

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-01-16  
Baltimore, Maryland 21244-1850



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**State Demonstrations Group**

August 23, 2017

Ms. 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:

This letter is to inform you that the Centers for Medicare and Medicaid Services (CMS) has approved the attached evaluation design for the Public Hospital Redesign Incentives in Medi-Cal (PRIME) Program authorized under the section 1115(a) demonstration entitled "Medi-Cal 2020" (11-W-00193/9), as submitted by the state and as modified through our discussions. A copy of the approved PRIME evaluation design is enclosed.

As a part of this approval, CMS requests that the state provide updates in its quarterly demonstration monitoring reports regarding the availability of adequate data to conduct the evaluation as outlined in the approved evaluation design. The approved evaluation design includes measures that are dependent upon the availability of data, including information on costs. Once the state is able to confirm the availability of data, the state will submit a revised evaluation design to CMS clarifying the data sources for the affected measures.

We look forward to continuing to work with you and your staff on the Medi-Cal 2020 Demonstration. If you have any questions, please contact your project officer, Mrs. Heather Ross, at either 410-786-3666, or by email at [Heather.Ross@cms.hhs.gov](mailto:Heather.Ross@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

## **Evaluation Design for the Public Hospital Redesign and Incentives in Medi-Cal (PRIME) Program**

The Public Hospital Redesign and Incentives in Medi-Cal (PRIME) program is part of California's Medi-Cal 2020 1115 waiver approved by the Centers for Medicare and Medicaid Services (CMS) on December 30, 2015. PRIME aims to expand access and improve health outcomes in California's designated public hospitals (DPHs) and municipal public hospitals (DMPHs) (referred to as PRIME entities) while managing utilization and cost. PRIME is designed to establish or improve infrastructure to manage high-cost populations through a range of interventions, expand capacity through enhanced efficiency and reductions in unnecessary utilization, and build capabilities to support the transition to value-based purchasing. The California Department of Health Care Services (DHCS) will monitor performance, distribute PRIME funds, and provide support and technical assistance to PRIME entities.

Under the Special Terms and Conditions (STC) of this waiver, CMS requires an evaluation of the PRIME demonstration to determine whether this initiative has achieved the program's intended goals.

