

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

November 18, 2016

Mari Cantwell
Chief Deputy Director
Department of Health Care Services
Director's Office, MS 0000
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Cantwell:

The Centers for Medicare & Medicaid Services (CMS) has reviewed the draft evaluation design for California's Public Hospital Redesign and Incentives in Medi-Cal (PRIME) Program under California's section 1115 demonstration project, entitled California Medi-Cal 2020 Demonstration (Project Number 11-W-00193/9).

Please see the enclosed document, which details CMS comments and feedback on the draft evaluation design. CMS asks the state to review these comments and incorporate any changes within 60 days of receipt of this letter. If you have any questions, please contact your project officer, Ms. Sandra Phelps, at either 410-786-1968 or by email at Sandra.Phelps@cms.hhs.gov.

We appreciate your cooperation throughout the review process.

Sincerely,

/s/

Angela D. Garner
Director Division of System Reform Demonstrations

Enclosure

cc: Henrietta Sam-Louie, ARA Region IX

CMS Feedback on PRIME Draft Evaluation Design

November 18, 2016

The Centers for Medicare & Medicaid Services (CMS) assessed the degree to which the PRIME draft evaluation design aligns with the requirements specified by the Medi-Cal 2020 Demonstration's special terms and conditions (STCs), and provides recommendations for changes to the draft evaluation design. Overall, California's draft evaluation design for the PRIME program does not fully comply with the requirements as stated in the STCs, and we cite limitations below that might prevent a robust evaluation of PRIME. At a minimum, we recommend the state revise the evaluation design to include research questions with testable hypotheses that address the impact of PRIME at the state and system level, include metrics that assess the impact of PRIME on cost, and require the use of Medicaid administrative claims and encounter data to measure program outcomes.

Review of evaluation design's alignment with STCs

Table 1 presents a detailed comparison of the evaluation design requirements, per the STCs, and the evaluation design submitted by California. CMS noted several discrepancies between the requirements specified in the STCs and the evaluation design. First, the STCs require the evaluation design to include specific research questions and testable hypotheses that address the goals of the demonstration at the state and system level. Although the evaluation design includes five evaluation areas and many testable hypotheses within each area, it does not include research questions to be addressed by the evaluation. Further, the hypotheses do not address how the state expects PRIME will affect the goals of the demonstration at both the state and system level. In addition, the STCs declare that measures must adequately assess the effectiveness of the demonstration in terms of cost or cost-avoidance impact. The evaluation design does not include any metrics that assess the impact of PRIME on costs. We flag that cost or cost-avoidance analysis is particularly important to include given the program and the lack of cost analyses in the Bridge to Reform (BTR) Delivery System Reform Incentive Payments (DSRIP) program evaluation.

More broadly, the STCs specify that the evaluation, to the greatest extent possible, should determine the causal impacts of PRIME, and that the statistical methods should allow for the effects of PRIME to be isolated from other initiatives occurring in the state. The methods and data sources described in the evaluation design will not allow for the state or CMS to draw causal inferences, nor will the methods allow for the effects of PRIME to be isolated from other initiatives occurring in the state. This is in part because the evaluation design does not include any type of comparison group and relies on aggregate metrics reported by the participating hospitals to measure program impact. We recommend that analyses be required that do not rely solely on aggregating metrics across DPHs and/or DMPHs across PRIME years. For example, metrics that are aggregated across PRIME years do not distinguish high and low performers/projects and do not identify circumstances where performance markedly improves or declines. In addition, the pre-post design does not have a long enough pre period to control for trends in the outcomes of interest that were occurring before PRIME began. Finally, because the current design is based on data reported by the participating hospitals, assessing the impact of PRIME on the outcomes of interest at the state level will be difficult and require controlling for the number of Medi-Cal beneficiaries served by each participating hospital.

