State Demonstrations Group

April 21, 2023

Jacey Cooper
State Medicaid Director
Chief Deputy Director, Health Care Programs
California Department of Health Care Services
1501 Capitol Avenue, 6th Floor, MS 0000
Sacramento, CA 95814

Dear Ms. Cooper:

The Centers for Medicare & Medicaid Services (CMS) approved the Evaluation Design for California's Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) amendment to the section 1115 demonstration entitled, "California Advancing and Innovating Medi-Cal (CalAIM)" (formerly "Medi-Cal 2020") (Project No: 11-W-00193/9). 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 January 28, 2022, 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 California "California Advancing and Innovating Medi-Cal (CalAIM)" section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle
Daly -S

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Danielle Daly -S
Date: 2023.04.21
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Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Cheryl Young, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

State of California—Health and Human Services Agency
Department of Health Care Services

MICHELLE BAASS
DIRECTOR

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GOVERNOR

Department of Health Care Services
California Advancing and Innovating Medi-Cal (CalAIM) Demonstration
Project No. 11-W-00193-9

COVID-19 Public Health Emergency Section 1115(a)
Demonstration Amendment –
Managed Care Risk Mitigation Strategies
Evaluation Design

December 30, 2022

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A. General Background Information

On March 13, 2020, pursuant to Section 1135(b) of the Act, the Secretary of Health and Human Services invoked his authority to waive or modify certain requirements of Titles XVIII, XIX, and XXI of the Act because of the consequences of the COVID-19 pandemic. As a result, on March 22, 2020, the Centers for Medicare & Medicaid Services (CMS) announced a Section 1115 demonstration opportunity available to states under title XIX (Medicaid) of the Act. In response, California submitted a Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) Section 1115 demonstration application on December 29, 2021. On January 28, 2022, CMS approved the application as an amendment under the "California Advancing and Innovating Medi-Cal" section 1115(a) demonstration (Project Number 11-W-00193-9).

California's goal during the Managed Care Risk Mitigation COVID-19 PHE demonstration period is to add one or more risk-sharing arrangements, specifically risk corridors, to support making appropriate payments to managed care organizations during the COVID-19 PHE to help maintain beneficiary access to care.

As part of the demonstration's Monitoring and Evaluation Requirements, CMS requires California to develop a "simplified" Evaluation Design to understand the successes, challenges, and lessons learned in implementing the demonstration. This Evaluation Design addresses CMS' Managed Care Risk Mitigation COVID-19 PHE Medicaid Section 1115 Demonstration: Guidance for Monitoring and Evaluation Requirements.

This Evaluation Design will guide the federally required Final Report and is organized as follows:
- **Section A.** General Background Information
- **Section B.** Evaluation Questions and Hypotheses
- **Section C.** Methodology
- **Section D.** Methodological Limitations
- **Section E.** Preparing the Final Report

B. Evaluation Questions and Hypotheses

Table 1 outlines the hypotheses and research questions related to understanding the successes, challenges, and lessons learned in implementing the demonstration.

Table 1. Hypotheses and Research Questions

Research Question (RQ)	
Hypothesis 1 – The demonstration will facilitate attaining the objectives of Medicaid.	
RQ 1.1	What retroactive risk sharing mechanisms did the state ultimately implement with the managed care plans under the demonstration authority?
RQ 1.2	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?
RQ 1.3	What problems may 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?
RQ 1.4	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?
RQ 1.5	What actions did the state take to address challenges presented by the implementation of retroactive risk mitigation strategies? To what extent were those actions successful in the context of the PHE?
RQ 1.6	What were the principal lessons learned for any future PHEs in implementing the demonstration flexibilities?
Hypothesis 2 – The authority will support Medi-Cal in making appropriate payments during the COVID-19 PHE to help with maintenance of beneficiary access to care that would have otherwise been challenging due to the prohibitions in Section 438.6(b)(1).	
RQ 2.1	To what extent did the retroactive risk sharing implemented under the demonstration authority result in more accurate payments to the managed care plans?

C. Methodology

This section provides details on the proposed methodology for the Evaluation Design, including anticipated data sources, analytic methods, and evaluation reporting periods.

Section C.1 summarizes the types of data that will be used to prepare the Final Report.

Section C.2 outlines California's proposed analytic methods for the Evaluation.

Section C.3 includes analytic tables that detail the evaluation approach for each hypothesis. The analytic tables outline the planned research questions, outcome measures, data sources, and analytic approaches.

1. Data Sources

The state will compile data for the Evaluation from qualitative and quantitative data sources including staff interviews and state and administrative data.

Document Review

To examine information related to the risk sharing mechanisms implemented with the managed care plans, the state will conduct a review of relevant documentation (e.g., managed care contracts, All Plan Letters, methodology documents, other similar instruction).

Staff Interviews

The State will conduct Medi-Cal staff interviews to evaluate if the demonstration facilitated attaining the objectives of Medicaid. California will identify Medi-Cal interview participants based on involvement in the implementation of the risk sharing mechanisms.

