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 two models of care delivery for children enrolled in the CCS program, namely, a provider-based Accountable Care Organization (ACO) and an existing Medi-Cal Managed Care Plan (MCP). The overarching goal of the CCS pilot project is to test two integrated delivery models for the CCS population that results in achieving desired outcomes related to improved access to care; improved patient and family satisfaction; increased provider satisfaction with the delivery of and the reimbursement of services; high quality care; improved care coordination by reducing inpatient and emergency room care; and reduced total cost of care.

These demonstration projects will enable California to create health care delivery systems that respond to the specific needs of regions and populations throughout the state. Through a comprehensive evaluation, the pilots will help inform best practices so that at the end of the five-year demonstration period, recommendations may be made on restructuring of the CCS program design and delivery systems. This draft evaluation design 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 improved access to care; improved patient and family satisfaction; increased provider satisfaction with the delivery of and the reimbursement of services; high quality care; improved care coordination by
reducing inpatient and emergency room care; and reduced total cost of care. The two models of care delivery include a provider-based ACO and an existing MCP.

Per the 1115 Waiver, the state must address the following evaluation questions:

1. What is the impact of the pilots on children’s access to CCS services?
2. What is the impact of the pilots on clients’ satisfaction?
3. What is the impact of the pilots on providers’ satisfaction with the delivery of and the reimbursement of services?
4. What is the impact of the pilots on the quality of care?
5. What is the impact of the pilots on care coordination?
6. What is the impact of the pilots on amounts expended on CCS services, and the total cost of care?

Therefore, the objective of the evaluation is to demonstrate the integrated delivery system will:

1. Improve access to care;
2. Improve patient and family satisfaction;
3. Increase provider satisfaction with the delivery of and the reimbursement of services;
4. Deliver high-quality care;
5. Improve care coordination by reducing inpatient and emergency room care; and
6. Reduce the total cost of care.

**Evaluation Design and Methods**

As the CCS Demonstration Project is a pilot, of the 185,000 CCS population served in California, only 1,500 CCS children in one MCP county and 500 in one ACO county will be participating. The small pilot population size creates a challenge to only use quantifiable evaluation measures. As such, the CCS pilot evaluation design incorporates qualitative processes and/or outcome measures along with the quantitative analysis to adequately assess the effectiveness of the demonstration in terms of improved access to care, quality, care coordination, patient satisfaction, provider satisfaction, and total cost of care.

Since there are counties where the CCS services will not be incorporated into managed care or an ACO, the evaluation will utilize a difference-in-differences design. Fee-for-Service (FFS) CCS children from the non-pilot counties can serve as a comparison group for this design. 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 FFS CCS comparison group. The majority of the CCS children reside in FFS for their CCS condition; therefore, FFS provides the largest pool of beneficiaries for a comparison group in most measures. Some children also have managed care and this will be considered by the independent evaluation when finalizing the comparison group
criteria and parameters. All required data will be pulled, post implementation, for the same time period, for both the pilot (MCP/ACO) and FFS CCS county.

The evaluation will meet the standards of leading academic institutions and academic journals. Data may be reported at the aggregate delivery system (MCP or ACO) or county level. When necessary, the data will be adjusted and/or controls will be put into place to maximize utility. Should there be data limitations, the data will be modified as needed, and only used appropriately to avoid misinterpretation. Any modifications and changes will be reported in the final evaluation report, which will consider how the findings may be generalized.

State or national benchmarks will be identified for use in evaluation of program progress and outcomes. For example, National Committee for Quality Assurance (NCQA) Medicaid benchmarks for performance will be utilized when possible.

**Evaluation Measures**

**Access to Care**
Access to comprehensive, quality health care is important for promoting and maintaining health, preventing and managing disease, reducing unnecessary disability and premature death, and achieving health equity.

**Evaluation Question:** What is the impact of the pilots on children’s access to CCS services?

**Hypotheses:** Compared to the existing FFS delivery system, an integrated delivery system (MCP/ACO) improves access to appropriate primary, specialty and behavioral health care, by increasing the number of children and young adults visiting with a PCP; screening for clinical depression; and utilization of outpatient, pharmacy, and mental health services.

