

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

October 4, 2023

Sarah Aker
State Medicaid Director
Medicaid Services Division
North Dakota Department of Human Services
600 E Boulevard Ave, Dept 325
Bismarck, ND, 58505-0250

Dear Director Aker:

The Centers for Medicare & Medicaid Services (CMS) approved the Evaluation Design for North Dakota's Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) section 1115 demonstration entitled, "North Dakota Managed Care Risk Mitigation COVID-19 PHE" (Project No: 11-W-00397/8). We sincerely appreciate the state's commitment to efficiently meeting the requirement for an Evaluation Design as was stipulated in the approval letter dated May 19, 2022, especially under these extraordinary circumstances.

In accordance with 42 CFR 431.424(c), the approved Evaluation Design may now be posted to the state's Medicaid website within 30 days. CMS will also post the approved Evaluation Design on Medicaid.gov.

Consistent with the approved Evaluation Design, the draft Final Report will be due to CMS 18 months after either the expiration of the demonstration approval period or the end of the latest rating period covered under the state's approved expenditure authority, whichever comes later.

We sincerely appreciate the state's commitment to evaluating the Managed Care Risk Mitigation COVID-19 PHE demonstration under these extraordinary circumstances. We look forward to our continued partnership on the North Dakota Managed Care Risk Mitigation COVID-19 PHE section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

**Danielle
Daly -S**

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Danielle Daly
Director

Division of Demonstration Monitoring and Evaluation

**State of North Dakota
Department of Health & Human Services**

**Managed Care Risk Mitigation COVID-19 PHE section 1115(a) Waiver Demonstration Evaluation
Design (Project Number 11-W-00397/8)**

June 28, 2023

Brief Background

On May 19, 2022, the State of North Dakota, Department of Human Services obtained approval from the Center for Medicare & Medicaid Services (CMS) to implement the North Dakota Managed Care Risk Mitigation COVID-19 PHE section 1115(a) (hereafter referred to as “PHE Demonstration”) (Project Number 11-W-00397/8) by waiving certain requirements to the extent necessary to respond to the continued spread of COVID-19. The PHE Demonstration approval was retroactively applied from March 1, 2020, through the end of the PHE.

To that end, the expenditure authority is expected to support the state with making appropriate, equitable payments during the PHE to help maintain beneficiary access to care, and to facilitate meeting any alternative or additional objectives specified by the state in its requests for the demonstration authority. This exemption allows the state to enter into a risk mitigation arrangement with a Medicaid managed care plan after the applicable contract period has begun, provided that the contract and rating period begin or end during the COVID-19 PHE. The period begin date is 1/1/2020 and the period end date is 12/31/2021 using an MLR risk mitigation arrangement.

The following expenditure authorities were granted as part of the PHE Demonstration, to provide additional supports to the state’s Medicaid program.

- Permit North Dakota to add or modify risk sharing mechanisms such as reinsurance, risk corridors, or stop-loss limits after the start of a rating period provided that the contract and rating period(s) begin or end during the COVID-19 PHE. The authority would allow one or more retroactive risk mitigation arrangements to remain. This expenditure authority exempts the state from compliance with the requirements under 42 C.F.R. § 438.6(b)(1) and allows [STATE] to add or modify the risk sharing mechanism(s) after the start of the rating period as specified in the state’s contracts with its Medicaid managed care plans. The authority would allow one or more retroactive risk mitigation arrangements to remain in place even if the state and the managed care plan had agreed to these arrangements after the requirements in section 438.6(b)(1) became effective. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation but before the start of the rating period. This authority lasts only for the duration of the PHE.
- More specifically, if the contract and rating period(s) begin or end during the COVID-19 PHE and the contract was signed prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period(s) ended on or after March 1, 2020, and ended prior to the last day of the PHE, the state

can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period began after March 1, 2020, and prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. A state can only retroactively implement risk sharing arrangements for multiple rating periods if the contract signature criteria as well as the rating period beginning and ending criteria are met for each rating period

Demonstration Objectives

The PHE Demonstration's key objective is to:

- Furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of beneficiaries receiving Medicaid benefits by mitigating the potential negative impacts of the COVID-19 PHE.
- Ensure that medical providers who furnish medical assistance in good faith, who are unable to comply with one or more requirements as a result of the COVID-19 pandemic, are reimbursed for such items and services, exempted from sanctions for such noncompliance (absent any determination of fraud or abuse), and to the extent feasible, protected from the negative fiscal impact of the COVID-19 PHE.

Evaluation Questions

The evaluation of the PHE Demonstration will test whether and how the waiver and expenditure authorities affected the state's response to the public health emergency, and how they affected coverage and expenditures. Evaluation Responses are tailored to each of the evaluation objectives and presented in Table 1 below.

Methodology

Data sources will be compiled data from qualitative and quantitative data sources included staff interviews and state and administrative data.

