DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

August 15, 2019

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

Dear Mr. Richard:

On July 25, 2019, the state of North Carolina submitted to the Centers for Medicare & Medicaid Services (CMS) a final evaluation design for the Enhanced Case Management and Other Services Pilot (ECM), a component of the state's section 1115(a) demonstration entitled "North Carolina Medicaid Reform" (Project No. 11-W-00313/4) approved on October 24, 2018. The evaluation design was submitted in fulfillment of the requirement for an ECM Pilot Program evaluation design as described in the special term and condition (STC) 21(P)(vii) of section VII.

I am pleased to inform you that CMS has approved North Carolina's evaluation design for the ECM Pilot Program. The design is consistent with the requirements outlined in the applicable demonstration STC's. We appreciate the state's commitment to a rigorous evaluation approach of their initiative.

CMS has added the approved ECM Pilot Program evaluation design to the demonstration STCs as part of Attachment H. A copy of the STCs that includes the new attachment is enclosed with this letter. Per 42 CFR 431.424(c), the approved evaluation design may now be posted to the state's Medicaid website within thirty days of CMS approval. CMS will also post the approved evaluation design as a standalone document separate from the STCs on Medicaid.gov.

We look forward to our continued partnership with you and your team on the North Carolina section 1115 demonstration. If you have any questions, please contact your project officer, Sandra Phelps, at Sandra.Phelps@cms.hhs.gov.

Sincerely,

/s/

Angela D. Garner
Director
Division of System Reform Demonstrations

Enclosure

cc: Bill Brooks, Director of Field Operations South
Shantrina Roberts, Deputy Director of Field Operations South

Enhanced Case Management and Other Services Pilots

Evaluation Design

North Carolina Department of Health and Human Services

June 24, 2019

This program is operated under an 1115 Demonstration that was approved by the Centers for Medicare & Medicaid Services on October 24, 2018.

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General Background Information

Health is affected by many factors beyond the medical care provided within the walls of a hospital or clinic. While access to high-quality medical care is critical, research shows that up to 80 percent of a person's health is determined by social and environmental factors and the behaviors that emerge as a result.[1,2] A substantial body of research has established that having an unmet resource need—including experiencing housing instability[3], food insecurity[4], unmet transportation needs[5], and interpersonal violence or toxic stress[6,7]—can significantly and negatively impact health and well-being, as well as increase healthcare utilization and costs.[1,8–11] On the other hand, addressing those needs can potentially improve health and healthcare utilization, which in turn can lower healthcare costs. For example, research indicates that providing housing assistance to adults who have physical and/or behavioral co-morbidities and are experiencing homelessness decreases unnecessary use of hospital care and associated healthcare costs.[12–14] Similarly, reducing the presence of asthma triggers (such as moldy carpets and broken air conditioners) in a child's home can reduce hospital visits and related costs[15,16], and nutritional assistance interventions have been associated with lower healthcare costs for food insecure individuals.[17,18] Notably, however, much of the research conducted to date has evaluated discrete interventions for specific, high-need populations, leaving unanswered critical questions regarding whether— and how—to scale and sustainably fund the integration of non-medical services into the healthcare system on a population-wide basis.

As such, North Carolina has designed the Enhanced Case Management and Other Services Pilots (the 'Pilots') to test evidence-based non-medical interventions for their

direct impact on North Carolina's Medicaid beneficiaries' health outcomes and healthcare costs, and then incorporate findings into the Medicaid program through various potential means, including changes to State Plan benefits, payment models including value-based payments, risk adjustment based on social needs, or other methods.

The Pilots were approved as one component of the North Carolina Medicaid Reform Demonstration and will cover the period November 1, 2019 through October 31, 2024. This evaluation design is specific to the Enhanced Case Management and Other Services Pilots and does not cover other elements of the 1115 demonstration, which will be the subject of a separate evaluation design.

The Pilots will be described in more detail below, but in brief they require Prepaid Health Plans (PHPs) to cover evidence-based interventions that address housing instability, transportation insecurity, food insecurity, and interpersonal violence/toxic stress for a subset of Medicaid beneficiaries. PHPs and their care managers will be responsible for determining who is eligible to receive the services and which services they will receive. A network of community-based organizations and social services agencies (collectively called 'human service organizations' [HSOs]) will deliver pilot services and will be established, managed and overseen by Lead Pilot Entities (LPEs), organizations that will serve as the essential connection between PHPs and HSOs, along with the beneficiaries clinical care team when appropriate. The coordination among these entities, and infrastructure necessary to support it, will help to address beneficiaries' non-medical needs in a way that conventional healthcare has not been able to do.

Evaluation of the pilots will utilize rapid cycle assessment, "a process by which practical problems are identified and addressed using analysis methods that are incremental and contextually informed"[19] — in order to efficiently ascertain which interventions are most promising, and which are not— which will be synthesized into an interim evaluation. This will then lead into a rigorous summative evaluation that will test the effectiveness of these programs using the strongest study design available, a randomized evaluation. This will provide not only evidence regarding effectiveness but will also provide a pathway to take what has been learned and operationalize it for state-wide implementation. This pathway will provide guidance using both health economic methodology in order to develop strategies to embed findings into the Medicaid benefit package and delivery and payment system, and implementation science methodology to codify best practices that will enable implementation and dissemination of effective interventions to scale statewide.

The Pilots have not yet been implemented and this evaluation design will apply to the initial implementation of the Enhanced Case Management and Other Services Pilots.

The Enhanced Case Management and Other Services Pilots will focus on certain high-risk, high-need individuals who meet both physical/behavioral health needs (**Table 1**) and risk factor (**Table 2**) criteria.

Table 1: Physical/Behavioral Health 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 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 (≥1 in past year).
Pregnant Women	Any	• Multifetal gestation • Chronic condition likely to complicate pregnancy, including hypertension and mental illness • Current or recent (month prior to learning of pregnancy) use of drugs or heavy alcohol • Adolescent ≤ 15 years of age • Advanced maternal age, ≥ 40 years of age • Less than one year since last delivery • History of poor birth outcome including: preterm birth, low birth weight, fetal death, neonatal death
Children	0-3	• Neonatal intensive care unit graduate • Neonatal Abstinence Syndrome • Prematurity, defined by births that occur at or before 36 completed weeks gestation • Low birth weight, defined as weighing less than 2500 grams or 5 pounds 8 ounces upon birth • Positive maternal depression screen at an infant well-visit
	0-21	• One or more significant uncontrolled chronic conditions or one or more controlled chronic conditions that have a high risk of becoming uncontrolled due to unmet social need, including: asthma, diabetes, underweight or overweight/obesity as defined by having a BMI of <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: Social 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.
Food Insecurity	As defined by the US Department of Agriculture commissioned report on Food Insecurity in America: • 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.
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.

Hypotheses and Evaluation Questions

The overarching goal of the Enhanced Case Management and Other Services Pilots is to improve health, healthcare utilization, and/or healthcare costs. They do this by making available services that are *in addition to* the physical, behavioral and non-medical services and care management that will be available to all North Carolina Medicaid Beneficiaries enrolled in Managed Care via the overall 1115 demonstration. North Carolina recognizes the impact of social risk factors, particularly those related to food, housing, transportation, and interpersonal violence, on health outcomes, and is interested in rigorously evaluating innovative strategies to help address these issues. As such, the goal of the pilots is directly in keeping with the overall goals of the Medicaid program, particular to provide medical assistance to vulnerable populations.

To meet these goals, North Carolina has a created a program whereby a Lead Pilot Entity (LPE) will serve a critical role in bridging the gap between health and human service organizations, contracting with the prepaid health plans (PHP) to develop, manage and oversee a network of HSOs providing pilot services to their eligible enrollees. It is critical that a Lead Pilot Entity be rooted in its community, understand its community dynamics, and be able to pull together a range of organizations with disparate expertise and experience to build partnerships and create a smooth experience for Pilot participants. By harnessing local strengths and knowledge, LPEs are well positioned to ensure effective, efficient service provision to eligible beneficiaries.

The evaluation of the Enhanced Case Management and Other Services Pilots will assess both the LPE's role in the Pilots and the effectiveness of the services provided.

Ultimately, North Carolina plans to incorporate what is learned from the pilot evaluation into a state-wide scale up of effective programs in order to improve health for Medicaid beneficiaries across the state of North Carolina.

This section of the evaluation design details the hypotheses that will be tested and the evaluation questions that will be answered to help support North Carolina's aims. Further, the evaluation design table **(Table 3)** provides an overview of the measures used, methods, and timeframe of the hypothesis testing, with more detail provided in the *Methodology* section that immediately follows. For the first two evaluation questions, an overall (non-population specific) assessment will be made. For the remaining questions, the evaluation will consider effects in eligibility categories (adults, pregnant women, children 0-3 [with additional needs-based criteria], and children/adolescents 0-21 [with additional needs-based criteria]).[a] As we discuss further in the *Methodology* section, for Hypothesis 6, which involves cost of care, we will focus our examination on the adult population. A brief description of analytic methods used is presented in the Table 3 footnote, with extensive detail in the *Methodology* section.

Following this, a driver diagram (**Figure 1**) depicts the rationale for the evaluation plan. In this view, the necessary secondary drivers are effective identification of eligible beneficiaries, enrollment and retention of beneficiaries in a Pilot that can make use of a robust network of resources to meet individuals' need(s), tailoring of services to individual's need(s), and fostering close collaboration between the individual, their health

[a]As short-hand, we refer to these eligibility categories by age or pregnancy status, but we note that there are additional criteria that further define these categories, and thus the categories are not fully defined by age/pregnancy status.

plan, the lead pilot entity, and service providers. This allows for reduction of social risk and improved clinical care, which in turn will promote the aim of the pilot, improvements in health, healthcare utilization, and healthcare cost. In determining whether the Enhanced Case Management and Other Services Pilots have met their aims, we believe it is important to take a nuanced approach that combines different outcome domains, including quantitative data on health outcomes and quality metrics, qualitative data on patient-reported outcomes, utilization data, and cost of care data. Interpreting findings from one domain in isolation is less important than understanding the cross-domain impact of the Pilots. For example, a component of the Pilots that produces smaller improvements in quality metrics while substantially increasing the patient experience of care and at low cost may be more in keeping with the overarching goals of the pilots than a component that produces slightly larger improvements in quality metrics but has no effect on patient-reported outcomes and is more expensive. The driver diagram offers a high-level, qualitative depiction. For specific, measurable goals related to the key outcome domains, further discussion is offered in the *Evaluation Measures* section, below.