Table 1. Comparison of evaluation design requirements and California’s evaluation design

Requirements specified in special terms and conditions	Requirements addressed in report	Requirements not addressed in report
<p><i>Specific aims and hypotheses:</i> This includes a statement of the specific research questions and testable hypotheses that address the goals of the demonstration, including safety net system transformation at the system and state level, accountability for and improvements in health outcomes and other health measures at the system and state level, and efforts to ensure sustainability and transformation of/in the managed care environments.</p>	<ul style="list-style-type: none"> • Included the testable hypotheses that address safety net system transformation, accountability for and improvements in health outcomes and other health measures, and efforts to ensure sustainability and transformation of/in the managed care environment 	<ul style="list-style-type: none"> • Did not include specific research questions • Did not include testable hypotheses at the system and state levels
<p><i>Performance measures:</i> This includes identification, for each hypothesis, of quantitative and/or qualitative process and/or outcome measures that adequately assess the effectiveness of the demonstration in terms of cost or cost avoidance impact, change in delivery of care from inpatient to outpatient, quality improvement, and transformation of incentive arrangements. Nationally recognized measures should be used where appropriate. Measures will be clearly stated and described, with the numerator and denominator clearly defined. To the extent possible, the state will incorporate comparisons to national data and/or measure sets. A broad set of metrics will be selected. To the extent possible, metrics will be pulled from nationally recognized metrics such as from the National Quality Forum, the Center for Medicare & Medicaid Innovation, meaningful use under Health Information Technology, and the Medicaid Core Adult sets, for which there is sufficient experience and baseline population data to make the metrics a meaningful evaluation of the California Medicaid system.</p>	<ul style="list-style-type: none"> • Includes identification of quantitative metrics or qualitative process for each hypothesis • Includes quantitative metrics that assess change in delivery of care from inpatient to outpatient, quality improvement, and transformation of incentive arrangements • Nationally recognized measures are incorporated • State considers recognized metrics (e.g., National Quality Forum–endorsed measures, Medicaid adult core set of quality measures) 	<ul style="list-style-type: none"> • Did not include quantitative metrics that adequately assess cost or cost avoidance impact • Did not clearly describe numerators and denominators^a • Did not incorporate comparisons with national data or measure sets
<p><i>Data Collection:</i> This discussion shall include a description of the data sources, the frequency and timing of data collection, and the method of data collection. The following shall be considered and included as appropriate:</p> <ol style="list-style-type: none"> i. Medicaid encounter and claims data in T-MSIS ii. Enrollment data iii. EHR data, where available iv. Semiannual financial and other reporting data v. Managed care contracting data vi. Consumer and provider surveys <p>Other data needed to support performance measurement</p>	<ul style="list-style-type: none"> • Discussion includes a description of possible data sources • Discussion includes frequency and timing of PRIME program reporting • Discussion includes description of possible methods of qualitative data collection • State considers use of Office of Statewide Health Planning and Development data • State mentions that it may include Medicaid encounter and claims data, enrollment data, financial data, and managed care contracting data 	<ul style="list-style-type: none"> • Did not consider EHR data
<p><i>Assurances Needed to Obtain Data:</i> The design report will discuss the state’s arrangements to ensure that the data needed to support the evaluation design are available</p>	<ul style="list-style-type: none"> • Not applicable 	<ul style="list-style-type: none"> • Did not discuss assurances needed to obtain data

