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

CENTERS FOR MEDICARE & MEDICAID SERVICES
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State Demonstrations Group

NOV 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,

[redacted]

Angela D. Garner
Director Division of System Reform Demonstrations

Enclosure
cc: Henrietta Sam-Louie, ARA Region IX

Draft for Discussion

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

Background on This Report

A variety of state reform initiatives help to shape California's health care landscape as well as Medi-Cal service delivery, health outcomes, and costs. One such initiative, the Public Hospital Redesign and Incentives in Medi-Cal (PRIME) program, is part of California's renewed 1115 waiver approved by the Centers for Medicare and Medicaid Services (CMS) on December 30, 2015. The PRIME program aims to expand access and improve health outcomes in California's public safety net hospitals and hospital systems while managing utilization and cost by: establishing or improving infrastructure to manage high-cost populations through a range of interventions (e.g., care management, care transitions, behavioral health integration); expanding capacity through enhanced efficiency and reductions in unnecessary utilization; and building capabilities to support the transition to value-based purchasing.

Under PRIME, the California Department of Health Care Services (DHCS) will play a key role in monitoring public hospital performance, distributing PRIME funds, and providing support and technical assistance for public hospitals participating in the demonstration.

As required by the Special Terms and Conditions (STC) of this waiver, this report provides an evaluation design for the PRIME demonstration, outlining methods to determine whether California's initiative has achieved intended program goals and objectives. It provides a blueprint for moving forward with an evaluation. Subject to CMS' approval of this design, DHCS will select an Independent Evaluator to develop interim and summative evaluation reports over the course of the demonstration.

This evaluation design document is organized as follows:

- Overview of the PRIME Demonstration
- Evaluation Framework
- Methods and Data Sources
- Evaluation Areas
    - Goals, Objectives, and Hypotheses
    - Measures and Measure Stewards
- Selection of Independent Evaluator, Evaluation Budget, and Timeline

Overview of PRIME Demonstration

Building on the experience and outcomes of California's Delivery System Reform Incentive Payment (DSRIP) Program, PRIME is a five-year, $3.7 billion federally funded demonstration that will provide funding to a diverse group of participating designated public hospitals (DPHs) and district and municipal public hospitals (DMPHs) throughout the state (hereafter referred to as "PRIME entities") through incentive payments linked to achieving project metrics and demonstrating improved outcomes.

PRIME entities from across the state submitted five-year plans to DHCS in April 2016. The selected PRIME entities will implement various health care improvement projects across three domains: (1) Outpatient Delivery System Transformation and Prevention; (2) Targeted High-Risk or High-Cost Populations; and (3) Resource Utilization Efficiency. To reflect differences in capacity and resources among California's safety net hospitals, participating DPHs are required to implement at least nine PRIME projects, including a specified number of projects (of which certain projects are required) from each domain. DMPHs, in contrast, are required to implement at least one project across the three domains. PRIME projects under each of the three domains include:

1. **Outpatient Delivery System Transformation and Prevention**
    1.1. Integration of Physical and Behavioral Health
    1.2. Ambulatory Care Redesign: Primary Care
    1.3. Ambulatory Care Redesign: Specialty Care
    1.4. Patient Safety in the Ambulatory Setting
    1.5. Million Hearts Initiative
    1.6. Cancer Screening and Follow-up
    1.7. Obesity Prevention and Healthier Foods Initiative
2. **Targeted High-Risk or High-Cost Populations**
    2.1. Improved Perinatal Care
    2.2. Care Transitions: Integration of Post-Acute Care
    2.3. Complex Care Management for High Risk Medical Populations
    2.4. Integrated Health Home for Foster Children
    2.5. Transition to Integrated Care: Post Incarceration
    2.6. Chronic Non-Malignant Pain Management
    2.7. Comprehensive Advanced Illness Planning and Care
3. **Resource Utilization Efficiency**
    3.1. Antibiotic Stewardship
    3.2. Resource Stewardship: High-Cost Imaging
    3.3. Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals
    3.4. Resource Stewardship: Blood Products

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.

A 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. A project toolkit containing extensive documentation for each project including project rationale, goals and objectives, and key activities to guide project development and implementation is available to PRIME entities.

The project toolkit also includes the specific metrics (clinical event outcomes, potentially preventable events, and patient experience measures) required to be reported by PRIME entities for each selected project. To receive funding, 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.

