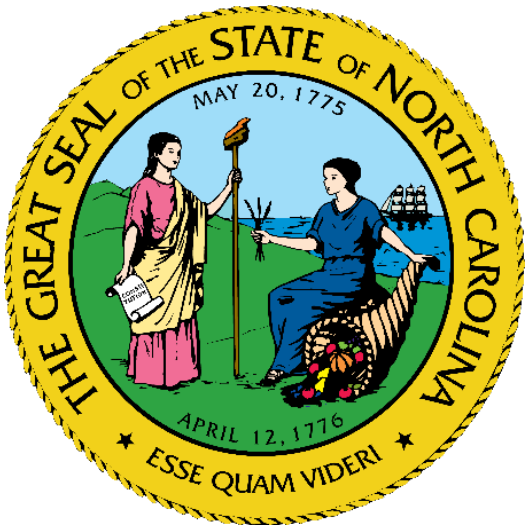

Public Health Emergency (COVID-19) Section 1115 Demonstration Evaluation Design

North Carolina Department of Health and Human Services

August 21, 2020

Background

North Carolina's Public Health Emergency (COVID-19) 1115 Waiver (waiver) was approved by the Centers for Medicare & Medicaid Services (CMS) on June 25, 2020. The waiver aims to evaluate the effectiveness of expedited eligibility for long-term care services and supports (LTSS), availability of these services, retainer payments, modified eligibility, and functional assessments during the public health emergency.

Evaluation Hypothesis and Research Questions

The state's evaluation seeks to verify the core hypothesis that the flexibilities afforded through the section 1115 demonstration authority were effective in ensuring Medicaid beneficiaries received uninterrupted care during the public health emergency. To investigate this hypothesis the state will seek to answer three research questions:

1. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?
2. Did the flexibilities of this demonstration assist in meeting the challenges beneficiaries, providers, and Medicaid staff faced during the public health emergency?
3. What lessons can be leveraged when responding to similar public health emergencies in the future?

Outcome Measures and Potential Data Sources by Waiver Authority

1. Expedited Eligibility for Long-Term Care Services & Supports

a. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?

i. Calculate expenditures (total) associated with HCBS-eligible (LTSS) individuals who are;

1. not determined eligible, and
2. determined eligible

after the expedited process, self-attestation, or alternative verification of individuals' eligibility (income/assets) and qualifying level of care. Compare against expenditures of HCBS-eligible individuals prior to COVID-19 through Medicaid claims data. (Data source – Medicaid claims)*

* Given the administrative complexity of reporting and the anticipated limited duration of this demonstration, the State may report expenditures on an estimated basis. Methods used to estimate the expenditures will be detailed in the final report.

b. What challenges did the COVID-19 public health emergency pose to the Medicaid program?
    i. Retrospective driver diagram/logic model of expedited eligibility intervention (Data source - facilitated discussion with Medicaid staff)
    ii. Metanalysis of documents describing the need for expedited eligibility prior to implementation (Data sources – some examples include North Carolina Institute of Medicine (NCIOM) reports, COVID-19 LTSS outbreak data, evaluation stakeholder engagement notes, COVID -19 federal requests [concurrence letter, disaster SPA, and initial 1115 PHE application] as well as other internal and external documentation)

c. How did the flexibilities of this demonstration assist in meeting those challenges?
    i. Stakeholder accounts of implementing expedited eligibility authority (Data source - interviews with Medicaid staff)

d. What lessons can be leveraged when responding to similar public health emergencies in the future?
    i. Stakeholder accounts of lessons learned through implementation of expedited eligibility authority (Data source - interviews with Medicaid staff)
    ii. Comparison of previous hurricane disaster actions to these disaster actions (Data sources - executive orders from previous hurricanes for example Matthew [2016], Florence [2018], and Dorian [2019], appendix Ks, concurrence letters, clinical policy changes as well as other internal and external documentation)