Requirements specified in special terms and conditions	Requirements addressed in report	Requirements not addressed in report
<i>Data Analysis:</i> This includes a detailed discussion of the method of data evaluation, including appropriate statistical methods that will allow for the effects of the PRIME to be isolated, to the extent possible, from other initiatives occurring in the state. The level of analysis may be at the beneficiary, provider, health plan, and program level, as appropriate. The analysis shall include population and intervention-specific stratifications, for further depth and to glean potential non-equivalent effects on different subgroups. Sensitivity analyses shall be used when appropriate. Qualitative analysis methods shall also be described, if applicable.	<ul style="list-style-type: none"> • Includes a description of potential qualitative methods 	<ul style="list-style-type: none"> • Did not provide detailed discussion of statistical methods that will allow for the effects of PRIME to be isolated from other initiatives occurring in the state • Did not describe level of analysis • Did not include population and intervention-specific stratifications
<i>Timeline:</i> This includes a timeline for evaluation-related metrics, including those related to procurement of an outside contractor, if applicable, and deliverables.	<ul style="list-style-type: none"> • Includes timeline for evaluation-related metrics 	<ul style="list-style-type: none"> • Not applicable
<i>Evaluator:</i> This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, how the state will assure no conflict of interest, and a budget for evaluation activities.	<ul style="list-style-type: none"> • Includes discussion of state's process for obtaining independent entity to conduct evaluation • Includes description of qualifications that the selected entity must possess • Includes description of how state will ensure no conflicts of interest • Includes a budget for evaluation activities 	<ul style="list-style-type: none"> • Not applicable
<i>Evaluation Budget:</i> A budget for the evaluation shall be provided with the evaluation design. It will include the total estimated cost as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation, such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses, and reports generation.	<ul style="list-style-type: none"> • Includes a budget for the evaluation • Includes total estimated cost 	<ul style="list-style-type: none"> • Did not include breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation

^aThe design plan relies on metrics included in the California PRIME Projects and Metrics Protocol and described in the PRIME metric specification manual, which will include a description of each measure's numerator and denominator. The PRIME metric specification has not been made available to the Mathematica team, so we were not able to assess the extent to which the numerators and denominators of the measures listed in the design plan are addressed in the manual. PRIME = Public Hospital Redesign and Incentives in Medi-Cal; EHR = electronic health record; T-MSIS = Transformed Medicaid Statistical Information System.

Recommendations

1. **STC alignment.** We first recommend addressing the discrepancies between the report and requirements detailed in the STCs. Most importantly, the evaluation design should (1) include research questions with testable hypotheses that address the impact of PRIME at both the state and system level; (2) include quantitative metrics focused on costs; (3) require the evaluator to use individual-level data; (4) allow the evaluator to employ a design with a comparison group; and (5) require the evaluator to use at least two years of data prior to implementation of PRIME to control for baseline trends, particularly if no other comparison group is feasible.

One approach the state could take in developing the research questions and hypotheses is to first develop research questions for each goal of the demonstration as specified in the

STCs: (1) safety net transformation at the system and state level, (2) accountability for and improvement in health outcomes and other health measures at the system and state level, and (3) efforts to ensure sustainability of transformation of/in the managed care environment. Once strong research questions have been developed based on these goals, we recommend the state develop secondary research questions within each domain, hypotheses that tie to those secondary research questions, and potential metrics to address the research questions. For examples, see Table 2.