Hypotheses and Evaluation Questions

Hypothesis 1: LPEs will enable effective delivery of Pilot services.

Evaluation Question 1a: How do LPEs establish the necessary infrastructure, workforce, and data systems needed to effectively contract with and build the capacity of a network of HSOs?

Evaluation Question 1b: How do LPEs oversee and maintain the ability of a network of HSOs to deliver pilot services, once established?

Hypothesis 2: The Enhanced Case Management and Other Services Pilot program will increase rates of Medicaid enrollees screened for social risk factors and connected to services that address these risk factors.

Evaluation Question 2a: Do the PHPs and care management entities participating in the Enhanced Case Management and Other Services Pilot in some regions of the state screen a higher proportion of Medicaid beneficiaries for their social risk factors, compared with PHPs and care management entities in areas of North Carolina not participating in the Enhanced Case Management and Other Services Pilot programs?

Evaluation Question 2b: Do PHPs and care management entities participating in the Enhanced Case Management and Other Services Pilots programs connect a higher proportion of Medicaid beneficiaries identified to have social risk factors to services that address these risk factors, compared with PHPs and care management entities not participating in an Enhanced Case Management and Other Services Pilots program?

Hypothesis 3: The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants.

Evaluation Question 3a: Do Pilot services improve social risk factors in qualifying adults (age ≥ 22 years)?

Evaluation Question 3b: Do Pilot services improve social risk factors in qualifying pregnant women?

Evaluation Question 3c: Do Pilot services improve social risk factors in qualifying young children (age 0-3 years)?

Evaluation Question 3d: Do Pilot services improve social risk factors in qualifying children/adolescents (age 0-21 years)?

Hypothesis 4: The Enhanced Case Management and Other Services Pilot program will measurably improve health outcomes in participants.

Evaluation Question 4a: Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in adults (age ≥ 22 years) with qualifying health and social risk factors?

Evaluation Question 4b: Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in pregnant women with qualifying health and social risk factors?

Evaluation Question 4c: Do Pilot services improve health outcomes, including PRO for parents and as reported by proxy, and quality of care metrics, in young children (age 0-3 years) with qualifying health and social risk factors?

Evaluation Question 4d: Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics

in children/adolescents (age 0-21 years) with qualifying health and social risk factors?

Hypothesis 5: The Enhanced Case Management and Other Services Pilot program will measurably improve healthcare utilization in participants.

Evaluation Question 5a: Do Pilot services improve healthcare utilization, including increasing primary care and preventive services/wellness utilization, and decreasing hospitalization and emergency department visits, in adults (age > 22 years) with qualifying health and social risk factors?

Evaluation Question 5b: Do Pilot services improve healthcare utilization, including increasing prenatal and postnatal care, in pregnant women with qualifying health and social risk factors?

Evaluation Question 5c: Do Pilot services improve healthcare utilization, including increasing primary care and preventive services/wellness utilization, and decreasing emergency department visits and hospitalizations, in young children (age 0-3 years) with qualifying health and social risk factors?

Evaluation Question 5d: Do Pilot services improve healthcare utilization, including increasing primary care and preventive services/wellness utilization, and decreasing emergency department visits and hospitalizations, in children/adolescents (age 0-21 years) with qualifying health and social risk factors?

Hypothesis 6: Enhanced Case Management and Other Services Pilot services will measurably improve healthcare costs.

Evaluation Question 6a: Do Pilot services improve total per beneficiary Medicaid expenditure in adults (age > 22 years) with qualifying health and social risk factors?

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
Health Outcomes, Utilization, Cost	H1 - LPEs will enable effective delivery of Pilot services	1a – LPE infrastructure, workforce, and data systems	All	All	n/a	Start date of service provision	All pilot programs	Descriptive statistics	Enhanced Care Management Pilot Report	Begin: Nov 2019 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H1 - LPEs will enable effective delivery of Pilot services	1a – LPE infrastructure, workforce, and data systems	All	All	n/a	Case Studies of LPEs	All pilot programs	Qualitative/Implementation analysis	Primary Data Collection	Begin: Nov 2019 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H1 - LPEs will enable effective delivery of Pilot services	1b –LPE service delivery	All	All	n/a	Case Studies of LPEs	All pilot programs	Qualitative/Implementation analysis	Primary Data Collection	Begin: Nov 2019 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H2 - The Enhanced Case Management and Other Services Pilot program will increase rates of Medicaid enrollees screened for social risk factors and connected to services that address these risk factors	2a – Social risk	All	All	n/a	Rate of Screening for Unmet Social Needs	All pilot participants compared with non-pilot areas	Chi-squared tests	Care Needs Screening Report	Begin: Nov 2020 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H2 - The Enhanced Case Management and Other Services Pilot	2b – Connection to services	All	All	n/a	Positive Screens for Unmet Social Needs; Proportion Connected to Services; Number of Beneficiaries Served; Number Lost to Follow-	All pilot participants compared with non-pilot areas	Chi-squared tests	Care Needs Screening Report, Enhanced Care	Begin: Nov 2020 End of Pilot Services: Oct 2024 Final Assessment: April 2026

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Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
	program will increase rates of Medicaid enrollees screened for social risk factors and connected to services that address these risk factors					Up; Number Withdrawn; Number Completed			Management Pilot Report	
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3a – Do Pilot services improve social risk factors in qualifying adults?	Adults	All Pilot Participants	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3a – Do Pilot services improve social risk factors in qualifying adults (over 22)?	Adults	High healthcare utilization (≥2 inpatient admissions or ≥4 emergency department visits in 12 months prior to pilot enrollment)	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes,	H3 – The Enhanced Case	3a – Do Pilot services improve	Adults	Hypertension	Number of pilot participants;	Improved social risk factors	All pilot participants compared with	Interrupted time series, regression with generalized	Care Needs Screening	Begin: Feb 2021 End of Pilot Services: Oct 2024

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
Utilization, Cost	Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	social risk factors in qualifying adults (over 22)?			Pilot services utilization and retention rates		pre-intervention measurements, and compared with non-pilot areas	estimating equations (GEE), difference-in-difference analysis	Report, Enhanced Care Management Pilot Report	Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3a – Do Pilot services improve social risk factors in qualifying adults (over 22)?	Adults	Diabetes Mellitus	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3b – Do Pilot services improve social risk factors in qualifying pregnant women?	Pregnant Women	History of poor birth outcome	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will	3b – Do Pilot services improve social risk factors in qualifying	Pregnant Women	Gives birth while enrolled	Number of pilot participants; Pilot services utilization and	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-	Care Needs Screening Report, Enhanced Care Manage	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