2. Long-Term Care Services and Supports (LTSS)

a. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?
    i. The proportion of beneficiaries receiving LTSS HCBS (all community-based) services or waiting for waiver-eligibility (i.e. not on a waiver) who were admitted to a facility (specify facility type) has/not increased since the beginning of the COVID-19 policy flexibility compared to 6 months before the COVID-19 pandemic (first NC case March 1, 2020). (Data source – Medicaid claims)
    ii. The admission rate for beneficiaries served in a care facility during the COVID-19 policy flexibility period is/not consistent with the admission rate for beneficiaries served 6-12 months before the COVID-19 policy flexibility period. (Data source – Medicaid claims)

b. What challenges did the COVID-19 public health emergency pose to the Medicaid program?
    i. Retrospective driver diagram/logic model of LTSS authority (Data source - facilitated discussion with Medicaid staff)
    ii. Metanalysis of documents describing the need for LTSS authority prior to implementation (Data sources – some examples include NCIOM reports, COVID-19 LTSS outbreak data, evaluation stakeholder engagement notes, COVID -19 federal

requests [concurrence letter, disaster SPA, and initial 1115 PHE application] as well as other internal and external documentation)

c. How did the flexibilities of this demonstration assist in meeting those challenges?
    i. Stakeholder accounts of implementing LTSS authority (Data source - interviews with Medicaid staff)

d. What lessons can be leveraged when responding to similar public health emergencies in the future?
    i. Stakeholder accounts of lessons learned through implementation of LTSS authority (Data source - interviews with Medicaid staff)
    ii. Compared with the general Medicaid beneficiary population, the HCBS and/or waiver beneficiary groups did/not see a proportionate rate of COVID-19 or Influenza like illness (ILI) diagnosis. (Data source – Medicaid claims)
        1. Among beneficiaries 1905(a) or 1915(b)(3) LTSS services at least 6 months before the first confirmed NC COVID-19 positive case (March 1, 2020), the number of beneficiaries who had a claim with a COVID-19 or ILI diagnosis code on from each week of the COVID-19 pandemic period starting with the week of March 1, 2020. (Data source – Medicaid claims; State Lab case data received weekly under data use agreement [DUA] with North Carolina Division of Public Health [NC DPH])
        2. The number of community-based HCBS and/or waiver beneficiaries with a claim or encounter (any service) with a COVID-19 or ILI diagnosis code for each week of the COVID-19 pandemic period starting with the week of March 1, 2020. (Data source – Medicaid claims)
    iii. Comparison of previous hurricane disaster actions to these disaster actions (Data sources - executive orders from previous hurricanes for example Matthew [2016], Florence [2018], and Dorian [2019], appendix Ks, concurrence letters, clinical policy changes as well as other internal and external documentation)

3. Retainer Payments

a. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?
    i. For LTSS/waiver beneficiary claims, the amount per month in retention payments paid by Division of Health Benefits (DHB). (Data source – Medicaid claims and Local Management Entity/Managed Care Organization [LME/MCO] retainer payment tracker maintained by DHB's Associate Director of Budget)*
    ii. On average, the number of days (95% CI of mean) providers serving LTSS/waiver beneficiaries were paid retention payments since the beginning of the COVID-19

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policy flexibility period. (Data source – Medicaid claims and LME/MCO retainer payment tracker maintained by DHB's Associate Director of Budget)

b. What challenges did the COVID-19 public health emergency pose to the Medicaid program?
    i. Retrospective driver diagram/logic model of retainer payment intervention (Data source - facilitated discussion with Medicaid staff)
    ii. Metanalysis of documents describing the need for retainer payments prior to implementation (Data sources – some examples include NCIOM reports, COVID-19 LTSS outbreak data, evaluation stakeholder engagement notes, COVID -19 federal requests [concurrence letter, disaster SPA, and initial 1115 PHE application] as well as other internal and external documentation)

c. How did the flexibilities of this demonstration assist in meeting those challenges?
    i. Stakeholder accounts of implementing retainer payment authority (Data source - interviews with Medicaid staff)

d. What lessons can be leveraged when responding to similar public health emergencies in the future?
    i. Stakeholder accounts of lessons learned through implementation of retainer payment authority (Data source - interviews with Medicaid staff)
    ii. Comparison of previous hurricane disaster actions to these disaster actions (Data sources - executive orders from previous hurricanes for example Matthew [2016], Florence [2018], and Dorian [2019], appendix Ks, concurrence letters, clinical policy changes as well as other internal and external documentation)