Table 2. PRIME research questions, hypotheses, and proposed measures by domain

Research question	Hypotheses	Proposed outcome measures	
		or indicators	Level of analysis
Domain 1: How has PRIME transformed the delivery system both within the safety net system and the state?			
Has PRIME led to increased integration of primary and behavioral health services?	<ul style="list-style-type: none"> • PRIME will lead to improvements in follow-up after hospitalization for mental illness • PRIME will lead to initiation and engagement of alcohol and other drug dependence treatment at the state and hospital levels • PRIME will lead to increased screening for physical health conditions in patients with serious mental illness at the state and hospital levels 	<ul style="list-style-type: none"> • Follow-up after hospitalization for mental illness (adult core set measure, NQF-endorsed) • Initiation and engagement of alcohol and other drug dependent treatment (adult core set measure, NQF-endorsed) • Diabetes screening for people with schizophrenia or bipolar disorder who are using antipsychotic medication (adult core set measure, NQF-endorsed) 	<ul style="list-style-type: none"> • State • Hospital
Has PRIME led to primary care redesign?	<ul style="list-style-type: none"> • PRIME will lead to increased provision of colorectal cancer screening at the state and hospital levels • PRIME will lead to improved diabetes care at the state and hospital levels 	<ul style="list-style-type: none"> • Colorectal cancer screening • Comprehensive diabetes care: hemoglobin A1c testing 	<ul style="list-style-type: none"> • State • Hospital
Has PRIME led to specialty care redesign?	<ul style="list-style-type: none"> • PRIME will lead to fewer all-cause readmissions at the state and hospital levels 	<ul style="list-style-type: none"> • All-cause readmissions 	<ul style="list-style-type: none"> • State • Hospital
Has PRIME led to improvements in patient safety?	<ul style="list-style-type: none"> • PRIME will lead to improved monitoring for patients on persistent medications at the hospital level 	<ul style="list-style-type: none"> • Annual monitoring for patients on persistent medications (NQF-endorsed) 	<ul style="list-style-type: none"> • Hospital
Has PRIME led to improvements in maternal and perinatal health?	<ul style="list-style-type: none"> • PRIME will lead to improved postpartum care rates at the state level 	<ul style="list-style-type: none"> • Prenatal and postpartum care: postpartum care rate (adult core set measure, NQF-endorsed) 	<ul style="list-style-type: none"> • State
Has PRIME led to improvements in cancer care?	<ul style="list-style-type: none"> • PRIME will lead to improvements in breast cancer screening at the state and hospital levels 	<ul style="list-style-type: none"> • Breast cancer screening 	<ul style="list-style-type: none"> • State • Hospital
Has PRIME supported obesity prevention?	<ul style="list-style-type: none"> • PRIME will lead to increased body mass index screening and follow-up at the hospital level 	<ul style="list-style-type: none"> • Body mass index screening and follow-up 	<ul style="list-style-type: none"> • Hospital
Has PRIME led to improved care coordination between inpatient and outpatient care teams?	<ul style="list-style-type: none"> • PRIME will lead to improved care coordination between inpatient and outpatient care teams at the hospital level 	<ul style="list-style-type: none"> • CAHPS hospital survey: Care transition metrics (Agency for Healthcare Research and Quality measure) 	<ul style="list-style-type: none"> • Hospital
Has PRIME led to improved complex care management for high-risk medical populations?	<ul style="list-style-type: none"> • PRIME will lead to improvements in prevention quality at the state and hospital levels 	<ul style="list-style-type: none"> • Prevention quality overall composite measure (Prevention Quality Indicator #90) 	<ul style="list-style-type: none"> • State • Hospital

Research question	Hypotheses	Proposed outcome measures or indicators	Level of analysis
Has PRIME led to improved efficiency of resource utilization?	<ul style="list-style-type: none"> PRIME will lead to reductions in antibiotics treatment in adults with acute bronchitis at the state and hospital levels PRIME will lead to reductions in use of imaging studies for low back pain at the state and hospital levels 	<ul style="list-style-type: none"> Avoidance of antibiotic treatment in adults with acute bronchitis Use of imaging studies for low back pain 	<ul style="list-style-type: none"> State Hospital
Domain 2: Has PRIME improved population health outcomes for Medi-Cal beneficiaries?			
Have PRIME improved population health outcomes for groups targeted by the program?	<ul style="list-style-type: none"> PRIME will lead to improved control of high blood pressure PRIME will lead to improved control of diabetes PRIME will lead to fewer low-birth-weight births 	<ul style="list-style-type: none"> Controlling high blood pressure (adult core set measure, NQF-endorsed) Comprehensive diabetes care: hemoglobin A1c control Live births weighing less than 2,500 grams 	<ul style="list-style-type: none"> State Hospital
Domain 3: Will system transformations made under PRIME be sustainable in the managed care environment?			
Has PRIME reduced Medicaid per capita costs?	<ul style="list-style-type: none"> PRIME will lead to reduced Medicaid per capita costs 	<ul style="list-style-type: none"> Average cost per beneficiary per month 	<ul style="list-style-type: none"> State Attributed beneficiaries
Has PRIME led to improvements in person-centered care? ^a	<ul style="list-style-type: none"> PRIME will lead to improvements in how well clinicians communicate PRIME will lead to improvements in understanding of care 	<ul style="list-style-type: none"> Clinician communication (CAHPS ECHO survey) Understanding of care (CAHPS hospital survey) 	<ul style="list-style-type: none"> State Hospital
Has PRIME increased use of alternative payment models?	<ul style="list-style-type: none"> PRIME will lead to increased use of alternative payment models 	<ul style="list-style-type: none"> Percentage of attributed beneficiaries that receive care under a contracted alternative payment model 	<ul style="list-style-type: none"> Hospital

