California Advancing and Innovating Medi-Cal Medicaid Section 1115 Demonstration: Providing Access and Transforming Health Initiative, Global Payment Program, and Alignment and Integration for Dually Eligible Beneficiaries

CMS COMMENTS ON THE DRAFT EVALUATION DESIGN

December 5, 2022

I. Introduction

The Centers for Medicare & Medicaid Services (CMS) have reviewed the draft Evaluation Design for the "California Advancing and Innovating Medi-Cal" (CalAIM) Medicaid section 1115 demonstration (Project Number 11-W-00193/9) dated June 27, 2022. CMS approved the extension of the state's section 1115 demonstration on December 29, 2021 for a demonstration period from January 1, 2022, through December 31, 2026. CMS assessed California's draft Evaluation Design against the state's special terms and conditions (STC)[1] and CMS's evaluation design guidance.[2]

The draft Evaluation Design covers three demonstration components: (1) Providing Access and Transforming Health (PATH) Initiative, (2) the Global Payment Program (GPP), and (3) Alignment and Integration for Dually Eligible Beneficiaries. The Evaluation Design demonstrates a strong commitment to evaluating the impact on health inequities, and it identifies several important implementation evaluation questions. As we detail in Section II of this document, there remains several additional opportunities to further strengthen the Evaluation Design.

STC 96 (Evaluation Design Approval and Updates) asks that the state submit to CMS a revised Evaluation Design within 60 days after the state receives CMS's feedback. CMS also strongly encourages the state to coordinate with an independent evaluator in updating the Evaluation Design for the GPP, PATH, and Dual Integration program components. In addition, the state and CMS are working toward an amendment to the CalAIM demonstration that will significantly expand the demonstration's scope. Therefore, in determining next steps for updating this draft Evaluation Design, the state may wish to take into consideration the benefits of onboarding an independent evaluator and also the upcoming need for developing Evaluation Design related to the pending demonstration amendment. CMS looks forward to a conversation with the state to determine a due date for the revised Evaluation Design such that the state's efforts to revamp the design lead to the most effective and efficient outcomes.

[1] Available at https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ca-calaim-ca.pdf.
[2] Available at https://www.medicaid.gov/sites/default/files/2020-02/developing-the-evaluation-design.pdf and included as Attachment A in the STCs.

II. Recommendations

1. Identify an external evaluator and involve them in the development of the Evaluation Design

CMS encourages states to begin working with an external evaluator early in the Evaluation Design development process as the evaluator can help provide insights on the specific plans for data collection and analysis. For example, an external evaluator can help add necessary details about how focus groups will be identified and sample size calculations, which are important in determining whether the sampling is representative of the beneficiary population and whether the analysis will be adequately powered in order to detect reasonably sized effects. Also, the involvement of the independent evaluator during the design development phase is invaluable as it helps ensure that the actual conduct of the proposed evaluation activities will be largely feasible for execution.

2. Strengthen evaluation method and data sections

a) **Add more detail to the method section.** The state has outlined a strong set of evaluation goals, research questions, and hypotheses, but the current Evaluation Design would benefit from a more detailed description of analytic methods (such as the type of regression model appropriate for the outcomes specified and what data checks will be conducted to ensure that key assumptions are met for methods like difference-in-differences), survey methods (such as how beneficiaries will be sampled, how beneficiaries will be contacted, and estimated sample size based on typical response rates), and measure definitions (such as how "GPP non-behavioral health outpatient non-emergency, emergency, and inpatient med/surg services" will be defined in the Medi-Cal claims and encounters data). Partnering with an external evaluator during the design phase should help with this.

b) **Identify in-state and out-of-state comparison groups.** For the Alignment and Integration for Dually Eligible Beneficiaries analysis research questions, the state proposes difference-in-differences (DID) analysis using comparison groups composed of beneficiaries outside the 12 counties subject to the Medi-Cal matching plan policy. For the PATH and GPP components, the state generally proposes a pre/post comparison design to assess the effects of the demonstration. Although the pre/post design may be necessary when no comparison group can be identified, it can be biased by confounders that change over time, including conditions related to the COVID-19 public health emergency (PHE) and changes to the labor market and overall economy.