MCO Medical Loss Ratio and Supplemental Data Reports

MCOs submit regular medical loss ratio (MLR) reports which provide aggregate revenue, claims costs, and other financial metrics for the purposes of calculating MLRs. In addition, MCOs submit ad-hoc supplemental data reports (SDRs) specific to the services and populations covered by implemented risk mitigation mechanism(s). Medi-Cal will examine the annual MLR submissions, when relevant, and the ad hoc SDRs to evaluate, in part, to what extent the risk sharing implemented under the demonstration authority resulted in more accurate payments to the MCOs.

Medi-Cal Claims Data

The State will use claims cost data to estimate the unforeseeable impact of COVID-19 on utilization patterns.

Bridge Period, CY 2021, and CY 2022 Rate Development Exhibits

Medi-Cal's actuaries will provide Bridge Period (July 1, 2019 – December 31, 2020), CY 2021, and CY 2022 Rate Development Exhibits containing target MLRs by program, as calculated during rate development. Medi-Cal will examine these Exhibits to evaluate, in part, to what extent the risk sharing implemented under the demonstration authority resulted in more accurate payments to the MCOs.

2. Analytic Methods

As part of the 1115 demonstration approval, CMS required California to develop a "simplified" Evaluation Design that does not undertake evaluations that would prove overly burdensome and impractical for data collection or analyses, but rather focuses on using qualitative methods and descriptive statistics to understand how this flexibility helped California respond to the

COVID-19 PHE. As such, California will use qualitative and descriptive statistics methods to conduct the Evaluation.

Qualitative Analysis

The state will collect qualitative data through methods such as staff interviews. Where applicable, the qualitative data will be categorized and coded systematically. The state will use thematic analysis, which is a systematic and iterative data coding and analysis process that will allow the state to identify themes or patterns within the responses.

Descriptive Analyses

For research questions assessing payments to managed care plans, the state will calculate standard summary statistics to report findings.

3. Analytic Table

Table 2 outlines the hypotheses, research questions, outcome measures, data sources, and analytic approaches for this Evaluation Design.

Table 2. Analytic Table

Research Question	Outcome Measure(s)	Data Source(s)	Analytic Approach
Hypothesis 1 – The demonstration will facilitate attaining the objectives of Medicaid.			
RQ 1.1: What retroactive risk sharing mechanisms did the state ultimately implement with the managed care plans under the demonstration authority?	- Type(s) of risk sharing mechanism(s) implemented with the managed care plans Terms of implemented risk sharing mechanism(s)	- Document review	- Qualitative analysis
RQ 1.2: 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?	- Benefits/successes of adding a risk sharing mechanism that would not have been realized if the demonstration authority were not in place	- Medi-Cal Staff Interview(s)	- Qualitative analysis
RQ 1.3: What problems may 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?	- Description of how the demonstration authority addressed or prevented problems related to the application of section 438.6(b)(1)	- Medi-Cal Staff Interview(s)	- Qualitative analysis
RQ 1.4: 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?	- Description of challenges (if any) related to implementing the risk sharing mechanism(s) with the managed care plans	- Medi-Cal Staff Interview(s)	- Qualitative analysis
RQ 1.5: What actions did the state take to address challenges presented by the implementation of retroactive risk mitigation strategies? To what extent were those actions successful in the context of the PHE?	- Description of actions taken by California to address the challenges identified (if any) in RQ 1.4 - Description of whether, and how, these actions were successful	- Medi-Cal Staff Interview(s)	- Qualitative analysis

Research Question	Outcome Measure(s)	Data Source(s)	Analytic Approach
RQ 1.6: What were the principal lessons learned for any future PHEs in implementing the demonstration flexibilities?	- Description of lessons learned for future PHEs in implementing the demonstration flexibilities	- Medi-Cal Staff Interview(s)	- Qualitative analysis
Hypothesis 2 – The authority will support Medi-Cal in making appropriate payments during the COVID-19 PHE to help with maintenance of beneficiary access to care that would have otherwise been challenging due to the prohibitions in Section 438.6(b)(1).			
RQ 2.1: To what extent did the retroactive risk sharing implemented under the demonstration authority result in more accurate payments to the managed care plans?	- MLRs by program prior to the application of the risk corridor, both at an aggregate-level as well as MCO-specific - MLRs by program after application of the risk corridor, both at an aggregate-level as well as MCO-specific - Target MLR by program as calculated during rate development - Medi-Cal utilization trend metrics - Per Member Per Month (PMPM) Units per 1,000 members	- Annual MCO MLR Submissions - Medi-Cal Claims and/or Encounter Data - Rate Development Exhibits	- Descriptive analysis

D. Methodological Limitations

Given the simplified nature of this Evaluation Design, California 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 Medi-Cal 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. Medi-Cal will do its best to minimize these limitations, for example, by creating a scripted interview template.
- **Staff Interviews.** The State plans to conduct a limited number of Medi-Cal staff interviews to evaluate RQs 1.2 – 1.6. The State will schedule interviews with the critical Medi-Cal staff members that were involved in the development and implementation of the risk corridor. If any of these critical staff members depart Medi-Cal prior to the interview, it may be difficult to fully evaluate RQs 1.2 – 1.6.

E. Preparing the Final Report

Medi-Cal will submit to CMS a Final Report for this demonstration 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.