^a According to the alternative payment model framework developed by the Health Care Payment Learning and Action Network and supported by CMS, APMs are one means for accomplishing the larger goal of person-centered care. See <https://hcp-lan.org/workproducts/apm-whitepaper-total.pdf>.

PRIME = Public Hospital Redesign and Incentives in Medi-Cal; NQF = National Quality Forum; CAHPS = Consumer Assessment of Healthcare Providers and Systems; ECHO = Experience of Care and Health Outcomes.

- 2. Use of Medicaid claims and encounter data.** We believe it is insufficient to rely primarily on the metrics reported by the participating providers for the purposes of the quantitative evaluation. First, the metrics are reported at an aggregate level, which considerably limits the types of analyses that can be conducted by the evaluator. For instance, it is not possible to stratify the results by or control for individual characteristics, such as age or diagnosis. Furthermore, although the metrics were designed and identified through a rigorous process, nothing in the documentation suggests the data reported to DHCS will be verified for accuracy or consistency. It is therefore possible that there will be substantial variation across participating entities in how the metrics are calculated, even if the PRIME metric specification manual provides clear guidance.¹ Finally, the metrics are only reported by the participating hospitals, so a broader assessment of the impact of PRIME at the state level cannot be made. Rather than rely on the required metrics reported by the participating entities, we recommend the state request the evaluator use Medicaid claims and encounter data as the

¹ We do not currently have access to the California PRIME metrics specification manual.

primary data source. DHCS is already required to use these data to assign beneficiaries to the participating entities,² and we believe it would be helpful to make these data available to the evaluator. Unlike the proposed data sources, Medicaid claims and encounter data can be used in rigorous analyses, such as interrupted time series analyses. This technique uses trends in the outcome of interest prior to implementation of an intervention to estimate what the trends would have looked like in the post period in the absence of the intervention. The actual trends are then compared to the estimated trends to see if there is a significant difference between the two. This method is particularly useful if a comparison group cannot be identified.

In addition, using Medicaid administrative data will give the state more flexibility in establishing a baseline period than the current approach, which proposes to use provider reporting from the first year of the demonstration period. Because PRIME is building off of BTR DSRIP program, we recommend that the state compare the outcomes of interest after implementation of PRIME to (1) trends in the outcomes of interest in the two years prior to DSRIP and (2) trends in the outcomes of interest during the DSRIP demonstration period. Modeling these three time periods will help us better estimate trends in the outcomes of interest in light of changes that may have occurred as a result of DSRIP. For example, we might expect the outcomes of interest to show greater improvement during the PRIME period because it includes the DMPHs which did not participate in DSRIP.

Finally, to the extent that the Medicaid administrative data are complete for all Medicaid beneficiaries in California, the data can be used to more broadly assess the impact of PRIME at the state level.

Although these data can be useful for causal inference, they lack important clinical data that can be found in electronic health records or chart-based data. For instance, although it is possible to determine if an individual received a hemoglobin A1c (HbA1c) test, it is not possible to see the results of the test to determine if the individual's HbA1c levels are under control. We encourage the state to consider including some analyses of chart-based data to examine the impact of PRIME on health outcomes.