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. The first payments to PRIME entities were awarded based on the submission and approval of hospital five-year plans. Payments associated with performance will begin September 2016 and will be contingent upon meeting reporting requirements. The demonstration will run until June 30, 2020. For Medi-Cal 2020 waiver documents providing additional details on participating PRIME entities, PRIME projects and metrics, and program funding mechanics, please see DHCS' website.[1]

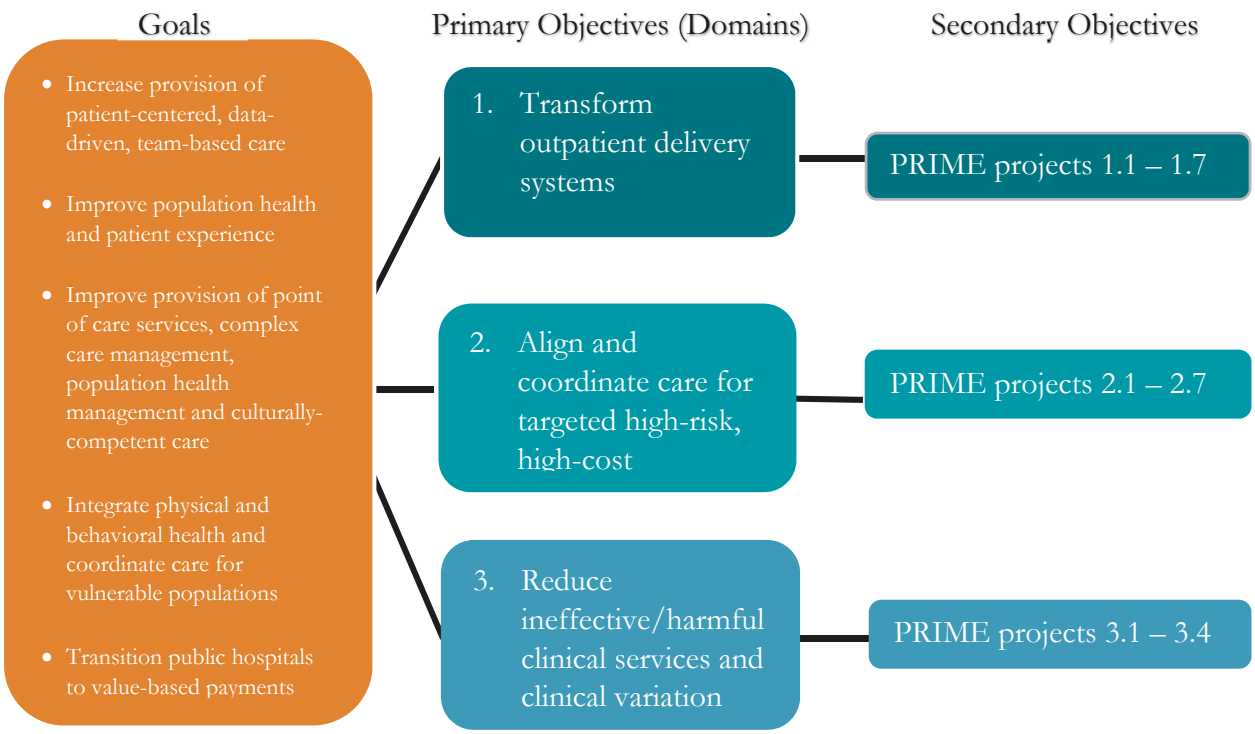
Evaluation Framework

Through PRIME, California is working to support improved health outcomes and system transformation including better care, better quality, and enhanced value by- improving public hospital delivery of care to patients through a range of interventions (e.g., care management, care transitions, and behavioral health integration); expanding the public hospital system's capacity through enhanced efficiency and reductions in unnecessary utilization; and building capabilities to support the transition to value-based purchasing. These goals are supported by three primary objectives (domains), under which PRIME activities (projects) have been organized (see Figure 1).

The PRIME evaluation will be an outcomes-based evaluation. The emphasis of the evaluation will be on how PRIME has impacted patients and providers, and how it has influenced the work of public hospital systems over the five-year demonstration.

[1] See http://www.dhcs.ca.gov/provgovpart/Pages/PRIME.aspx.

Figure 1. Evaluation Framework for PRIME Program in California



The evaluation of the PRIME program will assess its effectiveness, at a safety net system and state level, in the following areas:

1. Transforming outpatient delivery systems with a focus on prevention;
2. Transforming how care for targeted high-risk or high-cost populations is aligned and coordinated;
3. Utilizing resources efficiently;
4. Improving health and health system outcomes that cross PRIME project domains through better care, better quality, and enhanced value;
5. Moving the safety net toward sustainable change in a managed care environment.

Methods

The independent evaluation will be a multi-method, outcomes-focused study to assess the extent to which the California PRIME initiative has achieved the intended program goals and objectives designed to lead to improved quality and value of care provided by California's safety net hospitals and hospital systems. The quality improvement interventions that comprise the PRIME demonstration involve extensive ongoing data collection, reporting, and program monitoring.

