Introduction
The California Children's Services (CCS) Program provides health care services including diagnostic, treatment, medical case management, and Medical Therapy Program services to children from birth up to 21 years of age with CCS-eligible medical conditions. Examples of CCS-eligible conditions include, but are not limited to, chronic medical conditions such as cystic fibrosis, hemophilia, cerebral palsy, heart disease, cancer, hearing loss, and traumatic injuries.

The CCS Program is administered as a partnership between local CCS county programs and the Department of Health Care Services (DHCS). Throughout California, CCS authorizes services for approximately 185,000 children served by a network of CCS-paneled specialty and subspecialty providers, and CCS-approved hospitals and special care centers. Historically, CCS only funds and manages the care of the CCS conditions, and not the primary care or care of non-CCS eligible health conditions, leading to fragmentation of health care.

Under the 1115 Waiver, the State of California will pilot up to two models of care for children enrolled in the CCS program. By testing these models of care, California believes it will be able to create health care delivery systems that respond to the unique needs of regions and populations throughout the state. The pilots will also help inform best practices, through a comprehensive evaluation component, so that at the end of the five-year demonstration period decisions can be made on permanent restructuring of the CCS program design and delivery systems. This draft outlines the evaluation component of the Section 1115 waiver for the CCS Demonstration Projects.

Goal and Objectives
The overarching goal of the CCS pilot project is for the State to test two integrated delivery models for the CCS population that results in 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. The two models of care delivery include a provider-based Accountable Care Organization (ACO) and an existing Medi-Cal Managed Care Plan (MCP).

The objective of the evaluation is to demonstrate the effectiveness of an integrated delivery model for the CCS population by:
1. Ensuring that the CCS population has access to timely and appropriate, high quality and well-coordinated medical and supportive services that are likely to maintain and enhance their health and functioning and meet their developmental needs.
2. Increasing patient and family satisfaction with the delivery of services provided through the CCS program.
3. Increasing satisfaction with both the delivery of and the reimbursement of services.
4. The State’s ability to measure and assess those strategies that are most and least effective in improving the cost-effectiveness of delivering high-quality, well-coordinated medical and supportive services to the CCS population.
5. Increasing the use of community-based services as an alternative to inpatient care and emergency room use.
6. Reducing the annual rate of growth of expenditures for the CCS population.

**Evaluation Design and Methods**

The CCS pilot evaluation design incorporates quantitative and/or qualitative process and/or outcome measures that adequately assess the effectiveness of the demonstration in terms of cost of services and total costs of care, improved health outcomes and system transformation including better care, better quality, and enhanced value, change in delivery of care from inpatient to outpatient, and quality improvement under managed care.

The evaluation will meet the standards of leading academic institutions and academic journals. Data will be reported at the beneficiary, provider, health plan, and statewide levels. Significant attention will be given to ensuring use of the best available data and the cleanliness of it when utilized. When necessary, the data will be adjusted and/or controls will be put into place to maximize the use of it. Should there be data limitations, the data will be modified as needed and only used appropriately so as not to misinterpret it. Any modifications and changes will be reported in the final evaluation report. The final evaluation report will also consider how the findings from the evaluation may or may not be generalized.

The evaluation will compare pre- and post-pilot implementation data whenever possible. Research has shown that it can take up to two years for beneficiaries to become adjusted to a change in delivery system. Therefore, for the two pilot programs, an analysis will be conducted of the experience of CCS children 24 months prior to the pilot and 24 months post implementation of the pilot. Furthermore, the evaluation shall also evaluate the managed care plans or ACO participating in the pilot as compared to the CCS program in selected counties where CCS services are not incorporated into managed care or an ACO.

Because additional data are available for the post-pilot implementation population and only certain assessed requirements exist for the post pilot implementation, additional metrics and data may only be available for the post pilot implementation period of time. All measures will be benchmarked against available state and national standards and benchmarks. For example, NCQA Medicaid benchmarks
for performance will be utilized when possible.