To demonstrate access to 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. Screening for Clinical Depression and Follow-Up Plan
3. Utilization of OP, Pharmacy, and Mild/Moderate Mental Health Services for CCS children

**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.
o CCS Children 7 – 11 years who had a visit with a PCP during the measure year or the year prior to the reporting period.

o 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: HEDIS¹

• Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties

• Data Sources: Post implementation, claims/encounter data

Measure 2: 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 conditions².

• Definition: Screening for Clinical Depression and Follow-Up Plan performed by PCP or appropriate clinician in PCP office. 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 0418³

• Sampling methodology: As determined by NQF 0418

• Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties

• Data Sources: Post Implementation, Chart Review, and claims/encounter data

Measure 3: Utilization of OP, Pharmacy, and Mild/Moderate Mental Health Services for CCS children

• OP Visits per 1,000 Member Months

• Prescriptions per 1,000 Member Months

• Mild to Moderate Mental Health Visits per 1,000 Member Months


² The World Health Organization (WHO), as seen in Pratt & Brody (2008)

• Description:
  o **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.
  o **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.
  o **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: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
• Data Sources: Claims and encounter data

### Client Satisfaction
Patient satisfaction is an important and commonly used indicator for measuring quality in health care. Patient satisfaction affects clinical outcomes.

**Evaluation Question:** What is the impact of the pilots on clients’ satisfaction?

**Hypotheses:** Compared to the existing FFS delivery system, an integrated delivery system (MCP/ACO) improves patient and family satisfaction with primary and subspecialty care access and quality of services.

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

**Measure 1: Surveys of families related to satisfaction with participation in 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 4
- **Evaluation Type:** Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
- **Data Source:** CAHPS data

### Provider Satisfaction

Provider satisfaction is important due to its association with the quality of care and patient satisfaction.

**Evaluation Question:** What is the impact of the pilots on providers’ satisfaction with the delivery of and the reimbursement of services?

**Hypothesis:** Compared to the existing FFS delivery system, an integrated delivery system (MCP/ACO) will increase physicians, hospitals/clinics, in-home pharmacy and DME providers’ 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 durable medical equipment (DME) providers for satisfaction, including changes in reimbursement.

**Measure 1: Surveys of physicians, hospitals/clinics, in-home pharmacy and DME providers assessing satisfaction with the delivery of services, as well as reimbursement of services, under the CCS pilot.**

- Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
- Data Sources: FFS CCS, ACO or MCP provider satisfaction survey data

DHCS will defer to the independent evaluator to propose a provider survey and the content of the survey. The independent evaluator will consider historical response rates when determining sample size for the sampling methodology and the analysis process. The independent evaluator will use the same satisfaction survey tool for the ACO, MCP, and FFS analysis.

**Quality of Care**

Quality of care is important healthcare systems to optimize health.

**Evaluation Question:** What is the impact of the pilots on the quality of care?

**Hypotheses:** Compared to the existing FFS delivery system, an integrated delivery system (MCP/ACO) delivers high-quality care by ensuring children 2 years of age receive appropriate childhood immunizations and children with type 1 or 2 diabetes mellitus reduce and/or control their A1c levels.

To demonstrate quality of care, DHCS shall measure the following:

1. Childhood immunizations.
2. Controlling HbA1c Levels.

The small pilot population size and narrow diagnosis focus creates challenges in identifying quality of care measures. As such, finding other measures than those selected above, found challenging due to not having a statistically significant sample size.
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.\(^5\)

- **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:** Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
- **Data Sources:** Claims and Encounter Data

Measure 2: Controlling HbA1c Levels
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%\(^6\)

- **Description:** Percentage of patients with type 1 or type 2 diabetes mellitus who had a most recent hemoglobin A1c (HbA1c) greater than 8 percent
- **Numerator:** Number of patients from the denominator whose most recent hemoglobin A1c level during the measurement year is greater than 8 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 / PCPI\(^7\)
- **Evaluation Type:** Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties

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• Data Sources: Claims/encounter data and chart review

**Care Coordination**
Care coordination is important to meet patients’ needs in the delivery of high quality, high-value health care.