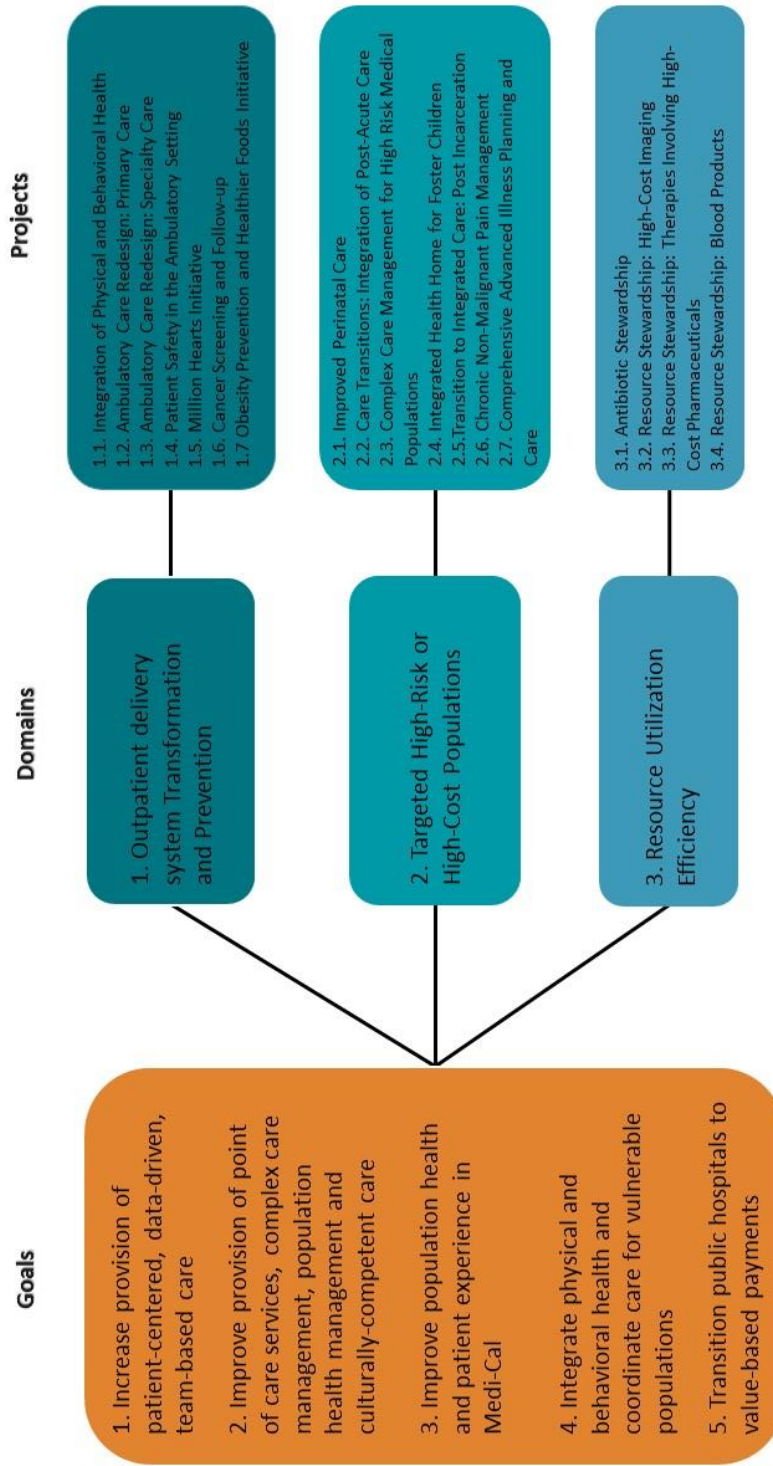
### **Overview of PRIME Demonstration**

Building on the experience and outcomes of the Delivery System Reform Incentive Payment (DSRIP) program, PRIME provides approximately \$3.7 billion in federal incentive payments to PRIME entities for demonstrating improved outcomes. PRIME goals and Projects that are designed to achieve these goals are displayed in Exhibit 1.

The protocol for PRIME Projects and metrics was developed and vetted through a consultative process involving clinical and quality experts, public hospital leadership, DHCS leadership, technical experts, and public stakeholders over the course of 18 months. Extensive documentation of rationale, goals and objectives, key activities that guide project development and implementation, and specific metrics (clinical event outcomes, potentially preventable events, and patient experience measures) are provided in Attachment Q.<sup>1</sup>

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**Exhibit 1. PRIME Program Goals and Projects**



To receive payment, PRIME entities must comply with pay-for-reporting requirements and achieve specific targets for the pay-for-performance metrics associated with their Projects over the course of the demonstration. Details of funding mechanism and funding protocols are described in Attachment II.<sup>1</sup> Across the five-year program, DPHs collectively may qualify for up to \$1.4 billion annually of combined state and federal funding, while DMPHs collectively may qualify for up to \$200 million annually.