**Evaluation Measures**
The evaluation shall provide a general beneficiary profile of each model including, age, gender, race and ethnicity, primary language spoken at home and CCS diagnoses. The evaluation shall look at the following enrollment measures:

**Measure 1: Percent of newly enrollment**
- **Numerator:** Number of unique children under age 21 with CCS-eligible medical conditions, deemed newly eligible during the reporting period
- **Denominator:** All unique children under age 21 with CCS-eligible medical conditions, during the reporting period
- **Data will be stratified by source of eligibility referral such as managed care plan, provider, etc. and monitor trends over time**
- **Baseline value:** TBD
- **Data Sources:** CMSNet Eligibility Data

**Measure 2: Average length of enrollment**
- **Definition:** The average length of time from original enrollment date of program to disenrollment rate
- **Data will indicate percent of continuous enrollment**
- **Baseline value:** TBD
- **Data Sources:** CMSNet Eligibility Data

Furthermore, the evaluation shall measure the following domains: access to care, client satisfaction, provider satisfaction, quality of care, care coordination and total cost of care. Each domain of the evaluation will respond to a fundamental evaluation question and hypotheses.

**Access to Care**
**Evaluation Question:** What is the impact of the pilots on children’s access to CCS services?
**Hypotheses:** An integrated delivery system ensures access to timely and appropriate, high quality and well-coordinated medical and supportive services that maintain and enhance the health for the CCS population.

To demonstrate access to timely and appropriate primary, specialty and behavioral health care, DHCS shall measure the following:
1. Percent of children and young adults 12 months–20 years of age who had a visit with a PCP.
2. Referral of a Child to Special Care Center (SCC)
3. Screening for Clinical Depression and Follow-Up Plan

**Measure 1: Percent of children and young adults 12 months–20 years of age who had a visit with a PCP**
Access to primary care is important for the health and well-being of children and adolescents.

- **Definition:** The measure reports on four separate percentages:
  - CCS Children 12–24 months who had a visit with a PCP during the reporting period.
  - CCS Children 25 months–6 years who had a visit with a PCP during the reporting period.
  - CCS Children 7–11 years who had a visit with a PCP during the measurement year or the year prior to the reporting period.
  - CCS Adolescents 12–20 years who had a visit with a PCP during the measurement year or the year prior to the reporting period.

- **Numerator:** Number of unique children, within defined age, with CCS-eligible medical conditions who had a visit with a PCP during the reporting period.
- **Denominator:** All unique children within defined age, with CCS-eligible medical conditions, during the reporting period.
- **Standard:** HEDIS\(^1\)
- **Evaluation Type:** 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
- **Data Sources:** FFS claims data and MCP/ACO encounter data

**Measure 2: Referral of a Child to Special Care Center (SCC)**

CCS has oversight of a system of SCCs that provide comprehensive, coordinated specialty health care to CCS clients with complex, physically handicapping medical conditions. SCCs consist of multi-disciplinary, multi-specialty teams that evaluate the child’s/adult’s medical condition and develop a comprehensive, family centered plan of health care that facilitates the provision of timely, coordinated treatment.

- **Definition:** This measure is based on the CCS requirement that certain CCS eligible medical conditions require a referral to a CCS Special Care Center for ongoing coordination of services.
- **Numerator:** Number of children in CCS, with medical conditions in the categories as listed in Numbered Letter 01-0108 requiring a Special Care Center Authorization, who actually received an authorization for services.
- **Denominator:** Number of children in CCS, with medical conditions in the categories as listed in Numbered Letter 01-0108 requiring a Special Care Center Authorization.
- **Standard/Source of Measure:** CCS Performance Measures from the FY 13-14 Plan and Fiscal Guidelines \(^2\)
- **Evaluation Type:** 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
- **Data Sources:** FFS claims/authorization data and MCP/ACO eligibility, authorization and encounter data

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\(^2\) [http://www.dhcs.ca.gov/formsandpubs/publications/Documents/CMS/PFG/1314/Section03.pdf](http://www.dhcs.ca.gov/formsandpubs/publications/Documents/CMS/PFG/1314/Section03.pdf)
Measure 3: Screening for Clinical Depression and Follow-Up Plan
Depression causes suffering, decreases quality of life, and causes impairment in social and occupational functioning. It is associated with increased health care costs as well as with higher rates of many chronic medical conditions.3