The evaluation is separate from these activities, but will build upon the foundation of the program by employing the metrics described in the PRIME Projects and Metrics Protocol.[2]

Both quantitative and qualitative data will be used in evaluating PRIME activities related to strategy, program implementation, effectiveness in collecting information on barriers, challenges, and facilitators in program design and implementation, as well as in identifying the factors associated with success or lack of success in achieving intended outcomes.

Quantitative Data Collection and Analysis

Quantitative methods will be used to evaluate statewide program outcomes using pre- and post-PRIME comparisons, yielding an assessment of the degree to which hypothesized changes have been achieved. The State and CMS will work together to ensure that the PRIME evaluation uses the best data available. Hospitals participating in the PRIME program have committed to collecting and reporting prescribed sets of carefully defined measures associated with the PRIME projects. These metrics will be used to quantify facets of each of the three PRIME objectives (domains): outpatient delivery system transformation (domain 1), care coordination for targeted high-risk or high-cost populations (domain 2), and efficiency in utilization of resources by public hospitals (domain 3), including improved health and health care delivery outcomes related to Project specific focus areas.

The performance metrics described in detail below comprise the greater part of the data designated for use in conducting the PRIME evaluation. The quantitative analysis of these metrics conducted as part of the evaluation will test the extent and direction of hypothesized changes over time, by comparing baseline data on these metrics to post-implementation data collected and reported over the course of the demonstration. The metrics will provide a baseline in the first year, and the metrics will be reported to the state twice per year.

The primary analytic method to assess the extent to which the PRIME project objectives are achieved over time will be univariate and multi-variate analysis for pre- and post-testing of a single group where the members of the group function as their own controls and multiple regression analysis will be used to determine group differences using controls and adjustments where appropriate and available.

Aggregate quantitative data available for the evaluation includes quality metrics on priority indicators reported to DHCS by the 23 Medi-Cal Managed Care Plans as well as selected CMS Core Measures calculated by DHCS. Evaluators could potentially use Office of Statewide Health Planning and Development (OSHPD) data for quantitative analysis, although time lags for data reporting may prevent the availability of this information in a timely manner. Where feasible, these data will be employed in developing a multi-variate model, for example, to support risk-adjustment. The OSHPD provides a wide range of relevant hospital data including annual financial disclosure reports, emergency department encounters by facility, quarterly utilization data, and ambulatory care sensitive hospital admissions. Additional data sources may include: Medicaid encounter and claims

[2] Medi-Cal 2020 Demonstration Special Terms and Conditions, Attachment Q. See http://www.dhcs.ca.gov/provgovpart/Documents/MC2020_AttachmentQ_PRIMEProjectsMetrics.pdf.

data, enrollment data, financial data, managed care contracting data, all dependent on timely availability.

The primary limiting factor related to the quantitative analyses conducted as part of the PRIME evaluation is the lack of comparison groups. The primary data source will be the PRIME metrics that have been painstakingly developed specifically as part of this program; and data collection and reporting on these metrics begins with the baseline data collection in the first year, with semi-annual reporting requirements thereafter. Beyond this, the program and evaluation budgets do not contemplate any further data collection that would support additional, more rigorous quasi-experimental evaluation involving an interrupted time series design. The reporting will include a robust discussion of the data limitations and will discuss the generalizability of results in the context of those limitations.

Performance Metrics

Performance metrics will be reported by PRIME entities in the Mid-Year and Year-End reports. Each PRIME project will be measured by a set of required metrics identified in the PRIME Projects and Metrics Protocol (Attachment Q). Using these metrics will ensure consistency and leverage the value of the strong foundation provided by the metrics and specifications developed over time with input from a wide range of involved stakeholders.

These metrics were designed and identified through a rigorous 18-month 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, 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. The Metric Specification Manual will be made available to the evaluator.

For PRIME projects where the current set of standard metrics does not adequately assess successful transformation (approximately 20% of all metrics) innovative metrics have been identified. 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 innovative metrics are noted with an asterisk in the tables that follow.

Qualitative Data Collection and Analysis

Qualitative data collection and analysis methods will be employed to contextualize the quantitative data by enabling the evaluators to access more nuanced and detailed aspects of the PRIME demonstration implementation and outcomes. Qualitative data collection activities support the development of the researchers' understanding of the complex phenomena at play in the

implementation of a range of quality improvement initiatives across a large number of widely variable institutions and communities across the State of California. In addition, qualitative methods enable researchers to take a more tailored, situation-specific approach to information gathering, as well as providing opportunities to address questions or concerns that may arise from reported quantitative data.

