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

THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COMMENTS ON THE DRAFT EVALUATION DESIGN

CMS' Comments: December 5, 2022

DHCS Responses: February 7, 2024

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 (STCs)[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

[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.

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 led to the most effective and efficient outcomes.

In response to CMS's recommendation, California DHCS has considered the benefits of onboarding an independent evaluator and selected the UCLA-RAND CalAIM Evaluation Team (Evaluation Team) to fulfill this role. We appreciate CMS's naming of opportunities to further strengthen the Evaluation Design and submit this letter in response to recommendations made by CMS in their December 2022 document.

CMS's recommendation considered only three components of the Evaluation Team has applied this recommendation to all four of the project components described in the Evaluation Design including (1) Providing Access and Transforming Health (PATH) Initiative, (2) the Global Payment Program (GPP), and (3) Alignment and Integration for Dually Eligible Beneficiaries (Duals Plan Alignment), and (4) Reentry Demonstration (REENTRY).

The Evaluation Team's responses to CMS' recommendations are shown below in italicized text.

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.

PATH: *The PATH evaluation design has been amended to specify data sources that the Evaluation Team anticipates receiving from DHCS or from PATH Third Party Administrator (TPA), such as PATH applications, reports, and invoices; ECM and Community Supports provider databases and Medi-Cal eligibility and claims data. The team also plans to complement these data with surveys of MCPs and community-based providers participating in ECM and Community Supports, followed by key informant interviews with the PATH TPA and with CPI facilitators, MCPs, and a purposive sample of community-based providers. In collaboration with RAND, the PATH team will further survey and conduct key informant interviews in select jails, prisons, and correctional facilities. The PATH evaluation design now also clearly specifies the evaluation questions, directional hypotheses, and related measures to answer these questions and test the hypotheses. Further details on analytic methods are also provided.*

GPP: *GPP services have already been defined by DHCS by Current Procedural Terminology (CPT) and International Classification of Diseases (ICD) codes. These codes and definitions, as well as appropriate citations supporting their use are documented in the Medi-Cal 2020 STCs.[3] These specifications note that DHCS may update the codes and descriptions contained in this table to reflect ongoing changes made by CMS or other nationally recognized entities. Updated codes and descriptions will be reflected in reporting guidance provided by DHCS to Public Health Care Systems (PHCS'). For example, Appendix A to this letter copies example codes from the Service Category 1: Outpatient Table to illustrate available documentation of measure definitions and sources.*

Duals Plan Alignment: *The Medi-Cal Matching Plan Policy is a concrete step forward for aligning and integrating Medicare and Medicaid services. Assessing the policy represents a complex endeavor.*

As currently conceived, the methods section has been expanded and includes more detailed descriptions of Goal #1 (analysis of plan switching) and Goal #2 (assessment of knowledge and satisfaction). Furthermore, we have included in the Duals

[3] Technical Corrections to the California section 1115 Medicaid demonstration, entitled "California Advancing and Innovating Medi-Cal", approved August 23, 2023. https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-STC-Technical-Corrections.pdf. Appendix 2. Table 7. Page 204/289.

evaluation design a more complete description of the variables of interest. We also have included a more detailed description of the members' survey including estimates for the number of cells for major comparisons (32) and an estimate for stability of estimates, using 25 to 50 responses per cell plus oversampling of race and ethnicity. We have included an additional section on power calculations for Goal #1 (impact of the policy on plan switching) and Goal #2 (knowledge and satisfaction surveys).

REENTRY: *The Reentry Demonstration evaluation will use mixed methods approaches to assess the implementation and its impact on access to services and improved health among JI individuals. The evaluation has been described across seven goals. Infrastructure development is part of the PATH evaluation. Enrollment, reenrollment, initiation of services, and post-release services and care outcomes will be assessed through a combination of routinely collected data from the criminal justice system, Medi-Cal enrollment and service claims/encounters, and possibly other routinely collected statewide data, such as hospital discharge and emergency department visits, which will capture certain types of acute care occurring during gaps in Medi-Cal enrollment. Where appropriate, we will employ difference-in-difference approach or other pre- / post-design. We will perform interviews with key stakeholders in prison, jails, juvenile facilities, Medicaid, CHIP, managed care plans, and community-based providers. To do qualitative analysis of the interview data, we will utilize qualitative coding of themes using software such as Depose, which will provide a systematic way to code and reveal themes in the data. Qualitative analysis will inform the interpretation of Goals 3, 4, and 5 by identifying strategies for improving connections between physical health, behavioral health, and health-related social needs and factors that facilitated or hindered those connections and approaches to address identified barriers.*

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.