- **Definition:** Screening for Clinical Depression and Follow-Up Plan
  Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.
- **Numerator:** CCS patients screened for clinical depression on the date of the encounter using an age appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the positive screen
- **Denominator:** Number of unique children aged 12 years and older with CCS-eligible medical conditions
- **Standard/Source of Measure:** NQF 0418
- **Sampling methodology:** As determined by NQF 0418
- **Evaluation Type:** Non-MCP/ACO CCS comparison to MCP/ACO pilot
- **Data Sources:** MCP/ACO chart review

**Client Satisfaction**
Evaluation Question: What is the impact of the pilots on clients' satisfaction?
Hypotheses: An integrated delivery system will improve patient and family satisfaction with the delivery of services provided through the delivery model.

To demonstrate client satisfaction, DHCS shall measure the following:
1. Satisfaction with both primary care and subspecialty care access and quality of services.
2. Grievance and appeals.

Measure 1: Surveys of families related to satisfaction with participation CCS Pilot including both primary care and subspecialty care access and quality of services.

- **Definition:** CAHPS Health Plan Survey 5.0H Child Version, Children With Chronic Conditions (Commercial and Medicaid)
- **Standard/Source of Measure:** HEDIS 5
- **Evaluation Type:** 1) Non-MCP/ACO CCS comparison to MCP/ACO pilot; and 2) Pre and Post ACO
- **Data Source:** CAHPS data

Measure 2: Grievance and Appeals

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3 The World Health Organization (WHO), as seen in Pratt & Brody (2008)
• Description: Number of ACO or MCP reported grievances and/or appeals for CCS children
  - a. Grievances by age and gender
  - b. Grievances by ethnicity
  - c. Grievances by type
  - d. Grievances by resolution
  - e. Appeals by age and gender
  - f. Appeals by ethnicity
  - g. Appeals by type
  - h. Appeals by resolution

• Standard/Source of Measure: Medi-Cal Managed Care Quality Dashboard
• Evaluation Type: MCP/ACO pilot, no comparison group identified due to non-comparable data prior to pilot or in non-MCP/ACO CCS cohort
• Data Sources: ACO or MCP grievance and appeals data

Provider Satisfaction
Evaluation Question: What is the impact of the pilots on providers’ satisfaction with the delivery of and the reimbursement of services?
Hypotheses: An integrated delivery system will improve provider satisfaction with both the delivery of and the reimbursement of services.

To demonstrate provider satisfaction, DHCS shall measure physician, hospital/clinic, in-home pharmacy and DME providers for satisfaction, including changes in reimbursement.

Measure 1: Surveys of physicians, hospitals/clinics, in-home pharmacy and DME providers for satisfaction, including changes in reimbursement under the CCS Pilot.
  • Description: ACO or MCP provider satisfaction survey
  • Standard/Source of Measure: N/A
  • Sampling methodology: Sample size shall vary based on provider network
  • Evaluation Type: 1) Non-MCP/ACO CCS comparison to MCP/ACO pilot; and 2) Pre and Post ACO
  • Data Sources: CCS, ACO or MCP satisfaction survey data

Quality of Care
Evaluation Question: What is the impact of the pilots on the quality of care?
Hypotheses: An integrated delivery system is a cost-effective means of delivering high-quality, well-coordinated medical and supportive services to the CCS population.

To demonstrate quality of care, DHCS shall measure the following:
  1. Childhood immunizations
  2. Subspecialty care for Diabetes - HbA1c Testing
  3. Lung Function for Cystic Fibrosis patients
Measure 1: Childhood Immunization Status

Childhood vaccines protect children from a number of serious and potentially life-threatening diseases such as diphtheria, measles, meningitis, polio, tetanus and whooping cough, at a time in their lives when they are most vulnerable to disease. Approximately 300 children in the United States die each year from vaccine-preventable diseases.6

- Description: The percentage of children 2 years of age who had appropriate childhood immunizations.
- Numerator: The percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (HepB), one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. This measure calculates a rate for each vaccine and nine separate combination rates.
- Denominator: Number of unique children 2 years of age with CCS-eligible medical condition(s)
- Standard/Source of Measure: HEDIS
- Evaluation Type: 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
- Data Sources: FFS claims data and MCP/ACO encounter data

Measure 2: Subspecialty care for Diabetes - HbA1c Testing

Blood sugar control is critical to reducing the development and progression of diabetes microvascular complications. Studies have shown that reducing A1c levels by just 1% can reduce the risk of developing eye, kidney, and nerve disease by 40%7.

