

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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State Demonstrations Group

November 14, 2024

Cynthia Beane
Commissioner
Bureau for Medical Services
West Virginia Department of Health and Human Resources
350 Capitol St., Room 251
Charleston, WV 25301

Dear Commissioner Beane:

The Centers for Medicare & Medicaid Services (CMS) approved the Evaluation Design for West Virginia's Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) amendment to the section 1115 demonstration entitled, "West Virginia Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders" (Project No: 11-W-00307/3). We sincerely appreciate the state's commitment to efficiently meeting the requirement for an Evaluation Design as was stipulated in the approval letter for this amendment dated May 18, 2023, especially under these extraordinary circumstances.

The approved Evaluation Design may now be posted to the state's Medicaid website within 30 days, per 42 CFR 431.424(c). 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 look forward to our continued partnership with you and your staff on the West Virginia Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle
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Danielle Daly -S
Date: 2024.11.14
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Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Nicole Guess, State Monitoring Lead, CMS Medicaid and CHIP Operations Group



**West Virginia Department of Human Resources (DoHS)
Bureau for Medical Services (BMS)**

**Managed Care Risk Mitigation
COVID-19 Public Health Emergency (PHE)
Section 1115(a) Demonstration
Draft Evaluation Design
May 19, 2023**

Table of Contents

A. General Background Information	3
B. Demonstration Objectives	3
C. Evaluation Questions and Hypotheses	4
D. Methodology.....	5
1. Data Sources.....	5
2. Analytic Methods	5
E. Methodological Limitations	6
F. Final Evaluation Report	7
G. Timeline	7

A. General Background Information

On January 24, 2022, West Virginia (State) submitted a Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) Section 1115 demonstration application to the Centers for Medicare & Medicaid Services (CMS) for review and approval. The demonstration was approved on February 2, 2022, and was retroactively applied to a start date of March 1, 2020.

As part of this demonstration, CMS approved expenditure authority for the State to add or modify a risk-sharing arrangement after the start of the rating period, as specified in the State's contracts with its Medicaid managed care organizations (MCOs), to maintain capacity during the PHE. This expenditure authority applies only to managed care contracts and rating periods that begin or end during the COVID-19 PHE.

The authority exempts, as necessary, the State from compliance with the current requirements in [42 CFR §438.6\(b\)\(1\)](#) until the end of the PHE. This flexibility allows one or more retroactive risk mitigation arrangements to remain in place even if the State and the MCO 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.

- If the contract and rating period began after March 1, 2020, and the contract was signed prior to the last day of the PHE, the State has the ability under this demonstration to retroactively implement one or more risk-sharing arrangements for the full duration of the rating period.
- As agreed upon with CMS, the State can only retroactively implement risk-sharing arrangements under this demonstration for multiple rating periods if the contract signature criteria as well as the rating period beginning and/or ending criteria are met for each rating period.

B. Demonstration Objectives

The purpose of this demonstration is to help the BMS Medicaid managed care program furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by the COVID-19 PHE. Specifically, this demonstration intends to advance Title XIX objectives by providing cost effective, efficient payments for medical assistance to low-income aged, blind, and disabled individuals, and providing access to needed medical services.

The central objective of the demonstration is to test whether an exemption from the regulatory prohibition in [42 CFR §438.6\(b\)\(1\)](#) promotes the objectives of Medicaid. This exemption allows the State to enter into or modify a risk mitigation arrangement with contracted MCOs after the applicable rating period has begun.

BMS anticipates that the flexibility provided under this demonstration authority will assist the State in promoting the objectives of the Medicaid program, given that the authority is expected to support states with making appropriate, equitable payments during the PHE to help maintain beneficiary

access to care. Maintaining access to care for members would otherwise have been challenging during the COVID-19 PHE period, as utilization trends shifted notably from historical trends.

C. Evaluation Questions and Hypotheses

Evaluation of the demonstration will be guided by and focused on the research questions detailed below. The State will work to best answer these questions in the Final Evaluation Report of the demonstration, based on demonstration outcomes.

