care events, and will revise evaluation analyses accordingly to provide the most policy relevant results on the specific components of the waiver and managed care program.

D. Data Sources

Table 8: Data Sources Requested for 1115 Waiver Evaluation

Data Source	Data Custodian	Periodicity	Dates Requested	Frequency of data needed
1. FFS Claims data	DHHS	Continuous	January 1, 2014 – Oct 31, 2024	Monthly
2. LME/MCO encounter data[a, b]	DHHS	Continuous	January 1, 2014 – June 30, 2021[c]	Monthly
3. PHP encounter data[a, b]	PHPs	Continuous	February 1, 2020 – Oct 31, 2024	Monthly
4. State Operated Facility utilization (public "IMD" utilization) [b]	State Operated Facilities	Continuous	January 1, 2014 – Oct 31, 2024	Monthly
5. CAHPS	DHHS will contract with an EQRO to implement the Adult and Child Version of the	Annual	2014 - 2024	Annually, or as administered

Data Source	Data Custodian	Periodicity	Dates Requested	Frequency of data needed
	Health Plan Survey annually			
6. **Provider Surveys**[d]	UNC-CH	Annual	2019 - 2024	
7. **NC Resource Platform / NCCare360 / pilot data**[b]	DHHS/Unite US/Foundation for Health Leadership & Innovation	Continuous	2019-2024	Quarterly
8. **Care management data**[b]	DHHS / CCNC / PHPs / LHD / AMHs / TP care management entities	Continuous	2014 - 2024	Quarterly
9. **PHP data - Plan data outside of encounter data that is reported to DHHS, include provider registries/networks**	PHPs	Annual	February 1, 2020 – October 31, 2024	Annual or as reported
10. **Comprehensive Clinical and Diagnostic Assessments**	PHPs	Continuous	February 1, 2020 – October 31, 2024	Monthly or as reported
11. **Immunization registry data**[b]	DPS	Continuous	January 1, 2014 – Oct 31, 2024	Quarterly
12. **Birth Certificate Data**[b]	State Center for Health Statistics	Continuous	January 1, 2014 – Oct 31, 2024	Annually
13. **Death Certificate Data**[b]	State Center for Health Statistics	Continuous	January 1, 2014 – Oct 31, 2024	Annually
14. **BRFSS**[d]	CDC / Publicly available	Annual	2014 - 2024	Annually
15. **Active, licensed providers in NC with prescribing privileges) (MD, DO, NP, PA)**[d]	Either NC Licensure data or NPPES	Continuous	2014 - 2024	Annually
16. **Number of providers with DEA DATA 2000 Waivers**[d]	DEA (requires subscription)	Monthly	2014 - 2024	Monthly

Data Source	Data Custodian	Periodicity	Dates Requested	Frequency of data needed
17. Controlled Substances Reporting System [b]	DHHS	Continuous	January 1, 2014 – Oct 31, 2024	Monthly
18. Practice Grouper, if not available through DHHS (tentative, not included in budget) [d]	IQVIA	TBD	January 1, 2014 – Oct 31, 2024	Quarterly
19. NC Department of Corrections Data (tentative, not included in budget) [b]	NC DOC	Continuous	January 1, 2014 – Oct 31, 2024	Quarterly
20. **NC Treatment Outcomes and Program Performance System (NC-TOPPS) [b] [tentative, subject to conversation with Data Custodian]**	NC DHHS	Continuous	January 1, 2014 – June 30, 2024 Oct 31, 2024	Annually
21. NC Hospital Discharge Data [d]	DHSR	Annual	2014 - 2024	Annually
22. Medical Panel Expenditure Survey [d]	AHRQ	Annual	2014 - 2024	Annually
23. National Survey on Drug Use and Health [d]	SAMHSA	Annual	2014 - 2024	Annually
24. Medicare data for dual eligibles [b]	CMS to DHHS	Continuous	January 1, 2014 – Oct 31, 2024	Monthly
25. Data from local health departments related to high risk maternity and peds populations [b]	LHDs	Continuous	January 1, 2014 – Oct 31, 2024	Monthly
26. State surveys related to surveys related to BH/SUD and I/DD	DHHS	Annual	2014 - 2024	Annually

[a] Encounter data are assumed to have actual payment information to service providers.