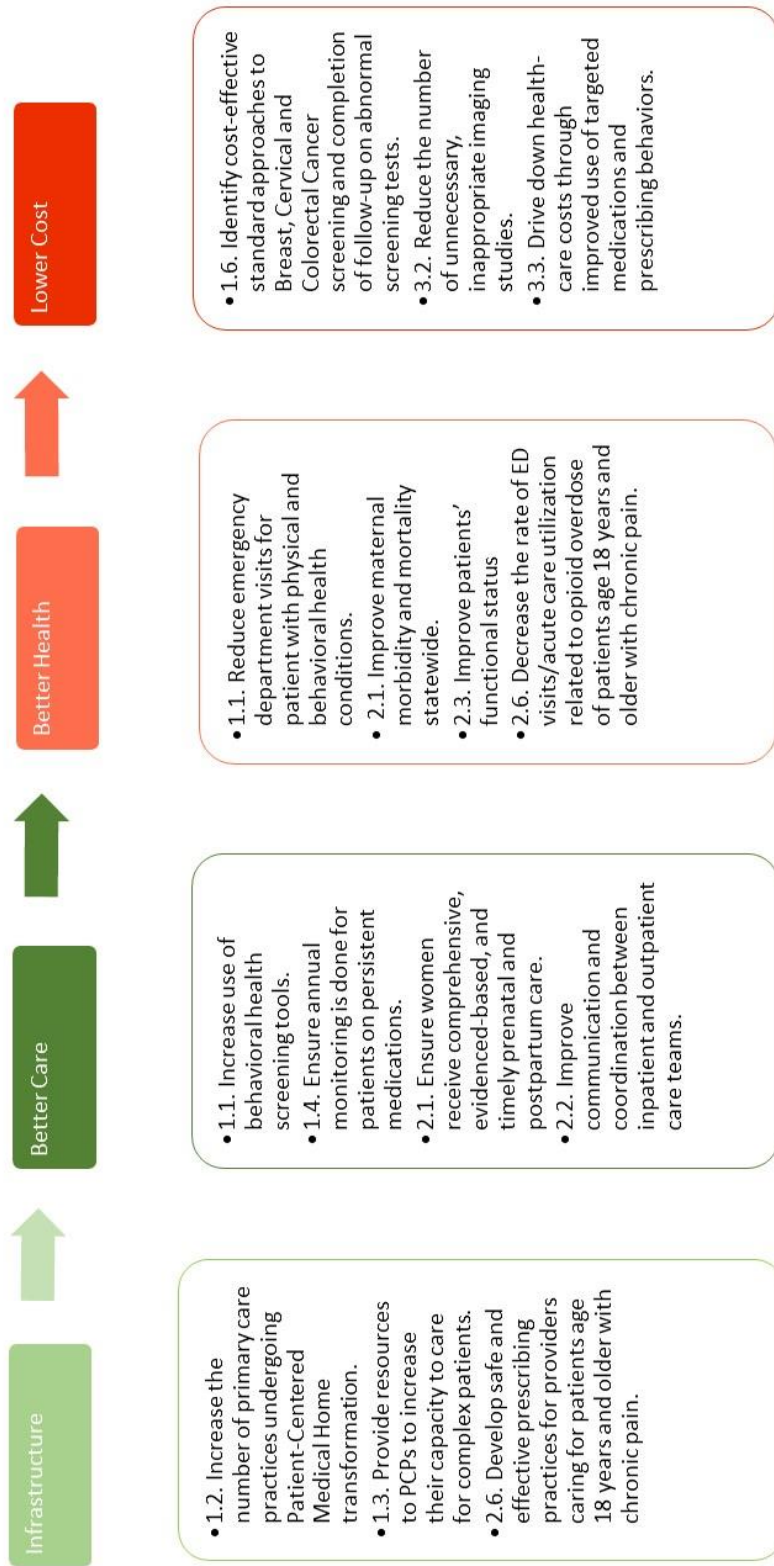
Participating DPHs were required to implement at least nine PRIME required and optional Projects from each Domain. DMPHs, in contrast, were required to implement at least one Project across three Domains: Outpatient Delivery System Transformation and Prevention; Targeted High-Risk or High-Cost Populations; and Resource Utilization Efficiency. PRIME entities submitted five-year plans to DHCS in April 2016. In June 2016, DHCS approved plans from 54 PRIME entities (17 DPHs and 37 DMPHs). Appendix A.1 provides the number of PRIME entities (both DPHs and DMPHs) that selected various Projects for the five-year demonstration. The first payments to PRIME entities were awarded based on the submission and approval of hospital five-year plans. Payments associated with performance began on September 2016 and are contingent upon meeting reporting requirements. The demonstration will run until June 30, 2020.

### **PRIME Evaluation Conceptual Framework**

PRIME is designed to achieve the Triple Aim of better care, better health, and lower costs. The three PRIME Domains target specific aspects of care delivery within PRIME entities that are most likely to achieve the Triple Aim. Domain 1 Projects are designed to develop/enhance the infrastructure and change the process of care delivery overall as well as reduce the prevalence of specific chronic conditions. Domain 2 Projects are designed to target specific high-risk or high-cost populations that require change in care delivery that is focused on their needs. Domain 3 Projects are designed to target inappropriate use of specific services. PRIME Projects generally include objectives that can be classified as process or outcome indicators. Process objectives indicate achievement of changes in processes demonstrating successful implementation of Project objectives. Outcome objectives demonstrate (1) improvements in patient health that have implications for efficiency and cost reduction and (2) improvements in efficiencies and cost reduction directly. The conceptual framework for PRIME evaluation is displayed in Exhibit 2 and includes examples of Project objectives and how achieving these objectives is likely to lead to the Triple Aim of better care, better health, and lower costs. For example, Project 1.1 in Domain 1 is designed to increase use of behavioral health screening tools (better care). Early identification and intervention of behavioral health problems is expected to reduce emergency department visits (better health). Reduction of emergency department visits is expected to reduce costs. Exhibit 2 also displays the expected impact of each objective under PRIME. The improvements in the Triple Aim will ultimately lead to PRIME entities that are efficient safety net providers that can operate under alternative payment methods such as those employed by managed care organizations. Improved efficiencies are essential in the ability of Medi-Cal to maintain high levels of eligibility and coverage given potential budget shortfalls.