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Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
	measurably improve the qualifying social risk factors in participants	pregnant women?			retention rates		with non-pilot areas	difference analysis	ment Pilot Report	
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3c – Do Pilot services improve social risk factors in qualifying young children (age 0-3 years)?	Children aged 0-3	NICU grad	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	3c – Do Pilot services improve social risk factors in qualifying young children (age 0-3 years)?	Children aged 0-3	Positive maternal depression screen	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying	H3d – Do Pilot services improve social risk factors in qualifying children/adolescents	Children /adolescents aged 0-21	Experiencing 3 or more ACEs	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
	social risk factors in participants	(age 0-21 years)?								
Health Outcomes, Utilization, Cost	H3 – The Enhanced Case Management and Other Services Pilot program will measurably improve the qualifying social risk factors in participants	H3d – Do Pilot services improve social risk factors in qualifying children/adolescents (age 0-21 years)?	Children/ adolescents aged 0-21	Asthma	Number of pilot participants; Pilot services utilization and retention rates	Improved social risk factors	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Care Needs Screening Report, Enhanced Care Management Pilot Report	Begin: Feb 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health Outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4a – Do Pilot services improve health outcomes in qualifying adults?	Adults	All Pilot Participants	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4a – Do Pilot services improve health outcomes in qualifying adults?	Adults	High healthcare utilization (≥2 inpatient admissions or ≥4 emergency department visits in 12 months prior to	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
				pilot enrollment)						
Health Outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4a – Do Pilot services improve health outcomes in qualifying adults?	Adults	Hypertension	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care; BP < 140/90 (summative)	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4a Do Pilot services improve health outcomes in qualifying adults?	Adults	Diabetes Mellitus	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care; BP < 140/90 (summative), HbA1c < 9.0% (summative)	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4b – Do Pilot services improve health outcomes in qualifying pregnant women?	Pregnant Women	History of poor birth outcome	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care; Reduction in live births weighing less than 2,500 grams (summative)	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4b – Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in pregnant women with qualifying health and social risks factors?	Pregnant Women	Gives birth while enrolled	Number of pilot participants; Pilot services utilization and retention rates	PRO; Experience of care	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	4c – Do Pilot services improve health outcomes in quality of care metrics, in qualifying children (age 0-3 years)?	Children aged 0-3	NICU grad	Number of pilot participants; Pilot services utilization and retention rates	PRO for parent; Child Health Measures (Life Skills Progression)	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment for parent/guardian	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and Encounter Data, NC Division of Public Health Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other	4c – Do Pilot services improve health outcomes in	Children aged 0-3	Positive maternal depression screen	Number of pilot participants; Pilot services	PRO for parent; Child Health Measures (Life Skills Progression)	All pilot participants compared with pre-intervention measurements;	Interrupted time series, difference-in-difference analysis,	Enhanced Care Management Pilot	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
	Service Pilot program will measurably improve health outcomes in participants	qualifying young children (age 0-3 years)?			utilization and retention rates		Purposeful sample for qualitative assessment for parent/guardian	regression with generalized estimating equations (GEE); qualitative analysis	Report, Primary Data Collection, Claims and Encounter Data, NC Division of Public Health Data	
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	H4d – Do Pilot services improve health outcomes in qualifying children/adolescents (age 0-21 years)?	Children /adolescents aged 0-21	Experiencing 3 or more ACEs	Number of pilot participants; Pilot services utilization and retention rates	PRO for parent and child; Child Health Measures (Life Skills Progression) (Age 0-5 only)	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment for parent/guardian	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and Encounter Data, NC Division of Public Health Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Health outcomes	H4 – The Enhanced Case Management and Other Service Pilot program will measurably improve health outcomes in participants	H4d – Do Pilot services improve health outcomes in qualifying children/adolescents (age 0-21 years?	Children/ adolescents aged 0-21	Asthma	Number of pilot participants; Pilot services utilization and retention rates	PRO for parent and child	All pilot participants compared with pre-intervention measurements; Purposeful sample for qualitative assessment for parent/guardian	Interrupted time series, difference-in-difference analysis, regression with generalized estimating equations (GEE); qualitative analysis	Enhanced Care Management Pilot Report, Primary Data Collection, Claims and	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
									Encounter Data	
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	5a – Do Pilot services improve health outcomes in qualifying adults?	Adults	All Pilot Participants	Number of pilot participants; Pilot services utilization and retention rates	Ambulatory Care Utilization; Impatient Utilization, Emergency Department Utilization	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2022 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	5a – Do Pilot services improve health outcomes in qualifying adults?	Adults	High healthcare utilization (≥2 inpatient admissions or ≥4 emergency department visits in 12 months prior to pilot enrollment)	Number of pilot participants; Pilot services utilization and retention rates	Ambulatory Care Utilization; Impatient Utilization, Emergency Department Utilization	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2022 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare	5b – Do Pilot services improve healthcare utilization, outcomes for qualifying pregnant women?	Pregnant Women	Gives birth while enrolled	Number of pilot participants; Pilot services utilization and retention rates	Attended prenatal visit (rapid cycle/interim) Percentage of deliveries with postpartum visit at appropriate time (summative) Attended >81% of expected prenatal visits (summative)	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
	utilization in participants									
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	H5c – Do Pilot services improve healthcare utilization in qualifying young children (age 0-3 years)?	Children aged 0-3	NICU grad	Number of pilot participants; Pilot services utilization and retention rates	Recommended well-child visits completed within first 15 months of life (Both Rapid Cycle Assessment/Interim Evaluation and Summative Evaluation) Number of hospitalizations (summative) Number of emergency department visits (summative)	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	H5c – Do Pilot services improve healthcare utilization in qualifying young children (age 0-3 years)?	Children aged 0-3	Positive maternal depression screen	Number of pilot participants; Pilot services utilization and retention rates	Recommended well-child visits completed within first 15 months of life (Both Rapid Cycle Assessment/Interim Evaluation and	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	H5d - Do Pilot services improve healthcare utilization in qualifying children /adolescents (age 0-21 years)?	Children /adolescents aged 0-21	Experiencing 3 or more ACEs	Number of pilot participants; Pilot services utilization and retention rates	Recommended well-child visits completed within first 15 months of life	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment
Utilization	H5 - The Enhanced Case Management and Other Services Pilot will measurably improve healthcare utilization in participants	H5d – Do Pilot services improve healthcare utilization in qualifying children /adolescents (age 0-21 years)?	Children/ adolescents aged 0-21	Asthma	Number of pilot participants; Pilot services utilization and retention rates	Recommended well-child visits completed within first 15 months of life (Both Rapid Cycle Assessment/Interim Evaluation and Summative Evaluation) Number of hospitalizations (summative) Number of emergency department visits (summative)	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Interrupted time series, regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2021 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Costs	H6 – The Enhanced Case Management and Other Services Pilot services will measurable improve healthcare costs	6a – Do Pilot services improve health outcomes in qualifying adults?	Adults	All Pilot Participants	Number of pilot participants; Pilot services utilization and retention rates	Total Medicaid spend per beneficiary; PHP spending, Inpatient/outpatient/emergency/ pharmacy spend (i.e., excluding post-acute, DME, and hospice claims less likely to be influenced by pilot services)	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2022 End of Pilot Services: Oct 2024 Final Assessment: April 2026
Costs	H6 – The Enhanced Case Management and Other Services Pilot services will measurable improve healthcare costs	6a – Do Pilot services improve total per beneficiary Medicaid expenditure in qualifying adults?	Adults	High healthcare utilization (≥2 inpatient admissions or ≥4 emergency department visits in 12 months prior to pilot enrollment)	Number of pilot participants; Pilot services utilization and retention rates	Total Medicaid spend per beneficiary; Inpatient/outpatient/emergency/ pharmacy spend (i.e., excluding post-acute, DME, and hospice claims less likely to be influenced by pilot services)	All pilot participants compared with pre-intervention measurements, and compared with non-pilot areas	Regression with generalized estimating equations (GEE), difference-in-difference analysis	Enhanced Care Management Pilot Report, Claims and Encounter Data	Begin: Nov 2022 End of Pilot Services: Oct 2024 Final Assessment: April 2026

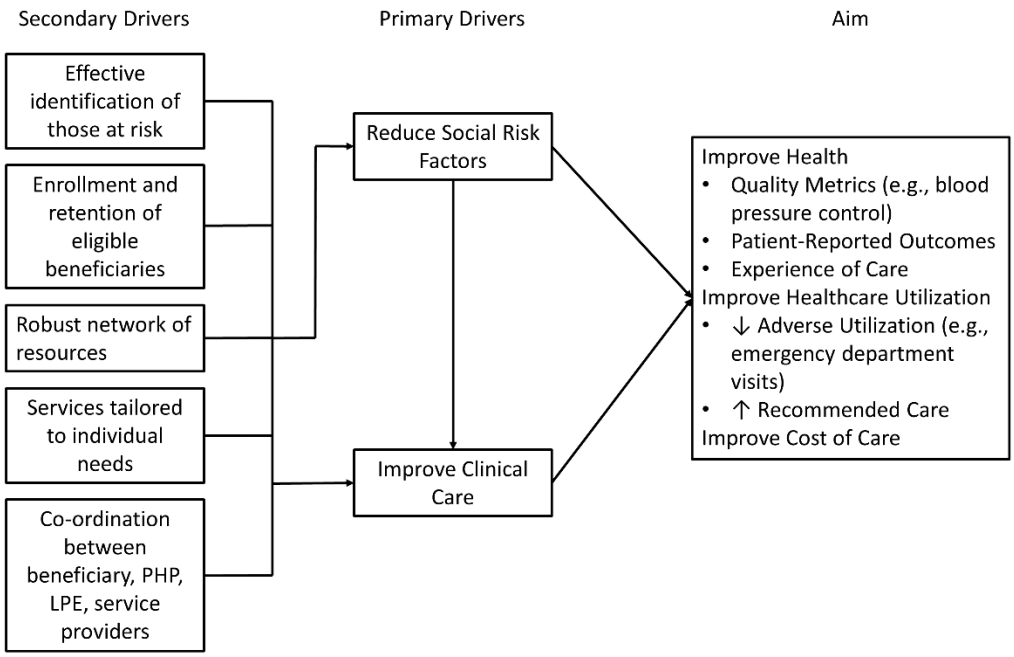
All participants will have at least one health-related social need (food insecurity, housing instability, transportation barrier, or experience interpersonal violence); Parentheses () indicates phase of evaluation: R = Rapid Cycle Assessment, S = Summative Evaluation; B = Both Rapid Cycle Assessment and Summative Evaluation. PRO = patient reported outcomes. The planned instruments used

Table 3: Evaluation design for Hypotheses and 1-6

Goal(s) Addressed	Hypothesis	Evaluation Question, Abbreviated	Pilot Pop.	Health-Based Risk Factor	Process Measure(s)	Outcome Measure(s)	Sample or. subgroups to be compared	Analytic Methods	Data Source	Approximate Time Period of Assessment

to measure these are the PROMIS-10 Global Health measure and the CDC's Measuring Healthy Days Health-Related Quality of Life measure. However, we will pilot test these measures during the rapid cycle assessment phase and modify instrument selection if needed. PRO will be assessed in adults in all circumstances. PROs will additionally be assessed in children aged ≥ 13 years.
Data sources used for all hypotheses: care management records, claims, primary data collection, interviews and focus group discussions transcripts
Analytic methods used for all hypotheses: Descriptive Statistics (B); Interrupted time series (R); Qualitative/ Thematic Analysis (B); Difference-in-Difference propensity score analysis (S); Randomized Evaluation (S)

Figure 1: Driver Diagram



Methodology

In order to answer the evaluation questions as robustly as possible, we will utilize a rigorous evaluation methodology. This methodology draws on guidance from CMS and PCORI regarding evaluation for complex interventions.[20–22] The evaluation will utilize two key phases to answer different evaluation questions—an initial rapid cycle assessment phase and a summative evaluation phase. Details of these evaluation phases are described below.

Evaluation Design

Overview

Because of the multiple evaluation questions and different phases of implementation for the pilots, the evaluation design is multi-faceted, using different approaches for different questions and at different times in the evaluation. All of the below described designs come together to form the overall evaluation design.

The evaluation will be organized into two key phases—a rapid cycle assessment phase that culminates in an interim evaluation and a summative evaluation phase. While both phases will be examining similar outcomes, their approach, and goals, are different. The overarching goal of the rapid cycle assessment[21,22] phase of the evaluation is to determine, as quickly as possible, if the pilots are operating as intended and whether pilot services are having their intended effects on targeted populations. By using an iterative process, North Carolina will be able to collect data to test the services, examine the results, and modify services or adopt a different service as appropriate. The goal of the rapid cycle assessment is to provide results to North Carolina so that appropriate steps can be taken to modify pilot services, as needed, in order to maximize their effectiveness and discontinue services that are less effective to ensure dollars are spent on services with a demonstrated impact. During this phase, the major comparisons will be within intervention recipients, before and after they receive intervention, using interrupted time series designs. It is expected that components of the pilots will be modified dynamically during this phase as the Pilots seek, iteratively, to find the most effective versions of their interventions. In addition to the quantitative rapid cycle assessments, qualitative assessments will also be

made, to obtain perspectives from both Pilot participants and the organizations delivering Pilot services, as described in more detail below. The rapid cycle assessments will culminate in an interim evaluation which will summarize all changes made during this period and the final iteration of the intervention programs that will be tested during the summative evaluation phase.