PATH: *The PATH intervention is designed to increase provider capacity and infrastructure needed to provide ECM/CS services and implement the JI initiative. Attributing outcomes to PATH implementation is challenging because WPC entities and HHP MCPs in most California counties transitioned to PATH by January 2022 and PATH initiatives were implemented statewide and in conjunction with another initiative focused on improving provider capacity and infrastructure (CalAIM Incentive Payment Program); thus, it is not feasible to construct a comparison group of providers in California counties or geographic areas without a PATH intervention. Due to significant across-state variation in provider and community characteristics, it is also not feasible to construct a comparison group of providers outside of California. However, in evaluating the PATH Support for Implementation of Enhanced Care Management and Community Supports initiative, UCLA will assess differences in rates and patterns of use of ECM and Community Supports by provider characteristics and by California regions and under-resourced community indices, and we will assess factors that may have affected different types of community-based providers' participation in PATH and in ECM and Community Supports. Similarly, for the PATH Reentry Capacity Building program, we will assess differences in the number of eligible individuals screened and enrolled in Medi-Cal prior to release and those that received 90-day pre-release services based on whether the facility received PATH funding and other facility characteristics.*

GPP: *DHCS initially proposed a pre/post comparison design to assess the effects of the demonstration. These data will be useful to identify changes in the type and number of services utilized by individuals utilizing GPP services. The Evaluation Team has included qualitative and mixed methods analyses to promote understanding of the mechanism by which GPP drives a shift in the provision of services from emergency and select inpatient services to non-emergency outpatient settings (GPP Goal 2). Beyond the pre-post design, we also see value in CMS's comment that the pre/post design can be biased by confounders that change over time and we agree with CMS' recommendation that GPP add a comparison group of similar beneficiaries who are not subject to the demonstration. This will be especially valuable now that PHCS' are systematically collecting quality and equity data.*

Nevertheless, constructing a valid comparison group is extremely challenging given the lack of available data on the quality of care provided to the uninsured—either

within or outside of California. We will initiate our efforts to construct a valid comparison group early in the evaluation by constructing and rigorously testing two potential comparison groups. First, we will explore an FQHC comparison group by aggregating facility-level data from HRSA's Uniform Data System (UDS) in states that have not yet expanded Medicaid. FQHCs in these states have a much larger percentage of uninsured patients than FQHCs in expansion states, and we will consider using the subset of FQHCs with the highest percentage of uninsured residents in these states. Second, we will explore using population surveys (particularly the Behavioral Risk Factor Surveillance System (BRFSS)), which captures screenings for three of the five quality measures on an annual basis (colorectal cancer screening, breast cancer screening, and cervical cancer screening). We will ensure that any comparison group used in the evaluation is well-matched to the sociodemographic profile of the target population and provides adequate statistical power. If we determine that comparison groups are not sufficiently robust for the analysis, we will conduct pre-post analyses as described below.

***Duals Plan Alignment**: We have expanded the discussion of the DID approach to assess the policy impact of the Medi-Cal Matching Plan Policy, including the identification of appropriate comparison groups within state. This is facilitated by the county-by-county managed care implementation model in California. With the policy beginning in 2022, the minimum baseline period for comparison would be 2021 with a one-year lookback for inclusion criteria for Dually enrolled individuals to be in the comparison.*

***Reentry:** The JI Reentry Demonstration will examine early reenrollment of individuals into Medi-Cal before release from incarceration. There are three measurable comparison groupings within state: (1) – pre- and post-introduction of the Reentry Demonstration, (2) staggered implementation, (3) individuals already enrolled in Medi-Cal at the time of incarceration. A major task for the evaluation will be obtaining data from incarcerate settings regarding health, eligibility, and enrollment pre- and post-implementation. This will require substantial coordination and leadership. Obtaining comparable data from other states is not feasible.*

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.

The Evaluation Team agrees with CMS's statement that using data from a longer baseline period can be helpful so that analyses can demonstration how processes and outcomes changed over time for the demonstration and comparison groups (where applicable). Baseline data are also necessary for analyses to check for parallel trends, a crucial assumption when implementing difference-in-differences analyses. Furthermore, the Evaluation Team believes it is important to include data available from the COVID-19 PHE period but also understand those data may starkly vary from the trends noted before and after PHE. Since exposure to PHE data is likely to enhance the understanding of real-world occurrences during that time, the Evaluation Team has proposed to consider a sensitivity analysis whereby we analyze and report data without and with inclusion of the PHE period.