   For the purposes of evaluating the PATH and GPP components, CMS recommends that the state consider identifying a comparison group composed of similar beneficiaries in California who are not subject to the demonstration. Finding suitable comparison groups will allow the state to implement the more

robust DID approach in assessing the impacts of these demonstration components, too. If no suitable in-state comparison group can be identified, the state could consider adding data from the Transformed Medicaid Statistical Information System (T-MSIS) to include comparison beneficiaries from other states. When comparison groups are used, the state could use matching methods to further improve balance between the treatment and comparison populations for key characteristics. Finding the comparison groups will allow the state to implement a more robust DID approach in assessing impacts of the different demonstration components.

c) **Use baseline data from before the demonstration for components that continue from previous demonstrations.** The state plans to use data from the approval period (2022 through 2026) and 2021 and to conduct pre/post analyses to assess most hypotheses. The state should consider adding data from previous approval periods, so it can analyze how demonstration outcomes changed over time for the demonstration and comparison groups (where applicable). When demonstration policies did not change from previous demonstrations, it is unlikely that outcomes would improve. Instead, hypotheses could be framed as outcomes not becoming worse relative to the baseline period. Furthermore, the state could consider excluding data from the period of the COVID-19 PHE from the baseline and follow-up periods when using a longer baseline period. Baseline data will also allow the state to check for parallel trends in difference-in-differences analyses, which are a crucial assumption when implementing DID.

3. Conduct a qualitative evaluation for the PATH component

The state proposes qualitative components for the GPP and Alignment and Integration for Dually Eligible Beneficiaries components, but not for PATH. A qualitative evaluation could help the state and CMS better understand barriers to implementation and successful adaptations, how external factors such as how the COVID-19 PHE may continue to influence implementation or moderate outcomes, and to better understand key stakeholder experience with the PATH component.

4. Further explore the impacts of the Alignment and Integration for Dually Eligible Beneficiaries component on access to care and health outcomes

The state currently proposes to assess dually eligible beneficiary satisfaction, but CMS asks that the state further explore the impacts of the Alignment and Integration for the Dually Eligible Beneficiaries demonstration component by including additional goals, hypotheses, and research questions related to health care access and quality of care for beneficiaries. The state notes that the program's goals include "improving alignment and integration" which could have other impacts on beneficiary outcomes beyond self-reported satisfaction. Furthermore, the state could explore whether this component has impacts on inequities in access to health care among dually eligible beneficiaries from historically under-resourced and marginalized populations by including subgroup analyses.

5. Include cost outcomes for the demonstration as a whole and an analysis of fiscal sustainability

STCs 97 and 98 ask that the state conduct a comprehensive demonstration cost assessment. The state must include in its revision a robust proposal that are aligned with those STCs, and these activities could substantially benefit from partnering with an independent evaluator during the design development phase.

6. Account for the potential confounding effects of the COVID-19 PHE

The COVID-19 PHE is impacting patterns of health care use and expenditures across the country, with large variations across regions and by beneficiary characteristics. The state should discuss how it plans to account for this in the evaluation. Possible modifications in the Evaluation Design to account for PHE effects include controlling for local area level measures of COVID-19 burden (for example, COVID-19 hospitalizations and deaths by county) and estimating yearly treatment effects to separately observe the impact of the demonstration during years affected by the PHE and years not affected by the PHE. The state should also be careful in interpreting demonstration impacts in its Interim and Summative Evaluation Reports and discuss potential biases that could arise from data captured during the PHE.

7. Add important information that currently are unavailable in the Evaluation Design

a) **Standardize definitions.** The state indicates that in some research questions, "historically under-resourced and marginalized populations" will be "defined by each county/MCP [managed care plan]." (p. 15). Allowing counties and MCPs to define these groups enables increased evaluation participation, but it could lead to inconsistent definitions that would be less comparable across the state. The state could consider providing more guidance to participating MCPs and counties

to harmonize definitions and increase comparability while still soliciting information on the make-up of the marginalized populations.

b) **Further describe inclusion/exclusion criteria.** The state provides general, high-level descriptions of the demonstration groups that are likely to be affected by the three programs for which this Evaluation Design is written. However, the state could provide more detail by further describing the inclusion and exclusion criteria for demonstration groups in a way that could more easily map to Medi-Cal enrollment data. Such an exercise could also help the state identify comparison groups that are similar to the treatment group but are excluded from the demonstration.

c) **Propose directional hypotheses.** The state clearly states directional hypotheses for most of its research questions. However, for Research Question 2 in the Alignment and Integration for Dually Eligible Beneficiaries section (p. 23), the state does not specify whether satisfaction will increase or decrease or a threshold for levels of dissatisfaction. The state could strengthen this hypothesis by stating a direction or a threshold.

d) **Provide additional information on third-party data.** In the Methodology section for PATH Goal 1 Research Question 1 (p. 14), the state could provide more detail by defining what data will be provided by third-party administrators or how those data will be collected, cleaned, and used in the evaluation.