Once the services have been optimized, we will transition to the summative evaluation phase to rigorously ascertain the effectiveness of the pilot services. The overarching goal of the summative evaluation is to test, as rigorously as possible, the 'final' version of the Pilots that were developed during the rapid cycle phase. The summative evaluation will rely on an adaptively randomized comparison to permit clear causal inference about not only the overall effect of the pilots but about which components are most effective and achieve their effects in the most resource efficient way. The goal of the summative evaluation is to produce knowledge that can guide the state in scaling up successful components of the Pilot into state-wide programs. In addition to the within participant comparison enabled by the adaptive randomized design, we will also use difference-in-difference analysis to compare the pilot regions to other regions of North Carolina. As in the rapid cycle assessment, this quantitative evaluation will be combined with qualitative evaluation, to obtain perspectives from both Pilot participants and the organizations delivering Pilot services, as described in more detail below.

The below sections detail how elements of the evaluation questions and hypotheses will be addressed and tested during the two phases. Each hypothesis will be tested during both evaluation phases. To recap, Hypotheses 1 and 2 deal with the LPE's role in

developing a network of HSOs to provide services to address social risk factors and PHPs' and care management entities' roles in screening and connecting enrollees to services, and Hypotheses 3-6 deal with outcomes related to improving social risk factors, improving health, and affecting healthcare utilization and cost.

Rapid Cycle Assessment and Interim Evaluation

Hypotheses 1 and 2

For Hypotheses 1 and 2, the overarching goal is to determine the effectiveness of the organizational strategy for the Enhanced Case Management and Other Services Pilots — namely fostering collaboration between a Lead Pilot Entity (LPE) that helps organize services in a local area, a prepaid health plan (PHP) and care management entity that identify eligible beneficiaries and provide care management services, and a network of human service organizations delivering the services. In the rapid cycle assessment phase of the evaluation, a key focus will be on ensuring the PHPs, care management entities and LPEs are able to build the necessary networks and infrastructure to support the pilots, and use that infrastructure to identify and bring into care those in need of pilot services. Under the overall 1115 demonstration in North Carolina, all PHPs and care management entities, whether or not they are in pilot regions, will be conducting a social risk factor screening, and helping to connect those with positive screens to resources that help address identified needs. Therefore, we will be able to determine whether the model used in the Pilots leads to differences compared with the approach being used in other areas of the state. Specifically, we will test whether this integration between PHPs, care management entities,

LPEs, and HSOs allows for better rates of screening rates for those with social risk factors and connecting those with positive screens to social services to address those needs than in other parts of the state. To further understand these issues, we will also seek to understand the workforce and time management of the pilot operations, including the LPE, the care management, and the HSOs involved. Further, to capture perspectives from participants, we will use qualitative research and implementation science methods, to asses five key features of participation[23]: 1) adoption and the decision to participate, 2) acceptability of the services, 3) compatibility and how the services help to address the individual's needs, 4) complexity and ease or difficulty actually accessing the services, and 5) whether the services would be used again in the future.

Hypotheses 3-6

To facilitate the goal of quickly determining which pilot components are working and which are not, the rapid cycle assessment will use a multi-faceted evaluation strategy based on the principles of rapid cycle evaluation advocated for by the Center for Medicare and Medicaid Innovation (CMMI).[21,22] Given the level of complexity of the pilots, simple quality improvement approaches that focus solely on process change, such as plan-do-study-act (PDSA) cycles, are unlikely to provide the reliable data needed in this situation. Instead, given the level of complexity of the pilots, we will use mixed method approaches that combine both quantitative and qualitative assessment of programmatic effects. For quantitative assessment, we will use a quasi-experimental individual-level interrupted time series approach. In this approach, the initial and on-going assessments of Pilot

participants will serve as the source of data, and each change in intervention received will indicate an interruption point in the analysis, allowing us to quickly determine what changes in health outcomes and healthcare utilization follow receipt of a pilot intervention. In addition, to focus on the participant's experience of care, we will use qualitative analyses to ensure that the pilot programs are patient-centered and effectively addressing the issues that participants view as key to their health. The results of these analyses will be fed back to North Carolina rapidly, enabling the state to act on these findings as described in the introduction to the rapid cycle assessment. Details of interrupted time series and qualitative methods used for the rapid cycle assessment are described in the *Analytic Methods* section below.

Summative Evaluation

Hypotheses 1 and 2

During the summative evaluation, we will continue to track performance measures regarding the identification, enrollment, and retention in services of the Pilots. We will add, however, qualitative evaluation of the LPE model, which will facilitate state-wide implementation of successful approaches. Specifically, we will use an implementation science-based case study approach in order to identify LPEs' best practices and barriers/strategies to resolve these barriers in achieving their goals. Key areas to be examined include start-up and establishing the LPE role, the role of technical assistance in establishing the LPE, developing a sufficient network of service providers, expanding the capacity of HSOs to provide necessary services, and integration between clinical providers,

HSOs, and PHPs, what are the essential functions of LPE, and what are the minimum resources necessary to support these functions.

Hypotheses 3-6

The overarching goal of the summative evaluation phase is to rigorously determine what pilot programs are effective, and to provide guidance on the path to statewide implementation of effective services. To this end, the evaluation can be thought of as encompassing an 'effectiveness' component and a 'guidance' component. These components will however occur simultaneously, and in some instances will draw from the same data sources. Unlike the rapid cycle assessment, which is designed to be a practical tool for driving "course corrections," the summative evaluation will allow the State to focus more granularly on evaluating and understanding the pilot services identified as "high effectiveness" through the rapid cycle assessment process to ensure they are scalable across diverse pilots and regions and therefore appropriate to incorporate into Medicaid managed care statewide. North Carolina will consider incorporating findings from the summative evaluation into the Medicaid program through various means, including changes to State Plan benefits, payment models, risk adjustment based on social needs, value-based payments or other methods.

A key challenge to be overcome in the Pilots is that, in order to be scalable, North Carolina needs to know not only does a particular intervention work 'overall', but which interventions work best in specific circumstances, and, if more than one might work, which offers the most value. Therefore, testing only a single type of intervention in a narrowly

defined sample would not be consistent with the goals of the Pilots. Instead, the evaluation design explicitly targets learning what interventions are effective and for whom, while always aiming to utilize resources most efficiently.

To these ends, the Pilot interventions will be "tiered" on increasing intensity levels, starting with 'light-touch' low intensity (and lower cost) interventions, coupled with ongoing assessments that escalate the intensity of the intervention based on a care manager's assessment of whether an individual's health and social risk factors have improved. For the evaluation, we will use a 'SMART' (sequential multiple-assignment randomized trial) design, starting in Demonstration Year 3, which uses randomization as individuals move through higher tiers to enable rigorous comparison of the components of the Pilots. Through this method, North Carolina has the opportunity to learn which population groups require higher intensity, higher-cost interventions (and which do not). This will allow the State to deploy these interventions most cost-effectively. Further, this method avoids confounding by the level or severity of an individual's need. For example, we ensure that when evaluating higher tier interventions, we are comparing individuals who similarly did not respond to lower tier interventions, thus ensuring our comparison group is actually comparable.

As **Figure 2** (below) depicts, for the SMART design all eligible beneficiaries who enroll in the Pilots will receive an intervention that is more intensive than that available outside of the Pilots, providing a benefit to all who participate. Individuals will begin at the lowest intensity intervention that can be reasonably expected to meet their needs. Most frequently, we anticipate this will be Tier 1 intervention in the domain(s) for which they

screened positive for social risk factors. However, owing to resource constraints, the pilots will not be able provide a higher level of service (Tier 2 or Tier 3) to all individuals. To work within the pilot's budget and allow evaluation, the Pilot will utilize randomization at each tier advancement. Randomization will only be employed during the summative evaluation phase of evaluation, and only for the cases where there is uncertainty as to what intervention will best meet the individual's needs.

For example, of all people who screen positive for food insecurity, and otherwise meet Pilot eligibility criteria, all will qualify for at least Tier 1 services, or the lowest tier of services that can reasonably be expected to meet their needs. For many of these individuals, the initial intervention will meet their need. However, at the time of reassessment, some will not yet have their need met and will become eligible for re-randomization. Of this group, a random subset will be approved to move to Tier 2, while the other subset will continue with the Tier 1 intervention for a longer duration of time, as they may not yet have had sufficient exposure to the intervention to see its effect. The same process will be followed for people to move up to Tier 3. The use of randomization ensures that those who do and do not receive Tier 2 and Tier 3 services will be comparable, and that evaluation findings will not be confounded by severity of need. Because individuals may have more than one social risk factor, changes in eligibility (for example, eligibility to receive Tier 2 services) will occur for all services. However, this change in eligibility is only one component of the determination as to whether one actually receives a service. In order to receive a service, an individual must, in addition, meet health and social risk factor criteria in order to receive the service. For example, imagine two individuals, both of whom have qualifying health risk factors. One individual reports food insecurity, and one

individual reports both food insecurity and transportation barriers. If both choose to enroll in the pilots, they will both receive Tier 1 services (assuming Tier 1 services can reasonably be expected to meet their needs). If Tier 1 services do not reduce their risk factors, they may be randomized to receive Tier 2 services. If this occurs, the individual with food insecurity and transportation barriers would receive Tier 2 services for food insecurity and transportation. The individual with food insecurity alone would receive Tier 2 services for food insecurity only. Though the second individual was randomized to be eligible for Tier 2 services, they would not receive Tier 2 transportation services, as they do not have a qualifying social risk factor (transportation barriers) for these services. Even once eligible, an individual will only receive increasingly intense services based their care manager's assessment than an increase in intensity of services is needed. On average, randomization guarantees that the distribution of social risk factors will be equal across groups (meaning that both those who are and are not randomized to Tier 2 interventions will have a similar number and similar types of social risk factors), allowing valid comparisons to be made between the groups.