PATH*: There are multiple baseline periods for PATH because services similar to ECM/CS were provided by the Whole Person Care (WPC) demonstration (baseline 2015-2016 and intervention 2017-2021) and Health Home Program (HHP) (baseline 2016-2017 and intervention 2018-2021). The Evaluation Team proposes to use these data to assess patterns of service use for beneficiaries that received WPC and HHP services and subsequently received ECM/CS. For these groups of beneficiaries, comparisons will be made prior to enrollment in WPC and HHP, during enrollment in those programs, and during enrollment in ECM/CS as feasible. Such analyses may be challenging due to churn in enrollment and selection bias among those with the longest enrollment due to higher level of complexity. The Evaluation Team proposes a baseline period of 2020-2021.*

GPP*: The number of years of pre-CalAIM data available for the analysis will depend on the ability and willingness of PHCS to generate historical quality data. We anticipate that PHCS will be able to contribute a variable number of years of pre-CalAIM quality data, and we can accommodate this heterogeneity in the analysis. Comparison group data are available for all measures from 2021 onward (and 5 of the 6 measures available from 2015 onward). We anticipate all six measures will continue to be gathered via the UDS through 2026. Because the Public Health Emergency (PHE) occurred primarily during the pre-CalAIM period and may introduce bias in the measurement of baseline quality, we will prefer to use a multi-year baseline period along with year fixed effects to account for year-specific shocks such as the PHE. To ensure robustness of our results we will also conduct a sensitivity analysis in which we exclude 2020 and 2021 from the baseline period. Baseline data for RQ3 can also begin in 2015 allowing us to see trends in data infrastructure and completeness among GPP utilizers. Of note, the new GPP Equity Protocol data will not be collected until 2023 and be available until 2024. While we intend to implement earlier data using demographic data from earlier GPP PYs, the*

most complete equity analyses will rely upon the 2023 equity data.

Duals Plan Alignment*: Enrollment policies were not impacted by COVID PHE.*

REENTRY: *Where possible, we will extend analyses back to 2017 to help account for trends and stable baseline prior to the COVID pandemic. At a minimum, we will look back at least one year prior to the Reentry Demonstration. Because of the sensitivity of data for incarcerated individuals, obtaining routinely collected data may be limited to years more proximal to the intervention due to privacy concerns. Detailed patient-level screening data associated with the intervention will not be available prior to the intervention. Nevertheless, it is possible to examine acute healthcare events occurring after incarceration using statewide hospital discharge and emergency department visits, which are independent of insurance status and the state death file to identify deaths after release.*

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.

We have added a robust qualitative evaluation for 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.

Duals Plan Alignment: *Based on further discussion with CMS' Center for Medicaid & CHIP Services (CMCS) and CMS' Medicare-Medicaid Coordination Office (MMCO), the survey will over-sample for race and ethnicity and individuals from the lowest quartile of the*

needs-metric (based on zip code of residence and ACS-based measure). Medicare health care access and quality of care is measured and reported by CMS, and DHCS relies on that information for those topics.

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.

An analysis of cost outcomes will be included for each of the evaluation design components. Below we briefly describe each component's strategy for cost analyses. As the Evaluation Team becomes more familiar with cost data available from demonstration and their comparison sites, we will further develop guidance for a comprehensive cost assessment. Below we include a brief description of these approaches. As we explore details of each project component, we will regularly update DHCS with progress of the Evaluation Team and include documentation about this progress within in the CalAIM Evaluation progress reports.