[b] Requires linkage to Medicaid identifiers

[c] The LME/MCO system is expected to no longer exist as of July 1, 2021

[d] does not require assistance from DHHS for access

Table 9: Measures

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
1.	Getting Care Quickly	NQF #: 0006 / AHRQ	CAHPS	1.1
2.	Getting Needed Care	NQF #: 0006 / AHRQ	CAHPS	1.1
3.	Use of primary care services	Quality Strategy Objective 2.3	Claims / Encounters	1.1
4.	Adolescent Well-Care	NCQA – HEDIS 17168	Claims / Encounters	1.1
5. – 8.	Children and Adolescents' Access to Primary Care Practitioners (4 measures)	NQF#: 2371 / NCQA - HEDIS	Claims / Encounters	1.1
9.	(Any) Annual Dental Visits	NQF#: 1388/ NCQA - HEDIS	Claims / Encounters	1.1
10.	Dental Sealants for Children at Elevated Caries Risk	NQF#: 2508/ NCQA – HEDIS / ADA	Claims / Encounters	1.1, 1.5
11.	Up to date on Childhood Immunizations	NQF#: 0038 / NCQA - HEDIS	Claims / Encounters/ immunization registry	1.1, 1.4
12. – 13.	Immunizations for Adolescents (2 measures)	NQF#: 1407 / NCQA - HEDIS	Claims / Encounters/ immunization registry	1.1, 1.4
14.	Customer Service	NQF #: 0006 / AHRQ	CAHPS	1.1
15.	Rating of Health Plan	NQF #: 0006 / AHRQ	CAHPS	1.1
16.	Rating of all Health Care	NQF #: 0006 / AHRQ	CAHPS	1.1
17.	Rating of Personal Doctor	NQF #: 0006 / AHRQ	CAHPS	1.1
18.	Adult BMI Assessment	NQF#: 0023 / NCQA - HEDIS	Claims / Encounter Data; PHP data	1.1
19.	Weight Assessment and Counseling for	NQF#: 0024/ NCQA - HEDIS	Claims / Encounter Data; PHP data	1.1, 1.4

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
	Nutrition and Physical Activity for Children/ Adolescents			
20.	Tobacco Use screening and follow-up	NQF# 2600	Claims / Encounter Data	1.1
21.	Breast Cancer Screening	NQF#: 2372 / NCQA - HEDIS	Claims / Encounter Data	1.1
22.	Cervical Cancer Screening	NQF#: 0032 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
23.	Flu vaccine for Adults age 18-64	NQF#: 0039 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4, 1.5
24.	Appropriate Testing (for strep) for Children with Pharyngitis	NQF#: 0002 / NCQA - HEDIS	Claims / Encounter Data	1.1
25.	Appropriate Treatment for Children with Upper Respiratory Infection	NQF#: 0069 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.5
26.	Medication Management for People with Asthma	NQF#: 1799 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
27.	Asthma Medication Ratio	NQF#: 1800 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
28.	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	NQF#: 0058 / NCQA - HEDIS	Claims / Encounter Data	1.1
29.	Annual Monitoring for Patients on Persistent Medications	NQF#: 2371 / NCQA - HEDIS	Claims / Encounter Data	1.1
30. – 31.	Pharmacotherapy Management of COPD Exacerbation	NQF#: 2856 / NCQA - HEDIS	Claims / Encounter Data	1.1

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
	(2 measures)			
32. – 33.	Statin Therapy for Patients with Diabetes (2 measures)	NQF#: 0547 / NCQA - HEDIS	Claims / Encounter Data	1.1
34.	Diabetes Screening for People with Schizophrenia or Bipolar Disorder who are Using Antipsychotic Medications	NQF#: 1932 / NCQA - HEDIS	Claims / Encounter Data	1.1
35. – 36.	Statin Therapy for Patients with Cardiovascular Disease (2 measures)	NQF#: 0543 / NCQA - HEDIS	Claims / Encounter Data	1.1
37.	Visits in the First 15 Months of Life	NQF#: 1392 / NCQA - HEDIS	Claims / Encounter Data	1.1
38.	Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life+	NQF#: 1516 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
39.	Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Claims / Encounter Data	1.1, 3.1
40.	Use of Imaging Studies for Low Back Pain	NQF#: 0052 / NCQA - HEDIS	Claims / Encounter Data	1.1
41.	Chlamydia Screening in Women	NQF#: 0033 / NCQA - HEDIS	Claims / Encounter Data	1.1
42.	Screening for pregnancy risk	NC Administrative Measure	Claims / Encounter Data	1.1
42.	Frequency of Prenatal Care (>=81% of expected visits)	NQF#: 1391 / NCQA - HEDIS	Claims / Encounter Data	1.1
43.	Prenatal and Postpartum Care+	NQF#: 1517 / NCQA - HEDIS	Claims / Encounter Data	1.1