To examine information related to the MLR risk mitigation arrangement negotiated with the MCO, North Dakota will conduct a review of relevant documentation (e.g., managed care contracts)

North Dakota will conduct interviews with ND Department of Health and Human Services (ND DHHS) staff to evaluate if the demonstration facilitated attaining the objectives of Medicaid. North Dakota will identify ND DHHS staff to be interviewed based on involvement in the implementation of the MLR risk mitigation arrangement.

Managed Care Organization (MCO) Medical Loss Ratio (MLR) reports, which provide aggregate revenue, claims costs, and other financial metrics will be utilized to evaluate, in part, the extent of the risk mitigation arrangement implemented under this demonstration authority resulted in more accurate payments to the MCO.

North Dakota will use claims cost data, collected and validated regularly by third party actuaries, to estimate the unforeseeable impact of COVID-19 on utilization patterns. This forms the basis of the standard 'encounter data' the actuary relies on for rate development.

As part of the 1115(a)-demonstration approval, CMS required North Dakota to develop a “simplified” Evaluation Design that does not undertake evaluations that would prove overly burdensome and impractical for data collection or analysis. As such, North Dakota will use qualitative and descriptive statistics methods to conduct the Evaluation.

Table 1: PHE Demonstration Evaluation Questions and Methodological Approach

Evaluation Questions	Measures	Data Source(s)	Analytic Approach
1. What PHE Demonstration flexibilities were implemented by the state?	For flexibilities that were implemented, how were they implemented?	Document Review	Qualitative Analysis
2. What retroactive risk sharing agreements did the state ultimately negotiate with the managed care plans under the demonstration authority?	Describe what, if any, risk sharing agreements that were implemented.	Document Review, ND DHHS Staff Interview	Qualitative Analysis
3. To what extent did the retroactive risk sharing implemented under the demonstration authority result in more accurate payments to the managed care plans?	Describe what, if any, change occurred to the payments to the managed care plans.	MCO CY20 & CY21 MLR's, ND Claims Data	Descriptive Analysis
4. In what ways during the PHE did the demonstration support adding or modifying one or more risk sharing mechanisms after the start of the rating period?	Describe how risk sharing agreements that were implemented, if any, were used.	ND DHHS Staff Interview	Qualitative Analysis
5. What does the state anticipate would have been caused by the application of section 438.6(b)(1) during the PHE that would have undermined the objectives of Medicaid, and how did the exemption address or prevent these problems?	Describe how PHE Demonstration flexibilities were used to address or prevent any PHE related problems.	ND DHHS Staff Interview	Qualitative Analysis
6. What were the principal challenges associated with implementing the retroactive risk mitigation strategies from the perspectives of the state Medicaid agency and Medicaid managed care plans?	What actions did the state take to address challenges presented by the implementation of the PHE Demonstration? To what extent were those actions successful in the context of the PHE?	ND DHHS Staff Interview	Qualitative Analysis
7. What were the principal lessons learned for any future PHEs in implementing the demonstration flexibilities?	Describe what, if any, lessons that the state learned.	ND DHHS Staff Interview	Qualitative Analysis

Methodological Limitations

With the simplified nature of this evaluation and Evaluation Report, North Dakota does not anticipate encountering extensive methodological limitations. However, there are a few limitations the state may encounter, which are described below.

- **Qualitative Analysis.** The main analytic approach North Dakota will use in this evaluation is qualitative analysis. There are a few widely known limitations to the qualitative analysis approach such as difficulty to demonstrate rigor, dependency of an individual's skills on research quality, and bias. North Dakota will do its best to minimize these limitations, for example, by creating a scripted interview template.
- **Staff Interviews.** North Dakota plans to conduct a limited number of ND DHHS staff interviews to evaluate questions 2, 4, 5, 6, & 7. North Dakota will schedule interviews with identified critical ND DHHS staff members that were involved in the development and implementation of the MLR risk mitigation arrangement. If any of the critical staff members involved in the development and implementation of the risk corridor depart ND DHHS prior to the interview, it may be difficult to fully evaluate the aforementioned questions.

Evaluator and Evaluation Report

This evaluation will be conducted internally by State of North Dakota staff. Data will be gathered as part of standard operations. State staff will draw upon the findings to describe the extent to which the administrative and program costs related to the demonstration were effective at achieving the objectives of the demonstration.

The final report will be organized based on the structured outlined in CMS' section 1115 demonstration evaluation guidance "Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) Medicaid Section 1115 Demonstration: Guidance for Monitoring and Evaluation Requirements". Per CMS guidance, the focus of the report will be on describing the challenges presented by the COVID-19 PHE to the Medicaid program, how the flexibilities of this demonstration assisted in meeting these challenges, and any lessons that may be taken for responding to a similar public health emergency in the future. The final report will be submitted no later than one year following the end of the PHE Demonstration authority. Per 42 CFR 431.428, the final report will capture all the requirements stipulated for an annual report. If the demonstration lasts longer than one year, the annual report information for each demonstration year will be included in the final report and will adhere to the stipulation of 42 CFR 431.428.