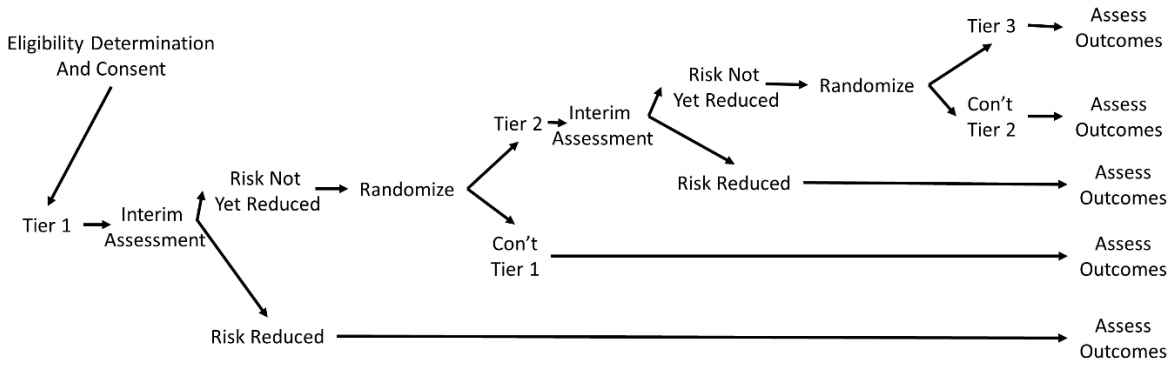
It is important to note that, at all times, the randomized evaluation will adhere to the ethical principle of equipoise regarding the effect of the interventions. This means that it must be plausible that the intervention in which the individual is participating may help them. For this reason, types of interventions that are definitively known to be more effective in particular circumstances (for example, because of scientific evidence that becomes available during the evaluation period), or types of interventions that are not likely to be effective (for example, because they did not show evidence of benefit during the rapid cycle assessment phase) will not be included in the randomized evaluation. Further,

it is important to note that the assessment of change related to intervention participation will occur at a time period such that it is still plausible to expect the intervention may offer benefit to the individual if they participate in it for a longer period of time. The evaluation design is not proposing to continue to provide services that do not work for a particular individual. Rather, it seeks to understand if a change in intervention type is more effective than an extended duration of the initial intervention. This type of information, determining when to switch an individual to a different intervention versus when to continue with an intervention, is crucial for determining how to scale the Enhanced Case Management and Other Services Pilots, particularly with regard to setting eligibility criteria and knowing how long to provide services for. It is also important to note that the Figure 2 depicts a model of the SMART design with linear progression through the tiers. However, real-world operational decisions necessary to care for the individual will always take priority, and so this model may not reflect day-to-day operations in all cases. Instead, it serves as guiding principles that will enable maximal learning from the Pilots.

Because of the extreme complexity of the social risk factors, and in particular because it is not possible to know a priori whether an individual will respond to a particular intervention, the SMART design is the only feasible evaluation design that can guarantee unconfounded comparisons to be made between those who do and do not receive the pilot services.

Figure 2: SMART Design

Attachment H: Enhanced Case Management and Other Services Pilot Program Evaluation Design



Target and Comparison Samples

For Hypothesis 1, the target sample is the LPEs. No comparison sample is needed for this question. For Hypothesis 2, the primary comparison will be between individuals in the Pilots compared with Medicaid beneficiaries who would likely be eligible for the Pilots (based on their response to statewide social need screening and assessment of clinical characteristics using their Medicaid claims data) but do not live in areas where an Enhanced Case Management and Other Service Pilot program is operating. For Hypotheses 3-6, the target and comparison sample will differ based on the phase of the evaluation. For the rapid cycle assessment, as described in more detail below, the primary comparison will be within Pilot participants using an interrupted time series approach. For the summative evaluation, the primary comparisons will be, among those in the Pilots who did not respond to Tier 1 services at the time of interim assessment, between those who did and did not get Tier 2 services, and, among those in the pilots who received but did not respond to Tier 2 services, between those who did and did not receive Tier 3 services.

In addition to these comparisons, North Carolina has an interest in understanding if individuals in the pilots, overall, saw improved outcomes compared with other individuals in the Medicaid managed care program (but not in the pilots). Because it would be unethical not to provide any services to individuals in the pilots (i.e., not receive at least Tier 1 services), it is not possible to use a randomized design to answer this question. Instead, we will use a difference-in-difference design, drawing a comparison from other individuals in North Carolina who would have likely qualified for Tier 1 services but were not living in pilot regions and were thus ineligible. We describe, in the *Analytic Methods* section below, efforts made to ensure the individuals in this comparison group are indeed

comparable. Analyses will be conducted at the beneficiary level. For hypothesis testing, we do not plan any stratification into subgroups. However, as exploratory analyses to help guide North Carolina decision making regarding state-wide scale-up, we will investigate heterogeneous treatment effects (differences in outcomes across groups) based on factors that could be used as eligibility criteria, particularly comorbidities, patterns of pre-intervention healthcare utilization, age, and social risk factors.

For most analyses, the data used, as detailed in the *Data Sources* section below, will come from information collected as part of Pilot services operations or from healthcare claims. Thus, data will be available for all participants and sampling will not be needed. However, there will be some areas where additional information that is not collected as part of Pilot operations may be needed. This may include patient-reported outcomes, such as the PROMIS-10 Global Health Assessment and health-related quality of life. For these instances, our goal is to conduct primary data collection with all participants, and we have included dedicated staff in our analysis plan to collect this information. However, since we cannot know *a priori* how many individuals will choose to enroll in pilot services, there may be some larger segments of the eligible population where it is logistically infeasible to collect primary data from all Pilot participants. In these cases, we will use a random sampling strategy (stratified by age, gender, and race/ethnicity) to select individuals for primary data collection. If this situation occurs, we will use power calculations as guidance to ensure a sufficient number of individuals are contacted.

For qualitative analyses, we will use a purposeful sampling strategy, as described in more detail in the *Analytic Methods* section.

For the evaluation, the inclusion and exclusion criteria will be identical to those that qualify individuals for pilots services (**Tables 1 and 2**). Below is **Table 4**, which presents the specific measures used for quantitative hypothesis testing, and is followed by **Table 5**, which presents power calculations for the hypothesis testing. In each case, sufficient power is well within the capacity of the Pilots, and thus we believe there will be adequate sample size for hypothesis testing.

Evaluation Period

An overall timeline for the five demonstration years (DY) of the Enhanced Case Management and Other Services Pilots is included as attachment 3. If these periods change during implementation the evaluation period dates will be adjusted accordingly. To summarize this timeline, assessment of specific evaluation questions will begin when sufficient data to analyze them first accrues. Evaluation Question 1 will begin to be assessed beginning when the pilot sites are selected as the sites prepare to deliver pilot services (currently scheduled for Nov 1, 2019). We will continue to assess the hypotheses related to Evaluation Question 1 throughout pilot service delivery (ending October 2024), with final assessments being conducted after service delivery ends, in preparation for the submission of the final report in April 2026. Evaluation Question 2 will first be assessed in the quarter after the start of pilot service delivery (pilot services scheduled to start in approximately November 2020, first assessment in approximately February 2021), and assessment will continue throughout the service delivery period (ending in October 2024), with final assessments in preparation for the submission of the final report in April 2026. To give time for the interventions to affect the social risks of participants, Evaluation Question 3 will first be assessed in the second quarter after the start of pilot service delivery (pilot services scheduled to start in approximately November 2020, first assessment in approximately May 2021), and assessment will continue throughout the service delivery period (ending in October 2024), with final assessments in preparation for the submission of the final report in April 2026. Because we anticipate it will take longer to accumulate sufficient observations to see changes in the outcomes for Evaluation Questions 4 and 5, these will have a longer lag time of 1 year before initial assessment (pilot services

scheduled to start in approximately November 2020, first assessment in approximately November 2021), and assessment will continue throughout the service delivery period (ending in October 2024), with final assessments in preparation for the submission of the final report in April 2026. We suspect it may take longer for sufficient events to accumulate to analyze two specific utilization outcomes, emergency department visits and inpatient admissions, because these are an order of magnitude less common than outpatient utilization. Therefore these will be primary assessed as part of the summative evaluation (beginning November 2022) and assessment will continue throughout the service delivery period (ending in October 2024), with final assessments in preparation for the submission of the final report in April 2026. Evaluation Question 6 will be assessed as part of the summative evaluation (beginning November 2022) and assessment will continue throughout the service delivery period (ending in October 2024), with final assessments in preparation for the submission of the final report in April 2026. Randomization will occur during this time. As detailed in the *Analytic Methods* section below, for some analyses pre-intervention data will be used to facilitate comparisons. Following the end of service delivery in November 2024, the summative evaluation will continue to conduct implementation science assessments with the service providers, analyze summative data, and evaluate for lagged effect. The final summative evaluation report will be submitted to CMS by April 30, 2026.

Evaluation Measures

Evaluation measures are selected from nationally recognized metrics and designed to harmonize with the quality metrics North Carolina is using for managed care plan accountability. The below **Table 4** details implementation and process, and outcome measures, for the rapid cycle assessment. Implementation and process measures are meant to help determine the reach of the interventions (i.e., whether they are engaging the appropriate individuals, that Pilots are enrolling beneficiaries and that beneficiaries are accessing Pilot services), whether the interventions are having the intended effect of addressing social risk factors, and whether the financing mechanisms are functioning appropriately. Outcome measures are intended to assess the effectiveness of the programs in addressing social risk factors, improving health outcomes, healthcare utilization, and healthcare costs. These measures will be supplemented by qualitative evaluation. In particular, Hypothesis 1 and the experience of care component of Hypothesis 4 will rely heavily on qualitative evaluation. We think it is critical to view healthcare utilization as having both desirable and undesirable components. Increasing use of recommended healthcare such as preventive care, prenatal care, and wellness visits is a desirable outcome. It is also important to note that emergency department visits and inpatient hospitalization represent the appropriate level of care in many circumstances, and seeing an absolute change in their use, without considering the reasons for this, cannot be determined to be desirable or undesirable on its own. Rather, as our driver diagram emphasizes, desirable reductions in utilization of emergency department or inpatient hospitalizations are brought about by addressing both the health and social risk factors for their use. Therefore, our analyses of changes in utilization will be done in the context of

simultaneously analyzing changes in social risk and health outcomes. For subgroups of Pilot participants where particular types of utilization are too rare to determine if the Pilots had an effect, it will be important to rely on changes to well-established risk factors for these types of utilization to understand whether the interventions are likely to affect utilization if they are scaled-up. It is also important to note that utilization patterns likely differ substantially between pediatric and adult populations. In general, pediatric utilization is more focused on preventive care and wellness visits, and children have lower rates of emergency department and inpatient utilization. Further, because of the pathophysiology of many disease processes, which accumulates over long periods of time, the social risk factors children are exposed to may not manifest as poor health and adverse healthcare utilization until they are adults. Therefore, we expect that the major changes in adverse utilization, and its attendant costs that could be attributed to the Pilots, will occur in adults. Thus, we are focusing our evaluation of changes in these outcomes on the adult population. For cost evaluation, are interested in understanding changes in costs both from the perspective of the state and from the perspective of the prepaid health plans, and will analyze outcomes from both perspectives. For children/adolescents, we expect to see improvements in their social risk factors, health outcomes, and increased primary care and wellness visit utilization.