- Description: Percentage of patients with type 1 or type 2 diabetes mellitus who had a most recent hemoglobin A1c (HbA1c) greater than 9 percent
- Numerator: Number of patients from the denominator whose most recent hemoglobin A1c level during the measurement year is greater than 9 percent
- Denominator: Number of unique children under age 21 with CCS-eligible medical conditions with a diagnosis of type 1 or type 2 diabetes mellitus during the measurement year
- Standard/Source of Measure: NCQA / NQF/ PQRI/ PCPI8
- Evaluation Type: Non-MCP/ACO CCS comparison to MCP/ACO pilot
- Data Sources: MCP/ACO encounter data and chart review

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Measure 3: Lung Function for Cystic Fibrosis patients
Forced Expiratory Volume or FEV₁, measures one’s capacity to breathe and access oxygen normally. Health people will have a FEV₁ range from 85 percent to 115 percent. Children with cystic fibrosis on average lose about 2 percent to 4 percent of their lung function each year, making it important to continuously monitor lung function and seek ways to improve this outcome⁹.

- Description: Percentage of patients with cystic fibrosis who had a recent FEV₁ greater than the national average lung function for Cystic Fibrosis patients.
- Numerator: Number of unique children with diagnoses with cystic fibrosis, with CCS-eligible medical conditions, who had a recent FEV₁ equal to or greater than the national benchmark for FEV₁ in cystic fibrosis children
- Denominator: Total number of unique children with diagnoses with cystic fibrosis, with CCS-eligible medical conditions, during the reporting period
- Standard/Source of Measure: Cystic Fibrosis Foundation¹⁰
- Evaluation Type: 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
- Data Sources: FFS claims data and MCP/ACO encounter data

Care Coordination
Evaluation Question: What is the impact of the pilots on care coordination?
Hypotheses: An integrated delivery system increased the use of community-based services as an alternative to inpatient care and emergency room use.

To demonstrate care coordination, DHCS shall measure the following:
1. Family Experiences with Care Coordination (FECC)
2. Utilization of ER, IP, OP, Pharmacy and Mild/Moderate Mental Health Services

Measure 1: Family Experiences with Care Coordination (FECC) Survey
Comprehensive, well-coordinated care has shown to improve patient and family experiences of care and patient medical outcomes. Care coordination interventions for medically complex children have also been associated with decreased unmet specialty care needs, decreased hospitalizations, and lower costs. Improving care coordination for children with medical complexity is likely to improve many aspects of care received by these children and families.¹¹

- Definition: FECC Survey
- Numerator: The FECC Survey is composed of 10¹² separate and independent quality indicators related to care coordination for children with medical complexity. Each indicator’s numerator is determined by caregiver

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⁹ https://www.cincinnatichildrens.org/service/c/cystic-fibrosis/quality
¹⁰ https://www.cff.org/2013_CFF_Annual_Data_Report_to_the_Center_Directors.pdf
¹² file:///C:/Users/jcooper/Downloads/pediatric_measure_worksheets.pdf
response to specific questions, as described in the detailed measure specifications.

- Denominator: All unique children, with CCS-eligible medical condition
- Standard/Source of Measure: Center of Excellence on Quality of Care Measures for Children with Complex Needs (COE4CCN)
- Sampling methodology: Based on COE4CCN specifications
- Evaluation Type: 1) Non-MCP/ACO CCS comparison to MCP/ACO pilot; and 2) Pre and Post ACO
- Data Sources: CCS, ACO or MCP FECC survey data

**Measure 2: Utilization of ER, IP, OP, Pharmacy and Mild/Moderate Mental Health Services for CCS children**

- ER Visits per 1,000 Member Months
- ER Visits with an IP Admission per 1,000 Member Months
- IP Admission per 1,000 Member Months
- OP Visits per 1,000 Member Months
- Prescriptions per 1,000 Member Months
- Mild to Moderate Mental Health Visits per 1,000 Member Months

**Description**

- **Emergency Room (ER) Visits**: This measure captures the number of ER visits per month. A visit consists of a provider, member and date of service. This measure is displayed per 1,000 member months.