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## Exhibit 2. PRIME Evaluation Conceptual Framework



## Methods

### *Qualitative and Quantitative Data Collection*

The data for PRIME evaluation will include qualitative and quantitative data. The qualitative data will include available data from DPH and DMPH annual reports, which include self-reported data on performance of PRIME required metrics, challenges faced and successful strategies employed in achievement of Project objectives. These data will be supplemented with detailed and structured surveys of DPHs and DMPHs and semi-structured interviews with key PRIME personnel of a representative sample of these hospitals. The structured surveys will gather further information on Projects implemented by each hospital, using the Consolidated Framework for Implementation Research (CFIR)<sup>2</sup> domains as appropriate. DPHs and DMPHs had flexibility to choose different approaches to implement each Project leading to difficulty in attributing the outcomes achieved by each hospital to specific types of interventions. As such, this information will be most useful in interpreting the quantitative findings and how they were achieved. Additional data will be gathered on other concurrent projects with goals similar to PRIME Projects, key lessons learned, and sustainability of PRIME Projects.

DHCS will ensure that the evaluator has access to quantitative data sources including individual level data from confidential discharge data from the California Office of Statewide Health Planning and Development (OSHPD) and Medi-Cal fee-for-service (FFS) claims and managed care encounter data when available. The evaluator will be required to use two years of data prior to implementation of PRIME to control for baseline trends, and all the years available during PRIME implementation. Medi-Cal data will allow for assessment of the impact of PRIME on Medi-Cal enrollees' inpatient and outpatient service use and expenditures. OSHPD data will allow for assessment of impact of PRIME on all California inpatient discharges. The evaluator will use all available and appropriate data to conduct the evaluation and will refine the evaluation hypotheses and research questions accordingly.

The quantitative data submitted by DPHs and DMPHs for use by the external evaluator will adhere to the PRIME Metric Specification Manual based on metrics outlined in Attachment Q. Following biannual data submission by each entity, DHCS conducts a comprehensive clinical review of the data to determine whether on-site audits or for-cause audits of specific entities are necessary.

Based on data that have undergone the above processes for assuring data quality, the evaluator will use an existing and validated methodology to identify the appropriate numerators and denominators for the quantitative outcomes used in PRIME evaluation. Many of the quantitative outcomes will be based on metrics endorsed by organizations such as National Quality Forum (NQF), Agency for Healthcare Research and Quality (AHRQ), National Committee for Quality Assurance (NCQA), and/or CMS, and have detailed measure specifications.

Additionally, DHCS requires all participating PRIME entities to adhere to a PRIME Data Integrity Policy. This policy outlines hospital responsibilities, standards and the State's expectations around collecting, validating, sharing and maintaining data. The Data Integrity Policy also outlines the reserved right for internal and external review and audits of data reported and its supporting

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documentation. Additionally, DHCS will ensure, to the extent possible, that the evaluator use the most reliable data source for each particular analysis including, but not limited to, Medi-Cal FFS claims data and managed care encounter data, mandated PRIME entity reported data, Medi-Cal-specific CMS core set metrics, EHR incentive program data, and OSHPD data. Under guidance from the DHCS Chief Medical Information Officer, Medi-Cal data routinely undergo data quality checks prior to mandated, regular data submissions to CMS.

### **Evaluation Questions and Related Hypothesis**

Exhibit 3 shows the objectives of each PRIME Domain and Project to be used for the PRIME evaluation, how the objectives are hypothesized to achieve the desired outcomes, and the qualitative and quantitative research questions that will be used to test the proposed hypotheses.