Table 5 includes power calculations that specify effect sizes for quantitative outcomes. Because there is currently no systematic collection of social risk factor data, which is necessary to define the population that the Pilots serve, we are not able to use other states or the pre-1115 demonstration experience of North Carolina Medicaid beneficiaries as a priori benchmarks for these outcomes. Instead, the benchmarks for the

analyses will become available once systematic social risk factor data collection occurs. Since this will occur prior to the start of pilot services, this will allow us to determine the level of these outcomes before any changes related to the pilots. As described in the study design, these outcomes will be compared across the state of NC (when comparing Pilot participants overall to those in the rest of the state) and within the Pilots (when comparing those who received different pilot services but otherwise had similar clinical and social risk factors). Because interventions contained within the pilots have not previously been done at this scale, there is substantial uncertainty regarding what effect sizes are possible. The power calculations table specifies effect sizes that, based on examination of prior studies (when available) or expert consultation, we believe to be plausible. For example, we believe a 5% increase in the proportion of adults with hypertension (and other qualifying clinical and social risk factors) achieving blood pressure control is plausible on the basis of a prior study of health-related social needs screening and referral.[24] As another example, the Pregnancy Medical Home project[25], conducted among North Carolina Medicaid beneficiaries, saw approximately 3% fewer low-birth weight births than would be expected in the absence of the intervention, and so we have targeted a 3% absolute difference as plausible. The footnotes for Table 5 give further information about the sources of the data used to generate these estimates. We have designed the evaluation to have sufficient sample to detect effect sizes that we believe are likely to result from the intervention. As noted above, however, we think it is important to draw a distinction between effect sizes that are plausible and effect sizes that are meaningful. Given the multifaceted nature of the evaluation, we think it is important to interpret quantitative effect sizes in the context of other factors (including qualitative findings and the cost of the intervention), in order to

more fully describe the value of the services. For example, a quantitatively large effect size for a program that does not improve the experience of care and is costly may not be preferable to a smaller effect size that is qualitatively more acceptable and less costly. Further, expenditures related to the pilots need to be explicitly considered in the context of the changes in outcomes that these expenditures produce, in order to understand the value of the Pilots. Given the uncertainty of empirical work, it is possible that the actual effects sizes we observe may differ from those used in the Table 5 calculations.

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency
H4a	Comprehensive Diabetes Care: HbA1c poor control (>9.0%). NQF #: 0059*	The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H4a	Controlling High Blood Pressure NQF #:0018*	The percentage of beneficiaries 18–85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled during the measurement year based on the following criteria: • Beneficiaries 18–59 years of age whose BP was > 140/90 mm Hg • Beneficiaries 60–85 years of age with a diagnosis of diabetes whose BP was > 140/90 mm Hg • Beneficiaries 60–85 years of age without a diagnosis of diabetes whose BP was > 150/90 mm Hg Note: Use the Hybrid Method for this measure. A single rate is reported and is the sum of all three groups.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5d	Medication Management for People With Asthma (Medication Compliance 75% Rate only) NQF# 1799	The percentage of members 5-21 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period. Reported as 2 rates: •Age 5 -11: 75% of treatment period; • Age 12-18: 75% of treatment period	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H4a; H4b; H4c; H4d	Global Health Assessment	PROMIS Health Questionnaire (self-report version for adults and children ≥13 years, version for parent/guardian proxy reporting for younger children)	NIH / Health Measures	P	Evaluation Team	Annually
H4a; H4b; H4c; H4d	Health Related Quality of Life	Assessed using the "Measuring Healthy Days" tool. Reported in categories of • Total; • Physical; • Mental	CDC	P	Evaluation Team	Annually

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency
H4c, H4d	Life Skills Progression	Outcome measurement instrument used by programs serving children that have been exposed to adverse life events or toxic stress. We will emphasize the Relationship with Children domain.	NC Division of Public Health, Children and Youth	S	NC Division of Public Health	Annually
H5b	Prenatal and Postpartum Care (Both Rates) NQF #: 1517	The percentage of deliveries of live births on or between November 6 of the year prior to the measurement year and November 5 of the measurement year. For these women, the measure assesses the following facets of prenatal and postpartum care. • *Timeliness of Prenatal Care*. The percentage of deliveries that received a prenatal care visit as a beneficiary of the organization in the first trimester, on the enrollment start date or within 42 days of enrollment in the organization. • *Postpartum Care*. The percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5d	Adolescent Well-Care Visit NQF #:	Percentage of adolescents ages 12 to 21 who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetric/gynecologic (OB/GYN) practitioner during the measurement year.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5c; H5d	Visits in the First 15 Months of Life NQF #: 1392	The percentage of children 15 months old who had the recommended number of well-child visits with a PCP during their first 15 months of life.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5d	Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life	The percentage of children 3-6 years of age who had one or more well-child visits with a PCP during the measurement year.	NCQA - HEDIS	S	Claims and Encounter Data, Division of	Quarterly

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency
	NQF #: 1516				Health Benefits	
H5c; H5d	Children and Adolescents' Access to Primary Care Practitioners	Percentage of children and adolescents ages 12 months to 19 years who had a visit with a primary care practitioner (PCP). Four separate percentages are reported: •Children ages 12 to 24 months and 25 months to 6 years who had a visit with a PCP during the measurement year •Children ages 7 to 11 years and adolescents 12 to 19 years who had a visit with a PCP during the measurement year or the year prior to the measurement year	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H4c	Live Births Weighing Less than 2,500 Grams NQF #: 1382	The percentage of births with birthweight <2,500 grams	CDC	S	Birth Certificates, Department of Public Health	Annually
H1a; H2a	Rate of Screening for Unmet Social Needs**	The percentage of beneficiaries screened for unmet social needs from the health risk screening within measurement period	NC DHHS	S	Care Needs Screening Report, Division of Health Benefits	Quarterly
H1a; H2a	Positive Screens for Unmet Social Needs**	The percentage of beneficiaries who screened positive for unmet social needs from the health risk screening within measurement period, reported by non-mutually exclusive categories of • Food Insecurity •Housing Instability or Homelessness •Transportation Barrier •Experience Interpersonal Violence	NC DHHS	S	Care Needs Screening Report, Division of Health Benefits	Quarterly
H1a; H2a; H3a; H3b; H3c; H3d	Positive Screens for Unmet Social Needs Connected to Services**	The percentage of beneficiaries who screened positive for unmet social needs from the health risk screening within measurement period, who were then connected to at least 1 service to address their need	NC DHHS	S	Care Needs Screening Report, Division of Health Benefits	Quarterly

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency
H1a; H2a; H3a; H3b; H3c; H3d	Number of Beneficiaries Served**	The total number of beneficiaries served by pilot programs in the reporting period	NC DHHS	S	Enhanced Care Management Pilot Report, Division of Health Benefits	Quarterly
H1a; H2a; H3a; H3b; H3c; H3d	Number lost to follow-up**	The number of beneficiaries served by pilot programs at one point in the reporting period who were lost to follow-up	NC DHHS	S	Enhanced Care Management Pilot Report, Division of Health Benefits	Quarterly
H1a; H2a; H3a; H3b; H3c; H3d	Number withdrawn**	The number of beneficiaries served by pilot programs at one point in the reporting period who withdrew from participation	NC DHHS	S	Enhanced Care Management Pilot Report, Division of Health Benefits	Quarterly
H1a; H2a; H3a; H3b; H3c; H3d	Number completed**	The number of beneficiaries served by pilot programs at one point in the reporting period who completed participation	NC DHHS	S	Enhanced Care Management Pilot Report, Division of Health Benefits	Quarterly
H1a	Payment Completion**	Percentage of completed payments made to service providers	NC DHHS	S	Enhanced Care Management Pilot Report, Division of	Quarterly

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency
					Health Benefits	
H1a	Payment Lag Time**	Time from receipt of service to payment completion	NC DHHS	S	Enhanced Care Management Pilot Report, Division of Health Benefits	Quarterly
H6a	Total Cost of Care**	Total Medicaid spend per beneficiary per month	NC DHHS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5a; H5b; H5c; H5d	Ambulatory Care (AMB)	This measure summarizes utilization of ambulatory care in the following categories: outpatient visits, ED visits. Results reported as visits per 1,000 beneficiary months. Will also be reported by clinical category (e.g. in those with asthma, diabetes mellitus, etc.)	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly
H5a; H5b; H5c; H5d	Inpatient Utilization-General Hospital/Acute Care (IPU) NQF #: 1598	This measure summarizes utilization of acute inpatient care and services in the following categories: total inpatient, maternity, surgery, medicine.	NCQA - HEDIS	S	Claims and Encounter Data, Division of Health Benefits	Quarterly

Demographic Variables	
Variable	Source
Age	Member Eligibility File, Division of Health Benefits
Gender	Member Eligibility File, Division of Health Benefits
Race/Ethnicity	Member Eligibility File, Division of Health Benefits

Primary data collection indicates data that will be collected by the evaluation team specifically for the evaluation. Secondary data collection indicates data that will be collected as Medicaid claims or in the process of program operation by the PHPs and/or LPEs.