The objectives of qualitative data collection in evaluation are to provide robust information to answer questions about program outcomes and impact; to use data collection methods appropriate for specific types of stakeholders; and to support the collection and analysis of contextual information and input to help explain factors that may affect program implementation and outcomes.

Qualitative data collection strategies may include: document and archival reviews; technical expert panel review to consider intended and unintended impacts based on contextual features; case study approaches to allow for comparison across communities and/or PRIME entities and assess policy options and contextual factors in real world scenarios; qualitative program data reviews to investigate programmatic data provided by PRIME entities or other stakeholders on outputs and outcomes, among other topics; and key informant interviews with stakeholders and other relevant individuals or officials related in some way to program implementation, outcomes, and so on.

Participating PRIME entities will provide narratives on data methodology, reporting infrastructure, improvements and interventions implemented over the course of PRIME, lessons learned in meeting project objectives, as well as challenges and planned remediation for any metric targets not met. Evaluators will also have access to the approved 5-Year PRIME Plans, which include information from all PRIME entities around project selection, system background, and planned improvements for meeting PRIME objectives, as well as to quarterly monitoring reports submitted by DHCS to CMS that reflect overall PRIME progress, and summary data submitted by the DPHs to DHCS regarding the achievement of the required APM targets in 2018, 2019 and 2020.

Key informant interviews are structured interviews that offer a flexible and effective—albeit potentially resource-intensive—method for assessing perceptions and attitudes regarding program activities and outcomes and for supplementing quantitative findings. Interviews can provide a rich source of data, particularly where relevant issues are too diffuse or nuanced for closed-ended questions. Interviews will be conducted with PRIME participating entities, program personnel, State officials, and others as needed to provide background and insight into the activities and effectiveness of the PRIME program.

Evaluation Areas

1: Evaluating the extent to which PRIME entities have made progress on outpatient delivery system transformation

PRIME entities implementing Outpatient Delivery System Transformation and Prevention projects (Domain 1) will seek to integrate physical and behavioral health care delivery; develop culturally and linguistically appropriate, multi-disciplinary care teams; restructure and enhance data infrastructure within their ambulatory care systems with a focus on preventive services and early diagnosis and treatment; develop effective linkages to specialty care, including mental health and substance use services, as well as other needed services that support the social and well-being needs of patients; and improve efficiency, patient safety, and patient care experiences.

We hypothesize that the following will be true across California's public hospital system as projects in Domain 1 are implemented:

- Integration of behavioral health with primary care will increase, in order to identify behavioral health diagnoses early, treat patients rapidly, and ensure that treatments for medical and behavioral health conditions are compatible;
- Through ambulatory care redesign and infrastructure investment, patients will experience access to high quality, efficient and equitable primary and specialty care;
- Patient outpatient safety will improve through the implementation of standardized monitoring, notification, and workflows;
- Evidence-based approaches to achieving clinical targets such as tobacco cessation, hypertension control, and appropriate aspirin use will be identified, standardized, and implemented (through Million Hearts® Initiative);
- Evidence-based approaches to high clinical impact cancer screening and follow-up services will be identified, standardized, and implemented; and
- Evidence-based approaches to obesity prevention and hospital healthier food initiatives will be identified, standardized, and implemented.

The outcomes, measures, and data sources that will be used in the PRIME evaluation to test these hypotheses are listed below in Table 1.

Table 1: Outpatient Delivery System Transformation Outcome Variables and Measures

Primary Topic	Outcome	Measure Name	Measure Steward*
Integration of Behavioral Health and Primary Care	Increased care coordination/ management	Care Coordinator Assignment	University of Washington/Coordinated Care Initiative*
	Increased control of diabetes	Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (NQF# 0059)	NCQA
	Increased depression remission	Depression Remission at 12 Months CMS159v4 (NQF# 0710)	MN Community Measurement
	Increased screening and follow-up	Screening for Clinical Depression and Follow-Up (NQF# 0418)	CMS
	Increased screening	Alcohol and Drug Misuse (SBIRT)	Oregon CCO
	Increased screening tools, access to services	Tobacco Assessment and Counseling (NQF# 0028)	AMA-PCPI
Ambulatory care redesign: Primary Care	Decreased preventable acute care utilization	Prevention Quality Overall Composite #90	AHRQ
	Increased screening	Alcohol and Drug Misuse (SBIRT)	Oregon CCO
	Improved patient experience with providers	CG-CAHPS: Provider Rating (NQF# 0005)	AHRQ
	Increased screening	Colorectal Cancer Screening (NQF# 0034)	NCQA
	Increased control of diabetes	Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (NQF# 0059)	NCQA
	Improved health indicators	Controlling Blood Pressure (NQF # 0018)	NCQA
	Increased ability to reduce disparities in health and health care	Documented REAL and/or SO/GI disparity reduction plan	DHCS*
	Increased provision of recommended preventive health services	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (NQF# 0068)	NCQA
	Improved identification of disparities in health and health care	Primary Care Redesign project metrics stratified by REAL and SO/GI categories	DHCS*
	Reduced disparities in health and health care	REAL and/or SO/GI disparity reduction	DHCS*
	Increased screening	Screening for Clinical Depression and follow-up (NQF# 0418)	CMS