Exhibit 4 includes the evaluation metrics per Project including those specified in Attachment Q<sup>1</sup> and additional metrics that could be used to assess the impact of specific Project or the overall impact of PRIME. For example, the Attachment Q metrics for Project 1.1 (integration of physical and behavioral health) include measures of screening for alcohol and drug misuse, care coordinator assignment, comprehensive diabetes care, depression remissions at 12 months, screening for clinical depression and follow-up, and tobacco assessment and counseling. Additional quantitative measures for assessing the impact of this Project are mental health and substance use service rates, emergency department visit and hospitalization rates with mental health and substance use diagnosis. A number of additional measures assessing the broad impact of PRIME are also included in Exhibit 4, such as rates of all-cause emergency department visits and hospitalizations overall and by race/ethnicity or preferred language.

This exhibit also includes the number of PRIME entities that are implementing a given Project as a proxy for the likely impact of the Project statewide and the likelihood of detecting an impact. In other words, projects that are implemented for many PRIME entities are likely to be analyzable given the larger sample sizes and their impact is more likely to be detectable. The likely source of data for each metric and whether it can be used to assess impact on costs is also indicated. For example, the evaluator will determine the success of PRIME entities in assessing alcohol and drug misuse under Project 1.1 from PRIME entity reports submitted to DHCS. The evaluator will use the qualitative data to assess the implementation process of PRIME entities for this Project. The inclusion of additional metrics, testing of the proposed hypothesis, and answering the research questions are dependent on availability and quality of data. The evaluator will examine the data available in Medicaid Claims and OSHPD and determine if the numerator and denominators for each proposed measure can be constructed. The evaluator will report on data limitations in quarterly reports to DHCS and CMS. In the absence of data that allow the creation of a metric in the claims data, the evaluator will rely on self-reported metrics provided by PRIME Entities and will discuss data limitations in the interim and final reports.

The evaluation will include analyses of four other measures that are not expected to change as a result of PRIME, including severe sepsis mortality, central line blood stream infections, hospital acquired pressure ulcers, and venous thromboembolisms. These measures are selected because they are not targeted and are unlikely to be impacted by any of the PRIME projects. Furthermore, the

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evaluator has developed a detailed and valid methodology to assess these measures using OSHPD data.

### ***Analyses Methods***

The evaluator will use a quasi-experimental pre-post, intervention-comparison group analytic design and difference-in-difference (DD) methodology for analyses of quantitative data, when possible. This method is most likely possible for measures that are available in state-level Medi-Cal and OSHPD data. In the absence of these state-level data, the evaluator will employ the DD methodology to analyze entity-level data reported by PRIME entities in biannual reports to compare DPH and DMPH performance in Projects that were selected by both entities during PRIME. These analyses are useful when measures cannot be created in state-level administrative data and since state-level administrative data are not based on detailed information available in electronic health records and patient charts. Furthermore, to support entity-level data analyses methods, DPH and DMPH-reported metrics were designed and identified through a rigorous 18-month consultative process involving more than 100 clinical and quality experts, information technology and reporting experts, public hospital leaders, and statewide public stakeholders. The metrics were drawn, as much as possible, from nationally recognized measures that were carefully chosen and vetted by recognized, authoritative entities able to assess clinical relevance, feasibility and appropriateness of a metric. These vetting organizations are referred to as Measure Stewards and include NCQA, American Medical Association (AMA), and CMS. The PRIME Metric Specification Manual clearly defines each measure, spells out the denominator and numerator definitions, names the specification source, specifies the target population, lists the associated encounter codes, and provides explicit reporting instructions. For PRIME Projects where the current set of standard metrics does not adequately assess successful transformation innovative metrics have been identified (approximately 20% of all metrics). Innovative metrics are those that have not yet undergone a vetting and testing process by a Measure Steward. Innovative metrics will enable PRIME entities to demonstrate progress toward coordinated, team-based, patient-centered care, in a manner not afforded by many of the standard metrics.