PATH: *The Evaluation Team proposes to examine all PATH expenditures and resources as well as payments to providers for ECM/CS services. The Evaluation Team will further examine the patterns of payments for service used for beneficiaries that received WPC and HHP services and subsequently received ECM/CS as well as beneficiaries that received ECM/CS services for the first-time following PATH implementation. These analyses will be stratified by provider type, region, and whether the provider received PATH funding or resources.*

GPP: *The Evaluation Team will use audited P14 workbooks from each PHCS to measure the cost of services provided to the uninsured provided by the PHCS. We will then derive per capita cost estimates using unduplicated patient counts from the GPP encounter data. These analyses will support pre-post analyses of per-capita spending from as early as 2015 through the end of GPP. Cost data for a comparison group comprising non-GPP counties could be derived from a combination of hospital and ED encounter-specific charges reported in the HCAI data supplemented with UDS financial cost data reported by FQHCs in the UDS. Although the cost of care for the uninsured may be defined differently for the PHCS and comparison group, these differences should be stable over time and should be netted out in our difference-in-differences analysis. We will ensure alignment of the cost analyses across all other Cal-AIM components.*

Duals Plan Alignment*: Not applicable.*

REENTRY*: The Evaluation Team will attempt to perform a cost analysis for the Reentry Demonstration pre- and post-implementation using health care expenditures data from the*

correctional system, monthly Medi-Cal enrollment, plan capitation rates, and service claims, and monthly estimates for public healthcare costs for uninsured individuals. Costs of implementation (infrastructure dollars from PATH for Reentry) will be included in the year-over-year cost estimates. For cost analyses, it is assumed that prior to the intervention, individuals upon release will not have health insurance. This is mostly true, but we will not be able to assess whether an individual has commercial health insurance (through a spouse or as a dependent).

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.

The Evaluation Team agrees with these suggestions and will consider implementing them as we account for the potential confounding effects of the COVID-19 PHE.

PATH: *All proposed PATH baseline periods are impacted by the PHE. However, the previous evaluation of WPC and HHP have assessed PHE impact. These analyses demonstrated that the PHE temporarily increased service use for Medi-Cal beneficiaries with COVID-19; for all other beneficiaries, there was a sharp decrease in all service use between March - June 2020, followed by a nearly complete recovery of the number of outpatient services (due to use of telehealth) and a less than complete recovery of ED visits and hospitalizations which continued into December 2021. Our examination of COVID-19 related service showed high rates of hospitalizations and primary care visits, moderate use of ED visits, and low use of specialty, laboratory services, and long-term care stays. These rates were similar to those for the control population. The UCLA evaluation team used a COVID-19 indicator (beneficiaries with a COVID-19 diagnosis in any claims) in selection of the control group and in difference-in-difference models to ensure that parallel trends assumptions of these models were confirmed. The PATH team proposes to follow a similar approach to address the impact of the PHE on baseline data for the PATH intervention. The team anticipates that the impact of the PHE on baseline data will be similar for both the intervention and control groups.*

GPP: *Because the Public Health Emergency (PHE) occurred primarily during the pre-CalAIM period and may introduce bias in the measurement of baseline quality, we will prefer to use a multi-year baseline period along with year fixed effects to account for year-*

specific shocks such as the PHE. To ensure robustness of our results we will also conduct a sensitivity analysis in which we exclude 2020 and 2021 from the baseline period.

Duals Plan Alignment*: Not applicable.*

REENTRY*: As described above, to the extent possible, the Evaluation Team will extend analyses back to 2017 to help account for trends and stable baseline prior to the COVID pandemic. Because of the sensitivity of data for incarcerated individuals, obtaining routinely collected data may be limited to years more proximal to the intervention due to privacy concerns.*

The Evaluation Team's approach will make use of cohorts of individuals released from the incarceration system so that we are able to select treatment groups and control groups around the timing of the policy. We will also identify additional control cohorts from prior to the policy to be able to estimate models that can identify a causal effect. Thus, we will identify control cohorts over the same periods in prior years (e.g., 6 months pre and 6 months post the policy for years around the time the program is rolled out and the same calendar periods for years prior to the policy rolling out). While in practice we could use the year of the program and one year before to identify these groups (i.e., 2 cohorts) this may lead to noisy estimates. Such noise could result in our findings indicating that the program had no impact due to noise rather than a true null effect. Increasing the number of control cohorts (back to 2017 for example) would allow us to identify more precise estimates. More precision (afforded by these earlier cohorts) will therefore be important in allowing us to provide precise estimates of the effect of the program and ensure that the evaluation is powered to identify an effect if one exists.

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.