3. **Outcomes at hospital level.** Another important consideration for the quantitative analysis is the extent to which the evaluator can identify outcomes at the hospital level, particularly in Medicaid administrative data. If the state is exclusively interested in understanding the impact of PRIME on beneficiaries assigned to each DPH or DMPH, the evaluator could use the list of assigned lives that DHCS provides to the participating providers to calculate hospital-level measures. Should the state be interested in provider performance more broadly, we recommend the evaluator explore the usability of provider

² The PRIME population for each entity is composed of (1) all Medi-Cal managed care primary care lives assigned to the participating PRIME entity as listed by DHCS at the end of each measurement period and (2) all individuals with at least two encounters at the participating PRIME entity for an eligible primary care service during the measurement period.

identifiers in the data. If the evaluators cannot rely on the administrative data to identify specific DPHs and DMPHs, they may want to work with individual hospitals to obtain data.

4. **Alternative payment methodologies.** Given that the purpose of the PRIME program is to support state's efforts to adopt alternative payment methodologies (APMs), we believe the design plan should give more attention to this topic. Currently, the design plan includes two measures embedded within the fourth evaluation focus area to assess the shift to value-based payment systems: (1) the number of DPHs meeting statewide alternative payment targets and (2) types of APMs and variability across PRIME entities. We suggest that the evaluation design provide additional information about how these measures could be calculated by an independent evaluator. We expect that, at this time, the only source describing the types of payment arrangements between a managed care organization (MCO) and PRIME participating providers is managed care contracting data, but more information and more detail is needed.
5. **Additional measures.** In addition to calculating the measures reported by the participating entities, it would helpful if the evaluation includes additional measures. For instance, the participating entities are not reporting any measures relating to cost or cost avoidance, but the STCs require the state to measure the effectiveness of the demonstration in these terms. In addition, the state could opt to include measures that align with the goals of the projects but are not reported (for instance, using the initiation and engagement of alcohol and other drug dependence treatment measures to assess improvements in physical/behavioral health care integration). This type of analysis will help the state understand if participating entities are improving performance on specific measures or if they are improving outcomes more broadly. Finally, the state could include measures that are not expected to change as a result of PRIME to act as a comparison or falsification test, another technique that is commonly used when a comparison group cannot be identified.
6. **Qualitative analyses.** The evaluation design can also improve its approach to the qualitative analyses. Currently, the evaluation design is inconsistent in how it describes the qualitative analysis. In the qualitative data collection and analysis section, the state describes several possible qualitative methods that an evaluator could employ, including document reviews, technical expert panels, case studies, program data reviews, and key informant interviews. However, these methods are not explicitly tied to the qualitative evaluation area described in the design, which focuses on determining the key lessons learned about safety net transformation in a managed care environment and sustainability from the perspective of PRIME stakeholders. Instead, the methods discussed in this section focus on semi-structured key informant interviews and/or surveys. The qualitative analysis is not meant to explain factors that "may" affect the program as was seen in the previous BTR DSRIP evaluation. The BTR evaluation had a qualitative analysis that asked DSRIP participants for their "perceived" impact of DSRIP rather than analyses that used qualitative factors or information to relate or correlate the actual impact.

The discussion of the qualitative methods should be consistent throughout the evaluation design, and the choice of methods should be based on the analytical objectives. In an evaluation such as this one, qualitative methods can be particularly helpful in understanding the factors that facilitate and impede the effectiveness of implementation, as well as informing the impact analysis (for instance, qualitative findings can help in the interpretation of quantitative findings related to the impact of interventions on patient outcomes, provider behavior, quality of care, cost, and other key outcomes). We suggest that the state first develop a qualitative data collection and analysis plan to support an implementation analysis using an evidence-based framework such as the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). The CFIR can be used as a practical guide for systematically assessing potential barriers and facilitators in implementing a new program such as PRIME. The methods used for such an implementation analysis can include document reviews (for instance, reviews of program narratives reported by PRIME participating providers), focus groups, or semi-structured key informant interviews. In addition to an implementation analysis, qualitative methods can also be used as described in the fifth evaluation area focused on key lessons learned and sustainability of the program.

References

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