4. Modified Eligibility

a. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?
    i. The proportion of beneficiaries eligible for 1905(a) or 1915(b)(3) LTSS services has/not increased since the beginning of the COVID-19 policy flexibility compared to 6 months before the COVID-19 pandemic (first NC case March 1, 2020). (Data source – Medicaid claims)*

b. What challenges did the COVID-19 public health emergency pose to the Medicaid program?
    i. Retrospective driver diagram/logic model of modified eligibility intervention (Data source - facilitated discussion with Medicaid staff)
    ii. Metanalysis of documents describing the need for modified eligibility prior to implementation (Data sources – some examples include NCIOM reports, COVID-19 LTSS outbreak data, evaluation stakeholder engagement notes, COVID -19 federal requests [concurrence letter, disaster SPA, and initial 1115 PHE application] as well as other internal and external documentation)

c. How did the flexibilities of this demonstration assist in meeting those challenges?
    i. Stakeholder accounts of implementing modified eligibility authority (Data source - interviews with Medicaid staff)

d. What lessons can be leveraged when responding to similar public health emergencies in the future?
    i. Stakeholder accounts of lessons learned through implementation of modified eligibility authority (Data source - interviews with Medicaid staff)
    ii. Comparison of previous hurricane disaster actions to these disaster actions (Data sources - executive orders from previous hurricanes for example Matthew [2016], Florence [2018], and Dorian [2019], appendix Ks, concurrence letters, clinical policy changes as well as other internal and external documentation)

5. Functional Assessments

a. What were the administrative costs and health services expenditures for demonstration beneficiaries and how did these outlays affect the state's response to the public health emergency?
    i. Calculate additional expenditures associated with individuals who received a higher level of care than they otherwise would have because of a delayed functional assessment. (Data source – Medicaid claims)*

b. What challenges did the COVID-19 public health emergency pose to the Medicaid program?
    i. Retrospective driver diagram/logic model of functional assessments intervention (Data source - facilitated discussion with Medicaid staff)
    ii. Metanalysis of documents describing the need for functional assessments authority prior to implementation (Data sources – Some examples include NCIOM reports, COVID-19 LTSS outbreak data, evaluation stakeholder engagement notes, COVID -19 federal requests [concurrence letter, disaster SPA, and initial 1115 PHE application] as well as other internal and external documentation)

c. How did the flexibilities of this demonstration assist in meeting those challenges?
    i. Stakeholder accounts of implementing functional assessments authority (Data source - interviews with Medicaid staff)

d. What lessons can be leveraged when responding to similar public health emergencies in the future?
    i. Stakeholder accounts of lessons learned through implementation of functional assessments authority (Data source - interviews with Medicaid staff)
    ii. Comparison of previous hurricane disaster actions to these disaster actions (Data sources - executive orders from previous hurricanes for example Matthew [2016],

* Given the administrative complexity of reporting and the anticipated limited duration of this demonstration, the State may report expenditures on an estimated basis. Methods used to estimate the expenditures will be detailed in the final report.

Florence [2018], and Dorian [2019], appendix Ks, concurrence letters, clinical policy changes as well as other internal and external documentation)

Evaluation Methods

The state will use a mixed-method design to test the evaluation hypotheses.

Qualitative

Measures 1bi, 1ci, 1di, 2bi, 2ci, 2di, 3bi, 3ci, 3di, 4bi, 4ci, 4di, 5bi, 5ci, 5di

Qualitative data in the form of interviews and facilitated discussions will be analyzed to understand Medicaid staffs' experience planning and implementing the demonstration authorities. These data will be collected from staff that led the planning and implementation of the respective authority and any additional key informants identified by those implementation leads. All details pertaining to selection of interviewees and preparation of interview guides, including questionnaires, and how data were analyzed will be included in the evaluation report.