Primary Topic	Outcome	Measure Name	Measure Steward*
	Increased capture of SDOH	REAL data completeness	DHCS*
	Increased capture of SDOH	SO/GI data completeness	DHCS*
	Increased screening, access to services	Tobacco Assessment and Counseling (NQF #0028)	AMA-PCPI
Ambulatory care redesign: Specialty Care	Improved communication and coordination between providers	Closing the referral loop: receipt of specialist report (CMS50v4)	CMS
	Decreased acute care utilization	DHCS All-Cause Readmissions	DHCS
	Improved health indicators	Influenza Immunization (NQF# 0041)	NCQA
	Decreased preventable acute care utilization	Post procedure ED visits	San Francisco Health Network (SFHN)*
	Improved communication and coordination between providers	Referral Reply Turnaround Rate	Los Angeles County Department of Health Services (LAC DHS), SFHN*
	Increased alternatives to face-to-face specialty encounters	Specialty Care Touches: Specialty expertise requests managed via non-face to face specialty encounters	Los Angeles County Department of Health Services, UC Davis *
	Increased screening, access to services	Tobacco Assessment and Counseling (NQF #0028)	AMA-PCPI
Patient safety in the Ambulatory Setting	Increased follow-up for diagnostic testing	Abnormal Results Follow-Up	Alameda Health System (AHS)*
	Increased monitoring for patients on persistent medications	Annual Monitoring for Patients on Persistent Medications (NQF# 2371)	NCQA
	Increased monitoring for patients on persistent medications	INR Monitoring for Individuals on Warfarin (NQF# 0555)	CMS
Million Hearts® Initiative	Increased provision of recommended preventive health services	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (NQF# 0068)	NCQA
	Improved health indicators	Controlling Blood Pressure (NQF # 0018)	NCQA
	Increased use of screening tools, follow-up plan	PQRS # 317 Preventative Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	CMS
	Increased screening, access to services	Tobacco Assessment and Counseling (NQF #0028)	AMA-PCPI

Primary Topic	Outcome	Measure Name	Measure Steward*
Cancer Prevention and Follow-up	Increased screening	Breast Cancer Screening (NQF# 2372)	NCQA
	Increased screening	Cervical Cancer Screening (NQF# 0032)	NCQA
	Increased screening	Colorectal Cancer Screening (NQF# 0034)	NCQA
	Increased follow-up for abnormal screening exams	BIRADS to Biopsy	Los Angeles County Department of Health Care Services, San Francisco Health Network*
	Increased follow-up for abnormal screening exams	Receipt of appropriate follow-up for abnormal CRC screening	San Francisco Health Network *
Obesity Prevention	Increased screening and follow-up	BMI Screening and Follow-up (NQF# 0421)	CMS
	Increased hospital food quality	Partnership for a Healthier America's Hospital Health Food Initiative external food services verification	DHCS
	Increased screening, access to services	Weight Assessment & Counseling for Nutrition and Physical Activity for Children & Adolescents (NQF# 0024)	NCQA

* Denotes innovative metrics.

2: Evaluating the extent to which PRIME entities have aligned and coordinated care for targeted high-risk or high-cost populations

PRIME entities implementing projects in Domain 2 will make investments in care integration and coordination for targeted high-risk or high-cost populations, including: women and newborns; individuals transitioning from inpatient care to outpatient settings; individuals in need of complex care management; foster children; individuals transitioning into society from incarceration; individuals with chronic non-malignant pain management; and individuals who would benefit from palliative care and end of life planning.

We hypothesize that the following will be true across California's public hospital system as projects in Domain 2 are implemented:

- Perinatal care quality and safety will be improved;
- Coordination and continuity of health care will increase for high-risk patients, including those with chronic health conditions, behavioral health conditions and/or housing instability, as they move from hospital to the ambulatory care settings;
- Complex care management strategies for targeted high-risk patients will be implemented;
- Providers' and care teams' ability to identify and help manage patients' chronic non-malignant pain will be improved; and

- Access to care in alignment with patient preferences will increase for patients facing advanced illness.

The outcomes, measures, and data sources that will be used in the PRIME evaluation to test these hypotheses are listed below in Table 2.