The selection of comparison hospitals will follow a similar process as that employed in the DSRIP evaluation by UCLA. Comparison hospitals will be identified using hospital and patient characteristics available in OSHPD financial and patient discharge data. A mix of exact and distance matching methods will be used to identify hospitals that are most similar to the 17 DPHs and 37 DMPHs. Two-sided t-tests will be used to assess the differences in matching characteristics between PRIME entities and comparison hospitals. The DD analyses will be based on multivariate regression model to control for variations in patient demographic, case mix, and other relevant characteristics. Multi-level random effects models will be used to adjust for repeated measures and the nesting of patients within hospitals. Using regression models, the evaluator will be able to compare the performance of PRIME entities with the most similar private hospitals, DPHs vs. DMPHs, participating vs. non-participating DPHs and DMPHs, and highest performing and lowest performing individual DPHs and DMPHs for quantitative measures.

The regression models will account for the multilevel nature of the data. The data will include all services used per patient over time. Thus, time is nested in individuals and individuals are nested in hospitals. The evaluator will use linear mixed model or generalized linear random effect models as

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appropriate for the outcome variables using three level models available in Stata 14. The random effect models allow for a clearer disentangling of program effect from individual effects and ranking of hospitals based on the outcome measures. The regression models will include the quantitative variables listed in Exhibit 4, time (pre and post), individual level controls (e.g., age, gender, race/ethnicity, comorbid conditions), and hospital level variables (e.g., number of beds, hospital type). These models will address the inter-correlation due to repeated measures overtime. The evaluator will also assess the utility of using interrupted time series models, which are a variation of the models described above. In these models, a binary indicator of time indicates PRIME implementation period versus baseline and the interaction term of the binary time variable with the continuous time variable to allow for the shift in trends between baseline and implementation periods. The evaluator will assess whether the impact of PRIME on race/ethnicity and preferred language required stratified models by assessing the adjusted rates (using the margins command in STATA) of outcomes such as ED visits by race/ethnicity or preferred language in a single model vs. stratified models by race/ethnicity or preferred language. The need for stratified models by DPH or DMPH indicators will be assessed.

Qualitative analyses methods will include thematic analyses of challenges and successful approaches to deal with challenges in PRIME entity annual reports. The approved Five-Year PRIME Plans, which include information from all PRIME entities around Project selection, system background, and planned improvements for meeting PRIME objectives will also be used to develop the context for PRIME implementation. The structured surveys with a key informant at all PRIME entities and semi-structured interviews with a representative sample of key informants will also be analyzed thematically to assess the variations in implementation process employed by PRIME entities. This information will be used to contextualize the quantitative findings and identify the potential sources of success or barriers to achieving targeted performance levels. These analyses allow for identifying more than a single successful approach to achieving improvements in specific Projects.

Qualitative analyses will also assess sustainability of PRIME Projects, by assessing the synergies between PRIME Project objectives with PRIME entities' strategic mission, incorporation of these Projects into the daily routine operations, non-PRIME concurrent activities and projects, and self-reported intentions to continue to gather Project metrics and use them in quality improvement activities after the conclusion of PRIME.

Using both qualitative and quantitative findings, the evaluation will address overarching questions such as aspects of PRIME Projects that could be implemented in other state Medicaid programs.

In addition to the above analyses, the evaluation will compare the self-reported metrics by PRIME entities and metrics calculated based on claims and encounter data with existing national benchmarks. National benchmarks are likely to be available for broadly used metrics such as those developed by NCQA, AHRQ, and CMS. The evaluator will identify such benchmarks, assess comparability with PRIME metrics, and compare PRIME metrics with these benchmarks in the evaluation.

## **Evaluation Limitations**

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Further analyses specific to national data will not be included in this evaluation due to limitations of poor comparability to participating PRIME entities and a significant time lag of available datasets.

In addition, the evaluation will not include analyses of EHR data from PRIME Entities for several reasons. PRIME entities have multiple electronic record systems with different features and capabilities, variations in data collection and storage methods, and different abilities to extract and submit files for external evaluation. In addition to level of effort required to obtain the data (developing and obtaining Data Use Agreements, assessing data limitations and usability, working with each organization to identify the correct information, assisting organizations with limited IT to extract data from their EHRs, setting up secure data transfer protocols, extensive discussion and repeated data extraction to address errors), the extent of the analyses possible with such data depend on the availability of data in an analyzable format. For example, different entities may store the same information in their EHRs in searchable fields, notes, or attached PDF files. These variations reduce the analyzability of the data.