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
44.	Pregnant smokers screened and treated for tobacco use	NC Modified measure	Birth certificate / Claims / Encounter Data	1.1
45.	All-Cause Hospital Readmission	NQF#: 1768 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
46. – 47.	30-day hospital readmission rate following hospitalization for SUD or OUD	--	Claims / Encounter Data	1.1
48.	Comprehensive Diabetes Care: HbA1c poor control (>9.0) +	NQF#: 0059 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
49. – 57.	Comprehensive Diabetes Care (9 measures)	NQF#: 0061, 0575, 0055 / NCQA - HEDIS	Claims / Encounter Data	1.1
58.	Diabetes Short-term Complication Admission Rate	PQI-01, PDI-15	Claims / Encounter Data	1.1, 1.4
59.	Controlling High Blood Pressure	NQF#: 0018 / NCQA - HEDIS	Claims / Encounter Data	1.1, 1.4
60.	COPD or Asthma in Older Adult Admissions	PQI-05	Claims / Encounter Data	1.1, 1.4
61.	Heart Failure Admissions	PQI-08	Claims / Encounter Data	1.1, 1.4
62.	Receipt of Preventative Dental Services	NQF#: 1334 / CMS-416	Claims / Encounter Data	1.1
63.	Asthma Admissions in Younger Adults	PQI-15	Claims / Encounter data	1.1, 1.4
64.	Gastroenteritis Admissions	PDI-15	Claims / Encounter data	1.1, 1.4
65.	Urinary Tract Infection Admissions	PDI-18	Claims / Encounter data	1.1, 1.4
66.	Death rate by group (e.g., SUD, SMI)	--	Claims / Encounter data linked with death certificate data	1.1

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
67.	Live Births Weighing Less than 2500 Grams +	NQF#: 1382 / CDC (NC Modification)	Birth Certificate / Medicaid eligibility	1.1
68.	Infant Mortality		Birth Certificate / Death Certificate data	1.1
69.	Healthy Days		BRFSS	1.1
70.	Tobacco Use Rate (multiple measures)	Public Health Measures	BRFSS / CAHPS	1.1
71.	Overweight / Obesity Rate	--	BRFSS / CAHPS	1.1
72.	Death rate post prison release	--	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	1.1
73. – 74.	Antidepressant Medication Management (two measures)	NQF#: 0105/ NCQA - HEDIS	Claims / Encounter data	1.2, 1.4
75.	Depression screening among those with SUD	NQMC: 004006	Claims / Encounter data	1.2
76. – 77.	Follow-up After Hospitalization for Mental Illness or Alcohol / Other Drug Treatment+ (7/30 days)	NQF#: 0576/ NCQA - HEDIS	Claims / Encounter data	1.2, 1.4
78. – 79.	Follow-up for Children Prescribed ADHD Medication (2 measures)	NQF#: 0108/ NCQA - HEDIS	Claims / Encounter data	1.2, 1.4, 1.5
80.	Initiation and Engagement of SUD Treatment+	NQF#: 0004/ NCQA - HEDIS	Claims / Encounter data	1.2, 1.5, 3.1
81.	Medical Assistance with Smoking and Tobacco Use Cessation	NQF#: 0027/ NCQA - HEDIS	Claims / Encounters; PHP data; CAHPS	1.2, 1.4