Table 2: Targeted High-Risk or High-Cost Populations Outcome Variables and Measures

Primary Topic	Outcome	Measure	Measure Steward*
Improvements in Perinatal care	Increased support and rates of exclusive breastfeeding	Exclusive Breast Milk Feeding (PC-05) (NQF# 0480)	JNC
		Baby Friendly Hospital designation	Baby-Friendly USA
	Decreased maternal and neonatal morbidity and mortality	OB Hemorrhage: Massive Transfusion	CMQCC
		OB Hemorrhage: Total Products Transfused	CMQCC
		Severe Maternal Morbidity (SMM) per 100 women with obstetric hemorrhage	CMQCC
		Unexpected Newborn Complications (UNC) (NQF# 0716)	CMQCC
	Decreased cesarean section rate	PC-02 Cesarean Section (NQF# 0471)	JNC
	Increased prenatal/postpartum care	Prenatal and Postpartum Care (PPC) (NQF# 1517)	NCQA
Care transitions: Integration of Post-Acute Care	Decreased acute care utilization	DHCS All-Cause Readmissions	DHCS
	Increased patient capacity for self-management	H-CAHPS: Care Transition Metrics (NQF# 0166)	AHRQ
		Medication Reconciliation: 30 days (NQF# 0097)	NCQA
		Reconciled Medication List Received by Discharged Patients (NQF# 0646)	AMA-PCPI
	Improved communication and coordination between care teams	Timely Transmission of Transition Record (NQF# 0648)	AMA-PCPI
Complex care management for high-risk medical populations	Increased care coordination/ management	Care Coordinator Assignment	University of Washington/ Coordinated Care Initiative
		Timely Transmission of Transition Record (NQF# 0648)	AMA-PCPI
	Improved patient safety	Medication Reconciliation: 30 days (NQF# 0097)	NCQA
	Decreased preventable acute care utilization	Prevention Quality Overall Composite PQI #90	AHRQ

Primary Topic	Outcome	Measure	Measure Steward*
Integrated Health home for foster children	Increased screening	Developmental Screening in the First Three Years of Life (NQF# 1448)	NCQA
		Screening for Clinical Depression and follow-up (NQF# 0418)	CMS
		Well Child Visits – First 15 months of life (NQF# 1392)	NCQA
		Well Child Visits - Third, Fourth, Fifth, and Sixth Years of life (NQF# 1516)	NCQA
		Adolescent Well-Care Visit	NCQA
	Increased screening, access to services	Tobacco Assessment and Counseling (13 yo and older) (Variation on NQF #0028)	AMA-PCPI
	Improved care coordination and communication	Screening for Clinical Depression and follow-up (NQF# 0418)	CMS
		Documentation of Current Medications in the Medical Record (0-18 yo) (Variation on NQF# 0419)	CMS
Transition to Integrated Care: post incarceration	Increased screening	Screening for Clinical Depression and follow-up (NQF #0418)	CMS
		Alcohol and Drug Misuse (SBIRT)	Oregon CCO
	Increased screening, access to services	Tobacco Assessment and Counseling (NQF #0028)	AMA-PCPI
	Improved health indicators	Controlling Blood Pressure (NQF # 0018)	NCQA
	Decreased preventable acute care utilization	Prevention Quality Overall Composite #90	AHRQ
Chronic Non-malignant pain management	Improved prescribing practices	Assessment and Management of Chronic Pain: Patients with chronic pain prescribed an opioid who have an opioid agreement form and an annual urine toxicology screen	AHRQ
	Increased screening	Alcohol and Drug Misuse (SBIRT)	Oregon CCO
		Screening for Clinical Depression and follow-up (NQF #0418)	CMS
	Improved prescribing practices	Patients with chronic pain on long term opioid therapy checked in PDMPs	AHRQ/SFHN, AHS, UCSD *

Primary Topic	Outcome	Measure	Measure Steward*
	Increased use of multi-modal pain management	Treatment of Chronic Non-Malignant Pain with Multi-Modal Therapy	SFHN, AHS, UCSD *
Comprehensive Advanced illness planning and care	Increased access to palliative care services	Ambulatory Palliative Care Team Established	University of California, San Francisco (UCSF) *
	Increased concordance between patient/family preference and care	MWM#8 - Treatment Preferences (Inpatient) (NQF# 1641)	UNC Chapel Hill
		MWM#8 - Treatment Preferences (Outpatient)	University of California, San Francisco (UCSF) + CMS *
	Increased advanced care planning	Advance Care Plan (NQF# 0326)	NCQA
	Increased timely access to palliative care services	Palliative Care Service Offered at Time of Diagnosis of Advanced Illness	University of California, San Francisco (UCSF) *
		Proportion Admitted to Hospice for Less than 3 Days (NQF# 0216)	ASCO

* Denotes innovative metrics.