### **Selection of Independent Evaluator, Evaluation Budget, and Timeline**

The State will select an external evaluator that has the expertise, experience, and impartiality to conduct a sophisticated program evaluation that meets all requirements specified in the Terms and Conditions including specified intervention timeframes. Desired qualifications and experience include: multi-disciplinary, health services research training and experience; an understanding of and experience with the Medicaid and Medi-Cal programs; familiarity with California state programs and populations; and experience conducting complex, multi-faceted evaluations of large, multi-site health and/or social services programs. Potential evaluation entities will be assessed on their relevant work experience, staffing levels and expertise, data analytic capacity, proposed resource levels and availability, and the overall quality of their proposal.

In the process of identifying, selecting, and contracting with an independent evaluator, the State will take appropriate measures to prevent a conflict of interest. Specifically, individuals in PRIME entities providing clinical care or managing PRIME Projects will not be part of the external evaluation staff.

The total budget for the evaluation activities is estimated at a total of \$2.2M. This estimated budget amount will cover all evaluation expenses, including salary, fringe, administrative costs, other direct costs such as travel for data collection, conference calls, etc., as well as all costs related to quantitative and qualitative data collection and analysis, and report development. More detail and justification for proposed costs can be seen in the attached Exhibits A, A2, and B.

The State will select and enter into a contract with an independent entity to conduct the evaluation of the PRIME program to meet the timeframes and deliverables. Once approved, the evaluation design will become Attachment S to the Special Terms and Conditions.

The evaluator will receive the semi-annual data reports on metrics submitted by PRIME participants. These data reports are due after the mid-year report measurement periods (January to December each demonstration year) and after the final year-end report measurement periods (July to

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June of each demonstration year). The evaluator will conduct ongoing analyses of these data to inform both the interim and summative evaluation reports.

An interim evaluation report including the same core elements as the final evaluation report will be prepared at the completion of DY14. The State will submit draft of this report to CMS by the end of the 1<sup>st</sup> quarter of DY15. The final interim evaluation report will be submitted within 60 days after receiving CMS' comments on the draft report.

A summative evaluation report that includes analysis of data from DY15 will be prepared by the evaluator. First, a preliminary summative evaluation report will be submitted to CMS within 180 days following the completion of the final demonstration year. This preliminary summative evaluation report will include documentation of outstanding assessments due to data lags. Then, within 360 days of the end of the demonstration, the State will submit the final summative evaluation report for CMS review. Finally, the State will respond to CMS' comments on the final summative evaluation report within 60 days.

The final summative evaluation report will include, at a minimum: an executive summary, a description of the demonstration's programmatic goals and strategies, a description of the study design, a discussion of the findings, conclusions, policy implications, and a discussion of this demonstration within an overall Medicaid context. Exhibit 5 shows the timeline for the major evaluation activities and deliverables.

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## Exhibit 5. PRIME Evaluation Timeline

	DY12 (2016-17)				DY13 (2017-18)				DY14 (2018-19)				DY15 (2019-20)				POST-DEMO (2020-21)			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Evaluation Timeline</b>																				
Draft Evaluation design submitted to CMS	x																			
Final Evaluation design submitted to CMS			x																	
Contract with independent evaluator		x																		
<b>Semi-Annual Data Reports on Metrics from PRIME Entities</b>																				
DY11 final year-end report measurement period	x																			
DY12 mid-year report measurement period			x																	
DY12 final year-end report measurement period					x															
DY13 mid-year report measurement period							x													
DY13 final year-end report measurement period								x												
DY14 mid-year report measurement period										x										
DY14 final year-end report measurement period												x								
DY15 mid-year report measurement period														x						
DY15 final year-end report measurement period																	x			
<b>Evaluation Data Collection and Reporting</b>																				
Quarterly reports from evaluator on evaluation activities for State reporting to CMS						x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Qualitative Data Collection							x	x	x											
Quantitative Data Collection						x	x	x	x	x	x	x	x	x	x	x	x	x		
Interim Evaluation Report with Same Core Elements as Final Evaluation													x							
Final Summative Evaluation Report to CMS																				x

## References

<sup>1</sup> See <http://www.dhcs.ca.gov/provgovpart/Pages/PRIME.aspx>.

<sup>2</sup> <http://cfirguide.org/index.html>