PATH: *The Evaluation Team proposes using several indices to identify under-resourced communities, including the county, rural-urban commuting area codes (RUCAs), Social Vulnerability Index (SVI), and Healthy Places Index (HPI). These indices will be used to identify under-resourced communities, i.e., rural communities, those with high SVI scores, or those in the bottom two HPI quartiles.*

GPP: *GPP is also interested in using several indices to identify under-resourced communities, especially those in close proximity to PHCSs and to comparison sites. A unique challenge that has historically limited some equity analyses is that PHCSs may not have current and accurate addresses for the full census of GPP users. While PHCSs do collect zip code, this has previously been inadequate for utilizing Rural Urban Commuting Area (RUCA) codes without a complete address. Fortunately, a zip-code version of RUCA that approximates census tracts is now available and may be usable for GPP analyses.*

Duals Plan Alignment*: For the Duals, we have added detail in the background and methods sections and have standardized the language to clarify how plan enrollment occurs and the implementation of the policy. The previous description lacked the detail for an external reader to understand the timing and distribution of the three impactful policies for Duals – (1) county-specific Medi-Cal managed care plan implementation models, (2) mandatory managed care enrollment into Medi-Cal managed care plans (MCPs), and (3) the alignment policy of MCPs to MA plans if the MA plan managed care organization also had a contracted MCP. This includes a description of the enrollment process that can be used across evaluation components.*

REENTRY*: The Reentry Demonstration evaluation uses standard definitions for participating agencies, Reentry and JI individuals, and target conditions – including those for high-risk individuals.*

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.

PATH*: The PATH intervention is targeted to community-based providers defined by DHCS to include community-based organizations (CBOs), county, city, or local government agencies, federally qualified health centers, and Medi-Cal tribal and designees of Indian Health program, hospitals, and other providers approved by DHCS.*

GPP*: California operates GPP to assist PHCS' that provide health care for the* ***uninsured****. The GPP is meant to focus on value, rather than volume, of care provided. The purpose of the GPP is to support PHCS for their key role in providing services to California's remaining uninsured and to promote the delivery of more cost-effective and higher-value care to the uninsured. It is important to note that*

PHCSs are enrolled in GPP, not individuals. PHCSs report and obtain funding, through GPP for individual encounters associated with the uninsured. In order to receive funding for those encounters, the encounter must provide one of the specific service types specified in the CalAIM STCs.

Duals Plan Alignment*: Within the revised evaluation design, there is an expanded description of statewide county-based managed care implementation, mandatory managed care for Duals by county, and the Medi-Cal Plan Matching Policy. The primary group of interest are Duals with Medicare A and B in counties with the Matching Policy who want to change their MCPs. There is a more complete and careful description of possible enrollment and plan changes. There are no a priori exclusions from the Duals outside of the target evaluation period and their eligibility to be in a MA plan (e.g., having Medicare A and B). However, certain groups may be difficult to understand (such as individuals who enroll and disenroll from Medi-Cal or who change their MCPs multiple times). These may be excluded in the main analyses but do require greater subgroup analysis to understand their implications.*

REENTRY*: The Reentry Demonstration evaluation includes specific inclusion/ exclusion criteria for analyses among JI individuals. The inclusion criteria are broad as the demonstration covers state prisons, county jails, and youth detention facilities and is meant to bridge care to some of the state's most vulnerable individuals with a significant proportion having serious mental health, substance abuse, and related health issues. The major factors in defining the study population for the evaluation are person-level data availability for incarcerated settings and whether it will be possible to identify health status while in the incarcerated settings. This will be one of the first tasks of the Evaluation Team.*

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.

Below we present directional hypotheses for all for projects.

PATH Directional Hypotheses

- ***H 1****: The number of community-based providers contracted with MCPs to provide ECM or Community Supports will increase over time due to provision of PATH funding and resources. The number and proportion of community-based providers located in under-resourced communities will increase over time.*

- ***H 2****: Community-based providers are more likely to contract with MCPs to provide ECM or Community Supports if they participate in PATH, were contracted with MCPs prior to CalAIM, or had robust data sharing infrastructure in place prior to CalAIM.*
- ***H 3****: PATH will increase the number of eligible members that utilize ECM or Community Supports services and the number of ECM and Community Supports services used by eligible members. PATH will increase ECM and Community Supports utilization by helping MCPs and providers to (a) develop cross-sector collaborative relationships and infrastructure needed to implement ECM or Community Supports and (b) use effective strategies for identifying and engaging eligible members in ECM or Community Supports services.*
- ***H 4****: PATH will increase the number of ECM and Community Supports providers with data use agreements with MCPs, EHR technology or other electronic care management documentation system, and Medi-Cal billing systems. PATH will increase the number of ECM and Community Supports providers that had shared data with MCPs using these systems.*
- ***H 5****: PATH will improve institutions' capacity and infrastructure necessary to screen, enroll, and change the suspension status for individuals eligible for Medi-Cal prior to release. PATH will do so by enabling correctional facilities to invest in needed infrastructure and capacity development.*
- ***H 6****. PATH will improve institutions' capacity and infrastructure to provide pre-release services by providing funding to invest in needed infrastructure and capacity development.*
- ***H 7****: The number of eligible individuals screened and enrolled in Medi-Cal prior to release will increase over time.*