3: Evaluating the extent to which PRIME entities are utilizing resources more efficiently

PRIME entities implementing Resource Utilization Efficiency projects (Domain 3) will seek to reduce overuse and misuse of high-cost services; eliminate the use of ineffective or harmful services; and address inappropriate underuse of effective services within the public hospital system.
We hypothesize that the following will be true across California's public hospital system as projects in Domain 3 are implemented:

- Inappropriate antibiotic utilization for non-bacterial diseases will decline, and antibiotic use for bacterial infections will be optimized, with a special emphasis on agents with broad spectrum activity;
- Inappropriate utilization of high-cost imaging services will decline;
- Inappropriate use of high-cost pharmaceutical therapies will decline, and utilization of evidence-based and population resource stewardship approaches to the use of high-cost pharmaceutical therapies will increase;
- Wastage of blood products, both products dispensed to the patient care area and those in hospital inventory but never dispensed, will decrease, and appropriate use of blood and blood products by health providers will increase.

The outcomes, measures, and data sources that will be used in the PRIME evaluation to test these hypotheses are listed below in Table 3.

Table 3: Resource Utilization Efficiency Outcome Variables and Measures

Primary Topic	Outcome	Measure	Measure Steward*
Antibiotic Stewardship	Reduced inappropriate use, increased resource stewardship	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis (NQF# 0058)	NCQA
		Avoidance of Antibiotic Treatment with Low Colony Urinary Cultures *	University of California Davis (UCD), UC Irvine (UCI), UC San Diego (UCSD)
		National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF# 2720)	CDC
		Prophylactic antibiotics discontinued at time of surgical closure	CMS
		Reduction in Hospital Acquired Clostridium Difficile Infections	NHSN
Resource Stewardship: High-cost imaging	Reduced inappropriate use, increased resource stewardship	Imaging for Routine Headaches (Choosing Wisely)	Washington Health Alliance *
		Inappropriate Pulmonary CT Imaging for Patients at Low Risk for Pulmonary Embolism (NQF# 0667)	ACEP
		Use of Imaging Studies for Low Back Pain (red flags, no time limit) (Variation on NQF# 0052)	LAC Department of Health Services*
		Use of Imaging Studies for Low Back Pain (NQF# 0052)	NCQA
Resource Stewardship: Therapies involving high-cost pharmaceuticals	Reduced inappropriate use, increased resource stewardship	Adherence to Medications	Alameda Health Systems (AHS) *
		Documentation of Current Medications in the Medical Record (NQF# 0419)	CMS
		High-Cost Pharmaceuticals Ordering Protocols	AHS *
Resource Stewardship: Blood products	Reduced wastage, increased resource stewardship	ePBM-01 Pre-op Anemia Screening, Selected Elective Surgical Patients	AABB/TJC
		ePBM-02 Pre-op Hemoglobin Level, Selected Elective Surgical Patients	AABB/TJC
		ePBM-03 Pre-op Type and Crossmatch, Type and Screen, Selected elective Surgical Patients	AABB/TJC
		ePBM-04 Initial Transfusion Threshold	AABB/TJC

Primary Topic	Outcome	Measure	Measure Steward*
		ePBM-05 Outcome of Patient Blood Management, Selected Elective Surgical Patients	AABB/TJC

* Denotes innovative metrics.

4: Evaluating the impact of the PRIME demonstration on health outcomes and other health system measures that cross project domains

Across demonstration projects and interventions, PRIME entities will be working to support cross-cutting outcomes related to the Triple Aim of improved patient experience, improved population health, and reduced health care costs. We hypothesize that the following will be true across California's public hospital system as projects under the PRIME demonstration, as a whole, are implemented:

- Health indicators for patients with chronic conditions, including those with both physical and behavioral chronic conditions, will improve;
- Patient experience will improve;
- Disparities in health and the receipt of health care (e.g., targeted prevention services) will decline;
- Preventable hospital use will decline;
- DPHs will demonstrate a shift from fee-for-service payment to value-based payment systems; and

The outcomes, measures, and data sources that will be used in the PRIME evaluation to test these hypotheses are listed below in Table 4.