**Evaluation Question:** What is the impact of the pilots on care coordination?

**Hypotheses:** Care coordination in an integrated delivery system (MCP/ACO), compared to care coordination in the existing FFS delivery system, reduces inpatient and emergency room care, and ensures eligible medical conditions are referred to a CCS SCC for ongoing services.

To demonstrate care coordination, DHCS shall measure the following:
1. “All-Cause Readmissions.”
2. Utilization of ER, IP, OP, Pharmacy, and Mild/Moderate Mental Health Services.

**Measure 1: All-Cause Readmissions**
Discharge from a hospital is a critical transition point in a patient's care. Poor care coordination at discharge can lead to adverse events for patients and avoidable re-hospitalization. Hospitalization readmissions may indicate poor care or missed opportunities to coordinate care better. Research shows that specific hospital-based initiatives to improve communication with beneficiaries and their caregivers, coordinate care after discharge, and improve the quality of care during the initial admission can avert many readmissions. There is extensive evidence about adverse events in patients, and this measure aims to distinguish readmissions from complications of care and pre-existing comorbidities.8

• Description: This measure is used to assess the number of acute inpatient stays during the measurement year that were followed by an unplanned acute readmission for any diagnosis within 30 days and the predicted probability of an acute readmission, for children and youth under 21 years of age. Data are reported in the following categories.9

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1. Count of Index Hospital Stays (IHS) (denominator)
2. Count of 30-day readmissions (numerator)
3. Average adjusted probability of readmission

- Numerator: At least one acute readmission for any diagnosis within 30 days of the Index Discharge Date
- Denominator: All acute inpatient discharges for members aged 1-20 years as of the Index Discharge Date who had one or more discharges on or between January 1 and December 1 of the measurement year.

Source: NCQA / NQF measure

- Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
- Data Sources: Claims and Encounter 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

- 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.

- Standard: Medi-Cal Managed Care Performance Dashboard Indicators
- Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
- Data Sources: Claims and encounter data

Measure 3: Special Care Center (SCC) visit with 90 days of referral

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 coordinated treatment.
• Definition: This measure is based on the CCS requirement that certain CCS eligible medical conditions require a referral to a CCS SCC for ongoing coordination of services
• Numerator: Number of CCS clients with select conditions who have an initial visit to a SCC within 90 days of CCS receiving a request for authorization to a SCC
• Denominator: Number of CCS clients with select conditions who have an initial request for authorization to a SCC
• Standard/Source of Measure: Slight variation to CCS Performance Measures from the Fiscal Year 13-14 Plan and Fiscal Guidelines
• Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
• Data Sources: Post implementation, claims/encounter, and authorization data

**Total Cost of Care**
Total cost of care is important as an indicator which interventions provide the highest value for money to maximize health.

**Evaluation Question:** What is the impact of the pilots on amounts expended on CCS services, and the total cost of care?

**Hypothesis:** Total cost of care (including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary, and behavioral health services) will be reduced for CCS children in an integrated delivery system (MCP/ACO) compared to the existing FFS delivery system.

**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 or IHA
• Evaluation Type: Difference-in-differences design evaluating the MCP/ACO vs. FFS CCS Counties
• Data Sources: Claims and encounter data; for (including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary, and behavioral health services); the evaluation shall not include supplemental payments

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Evaluation Implementation

A. Evaluation Timeline
The State shall submit the CCS Draft Evaluation Design to CMS on September 19, 2016. The CCS Draft Evaluation Design shall be available on the Medi-Cal 2020 Website for stakeholder review and comment upon submission to CMS. Stakeholders can submit comments and questions regarding the draft design via the 1115 Waiver email inbox.

CMS shall provide comments on the draft design within 60 days of receipt, and the State shall submit the CCS Final Evaluation Design within 60 days of receipt of CMS’ comments. The State must implement the evaluation design, and describe progress relating to the evaluation in each of the quarterly and annual progress reports.

Consistent with 42 CFR 431.424(d), the State must submit to CMS an interim evaluation report in conjunction with its request to extend the demonstration, or any portion thereof. California must submit to CMS a draft of the CCS Final Evaluation Report by December 31, 2021.

B. Independent Evaluator
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 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.