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
82.	Continuity of Pharmacotherapy with OUD	NQF#: 3175	Claims / Encounter data	1.2
83.	Concurrent Use of Prescription Opioids and Benzodiazepines	PQA	Claims / Encounter data	1.2
84. – 85.	ED visits for SUD-related diagnoses and specifically for OUD (2 measures)	NQF: 2605	Claims / Encounter data	1.2, 3.2
86.	IP visits for SUD and specifically for OUD	--	Claims / Encounter data	1.2, 3.2
87.	Adherence to Antipsychotic Medications for Individuals with Schizophrenia	NQF# 1879 NCQA - HEDIS	Claims / Encounter data	1.2, 1.5
88.	Use of behavioral health care for people with SMI or SUD	--	Claims / Encounter data	1.2
89.	Use of pharmacotherapy for opioid use disorder (OUD)	NQF 3400	Claims / Encounter data	1.3
90.	Number of providers with DEA DATA 2000 waivers	--	DEA data	1.3, 3.2
91.	Number of providers with DEA DATA 2000 waivers who have written prescriptions for Medicaid enrollees for MAT	--	DEA data and Claims/Encounter data	1.3, 3.2
92.	Percent of SUD diagnosed beneficiaries who receive an SUD treatment service	--	Claims/Encounter data	1.3, 3.1
93.	Long-Term Use of Opioids		Claims / Encounter data, CSRS	1.3, 3.2

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
94.	Use of Opioids at High Dosage in Persons without Cancer	NQF#:2940/ PQA	Claims / Encounter data, CSRS	1.3, 3.2
95.	Use of Opioids from Multiple Providers in Persons Without Cancer	NQF#:2950/ PQA	Claims / Encounter data, CSRS	1.3
96.	Reduced incarceration for drug-related charges	--	DOC data	1.3
97.	Number / % of practices on the PHP panel that attest to being a level 3 AMH		PHP data	1.4
98.	Number of enrollees attributed to an Advanced Medical Home	Quality Strategy Objective 2.2	Enrollment data	1.4
99.	Number of enrollees receiving care management	--	Claims / encounters / enrollment	1.4
100.	Number of ED visits	NCQA - HEDIS	Claims/Encounter data	2.1
101.	Avoidable or preventable emergency department visits	NYU / Billings algorithm	Claims/Encounter data	2.1
102.	Number of hospital admissions	--	Claims/Encounter data	2.1
103.	Number of hospital days	--	Claims/Encounter data	2.1
104.	Hospital admissions for ambulatory sensitive conditions; avoidable or preventable inpatient hospitalizations	AHRQ PQI and PDI	Claims/Encounter data	2.1
105.	Coordination of Care (consumer perceptions)	NQF #: 0006	CAHPS	2.2

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
106.	Time to SDOH Screening from PHP attribution	--	Claims / Encounter data ; PHP data; NCcare360	2.2
107.	Enrollees Receiving Care Management during transitions in care	Enrollees Receiving Care Management during transitions in care	Claims / Encounter data; care management data systems	2.2
108.	Medication Reconciliation Post-Discharge	Medication Reconciliation Post-Discharge	Claims / Encounter data	2.2
109.	Total Expenditures to the Medicaid program and components	--	Claims / Encounter data	2.3, 3.3
110.	Out-of-pocket costs to Medicaid enrollees	--	Claims / Encounter data	2.3, 3.3
111.	Costs of Medicaid funded services and components	--	Claims / Encounter data	2.3, 3.3
112.	Provider satisfaction	(under development)	Provider survey	2.4
113.	Provider participation in Medicaid	(under development)	Claims / Encounter data	2.4
114.	Percent of diagnosed beneficiaries who receive a treatment service	--	Claims / Encounter data	3.1
115.	Death rate from overdose	--	Claims / Encounter data linked with death certificate data	3.2
116.	Death rate from overdose post-release	--	Death Certificate data linked with DOC data and Medicaid enrollment, claims, and encounters	3.2
117.	Percent of enrollees diagnosed with OUD receiving MAT	CMS	Claims / Encounter data	3.2
118.	Percent of enrollees diagnosed with OUD	--	Claims / Encounter data	3.2

Measure Number	Measure	Measure Custodian	Data source	Used for hypotheses
	receiving non-medication opioid treatment services			