Table 4: Health and Health System Outcome Variables and Measures

Primary Topic	Outcome	Measure	Measure Steward
Patient health indicators	Increased control of diabetes	Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (NQF# 0059)	NCQA
	Increased control of high blood pressure	Controlling Blood Pressure (NQF# 0018)	NCQA
	Reduced depression remission	Depression Remission at 12 Months CMS159v4 (NQF# 0710)	MN Community Measurement
Patient experience	Improved patient experience with providers	CG-CAHPS: Provider Rating (NQF# 0005)	AHRQ
Health disparities	Reduced disparities in health and health care	Documented REAL and/or SO/GI disparity reduction	DHCS
Hospital re-admissions	Reduced preventable hospital re-admissions	DHCS All-Cause Readmissions	DHCS

Primary Topic	Outcome	Measure	Measure Steward
Payment system	Shift to value-based payment system	DPHs meeting statewide APM targets	DHCS
	Shift to value-based payment system	Types of APMs (e.g., shared savings, bundled payments, capitation) and variability across PRIME entities	DHCS – methodology to be defined

5: Determining key lessons learned about safety net transformation in a managed care environment and sustainability from the perspective of PRIME stakeholders

Primary data collection will be used to inquire about impacts on Medi-Cal members, patients, and families, as well as PRIME project design and implementation experiences, barriers to and facilitators of project success, lessons learned regarding sustainability, and policy implications. The evaluation will include semi-structured interviews, and/or surveys of managers and clinical staff from PRIME entities; DHCS staff and contractors; and stakeholders to gather information about the following questions:

- What barriers were encountered by PRIME entities in implementing PRIME projects? What facilitated successful implementation? Were there unintended consequences of implementing certain projects? What were the lessons learned?
- How has the PRIME program demonstrated program and project-specific sustainability in a managed care environment?
- How did learnings from the PRIME program shape DHCS' Medi-Cal Quality Strategy and long-range planning to support better health for Medi-Cal beneficiaries? How did the learnings influence the development and implementation of new initiatives?
- What recommendations about program implementation can be gleaned to support other state Medicaid programs and initiatives around the country? What PRIME program elements could be replicated in other state Medicaid programs?
- How did the PRIME program interact with other health care reform initiatives underway such as waiver programs, health homes, quality collaboratives, etc.? How did it contribute to alignment with other programs at the state or federal level?
- How did the PRIME entities use Race, Ethnicity, and Preferred Language and Sexual Orientation and Gender Identity data to provide culturally competent care as part of an understanding of social determinants of health?
- What unique contributions did the PRIME program make, in light of the contributions and interactions with other initiatives?

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 $500,000 per year for four years (July 1, 2016 to June 30, 2020). 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 will provided through the evaluator selection process.

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 Standard 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 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 1st 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 include 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, and policy implications, and a discussion of this demonstration within an overall Medicaid context.

Appendix B.1 of the evaluation design includes a graphical timeline laying out the major evaluation activities and deliverables across the life of the project.

Appendix A.1

PRIME Domains, Projects, and Number of PRIME Entities Selecting Projects

PRIME Projects	Number of DPHs	Number of DMPHs		Total
Domain 1: Outpatient Delivery System Transformation and Prevention				
1.1 Integration of Physical and Behavioral Health*	17	6		23
1.2 Ambulatory Care Redesign: Primary Care*	17	7		24
1.3 Ambulatory Care Redesign: Specialty Care*	17	2		19
1.4 Patient Safety in the Ambulatory Setting	6	9		15
1.5 Million Hearts Initiative	6	10		16
1.6 Cancer Screening and Follow-Up	6	9		15
1.7 Obesity Prevention and Healthier Foods Initiative	2	7		9
Domain 2: Targeted High-Risk or High-Cost Populations				
2.1 Improvements in Perinatal Care*	16	4		20
2.2 Care Transitions: Integration of Post-Acute Care*	17	13		30
2.3 Complex Care Management for High Risk Medical Populations*	17	9		26
2.4 Integrated Health Home for Foster children	4	0		4
2.5 Transition to Integrated Care: Post Incarceration	3	2		5
2.6 Chronic Non-Malignant Pain Management	8	5		13
2.7 Comprehensive Advanced Illness Planning and Care	5	8		13
Domain 3: Resource Utilization Efficiency				
3.1 Antibiotic Stewardship	5	9		14
3.2 Resource Stewardship: High-Cost Imaging	5	4		9
3.3 Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals	7	1		8
3.4 Resource Stewardship: Blood Products	2	4		6

* Required for DPHs

Source: California Department of Health Care Services (DHCS), PRIME Project Selection Matrix. Available at: http://www.dhcs.ca.gov/provgovpart/Documents/PRIME/PRIMEProjectSelections-Web.pdf

Appendix B.1

Proposed 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
Evaluation Timeline																				
Evaluation design submitted to CMS	x																			
Contract with independent evaluator		x																		
Semi-Annual Data Reports on Metrics from PRIME Entities																				
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			
Evaluation Data Collection and Reporting																				
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				
Qualitative Data Collection		x x		x x		x x		x x		x x		x x		x x						
Interim Evaluation Report with Same Core Elements as Final Evaluation													x							
Preliminary Summative Evaluation Report Submitted to CMS																			x	
Final Summative Evaluation Report to CMS																				x