Metanalyses and Document Review

Measures 1bii, 1dii, 2bii, 2diii, 3bii, 3dii, 4bii, 4dii, 5bii, 5dii

The state will perform metanalyses of existing documentation to understand the challenges that led to implementation of the waiver authorities and how actions taken during the current public health emergency compare to actions taken during prior disasters.

Quantitative

Measures 1ai, 2ai, 2aii, 2dii1, 2dii2, 3ai, 3aii, 4ai, 5ai

Quantitative analyses of Medicaid Claims, State Lab and other monitoring data will be employed to understand how waiver authorities impacted costs and, where possible, the health of beneficiaries. Cost and utilization data will be used to estimate service expenditures and may be used to analyze whether the demonstration successfully maintained beneficiary service access.

Various quantitative approaches will be employed. The design presents descriptive quantitative trend analysis of costs, utilization, and COVID-19 cases; quantitative descriptive and trend analysis will leverage statistical tests and regression adjusted estimates to understand the effect of the demonstration, where possible. This trend analysis will consider the period beginning 6-12 months prior to the public health emergency and continuing through to the end of demonstration authority.

The state may adjust analytic approaches as the evaluation progresses to better fit the data collected and/or more clearly answer the questions posed. All evaluation approaches conducted, and applicable sensitivity checks will be documented in the evaluation reports.

Limitations

The unknown scope and timeline of the public health emergency make it difficult to determine ideal evaluation indicators and methods. Approaches that appear appropriate during the design, data collection and even analysis phases of the evaluation may lose meaning as the state's understanding of COVID-19, its symptoms and treatments and the associated pandemic evolves. This limitation is

unavoidable given the nature of the evaluand. The state has proposed a broad and flexible design intended to allow for maximum adjustment in the face of this uncertainty.

Qualitative findings will not be generalizable as individuals view experiences on a spectrum and therefore cannot be lumped into categories. Moreover, the state has elected not to collect qualitative data from beneficiaries and providers to avoid compounding the burden that the public health emergency has placed on these parties already. Though the state believes that this is the correct decision, it limits the evaluation's capacity to deliver an understanding of beneficiary and provider experiences of the public health emergency and associated waiver authority interventions.

The small number of beneficiaries affected by any given authority will likely not allow for the application of typical outcome indicators. Given the small populations, pre/post reporting of select outcomes (e.g., bedsores, weight loss, critical incidents, depression, anxiety, etc.) would likely be too noisy to be meaningful and ripe for misinterpretation. As in the case of the primary limitation stated above, the uncertain nature of the public health emergency, the state has proposed a flexible design that may allow for the incorporation and reporting of these data as feasible based on how demonstration flexibilities and the public health emergency unfold.

Evaluation Timeline

Completion of the 1115 COVID-19 demonstration evaluation is dependent on the end of the Public Health Emergency. The state will begin strategizing data collection and analysis within 30 days of evaluation design approval. Qualitative data will be collected quarterly throughout the demonstration. Quantitative data will be collected continuously throughout the demonstration. Documents will be compiled for metanalysis immediately following the end of the demonstration. All evaluation data will be verified and analyzed following the end of the demonstration. External researchers including the Sheps Center for Health Services Research at UNC Chapel Hill will be engaged to assist with analyses.

The following table outlines expected milestones:

Due Date/ Timeline	Milestone/ Deliverable
March 1, 2020	Official start of the COVID-19 Public Health Emergency Section 1115 Demonstration
August 21, 2020	Evaluation design submitted to CMS
Thirty days from evaluation design approval	Approved evaluation design posted to state website
Sixty days from the end of the public health emergency	Official end date of the COVID-19 Public Health Emergency Section 1115 Demonstration
First weekday after end of demonstration	Program documents are assembled for metanalysis
One year after the end of demonstration authority	Final report with consolidated monitoring and evaluation requirements