Table 4: Demographics and Quantitative Process and Outcome Measures for Enhanced Case Management and Other Services Pilots Evaluation

Evaluation Question /Hypothesis	Measure Name	Measure Description	Measure Steward	Primary (P) / Secondary (S) data collection	Data Source	Frequency

* NC plans to collect these measures, but their ultimate inclusion in the evaluation will be pending data availability

**Administrative and financial measures designed by the NC Department of Health and Human Services. Technical specifications currently under development.

Table 5: Power Calculations for Enhanced Case Management and Other Services Pilots Evaluation

Measure Name	Mean/Median and Effect Size Used for Power Calculation	Test Used for Power Calculation	N (total) for 80% Power	Evaluation Question
Comprehensive Diabetes Care: HbA1c poor control (>9.0%). NQF #: 0059*	47%, 5% absolute difference	Chi-Squared	545	H4a
Controlling High Blood Pressure NQF #:0018*	43%, 5% absolute difference	Chi-Squared	784	H4a
Medication Management for People with Asthma (Medication Compliance 75% Rate only) NQF# 1799	27%, 10% absolute difference	Chi-Squared	196	H5d
PROMIS Global Health Assessment	T-score 45; 5-point difference (HealthMeasures)	2-sample t-test	350	H4a; H4b; H4c; H4d
Health Related Quality of Life	22 days, 1-day increase (CDC)	2-sample t-test	504	H4a; H4b; H4c; H4d
Life Skills Progression	4, 1-point increase	2-sample t-test	200	H4c; H4d
Postpartum Care NQF #: 1517	60%, 5% absolute difference	Chi-Squared	242	H5b
Adolescent Well-Care Visit NQF #:	45%, 5% absolute difference	Chi-Squared	649	H5d
Visits in the First 15 Months of Life NQF #: 1392	59%, 5% absolute difference	Chi-Squared	593	H5c; H5d
Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life NQF #: 1516	67%, 5% absolute difference	Chi-Squared	712	H5d
Children and Adolescents' Access to Primary Care Practitioners	85%, 5% absolute difference	Chi-Squared	307	H5c; H5d
Live Births Weighing Less than 2,500 Grams NQF #: 1382	9%, 3% absolute difference	Chi-Squared	545	H4c

Table 5: Power Calculations for Enhanced Case Management and Other Services Pilots Evaluation

Measure Name	Mean/Median and Effect Size Used for Power Calculation	Test Used for Power Calculation	N (total) for 80% Power	Evaluation Question
Adverse Utilization	ED Visits: Mean .31 per year, .05 absolute difference (MEPS) Inpatient Hospitalizations: Mean .12 per year, .05 absolute difference (MEPS)	T-test	ED Visits: 3716 Inpatient: 3204	H5a; H5b; H5c; H5d
Total Expenditures on Care	$446 per member per month, $30 per member per month difference (KFF)[a]	T-test	19624	H6a

All tests assume two-sided significance levels of 0.05
Calculations performed with R package 'pwr' R version 3.4.2[26]
Source of data in parentheses if author calculations or otherwise from Adult or Child Medicaid Quality Measures:
https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2018-child-chart-pack.pdf
https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2018-adult-chart-pack.pdf
[a] this assumes a standard deviation of $750/month. Data from KFF = https://www.kff.org/medicaid/state-indicator/medicaid-spending-per-enrollee/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Data Sources

The evaluation of the Enhanced Case Management and Other Services Pilots will utilize a range of data sources, emphasizing existing and timely data. The proposed approach is designed to maximize use of existing data sources, limiting creation of new data to circumstances in which no other "real time" or "near real time" information can be gathered. The following key data sources will be required: Medicaid claims and encounter data including actual payment amounts and procedure codes, individual identifiers of periods of pilot enrollment and PHP affiliation, health outcomes from birth certificates linked to Medicaid enrollees (mother and child), assessment item results from all assessments given to Medicaid enrollees, including primary data collection for the purposes of evaluation, and services delivered to all pilot participants, which will be provide to North Carolina Medicaid via a dedicated Enhanced Care Management Pilot Report from the PHPs and LPEs. These and additional specific sources of data are detailed in the measures tables (**Table 4**). The primary method of linking data across data sources will be the Medicaid ID, which is unique to each participant. Data will be cleaned by experienced data analysts within the evaluation team. Data will also be validated as part of the cleaning process. Data submissions with substantial missing or out of expected range values will be validated with the submitting organization, and corrective action plans will be made in the case of repeated issues with data provision. While most data will be collected in the course of pilot operations, there will be primary data collection needed for some outcomes. The two types of primary data needed are quantitative data, to be obtained from surveys, and qualitative data. For the quantitative data, we plan to use primary data collection to capture patient reported outcomes and information on the experience of care.

For each sub-population being analyzed, we will undertake stratified random sampling and use response weights in our analysis to ensure representativeness of the survey sample. Based on pilot enrollment numbers, we will survey sufficient participants to ensure a margin of error of +/-3 % or less. Surveys will be conducted over the telephone by trained interviewers. Participants will be informed of the surveying at pilot enrollment, and because of ongoing contact between pilot participants and case managers, who can introduce the importance of the surveys to the participants, we anticipate sufficient enrollment in survey data collection. During the rapid cycle assessment, these data will be captured at pilot enrollment, at 3 months of enrollment, and at 6 months of enrollment. For the interim evaluation, all data collected up to that point will be used. During the summative evaluation, these data will be captured at pilot enrollment, at 3 months of enrollment, at 6 months of enrollment, and at 12 months of enrollment. If an individual discontinues pilot participation, either at their preference or because they are no longer a Medicaid beneficiary, we will attempt to conduct an exit interview around the time of discontinuation, and this will replace any remaining scheduled data collection. We currently plan to collect information using the PROMIS set of health indicators, which have versions that are validated for adults, children age 13 and older, and for parents or guardians to report regarding younger children who cannot be asked themselves. We will also use the CDC's "Measuring Healthy Days" health-related quality of life measure. However, because of the novelty of these programs, we plan to pilot-test these instruments for feasibility and to assure they are capturing relevant dimensions of participant experience. If changes are made on the basis of this piloting, we will submit these changes,

including new survey instruments, for CMS approval prior to implementation. Plans for qualitative data collection are detailed within the *Analytic Methods* section.

Analytic Methods

Given the complexity of the pilots, a mixed method approach will be used to evaluate all aspects of the Enhanced Case Management and Other Services Pilots. Below we detail methods used in different aspects of the evaluation, linked to specific evaluation questions and hypotheses.

Hypotheses 1 and 2

To test Hypothesis 1, we will examine the dates of service delivery and the capacity for service delivery the LPE builds in its HSO network. For Hypothesis 2 we will be comparing results from the pilot programs to results of the screening initiative undertaken by PHPs in other parts of the state. We will make both unadjusted comparisons (for example, using chi-squared tests) and adjusted comparisons using regression analysis. The adjusted comparisons will help isolate the effect of the pilots by accounting for demographic, clinical, and healthcare utilization differences in different areas of the state. For the regression models, we will test the distributional assumptions of the model in the data prior to conducting hypothesis testing analyses and select distributions for which the observed data meet the requisite assumptions.

Hypotheses 3-6: Interrupted Time Series Analysis

To quickly analyze whether pilot interventions are demonstrating expected effects, we will use an interrupted time series approach[27] for quantitative analysis in the rapid cycle assessment and interim evaluation. In this approach, comparisons are made before and

after the establishment of, or a change to, an intervention. During the rapid cycle assessment phase of the evaluation, program changes are expected to occur quickly, rendering it impractical to create an external comparison group. The quasi-experimental interrupted time series design is ideally suited to these situations as each change in the intervention can be modelled as new interruption point, allowing us to use the entirety of the accumulated data in analysis, which enhances the power to detect change. For some outcomes, there may only be one assessment prior to the intervention (for example, when analyzing social risk factors), but for others, there may be multiple events (for example, an emergency department visit 4 months, 2 months, and 1 month prior to the intervention, and 6 months after). The interrupted time series approach provides the flexibility to analyze both scenarios. For analyses, events will be converted into 'event-time' format denoting the number, including 0, of outcome events and in a given time period in relation to the intervention start date (either before or after). Further, individual-level regression models will be used to adjust for fixed-effects factors (for example: age, gender, race/ethnicity, health and social risk factors) in order to increase power and account for potential confounding factors. We will examine the data to determine whether the assumptions needed for interrupted time series analyses are met (for example, autocorrelation or seasonality issues) and make adjustments for these if needed. For the regression models, we will test the distributional assumptions of the model in the data prior to conducting hypothesis testing analyses and select distributions for which the observed data meet the requisite assumptions.

Hypotheses 3-5: Qualitative Analysis

Qualitative analyses will rely on primary data. A table summarizing the data collection for this is presented as **Table 6**, below. Participants will be selected using purposeful sampling. This means that the sampling strategy will explicitly select individuals based on characteristics of a population and the evaluation questions to yield information rich cases with the diversity of viewpoints. Categories and dimensions may include, but are not limited to, age, gender, race/ethnicity, education, employment, comorbidity, social risk factors, and areas of residence. The goal with this approach is to collect data that covers the breadth of experiences and expertise pilot participants possess. Data will be collected using a combination of qualitative research methods, as different methods are best suited in different circumstances. For example, when discussing possibly stigmatizing topics, individual interviews may promote more open dialogue than focus group discussions. When social context, group norms or values is important, (for example, regarding an eligibility determination process), focus group discussions with a larger number of participants may offer areas of synergy and differences on ideas and perspectives. The goal with the qualitative data collection will be to achieve thematic saturation regarding the given topics, and thus sample size will be adjusted in order to achieve this. For analysis, transcripts of interviews and focus groups will be transcribed verbatim and imported into ATLAS.ti 7.5.18, a qualitative software program to facilitate analysis. Codebooks will be created to analyze data with codes drawn from both the interview and discussion guides and from participants' words. We will use an iterative approach to identify and group emergent themes. Any disagreements will be resolved by discussion and consensus.