- **Emergency Room (ER) Visits with an Inpatient (IP) Admission**: This measure captures the number of ER visits that resulted in an inpatient admission per month. An admission consists of a member and date of admission to a facility. This measure is displayed per 1,000 member months.

- **Inpatient (IP) Admissions**: This measure captures the number of Inpatient Admissions per month. An admission consists of a member and date of admission to a facility. This measure is displayed per 1,000 member months.

- **Outpatient (OP) Visits**: This measure captures the number of OP visits per month. A visit consists of a provider, member and date of service. This measure is displayed per 1,000 member months.

- **Prescriptions**: This measure captures the number of prescriptions per month. A prescription consists of a National Drug Code, member, and date of service. This measure is displayed per 1,000 member months.

- **Mild to Moderate Mental Health Visits**: This measure captures the number of visits per month related to selected Psychotherapy Services and Diagnostic Evaluations. The selected procedure codes aim to capture mild to moderate mental health visits. A visit consists of a provider, member and date of service. This measure is displayed per 1,000 member months.

- **Standard**: Medi-Cal Managed Care Performance Dashboard Indicators
• Evaluation Type: 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
• Data Sources: FFS claims data and MCP/ACO encounter data

Total Cost of Care
Evaluation Question: What is the impact of the pilots on amounts expended on CCS services, and the total cost of care?
Hypotheses: An integrated delivery system reduces the annual rate of growth of expenditures for the CCS population.

Measure 1: Total cost of care
• Description: This measure is used to assess the total cost of care for children, with CCS-eligible medical conditions. The total cost of care includes all costs associated with treating members including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary and behavioral health services. DHCS would work with the independent evaluator on the most appropriate total cost of care measure based on the data available through Medi-Cal, CCS and the pilots.
• Potential Standard/Source of Measure: AHRQ\textsuperscript{13} or IHA\textsuperscript{14}
• Evaluation Type: 1) Pre-and-post pilot implementation; and 2) Non-MCP/ACO CCS comparison to MCP/ACO pilot
• Data Sources: FFS claims data and MCP/ACO encounter data; for (including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary and behavioral health services); the evaluation shall not include supplemental payments
• Considerations: If either demonstration pilot are paying capitation for this population, DHCS would either need to find a similar total cost of care measure or require that the MCP/ACO provide claims data to complete evaluation

Evaluator Selection
The State will contract with an independent entity and ensure that the entity is free of conflict of interest to conduct an evaluation of the CCS Demonstration Projects. The State will contract with an entity that does not have a direct relationship to the State of California, Department of Health Care Services (DHCS). A data use agreement will be included in the contract to allow for the sharing of data with and access to data by the independent entity for purposes of conducting the CCS Demonstration Projects evaluation. The State will seek application(s) from interested entities that have been identified based on prior experience and expertise in analyzing the experience of the population and working with the data that would be analyzed. Proposals will be scored; if a minimal score is not achieved, the State will seek proposals from additional entities.

\textsuperscript{14} http://www.iha.org/sites/default/files/resources/my_2016_value_based_p4p_manual.pdf
**Evaluation Timeline**
California shall submit the draft Evaluation Plan for the CCS Demonstration Pilot on September 19, 2016. CMS shall provide comments on the draft design and the draft evaluation strategy within 60 days of receipt, and California shall submit a final design within 60 days of receipt of CMS’ comments. The state must implement the evaluation design, and describe progress relating to the evaluation design in each of the quarterly and annual progress reports.

The draft Evaluation Plan will be posted on the DHCS webpage for stakeholder review and comment upon submission to CMS. The final design will include a summary of stakeholder comments and questions and a description of any changes made to the final design based upon stakeholder input.