1. What problems 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 help prevent these problems?
 - a. [Hypothesis 1](#): The Medicaid objective to provide efficient, appropriate payments for medical services that are actuarially sound would not be met without the implementation of the demonstration. Allowing risk-sharing mechanisms to be added after the start of the rating period with this exemption was critically important as the exemption granted necessary flexibility in an unprecedented moment of Medicaid operations.
2. In the context of the COVID-19 PHE, did an exemption from the regulatory prohibition of retroactive risk mitigation outweigh the harms in promoting the objectives of the Mountain Health Trust (MHT) and Mountain Health Promise (MHP) Programs?
 - a. [Hypothesis 2](#): Yes, in context of the COVID-19 PHE, the exemption promoted the objectives of MHT and MHP programs by maintaining accountability for the use of resources in a manner that assures access to appropriate, medically necessary, and quality healthcare services for all members.
3. What were the principal challenges associated with implementing the flexibility authorized under this demonstration from the perspectives of the State Medicaid agency and MCOs?
 - a. [Hypothesis 3](#): The principal challenge associated with implementing this demonstration from the perspectives of both the State Medicaid agency and the MCOs would be managing issues that stemmed from the PHE and being able to manage those matters in an appropriate fashion. With the onset of the PHE, entities managed and worked within unknown contexts, having to adapt to emerging circumstances in real time.
4. What were the principal lessons learned for any future PHEs in implementing the demonstration flexibilities?
 - a. [Hypothesis 4](#): The State will gather valuable insight through implementation of the demonstration, including the extent to which the State can effectively establish procedures, policies, and guidance to help manage unknown circumstances and navigate uncertainties and unexpected challenges brought about by the PHE. Should this demonstration prove helpful in promoting the objectives of Medicaid as BMS anticipates it will, the State and CMS can recognize this flexibility as a tool that could potentially be used to help manage future PHEs. At a higher level, this demonstration grants the State the opportunity to test retroactive application of flexibility and understand associated benefits and challenges.
5. Was there an adverse impact on the eligibility, enrollment, or coverage of Medicaid managed care beneficiaries because of this demonstration?

Hypothesis 5: There was likely no adverse impact to the eligibility, enrollment, and coverage of Medicaid managed care beneficiaries because of this demonstration.

D. Methodology

The State will conduct a retrospective evaluation of the affected risk rate periods and risk mitigation arrangements using qualitative methods and descriptive statistics to evaluate the successes, challenges, and lessons learned through implementation of the demonstration. The retroactive risk mitigation arrangements that BMS negotiated with the MCOs through this demonstration are identified in Table 1 below; primary data sources used to assess these arrangements are also provided.

Table 1: Risk Mitigation Arrangements with West Virginia MCOs

Risk Mitigation Arrangements	Mountain Health Trust	Mountain Health Promise	Data Sources	Additional Detail
Medical Loss Ratio (MLR)	X	X	MCO MLR Reporting	MHT and MHP MCO Contracts
Stop Loss	X	X	Stop Loss Claims	MHT and MHP MCO Contracts
Reinsurance	Mandatory before State Fiscal Year (SFY) 2023; Optional after SFY 2023	Mandatory before SFY 2023; Optional after SFY 2023	Reinsurance documentation	MHT and MHP MCO Contracts

1. Data Sources

For this evaluation, the State will compile information from qualitative and quantitative data sources including departmental staff interviews, MLR reports filed by the MCOs, State Medicaid claims data, and document reviews.

The State will conduct staff interviews to evaluate if the demonstration promotes the objectives of Medicaid. Interview participants will be identified by their involvement of the development and implementation of the risk mitigation arrangements. In addition, the State will also leverage MCO staff interviews during periodic on-site evaluations to determine how issues were handled during the PHE.

MLR reports filed by MCOs will be reviewed for information on aggregate healthcare spending on incurred claims, non-claim costs, and expenditures on quality improvement activities. MLR reporting will also be reviewed for data related to adjusted premium revenue and other financial metrics.

The State will conduct a review of claims and encounter data for utilization patterns. Additionally, the State will conduct a review of documentation, such as managed care contracts, methodology documents, or other similar instructions to evaluate the potential impacts of retroactive risk mitigation arrangements.

