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



State Demonstrations Group

March 16, 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 reviewed the proposed evaluation designs for California Children's Services (CCS), Seniors and Persons with Disabilities (SPD), Dental Transformation Initiative (DTI), and Global Payment Program (GPP) authorized under the section 1115(a) demonstration entitled "Medi-Cal 2020" (11-W-00193/9). We have completed a review of the evaluation designs in accordance with the special terms and conditions and have enclosed our comments and recommendations on the evaluation designs.

If you have any questions or would like to discuss our recommendations, please contact your project officer, Ms. Sandra Phelps, at either (410) 786-1968 or by email at <u>Sandra.Phelps@cms.hhs.gov</u>.

Sincerely,

/s/

Angela D. Garner Director Division of System Reform Demonstrations

Enclosures

cc: Henrietta Sam-Louie, ARA Region IX

Medi-Cal 2020 Demonstration: Draft Evaluation Designs for the California Children's Services (CCS), Seniors and Persons with Disabilities (SPD), Dental Transformation Initiative (DTI), and Global Payment Program (GPP)

CMS Feedback February 8, 2017

Summary Findings

- 1. CMS recommends more alignment between the demonstration goals/objectives for the initiative, the research questions, and the hypotheses for the four evaluation designs. Because this relationship is not clear in each of the designs, it is difficult to fully assess whether the proposed measures and data analyses processes are appropriate.
- 2. CMS recommends the state require each initiative to use a consistent format in describing its evaluation plan to assure that required topics are addressed. CMS further recommends the following sections be included:
 - a. Demonstration initiative goals/objectives
 - b. Research questions and hypotheses
 - c. Evaluation Design and approach
 - d. Performance measures, including a discussion of establishing baseline; numerators and denominators if self-developed measures; and performance targets or goals (i.e., expectation of achieving statistical significance or gap-togoal methodology, as appropriate)
 - e. Data collection or data sources (by performance measure)
 - f. Data analysis strategy including a discussion of challenges and proposed solutions.
 - g. Timeline which highlights key milestones and deliverable dates
 - h. Independent evaluator
- 3. CMS recommends the state standardize the language for "evaluator selection" across all of the proposed evaluation designs, unless there is an articulated reason for why they should be different. In addition, CMS recommends clarifying whether it is acceptable for one independent contractor to conduct more than one of the evaluations, or if an independent contractor must conduct each evaluation.

Demonstration Initiative-Specific Findings

A. California Children's Services (CCS) Draft Evaluation Design

Goals and Objectives

A1. There is inconsistency between the description of the goals of the pilot projects and the objectives of the evaluation. CMS recommends revising the goals and objectives to promote better alignment. The pilot projects' goals are described as "achieving the desired outcomes related to timely access to care, improved coordination of care, promotion of community-based services, improved satisfaction with care, improved health outcomes, and greater cost-effectiveness." However, the discussion of the objectives of the evaluation raises additional dimensions of focus including quality and satisfaction with the delivery and reimbursement of services. The evaluation objectives also commit to assess the pilot project's ability to "maintain and enhance their health and functioning and meet their developmental needs", which is potentially a broader commitment than "improved health outcomes" as described in the pilot projects goals.

A2. The goals/objectives or the research questions/hypotheses would be stronger if there were some sense of the target for improvement.

A3. The hypotheses would be stronger if they incorporated the comparisons as part of the statement. For example: What is the impact of providers' satisfaction with the delivery of and the reimbursement of services in the ACO model as compared with the Medi-Cal Managed Care Plan model?

Evaluation Design and Methods

A4. The section states that data "will be reported at the beneficiary, provider, health plan, and statewide levels;" however it is not clear throughout the remainder of the discussion whether all of the data will be reported as such or which data will be reported at which level.

A5. The proposed strategy in using "pre and post comparisons" is not clear. Is the state planning to compare changes in outcomes for individual beneficiaries (longitudinal design) across the pre and post periods, or compare the differences in outcomes for two groups of CCS children in the pre- and post-periods respectively (interrupted time-series design)? We recommend that the state consider a difference-in-differences design, if there are counties where the CCS services will not be incorporated into managed care or an ACO. CCS children from these counties can serve as a comparison group. Data will have to be obtained for the comparison group for the pre- and post-periods for the differences design to be feasible. This design allows for better causal inference of the impact of the CCS pilot in improving outcomes for children in counties where the pilot was implemented, relative to the comparison group.

Evaluation Measures

A6. The enrollment and demographic information is useful; however, given the stated evaluation goals, these are not measures that assess progress against the demonstration goals/objectives. These measures are more appropriate for quarterly or annual reporting measures as stated. CMS recommends including more relevant measures.