E. Methodological Limitations

Our analysis approach uses distinct time periods to examine different phases of waiver activities, although in reality, these are not as distinct as would be ideal. Efforts to create a managed care waiver were initiated by North Carolina's General Assembly some time before the baseline time period incorporated here. If provider behavior changed as a result of expectations of upcoming changes, then our baseline period would not capture a true baseline, but rather a baseline under increasing expectation of managed care implementation. We will use breakpoint analysis to examine whether outcomes may have changed prior to key implementation dates to see if there may have been anticipation effects. An additional concern when using encounter data is how accurate and complete these data are, given that the incentives for complete reporting are dampened over fee-for-service claims. Any deficits in quality of encounter data would confound the PHP analyses, since they would be contemporaneous to the implementation of capitated care. The evaluation team will continuously monitor the quality of encounter data as the PHPs are implemented, following monitoring techniques used to monitor encounter data in the MAX data, for example. We will report any data quality concerns to NC DHHS as soon as they are discovered, in an effort to improve data quality as the demonstration continues. We will also compare trends in utilization measures from encounter data to similar measures in NC claims data (Medicaid and BCBSNC) as well as external data sources (e.g., trends in the MEPS and BRFSS data), although these sources tend to have a greater lag. Finally, the evaluation will not be able to assess all aspects of the Demonstration due either to data limitations or statistical limitations. For example, we will not have information on enrollees' labor market status and thus cannot evaluate whether improved services increase the ability of enrollees to participate in the labor market. We also may not have complete information on provider satisfaction and engagement for those providers who are not currently participating in the Medicaid program. As new providers begin serving patients through PHPs, we will have records of these interactions, but will not be able to capture information from providers who do not serve enrollees in any given year. In addition, if participation in AMHs is high, we may not be able to assess the impact of AMH participation using in-state controls. We will contiuously seek ways to overcome these limitations throughout the evaluation period.

Attachment 1: Independent Evaluator

As stated in the Special Terms and Conditions, the State is required to select an independent evaluator for the 1115 Waiver Evaluation. Key requirements for the evaluator are that the evaluator be free of any conflict of interest, have experience with large scale evaluations, have experience working with the necessary data sources and types to evaluate the waiver, and have expertise with the evaluation methodologies that will be needed to evaluate the waiver. Further, the evaluator must be able to conduct a fair and impartial evaluation and prepare an objective evaluation report. Considering these factors, the State selected the Cecil G. Sheps Center for Health Services Research at The University of North Carolina at Chapel Hill ('the Sheps Center') to conduct the evaluation. The Sheps Center has a long history over several decades working with North Carolina Medicaid data (claims, provider, and de-identified beneficiary) and other state data sources including from Divisions of Public Health/State Health Statistics and Mental Health, Substance Use Disorder, and Intellectual/Developmental Disabilities. A thorough conflict of interest investigation was undertaken at the university level, and each investigator from the Sheps Center team had to complete a multi-faceted conflict of interest questionnaire. The team was found to have no conflicts of interest and the report has been attached. Under a Master Data Use Agreement, the Sheps Center will have access to necessary data and stringent conflict of interest policies are in place to ensure the absence of conflict of interest in the evaluation.

Attachment 2: Conflict of Interest Statement

UNC RESEARCH

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
CONFLICT OF INTEREST PROGRAM

BYNUM HALL, ROOM 301D
222 E. CAMERON AVENUE
CAMPUS BOX 9103
CHAPEL HILL, NC 27599-9103

T 919.843.9953
F 919.843.9005
coi@unc.edu

Conflict of Interest Certification Form

Sponsor: North Carolina Department of Health and Human Services (NCDHHS)
Reference: Contract #38132
UNC-CH Title: NC 1115 Waiver Evaluation
UNC-CH Lead PI: Marisa Domino
UNC CH Internal Reference: 18-5099

This letter is to certify that the University of North Carolina at Chapel Hill maintains a written policy and an administrative process for identification, evaluation and reporting of financial conflicts of interest meeting the requirements of Title 42 CFR Part 50, Title 42 CFR Part 94, Subpart F, NSF AAG Chapter IV.A, FAR 9.5 and other applicable federal regulations. Additionally, the Conflict of Interest Program at the University maintains a process of individual or organizational conflict of interest review which is responsive to any Sponsor's application or guidelines requesting this type of review.

Therefore, to the best of the Institution's knowledge and belief, it certifies:

ORGANIZATIONAL CONFLICTS OF INTEREST:
There are no facts relevant to any possible sources of organizational conflict of interest (such as ownership or proprietary rights) in conducting the research as defined in the proposal guidelines.

INDIVIDUAL CONFLICTS OF INTEREST:
This section certifies that any individual team members of Institution, who will perform work as investigators under this project have completed the disclosure process and there is a conflict of interest to report, as defined in the proposal guidelines.