2. Analytic Methods

The State will conduct qualitative and quantitative analyses on data collected as needed to evaluate the research questions posed in this demonstration. Consistent with CMS guidance, the

focus of this evaluation will be to respond to qualitative evaluation questions aimed at understanding the successes, challenges, and lessons learned in implementing the Managed Care Risk Mitigation COVID-19 PHE demonstration.

Table 2: Summary of Analytic Methods

Research Question	Outcome Measure	Data Sources	Analytic Approach
1. What problems 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 help prevent these problems?	Description of potential challenges and successes of adding risk mitigation arrangements.	Staff Interviews	Qualitative Analysis
2. In the context of the COVID-19 PHE, did an exemption from the regulatory prohibition of retroactive risk mitigation outweigh the harms in promoting the objectives of the Mountain Health Trust (MHT) and Mountain Health Promise (MHP) Programs?	Description of risk and benefits regarding implementation of risk mitigation arrangements.	Staff Interviews	Qualitative Analysis
3. What were the principal challenges associated with implementing the flexibility authorized under this demonstration from the perspectives of the State Medicaid agency and MCOs?	Description of challenges faced by the State and MCOs regarding implementation of risk mitigation arrangements.	Staff Interviews	Qualitative Analysis
4. What were the principal lessons learned for any future PHEs in implementing the demonstration flexibilities?	Description of lessons learned for future applications of demonstration flexibilities.	Staff Interviews	Qualitative Analysis
5. Was there an adverse impact on the eligibility, enrollment, or coverage of Medicaid managed care beneficiaries because of this demonstration?	Comparison of eligibility, enrollment, and coverage data throughout the contract periods during the PHE with historic baseline.	Eligibility, claims, and encounter data	Quantitative Analysis

E. Methodological Limitations

Evaluation of the retrospective arrangements described in this design document depends on data available at the time of evaluation. MCO data reporting must be timely, complete, and accurate for robust evaluations for each time period and to assess the impact of the COVID-19 PHE. Managed

care encounter data may be subject to a reporting lag, which may limit data available for the evaluation of this demonstration.

Also of note, calculations for this demonstration are based on data supplied by the MCOs for medical services as reported in encounter data and through the annual MLR reports. If data was not submitted for any services rendered, those services would therefore not be captured in the calculations for this demonstration and accompanying evaluation.

Lastly, there may be certain limitations inherent in qualitative analytic methods, such as the potential for incomplete or variability of data due to sampling size, subjectivity, bias, or recall of interview participants. The State will attempt to minimize these limitations by preparing a survey tool for consistency across interviews.

F. Final Evaluation Report

Per CMS guidance, West Virginia will work to ensure the focus of the Final Evaluation Report is on responding to the qualitative evaluation questions detailed above; these questions are intended to guide West Virginia in describing the challenges presented by the COVID-19 PHE to the Medicaid program, understanding how the flexibilities of this Managed Care Risk Mitigation COVID-19 PHE demonstration assisted in meeting these challenges, and documenting any lessons learned for responding to similar public health emergencies in the future. The report will analyze the extent to which the administrative and program costs related to this expenditure authority flexibility were effective at achieving the demonstration's objectives.

The Final Evaluation Report will synthesize information from staff interviews, managed care contracts and other data sources to help answer these evaluative questions; the report will cover all risk-sharing arrangements and rating periods that fall under the scope of the demonstration for the period the demonstration is approved for. The structure of the report will align with the structure outlined in CMS' 1115 Demonstration evaluation guidance. The report will also satisfy, as applicable, reporting requirements for an annual report as described in [42 CFR § 431.428](#).

The draft of the Final Evaluation Report for this demonstration project will be submitted to CMS for review and approval no later than 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. The anticipated time frame for this submission is during Calendar Year 2025.

G. Timeline

The timeline below provides a high-level overview of key dates related to the State's Managed Care Risk Mitigation COVID-19 PHE demonstration and associated deliverables required by CMS.

Figure 1: WV Managed Care Risk Mitigation COVID-19 PHE Demonstration Timeline

WV Managed Care Risk Mitigation COVID-19 PHE Section 1115 Demonstration High-Level Timeline