GPP Directional Hypotheses

- ***H 1:*** *PHCS improved the quality of care to the uninsured.*
- ***H 2:*** *PHCS increased the use of outpatient services, non-traditional services, and equity-enhancing services over the course of the GPP.*
- ***H 3:*** *PHCS improved the data collection, reporting and analytics infrastructure to identify and act on health inequities.*

Duals Plan Alignment Directional Hypotheses

- *Note: The Dual Hypotheses have changed to match the revised EDR. As suggested, all listed hypotheses are directional.* ***H1:*** *Fewer than 0.1 percent of Duals in mandatory aligned plans in Matching Plan Counties will request to change their MCP within 12 months of enrollment during the target period.*

- ***H2:*** *Duals in aligned plans during the target period, will be less likely to request to change their MCP than those in unaligned plans during the target period.*
- ***H3:*** *Duals who request to change from a mandatory aligned plan will be less likely to change their MA plans (and MCP) then Duals who request a change from unaligned MA plans during the target period.*
- ***H4****: Duals in a Medi-Medi Plan are less likely than those in other MA or Original Medicare to change their MCP Duals in MMPs will be less likely to change plans than those in other aligned plans that are not MMPs and less likely than those in unaligned D-SNPs.*
- ***H5:*** *Duals who request to change their MCP and who change their plans will be satisfied with the process for doing so during the target period.*
- ***H6:*** *Duals in Medi-Medi Plans will be more satisfied with the mandatory alignment of their MCP to their MA plan choice compared to Duals who are in in other type of MA plans.*
- ***H7:*** *Duals in counties with the policy will be more knowledgeable and will be more satisfied as the policy matures.*

REENTRY Directional Hypotheses

- ***H1:*** *The waiver will increase coverage, continuity of care, and appropriate service uptake.*
- ***H2:*** *The waiver will increase access to services prior to release and improve transitions and continuing of care upon release.*
- ***H3:*** *The waiver will improve coordination and communication between correctional systems, Medicaid and CHIP systems, managed care plans, and community-based providers.*
- ***H4:*** *The waiver will increase additional investments in health care and related services.*
- ***H5:*** *The waiver will improve connections between carceral settings and community services upon release to address physical health, behavioral health, and health-related social needs.*
- ***H6:*** *The waiver will increase access to interventions for behavioral health conditions, access to long-acting injectable anti-psychotics, and access to medications for addiction treatment for SUDs.*
- ***H7:*** *The waiver will reduce decompensation, suicide-related deaths, overdoses, and overdose-related deaths.*

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.

PATH: *The Evaluation Team will request these data as they emerge. We will then assess content and usability and process the data. We anticipate these data will include information on specific supports provided to providers as part of the PATH CPI, TA, and JI capacity-building initiatives and information on which providers participated in different TPA-led initiatives.*

GPP: *The Evaluation Team will seek Uniform Data Set data to characterize structure, utilization, and processes in comparison FQHCs. Additionally, GPP is considering the adequacy of CHIS data regarding uninsured individuals. will describe access to UDS data. Our planned use of these data sets is described in the methods section.*

Dual: *The primary data for these evaluations will be drawn from the Medi-Cal and Medicare enrollment data supplemented by the Evaluation Team survey results. Anticipated third-party data at this time include need-metrics by zip code based upon the American Community Survey. These are in the public domain.*

REENTRY: *The Reentry Demonstration will require data on health, healthcare, and incarceration from the different entities that house JI individuals – state prisons, county jails, and youth detention centers. These data will be updated during the demonstration period to include screening for eligibility for Medi-Cal, which will include individuals who are eligible (and enroll or do not enroll) and those who are not eligible for Medi-Cal. We will also likely use the state hospital discharge data and emergency department visit data as well as the state death file, which will create a consistent all-payer set of data that can be applied to all individuals whose data are included in the study.*