Dr. Pam Silberman, a co-investigator on this project, serves on the Board of Directors of Alliance Behavioral Healthcare, an entity subject to the policies evaluated in this project. The University has determined that the management for this relationship is as follows:

Disclosure in any public dissemination
Agreement and understanding that Dr. Silberman cannot discuss with Alliance Behavioral Healthcare (including but not limited to its Board, employees, volunteers), any on-going UNC research findings (such as what the policies are likely to be) until public dissemination of such policies.
If by some odd chance, the Alliance is used as an example or somehow brought into the policy or research discussion, Dr. Silberman would recuse herself from providing any commentary, opinion or analysis.

Dr. Marisa Domino, the Principal Investigator at the University, is aware of the above conflict and the related management.

FUTURE CONFLICTS OF INTEREST:

The individuals working on this project have been informed of their obligation to promptly report personal and/or organizational conflicts of interest to the Institution. The Institution will promptly report in writing to UNC-Chapel Hill's Award Specialist any organizational or individual conflicts of interest that may arise during the performance contract. The UNC-CH Award Specialist will coordinate any positive responses with the Sponsor.

By:

Name: _____Joy Bryde_____

Title: ____Conflict of Interest Officer_____

Date: ____15 February 2019_____

Attachment 3: Evaluation Budget

The estimated budget for the Evaluation of the 1115 and SUD waivers is approximately $1.5 million per demonstration year, running from May 1, 2019 – December 31, 2026, for a total of approximately $10.7 million. This budget covers expenses relating to the quantitative and qualitative analysis using numerous sources of data and mixed methods approaches. This amount covers salaries, fringes, administrative costs, direct costs for travel around the state for primary data collection, conference calls amoung the study team, computing related expenses, and transcription and coding expenses. The qualitative component accounts for approximately $1.8M while the quantitative component accounts for approximately $5.7M of the budget. The remaining amount are for administrative or expenses shared by both the quantitative and qualitative components that are difficult to distribute. The total amount does not include the Evaluation of the Enhanced Case Management and Other Services Pilots nor of the provider survey, which have been budgeted separately.

The Cecil G. Sheps Center for Health Services Research at UNC-Chapel Hill will perform the 1115 and SUD waiver evaluation in partnership with NC DHHS. Sheps Center faculty and staff have decades of experience in policy evaluation, including mixed methods evaluations with claims data analysis, survey data fielding and analysis, and qualitative interview and focus group analysis. The multidisciplinary team has expertise on a number of dimensions important to this project, including behavioral health, CMS processes and procedures, Federal waivers, financial and economic analyses, administrative data analytics, organizational behavior, quality of care metrics, data visualization, implementation science, social determinants of health, and safety net providers.

Attachment 4: Timeline and Major Milestones

Waiver Evaluation: Key Milestones

Activity	DY0	DY1	DY2	DY3	DY4	DY5	DY6	Post
Waiver Milestones								
Procure evaluation contractor								
Release RFP for standard plans								
SUD Component Implementation								
Implementation of standard plans								
Release RFP for tailored and specialized plans								
PHPs performance evaluated against Priority Measure Set								
Implementation of tailored and specialized plans								
Evaluation Milestones								
Contract for Evaluation Design		3/19						
Contract for Evaluation		5/19						
Hold regular meetings between DHHS and Evaluation team								
Collaborate on data sharing to facilitate evaluation								
Receipt of baseline claims and encounter data for the evaluation								
Calculation of Baseline Metrics								
Submit Draft Evaluation Design								
Receipt of PHP encounter data for evaluation								
Receipt of other secondary data sources including provider survey data and CAHPS								
Calculation and Monitoring of all Quantitative Metrics								
Submit Quarterly Progress Reports		9/19						
Submit Annual Report			1/20					
Submit Draft Interim Evaluation Report					11/21			
Submit Final Interim Evaluation Report								
Submit Draft Summative Evaluation Report								
Submit Final Summative Evaluation Report								
Submit Final Reports to DHHS								

DY=Demonstration Year

DY0 are activities that occurred prior to the implementation of the waiver

DY1= 1/1/2019 – 10/31/2019

DY2=11/1/2019 – 10/31/2020

DY3=11/1/2020– 10/31/2021

DY4=11/1/2021 – 10/31/2022

DY5=11/1/2022 – 10/31/2023
DY6=11/1/2023 – 10/31/2024
Post period extends beyond the end of DY6 for analysis only, pending any renewal or continuation of the waiver.