Access to Care

A7. The comparison groups are confusing. The Introduction implies that two delivery models are being tested: MCPs and ACOs, however language later in the section implies otherwise. The hypothesis would be stronger if the comparison was included in the sentence (e.g., pre vs. post pilot and non-MCP/ACO vs. MCP/ACO) and a sense of directionality was provided (e.g., no difference, greater than, or less than). For example, "The percent of children and young adults 12 months-2 years of age who had a visit with a PCP will be greater post pilot implementation versus pre pilot implementation and in MCP/ACO pilots versus non MCP/ACO pilots. "

A8. The hypothesis defines access as timely, appropriate, high quality, and well coordinated. The identified measures do not address all of these areas. For example, how will timeliness of services be measured? Referral to a special care center is not time-limited where the authorization for service must occur within XX number of days. Similar point for the depression screening and follow-up performance measure. Lastly, how will care coordination be measured?

Client Satisfaction

A9. The hypothesis would be stronger if the comparison was included in the sentence (e.g., pre vs. post pilot and non-MCP/ACO vs. MCP/ACO) and a sense of directionality was provided (e.g., no difference, greater than, or less than).

Provider Satisfaction

A10. CMS recommends clarifying the measure description to clearly state it is assessing satisfaction with the delivery of services, as well as reimbursement of services to align with the evaluation question and hypothesis.

A11. Given that a survey tool will be used, CMS recommends the state provide more information regarding the types of questions, sampling methodology, and analysis process. Further, CMS suggests the state clarify if the same satisfaction survey tool will be used for ACO, MCP and Non-ACO/MCP.

Quality of Care

A12. The hypothesis addresses topics of cost-effectiveness and coordination, which go beyond the evaluation question (and are addressed by subsequent sections of the design). CMS recommends the hypothesis be rewritten to focus specifically on quality of care, unless the state will also define how it will measure improved care coordination.

A13. There is an emphasis on process measures. CMS recommend the state also consider adding outcome related measures, such as reducing pediatric all-cause readmissions to the hospital or controlling HbA1c levels. Since providing effective care coordination is a demonstration objective, the state could consider outcome measures that can be positively impacted by well-coordinated care.

Care Coordination

A14. The link to the indicators in the FECC Survey is not accessible so CMS is unable to assess the appropriateness of this survey relative to the stated measure.

A15. The utilization indicators listed for Care Coordination make it difficult to determine if improved care coordination is occurring. See comment above under Quality regarding the use of outcome measures that are more likely to indicate if care coordination is having the desired effect. For emergency room use, CMS asks the state to consider applying an indicator that measures avoidable emergency room use to determine if the conditions that prompt an emergency room visit could be treated in a primary care or urgent care setting rather than at the emergency room. To measure the effectiveness of care coordination for mental health, consider using a measure like follow-up after hospitalization for mental illness.

B. Seniors and Persons with Disabilities (SPD) Draft Evaluation Design

Evaluation Objectives

B1. There are no stated research questions or hypotheses. CMS recommends the state develop research questions related to the goals/objectives of the SPD initiative, which encompass the three domains of focus articulated in the STCs – access to care, quality of care, and cost of care. Each research question should have a hypothesis or set of hypotheses that will be evaluated.

General Approach and Evaluation Design

B2. The section states that data "will be reported at the beneficiary, provider, health plan, and statewide levels", however, it is not clear throughout the remainder of the discussion whether all of the data will be reported as such or which data will be reported at which level.

B3. The proposed study design in using "pre and post comparisons" is not clear. Does the state plan to use an interrupted time-series design comparing outcomes for groups of SPD beneficiaries before and after transition into managed care? Will the differences in beneficiary characteristics between the pre-transition and post-transition groups be accounted for using suitable matching/weighting/regression methods? CMS recommends that the state's evaluator consider methods that allow for causal inference beyond merely comparing descriptive statistics for outcomes across the pre and post periods. For instance, the evaluator could use a comparison group comprised of SPD beneficiaries in counties that did not transition into managed care during the study period, and use a difference-in-differences design comparing changes in outcomes for beneficiaries in the intervention and comparison counties across the pre- and post-periods.

Data Sources and Types

B4. CMS recommends the data sources and the individual measures be aligned so it is clear which measures are derived from which data sources.

B5. The analysis described later in the document proposes to use data from a qualitative survey conducted by Carrie Graham; however, it is not clear whether this data is publicly available or if she has provided permission to use the data for the purpose of the evaluation.

Baseline Data and Pre-Transition Evaluation

B6. The state indicates that qualitative interviews will be conducted with the pre-transition population, however there is no discussion of how the population will be selected, the process for conducting the interviews, or examples of the types of questions or domains that will be addressed.

B7. For the Access to Care measures, CMS recommend that the state specify which of the HEDIS measures will be used to assess access to care, and the Network Access indicators be further defined. For Time and Distance, only distance (number of miles to primary care provider) will be measured, but not drive time. For type of specialists, will the state list the type of available specialists within a given distance to beneficiary's residences? What exactly will be captured and how will it be used for the evaluation?