Table 6: Qualitative Data Collection Planning					
Stakeholders	**Hypothesis**	**Evaluation Questions**	**Data Collection Method**	**Sample**	**Timeline**
Qualifying adults (age ≥ 22 years)	3, 4	Do Pilot services improve social risk factors in qualifying adults (age ≥ 22 years)? Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in adults (age ≥ 22 years) with qualifying health and social risk factors?	Focus group discussions	Two focus groups annually with up to 14 qualifying adults (age ≥ 22 years) representing each Service Tier Each focus group with approximately 7 participants per group	Years 2-5
Qualifying pregnant women	3, 4	Do Pilot services improve social risk factors in qualifying pregnant women? Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in pregnant women with qualifying health and social risk factors?	Focus group discussions	Two focus groups annually with up to 14 qualifying pregnant women representing each Service Tier Each focus group with approximately 7 participants per group	Years 2-5
Qualifying parents of young children (age 0-3 years)	3, 4	Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics, in pregnant women with qualifying health and social risk factors? Do Pilot services improve health outcomes, including PRO for parents and as reported by proxy, and quality of care metrics, in young children (age 0-3 years) with qualifying health and social risk factors?	Individual interviews	Up to five interviews annually with qualifying parents of young children (age 0-3 years) representing each Service Tier	Years 2-5

Table 6: Qualitative Data Collection Planning					
Stakeholders	**Hypothesis**	**Evaluation Questions**	**Data Collection Method**	**Sample**	**Timeline**
Qualifying parents of children/adolescents (age 0-21 years)?	3, 4	Do Pilot services improve social risk factors in qualifying young children (age 0-3 years)? Do Pilot services improve health outcomes, including patient-reported outcomes (PRO), experience of care, and quality of care metrics in children/adolescents (age 0-21 years) with qualifying health and social risk factors?	Individual interviews	Up to five interviews annually with qualifying parents of children/ adolescents (age 0-21 years) representing each Service Tier	Years 2-5
Key service providers in organizations delivering services	5	Do Pilot services improve social risk factors in qualifying children/adolescents (age 0-21 years)? Do Pilot services improve healthcare utilization, including increasing prenatal and postnatal care, in pregnant women with qualifying health and social risk factors? Do Pilot services improve healthcare utilization, including increasing primary care and preventive services/wellness utilization, and decreasing emergency department visits and hospitalizations, in young children (age 0-3 years) with qualifying health and social risk factors? Do Pilot services improve healthcare utilization, including increasing primary care and preventive services/wellness utilization, and decreasing emergency department visits and hospitalizations, in children/adolescents (age 0-21 years) with qualifying health and social risk factors?	Individual Interviews	Up to ten interviews annually 2-3 interviews with key individuals in 3-4 different organizations delivering services	Years 2-5
			Focus group discussions	Three focus groups annually with key organizations delivering services for "high effective" pilots Each focus group with approximately 7 participants per group (3 X 7=21 participants)	Years 5-7

Hypotheses 3-6: SMART Design

To determine whether Tier 2 and Tier 3 pilot services had their intended effect, a key method of analysis will be drawing comparisons between individuals who were and were not randomized to receive the services. Owing to the randomized nature of the design, unadjusted analyses will give unbiased estimates of intervention effects. However, to increase power and precision, we will conduct adjusted analyses using regression models. The control group in the SMART evaluation (individuals who were eligible for but did not receive services from a given Tier) will allow us to isolate the effect of the intervention programs. Analyses will be conducted using the intention-to-treat principle. To investigate whether differential loss to follow-up (censoring) could have affected the results, we will conduct sensitivity analysis that account for censoring using the inverse probability of censoring weighting approach. For the regression models, we will test the distributional assumptions of the model in the data prior to conducting hypothesis testing analyses and select distributions for which the observed data meet the requisite assumptions. Where applicable, regression models will account for repeated measurements within individuals. These methods will be applied to all outcomes associated with the randomized evaluation listed in Table 4.

Hypotheses 3-6: Difference-in-Difference Comparison

In order to compare Tier 1 services to receipt of 'standard' demonstration services, we will use a difference-in-difference evaluation, as all pilot participants will receive Tier 1

services and thus there is no 'internal' comparison group. Instead, to isolate the effect of the intervention, we will use individuals in other parts of the states, where pilots are not active, to serve as the comparison group. This will enable us to determine the incremental effect, if any, of the pilots over and above the other initiatives happening state-wide. We will select individuals who would have been eligible for the pilots, on the basis of health and social risk factors, had they lived in an area with pilot programs. From this set of individuals, we will use a high-dimensional propensity score approach[28–30], where the propensity score to be estimated is the probability of participating in the pilot programs conditional on data captured in claims and the social risk assessment all plans will administer to their beneficiaries. We will then additionally adjust for pre-intervention measurements of the outcome (for example, emergency department visits in the year prior to the intervention when analyzing the outcome of emergency department visits), and also area-level indicators of healthcare use (for example, emergency department visits per 1000 Medicaid beneficiaries in the region) and socioeconomic characteristics (from U.S. Census data sources such as the American Community Survey). We will further consider demographic and clinical differences in those who and do not participate in the pilots (differential selection) and issues of length of participation and loss of beneficiary status (churn). We will also conduct analyses of the level and trends in outcomes prior to the implementation of the Pilots, and, if differences are observed in outcomes trends, we will additionally using weighting techniques in order to create a comparison group that is as similar as possible to the pilot intervention group outcomes, in the absence of the pilots. We will analyze the same outcomes as in the SMART evaluation above (listed in Table 4). The high-dimensional propensity score[28] adjusted difference-in-difference analysis will use regression models for

hypothesis testing. For the regression models, we will test the distributional assumptions of the model in the data prior to conducting hypothesis testing analyses and select distributions for which the observed data meet the requisite assumptions. Where applicable, regression models will account for repeated measurements within individuals using generalized estimating equations. Data will reflect monthly, quarterly, or annual outcomes, as appropriate. Each outcome will be regressed in a separate model as a function of a series of binary indicators of actual pilot services received during the period, controlling for demographic factors and risk-adjustment factors such as chronic condition indicators. If individuals are in the pilot for a shorter time period than the period that the outcomes are observed (e.g., participants are in the pilot for several months, but some outcomes are only observed annually), appropriate adjustments will be made. Results from the GEE models will be converted to average marginal effects, which will reflect the impact the use of each service type has on the outcome in natural units. For example, we may find that the average marginal effect of tenancy support services is a $25 reduction in Medicaid-funded health services use, controlling for risk factors and other baseline covariates.

In addition to the main analyses described above, we will conduct a number of sensitivity analyses. First, it is likely that the effects of the pilots may occur with a lag. Therefore, we will also examine the effect of lagged participation on all outcomes as appropriate. This analysis will determine whether the pilot models create short versus long-run effects on spending and health outcomes. Second, it is likely that there are heterogeneous effects of the pilots across different groups of PHP enrollees, such as by number of need-based factors such as chronic conditions. We will run a limited number of

subgroup analyses as sample size permits in order to determine the effectiveness of the pilot services in specific subgroups.

Evaluation Challenges, Methodological Limitations, and Plans to Address Them

Despite the overall rigor of the evaluation design, there are important challenges and limitations to consider. Participants can opt-in or out of pilot participation, and some participants may lose Medicaid eligibility during the evaluation period. These issues are addressed by using randomization, the intention-to-treat principle for analyses, and inverse probability of censoring weighting in analyses comparing pilot participants. For analyses comparing pilot participants to non-pilot participants, these issues are addressed by using difference-in-difference analyses, explicitly considering length of participation, and analyzing characteristics of those who do and do not enroll. In the rapid cycle assessment, it is not possible to use an external comparison group given the pace with which the interventions evolve. In order to help mitigate this, an interrupted time series design is used. Additionally, the rapid cycle assessments need to balance the speed with which assessments occur and the statistical power of the analysis. Since the goal is quickly provide needed information, the rapid cycle assessment may lack power to detect smaller or longer-term intervention effects that would only become apparent with larger samples followed for long periods of time. However, given North Carolina's pressing need to prioritize the most effective interventions, we believe these limitations are offset by the benefits of the rapid cycle assessments—specifically the ability to quickly 'course correct' during the early phase of the evaluation. We also note that the summative evaluation has complementary strengths, allowing for longer term follow-up and detection of more subtle effects. The main limitation of the summative evaluation is the complexity of the evaluation design. Adding randomization inherently increases the amount of infrastructure and coordination needed to implement the evaluation. However, we believe the benefits of a

randomized design of the type we propose, which ensures all participants receive services likely to be effective for their social risk factors and physical/behavioral health conditions while still enabling us to make comparisons across types of interventions in order to determine their comparative effectiveness, vastly outweigh this limitation. Additionally, having sufficient participants for statistical power is always a concern. Because the evaluation design focuses the initial stage of the evaluation on ways to identify and retain pilot participants, this will maximize participation and thus statistical power.

Attachments

1. Independent Evaluator

As stated in the Special Terms and Conditions, the state is required to select an independent evaluator for the Enhanced Case Management and Other Services Pilots. Key requirements for the evaluator are that the evaluator be free of any conflict of interest with the pilots, have experience with large scale evaluations, have experience working with the necessary data sources and types to evaluate the pilots, and have expertise with the evaluation methodologies that will be needed to evaluate the pilots. 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. 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.

2. Evaluation Budget

Please see separate attachment

3. Timeline

Healthy Opportunities Pilots: Key Timelines														
		Milestones				Ongoing Pilot Services Occuring								
Activity	2019				2020				2021	2022	2023	2024	2025	2026
	Jan- Mar	Apr-Jun	Jul-Sept	Oct-Dec	Jan- Mar	Apr-Jun	Jul-Sept	Oct-Dec						
Waiver Effective Period														
1115 waiver effective dates				11/1								10/31		
Pilot Procurement, Launch and Service Delivery														
Release RFP														
Entities submits RFP responses														
State awards LPE contracts														
Pilot service delivery														
Evaluation Design and Reports Submission														
Submit evaluation design to CMS for review and approval	2/21													
Submit annual rapid cycle assessment to CMS									1st Quarter	1st Quarter	1st Quarter			
Submit Interim Evalutation											4th Quarter			
Conduct summative evaluation and prepare report														
Submit summative evaluation to CMS														4/30

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