Attachment 5: Abbreviations Used

AMH	Advanced Medical Home
CMS	Centers for Medicare & Medicaid Services
CSRS	Controlled Substances Reporting System
DOC	Department of Corrections
FFS	Fee-for-service
I/DD	Intellectual / Developmental Disability
IMD	Institute for Mental Disease
MAT	Medication-Assisted Treatment
OUD	Opioid Use Disorder
PHP	Prepaid Health Plan
SUD	Substance Use Disorder

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.[9,10] 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.

[9] North Carolina's Opioid Action Plan, 2017-2021. Available at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%208-22-2017.pdf.
[10] 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.[11]

[11] 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[12]	
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:

[12] 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.[13] 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

[13] 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	.4100	Do not reflect ASAM criteria
		Therapeutic community	.4300	Do not reflect ASAM criteria
		Non-medical community residential treatment services (adults and adolescents)	N/A	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	.6000	Do not reflect ASAM criteria
		Psychiatric unit, hospital	10A NCAC 13B .5200	
4-WM	Medically managed intensive inpatient withdrawal	Psychiatric hospital	.6000	Do not reflect ASAM criteria
			10A NCAC 13B	

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[14]
Outpatient Services[15]	≥ 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[16]	≥ 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[17]	≥ 1 provider of each crisis service within each LME-MCO region	
Specialized Services[18]	≥ 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

[14] 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.

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

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

[17] 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.

[18] 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[19]	≥ 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[20]	≥ 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[21]	≥ 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.

[19] Outpatient services include behavioral health services provided by direct-enrolled providers such as psychiatrists.
[20] Location-based services include ASAM levels 2.1 (SAIOP), 2.5 (SACOT) and OTPs.
[21] 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.[22] 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.[23]
- **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

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

[23] 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.[24]

- **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.

[24] 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.[25] 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.[26] 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.[27] 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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[25] 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.

[26] 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.

[27] 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.[28] 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.

[28] 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.[29]
- 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.

[29] 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)[30]

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.[31] 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.[32]

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

[30] 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.
[31] *Ibid*.
[32] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

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

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

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

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

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

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

Attachment G: Healthy Opportunities Pilot Program Eligibility and Services

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

Eligible Enrollees

Table 1: Needs-Based Criteria

Eligibility Category	Age	Needs-Based Criteria (at least one, per eligibility category)
Adults	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 and chronic renal failure, in accordance with Social Security Act section 1945(h)(2). • Repeated incidents of emergency department use (defined as more than four visits per year) or hospital admissions.
Pregnant Women	n/a	• Multifetal gestation • Chronic condition likely to complicate pregnancy, including hypertension and mental illness • Current or recent (month prior to learning of pregnancy) use of drugs or heavy alcohol • Adolescent ≤ 15 years of age • Advanced maternal age, ≥ 40 years of age • Less than one year since last delivery • History of poor birth outcome including: preterm birth, low birth weight, fetal death, neonatal death
Children	0-3	• Neonatal intensive care unit graduate • Neonatal Abstinence Syndrome • Prematurity, defined by births that occur at or before 36 completed weeks gestation • Low birth weight, defined as weighing less than 2500 grams or 5 pounds 8 ounces upon birth • Positive maternal depression screen at an infant well-visit
	0-20	• 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 <5th or >85th %ile for age and gender, developmental delay, cognitive impairment, substance use disorder, behavioral/mental health

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

Table 2: Risk Factors

Risk Factor	Definition
Homelessness and housing insecurity	Homelessness, as defined in 42 C.F.R. § 254b(h)(5)(A), and housing insecurity, as defined based on questions used to establish housing insecurity in the Accountable Health Communities Health Related Screening Tool.[33]
Food insecurity	As defined by the US Department of Agriculture commissioned report on Food Insecurity in America:[34] • Low Food Security: reports of reduced quality, variety, or desirability of diet. Little or no indication of reduced food intake. • Very low food security: Reports of multiple indications of disrupted eating patterns and reduced food intake
Transportation insecurity	Defined based on questions used to establish transportation insecurities in the Accountable Health Communities Health Related Screening Tool.[35]
At risk of, witnessing, or experiencing interpersonal violence	Defined based on questions used to establish interpersonal violence in the Accountable Health Communities Health Related Screening Tool.[36]

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

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

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

[36] *Ibid*.

Healthy Opportunities Pilot Program Services

Table 3: Healthy Opportunities Pilot Program Services

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

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

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

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