B8. For the Quality of Care measures, the plan refers to "see attached NCQA measure specifications;" however it is unclear which attachment is appropriate to review. Ambulatory care is presented as a subset to All-Cause Readmission; however, they are separate measures. Please clarify if this is a formatting error or if there is some other metric that the state plans to use. The data sources description for Quality of Care measures, like Comprehensive Diabetes Care, indicates that the state will use FFS claims data to calculate performance rates. There is no indication if data collection will be administrative only or hybrid and if the FFS and MCP data collection methodologies will be consistent.

B9. CMS recommends the state clarify which eight indicators related to comprehensive diabetes care will be used. Currently, the HEDIS indicators for comprehensive diabetes care include six indicators.

Post Transition Evaluation

B10. The narrative refers to an attachment for the Carrie Graham study; however, this was not included with the documents to review so CMS is unable to comment. It is also unclear whether this is the same qualitative study that is referred to in the earlier section or a different study that was or will be conducted.

B11. For the Access to Care measures, the measures are inconsistent with what was described in the baseline data evaluation. For comparison, CMS recommends the indicators be the same. For type of specialists, will the state list the type of available specialists within a given distance to beneficiary's residences? What exactly will be captured and how will it be used for the evaluation? In addition, CMS recommends measures be added to assess "person-centered approaches to service planning and delivery" as well as "care coordination and linkages to other service delivery systems" as those are mentioned in the Background as a focus of this initiative.

B12. For the Quality of Care measures, CMS recommends that the state use the same measures and approaches for data collection as described in the baseline section. The Post-Transition Evaluation section describes that HEDIS rates will be calculated using MCP encounter data for hybrid measures and audited EQRO data will be used for admin measures; however, the baseline section describes that rates will be calculated by claims and it does not indicate if hybrid methodology will be used. CMS recommends that the same data calculation methodology be applied to assess baseline and post-transition.

C. Dental Transformation Initiative (DTI) Draft Evaluation Design and Appendix

Introduction and Goals/Objectives

C1. CMS recommends a clearer relationship between the four domains and the stated goals/objectives.

Hypotheses

C2. CMS recommends research questions defined related to each of the stated goals/objectives, and then the hypothesis or hypotheses related to each of the research questions should be aligned.

C3. The goals/objectives or the research questions/hypotheses would be stronger if there was some sense of the target for improvement.

Design, Measures, Data Sources, and Analysis Plan

C4. The proposed interrupted time-series design with multiple baselines is strong. The access, quality and cost measures proposed in Appendix 1 mapped to the domains and evaluation hypotheses are comprehensive, and can be obtained from the administrative data sources noted. The quantitative analytic approaches proposed are rigorous.

C5. The qualitative data set and analysis is not clear. CMS recommends the state provide more details on what information will be conducted via qualitative methods and how it will be analyzed.

D. Global Payment Program (GPP) Draft Evaluation Design

Evaluation Requirements

D1. There are no stated research questions or hypotheses, only a reiteration of the required evaluation topics from the STCs. CMS recommends the state develop research questions related to the goals/objectives of the GPP initiative, which encompass the general domains of focus articulated in the STCs. CMS recommends each research question have a hypothesis or set of hypotheses that will be evaluated.

D2. The measures required by the STCs (e.g., number of uninsured individuals served; types of services provided; expenditures, etc.) can then be used as the mechanisms for assessing the demonstration's progress related to the research questions and hypotheses.

Data Collection

D3. The state should provide more details on how the self-assessment narratives from the participating designated public hospitals will be structured, collected, and analyzed.

Proposed Evaluation Design – First GPP Evaluation

D4. This section is not structured as an evaluation design, but rather as an outline perhaps with respect to how a final report may appear. CMS recommends that the state revise to utilize the format used for the other three for review. The state may want to consider an interrupted time-series design to compare changes in baseline and post-GPP trends in care and utilization for the uninsured.

D5. The State includes references to "Table 1 in Attachment FF" of the STCs as well as different categories of services referenced in the STCs. CMS recommends incorporating these references directly into the document, not just referenced.

Proposed Evaluation Design – Second GPP Evaluation

D6. This section is not structured as an evaluation design, but rather as an outline perhaps with respect to how a final report may appear. CMS recommends that the state revise this section in more of the format used for the other three for review.

D7. The state includes references to "Table 1 in Attachment FF" of the STCs as well as different categories of services referenced in the STCs. CMS recommends incorporating these references directly into the document, not just referenced.

D8. The measures to be used in assessing improvements in workforce involvement, including team based care, are not defined.

D9. The numerator and denominator, as appropriate, for "expenditures avoided or reduced" is not clear.